# Standard Operating Procedures (SOP) for QH Research Governance Officers

Office of Health and Medical Research

Queensland Health

June 2010

Queensland Government

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## ACKNOWLEDGEMENTS

These Standard Operating Procedures have been developed by the Research Ethics and Governance Unit of the Office of Health and Medical Research with valuable input and contributions from Queensland Health Research Governance Officers Network group members.

All QH RGOs are required to operate in accordance with these SOPs with effect from 1 July 2010.

# INTRODUCTION

## Purpose and scope

The Standard Operating Procedures (SOPs) in this document outline Queensland Health(QH) Institutional responsibilities for the conduct of research which are consistent with the guidelines contained in the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007) (the National Statement) and the NHMRC and Universities Australia *"Australian Code for the Responsible Conduct of Research"* (2007) (the Code) for research governance, Queensland Health Research Management Policy (QHRMP) and Therapeutic Goods Administration *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* 2000 (TGA GCP)

Each Institution has an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk, financial, Intellectual Property and Contractual management and ethical approval processes. The framework specifies the roles, responsibilities and accountabilities of all those who play a part in research and is adapted from the *Australian Code for the Responsible Conduct of Research* 2007)

The SOP applies to the conduct of all Human Research within or in association with Queensland Health (QH) facilities, patients, staff and data (medical and personal records or information). The SOP is to be applied by all QH Health Service Districts (HSDs) when reviewing single-site and multi-centre human research projects.

## Implementation

All QH HSDs will manage research and operate in accordance with these SOPs with effect from 1 July 2010. Districts may develop additional research governance operating procedures to deal with local matters not addressed in these SOPs to enhance efficiency.

Use the Standard Letter (SL) templates and Standard Form (SF) templates as listed in Appendix A where indicated in the SOPs. RGOs are required to use the standard letter (SL) templates and standard forms (SF) templates as generated by AU – RED and as listed in Appendix A where indicated in the SOPs. The standard letters and forms generated by AU-RED can be downloaded into MS Word for modification where necessary. **Throughout the SOPs standard letters and forms generated by AU-RED are marked with AU-RED ALERT.**

## Central Coordinating Service 'Early Alert'

For all HREC applications booked through the QH Central Coordinating Service, the relevant QH RGOs (i.e. those QH sites identified on the NEAF where the study is to be conducted) will receive an early alert of the research study once it has been validated by the HREC Administrator. This will be in the form of an email giving the short title of the study, the CPI, the reviewing HREC, date of ethical review and known participating sites in Queensland.

This is an early alert only. The RGO is not required to do anything at this stage. This is only an alert to inform the RGO that a study which may be conducted at the site is undergoing ethical review.

When HREC approval has been granted, the local site Principal Investigator will contact the RGO and submit a SSA application as per normal procedure

## DEFINITIONS AND APPREVIATIONS

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| Adverse event | Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.<br><br>An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. |
| Applicant | For multi centre studies the Coordinating Principal Investigator. For single site studies the Site Principal Investigator. |
| AuRED | A secure web-based Research Ethics Database that allows researchers to complete and submit a NEAF application online. |
| Central Coordinating Service (CCS) | The Central Coordinating Service (CCS) provides a "one stop shop" information service for the processing of multi-centre research applications within Queensland Health sites. Use of the Central Coordinating Service for multi-centre research in Qld Health sites is mandatory from 1 July 2010. On AU RED CCS will be identified under the heading CAS (Central Allocation Service). |
| Coordinating Principal Researcher | The investigator responsible for coordinating a research study. For single centred studies the terms "Coordinating Principal Investigator", "Coordinating Principal Researcher", "site Principal Investigator" and "Principal Investigator" are all synonymous. |

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| Clinical Research Coordinator | The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / research governance office(r). May also be known as the site coordinator, contact person, study liaison officer. |
| Contact person | The person designated by the PI to be responsible for liaising with the HREC / research governance office(r). May also be known as the site coordinator, clinical research coordinator, study liaison officer. |
| CPI | Coordinating Principal Investigator. The investigator responsible for coordinating a multi-centre research study, and the submission and communication of all subsequent requests and notifications to the site Principal Investigators. For single centred studies the terms "Coordinating Principal Investigator", "Coordinating Principal Researcher", "site Principal Investigator" and "Principal Investigator" are all synonymous. |
| HREC Coordinator | An employee of the institution who provides administrative support and advice on the institution's process of ethics review of research studies. The coordinator reports to the Chair of the HREC in matters related to the activities of the Committee. The terms "HREC administrator", "HREC coordinator" and "HREC secretariat" are all synonymous. |
| Low risk research | Section 2.1.6 of the National Statement on Ethical Conduct in Human Research describes research as "Low Risk" where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. |
| Minor amendment | An amendment not requiring review by a full HREC. Can receive approval outside of scheduled HREC meeting. Changes to the details of research that have no significant |

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| | implications for subjects or for the conduct, management or scientific value of the study and can be regarded as minor amendments (sometimes referred to as"administrative amendments"). Examples as follows:<br>• Correction of typographical errors in the protocol or other study documentation<br>• Amended contact details for the sponsor or study staff<br>• Appointment of new support staff |
| MCR | Multi-centre Research. Research to be conducted at more than one site (this may include sites other than Qld Health sites) and within the jurisdiction of more than one HREC. For applications via the CCS the research study must be conducted at more than one centre across HREC jurisdictions, and under the old system would have required submission to more than one HREC |
| Negligible risk research | Section 2.1.7 of the National Statement describes research as "negligible risk" where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk." |
| Principal Investigator | An investigator who acts as Principal Investigator at a study site i.e. the investigator responsible for the overall conduct of the research study at an individual site within a Health Service District of QH. For single centred studies the terms "Coordinating Principal Investigator", "Coordinating Principal Researcher", "site Principal Investigator" and "Principal Investigator" are all synonymous. |
| Quality Assurance | An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a quality assurance study. Attempts to clearly separate quality assurance from research are difficult. What really matters is |

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| | that:<br>(a) quality assurance is undertaken for a valid purpose and its outcomes are used to improve health care;<br>(b) those who undertake quality assurance adhere to relevant ethical principles and State, Territory and Commonwealth legislation; and<br>(c) where quality assurance proposals could infringe ethical principles that guide human research, independent ethical scrutiny of such proposals should be sought. |
| REGU | Research Ethics and Governance Unit. |
| Research Authorisation | Authorisation issued by the QH HSD District CEO or delegate to conduct research at the Health Service District/Site. Authorisation is contingent upon receiving HREC approval and a completed site-specific assessment. |
| RGO | Research Governance Office(r) / Function<br>The Office or coordinated function within an institution / district which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research study should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance). |
| Single-site research | Research to be conducted at one site only within the QLD public health system. If only one SSA needs to be generated the research is single site research. |
| Site Principal Investigator | An investigator who acts as Principal Investigator at a study site in a multi-centre research study i.e. the investigator responsible for the overall conduct of the research study at an individual site within a Health Service District of QH. For single centred studies the terms “Coordinating Principal |

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| | Investigator", "Coordinating Principal Researcher", "Site Principal Investigator" and "Principal Investigator" are all synonymous. |
| Site-specific Amendment | An amendment request for an authorised research study that may be submitted by the applicant to the site/District Research Governance Office/r only (by-passing the HREC). |
| Site coordinator | The person designated by the PI to be responsible for liaising with the HREC/District/Site research governance personnel. The terms "contact person", "clinical research coordinator", "site coordinator" and "study liaison officer" are all synonymous. |
| 60-day clock | The period of 60 days allowed for the issue of an ethical decision on an application. For research not requiring review at a full HREC meeting the clock starts on receipt of a valid application. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date. |
| SSA | Site Specific Assessment<br>The mechanism used by health service facilities within Queensland Health, to document the level of support and suitability of a research study to be conducted at a site, whether that study is multi-centre or single-site. |
| Stop Clock facility | For HREC applications, the time when the 60 day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification.<br><br>For SSA applications, the time when the 25 day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the District/Site RGO for |

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| | further information or clarification. |
| Study liaison officer | The person designated by the PI to be responsible for liaising with the HREC / District/site research governance personnel. The terms “contact person”, “clinical research coordinator”, “site coordinator” and “study liaison officer” are all synonymous. |
| Substantial amendment | An amendment to the terms of the HREC application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:<br>• the safety or physical or mental integrity of the subjects of the trial<br>• the scientific value of the trial<br>• the conduct or management of the trial<br>• the quality or safety of any investigational medicinal product used in the trial. |
| 25 day clock | The period of 25 days allowed for the SSA decision by the District CEO or delegate of a research application. The clock starts on receipt of a valid SSA. |
| Validation | An administrative check carried out by an HREC or RGO Administrator to verify that an application is complete and accepted for review. Decisions on validation should be made within one week of receipt. |
| Validation date | For research governance: the date on which a valid application is received by a RGO. |

## SECTION 1: SITE-SPECIFIC ASSESSMENTS (SSA)

### General Policy

The Site Specific Assessment is a major component of research governance which is separate to the ethical review considered by Human Research Ethics Committees (HRECs).

Prior to authorisation being granted by the District CEO or Delegate to commence a research project, the RGO undertakes a site-specific assessment (SSA) of the research project based on the information provided in the standard SSA form completed by the site principal investigator. This assessment considers the following matters:

- the appropriateness of the research project in terms of the research goals of the Health Service District and whether the institution wishes the research to be conducted at its site;
- the resource (financial, human, equipment, infrastructure) implications of the research project for the Health Service District and whether these resources are considered to be appropriate, accountable and available;
- the expertise and experience of researchers, and ensuring that relevant training for researchers is conducted before the research commences at the site;
- the compliance of the research project with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, bio-safety, professional standards, and radiation safety;
- the legal requirements of the research project;
- the financial accountability of the research project;
- authorisation of research which it assesses as being appropriate to be conducted at the site;
- coordination of on-site monitoring of research projects (related to research conduct, risk levels of research, and serious adverse events) at the recommendation of the authorising HREC or in response to local events;
- investigation of complaints, if requested by the designated person for handling complaints on research and research related activities conducted at the site.

The RGO reviews all SSA forms in order to assess and provide advice to the District CEO or Delegate. The RGO provides an outcome recommendation to the District CEO or Delegate, who retains responsibility for authorising the conduct of research at the District/Site.

In conducting the assessment, the RGO may seek advice/endorsement from other relevant District personnel as is considered necessary. This may include ongoing communication with the authorising HREC for further clarification and approval. Collaborative communication is encouraged to streamline processes, and to reduce duplication such as ethical issues regarding local recruitment processes.

Only matters concerning the suitability of the site for the project, such as access to resources, will be considered.

Prior to completion of the HREC review, the site investigator can discuss site-specific arrangements (such as, contractual arrangements and budget) with the RGO to assist in the completion of the SSA form.

Prior to completion of the HREC review, the site investigator (and sponsor, if applicable), should discuss site-specific arrangements (such as, departmental requirements) with the relevant Heads of Departments to assist in the completion of the SSA form.

A SSA form should not be submitted until a HREC has given ethical approval for the project.

## Elements of the Site-Specific Assessment Form

The main consideration is the suitability of the site to conduct the research. The following enables the RGO to perform the SSA efficiently:

- Identification of the research proposal and reviewing HREC;
- The RGO may need to discuss aspects of the project with the reviewing HREC should it be necessary; and
- Register the SSA Form data in AU-RED.
- Readily ascertain the nature of the research project and its implications for the HSD.

## 1. Project Details

The provision of this information enables the RGO to liaise with the reviewing HREC and register the completed SSA in the Australian Research Ethics Database (AU-RED).

It also identifies if the study is single site or multi-centre

If the study is multi-centre and is using a non standard clinical study agreement the RGO may contact the other site RGOs to see if the non standard clinical study agreements has already been reviewed and approved by another District

## 2. Description of Project in Plain Language

The provision of this information enables the RGO to readily ascertain the nature of the research project and its possible implications for the site.

## 3. Study Type, NHMRC Group and Fields of Research

The provision of this information allows for District reporting of the annual report to Chief Scientist.

### *NHMRC Group and Field of Research*

This information reflects disease and health issues that are relevant to the NHMRC Strategic Plan. It can also be used to enable districts to search on research being conducted in disease priority areas.

## 4. Research Personnel

The suitability of the Site Principal Investigator at the site, professional qualifications, knowledge of the research field, expertise in procedures involved, credentialing privileges and previous research experience.

A current CV (2-page maximum) must be provided for each researcher at the District/site. If the District/site already has a copy of the CV on file, an updated copy should be submitted every 2 years.

Credentialing refers to the credentialing scope of clinical practice. There is no requirement for the RGO to receive the credentialing documentation or make an assessment of the scope of practice. The investigator has declared that their scope of clinical practice covers their participation as an investigator in the study or that measures have been taken to address any deficits. This is to ensure that clinicians do not practice outside their scope of clinical practice.

## 5. Training

Evidence that the Site Principal Investigator and/or research team has training or experience in research methods (including informed consent), Good Clinical Practice (if applicable), and ability to undertake research governance responsibility for the local research. Whether extra research training is planned to fulfil the roles of researchers in the research project.

## 6. Recruitment

Recruitment methods are compliant with QH privacy policies, Federal and State privacy legislation. Whether the identified participant group is appropriate and available at the HSD site.

## 7. Anticipated start and finish dates for the research project

The provision of this information enables the RGO to consider whether the requested use of facilities, staff and resources will be available and whether it is appropriate to allow the research project to commence at this site, given the expected commencement and duration of the research project.

- Consider whether the requested use of facilities, staff and resources is appropriate and available at the HSD site.
- Whether it is appropriate to allow the research project to commence at this site, given the expected commencement and duration of the new research project and other on-going projects.
- Research should normally commence within 12 months of the date of approval. For clinical trials, the start date refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins. The finish date refers to when no further contact with participants/data source is foreseen including the data analysis and

reporting period. For non clinical trials, the start date is when final approval is given from the HSD.

## 8. QH policy on access to confidential information held by the department

The provision of this information enables the RGO to ensure that access to confidential health information held by QH meets the research requirements under s281 of the Public Health Act 2005. http://www.health.qld.gov.au/ohmr/documents/pha_legislation_2005.pdf

In addition, it assures the RGO that the researcher has contacted the data custodian to certify that the data is both available and accessible.

- When researchers require access and use of identifiable or re-identifiable data and confidential information, without consent, for the purposes of research, the provision of the *Public Health Act 2005* (QLD), s282 must be considered.
- This includes health information held and owned by QH from the:
  - Cancer Registry
  - Perinatal Statistics collection
  - Pap Smear Register
  - Register Screening Histories of Women
  - Inpatient Data
  - Pathology samples from QH Clinical and Statewide Services (CaSS) and including AusLAB data.
- Prior to commencing the research, the researcher must:
  - Seek HREC approval for the protocol and supporting documents;
  - Complete an SSA Form;
  - Discuss data requirements with the data custodian.
  - Further information on the provisions of the *Public Health Act 2005* (QLD), s282can be accessed at: http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

## 9. Research Using Information or Resources of Clinical and Statewide Services (CaSS)

For all research projects undertaken using resources held by Clinical and State-wide Services (CaSS) (facilities and tissue samples), researchers must make application to the CaSS Research

Committee after HREC approval has been given.
http://qheps.health.qld.gov.au/qhcss/research/cass_approval.htm

## 10. Research involving access to coronial material

The provision of this information enables the RGO to determine if the correct ethical approval processes have been followed. Research involving access to coronial material must have been approved by the QH Forensic and Scientific Human Ethics Committee and received approval from the State Corner to conduct the research.

- When researchers require access and use of data and confidential information from coronial autopsies, for the purposes of research, the provision of s53 of the Coroners Act 2003 must be considered.
- Fees may be levied by QHFSS to recover costs associated with ethical review and monitoring of research projects from applicants external to QH
- Further information re use of data and confidential information from coronial autopsies, for the purposes of research can be accessed through 'Site requirements' under the Forensic and Scientific Services HREC: Research Involving Material from Coroners' Autopsies: Advice to ethics committees and researchers: http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp.

## 11. Research involving adults with impaired capacity to consent

The provision of this information enables the RGO to determine if the correct ethical approval processes have been followed. Where a person is over the legal age of consent but is unable to give consent a written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken.

## 12. Research involving Aboriginal and Torres Strait Islander peoples including coincidental recruitment

The provision of this information enables the RGO to identify if the relevant engagement with Aboriginal and Torres Strait Islander communities, relevant to the site, has occurred. Researchers need to identify that they have consulted with the relevant Aboriginal and Torres Strait Islander communities.

## 13. Clinical Trials

The provision of this information and relevant documentation allows for relevant institution sign off.

Section 13 will only appear on the SSA Form if Section 5 Question 1 'Clinical Research' has been selected on the NEAF.

### *Study phase*

The study phase is used to enable searches of clinical trials phases to be performed in AU RED.

### *CTN / CTX notifications*

Relevant CTX/CTN documentation obtained if necessary

### *Clinical Trials Registry*

Section 19 of the Declaration of Helsinki (2008) states: "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject". In addition, the International Committee of Medical Journal Editors (ICMJE) has made an essential criterion for publication of a trial in one of their journals that the details of a trial should be publicly available in a clinical trials registry.

The investigator must explain why a clinical trial is not to be registered on a publicly accessible clinical trials registry

## 14. Clinical Studies – indemnity and insurance

The provision of this information (insurance and indemnity documents) enables the RGO to assess whether the required insurance and indemnity provisions are adequate.

If a standard MA CTA is used, insurance and indemnity arrangements are also covered in Schedule 3 & 4 of the CTA. For sponsored studies, the researcher should also supply the certificate of insurance to the RGO.

## 15. Research Study Agreements

Clinical study agreements describe the terms and conditions of conducting a study, including roles and responsibilities of stakeholders, payments, indemnity, insurance and compensation. Where

companies use the standard research study agreements without alteration, QH should accept these agreements without further legal review.

All other non standard Clinical Agreements not approved for use by QH e.g. other investigator initiated research, co-joint researchers, and students - non clinical research will need review by the District Health Services Lawyer or QH approved legal panel firm.

If a sponsor wishes to use their own (non approved) contract, or have amendments made to a standard MA CTA, a written undertaking should be obtained from the sponsor to pay for any legal fees incurred by Queensland Health for review of the non-standard contract.

The parties to a contract need to be properly identified to ensure that the correct legal entity is bound by the contract.

- Where a sponsor uses the standard Medicines Australia (MA) Clinical Trial Research Agreement (CTRA), the MA standard Contract Research Organisation (CRO) CTRA, the MA standard Collaborative group CTRA, or a QH approved standard research study agreement**, without alteration,** it is to be accepted without further legal review;
- Other non standard research study agreements not approved by QH should be referred for legal review. A Queensland Health Officer can access legal advice from the following sources:
- If you are part of a District, you should seek advice from the District Health Service Lawyer;
- If your District does not have a District Lawyer or you are not part of a District, you should

    (i) firstly, check if the research study agreement has been reviewed by a Qld Health lawyer at another site (contacts details for all QH District lawyers can be obtained at: http://qheps.health.qld.gov.au/lalu/pdf/qh_lawyers.pdf) and if not previously reviewed on behalf of a Qld Health site then

    (ii) seek advice from the Queensland Health Corporate Office Legal Unit by submitting a Request for Legal Advice Form (available on http://Queensland Healtheps.health.qld.gov.au/ibm/css/lalu/advice.htm) to the LALU email account. Queensland Health Corporate Office Legal Unit will assess if the contract can be reviewed by their unit or if there is a need to brief DLA Phillips Fox (the single panel firm contracted to QH for assessment of research study agreements)

- Industry sponsored trials – Names of companies with specific clauses for Schedule 7 of the MA CTA approved for use in Qld Health institutions are available on the REGU website: http://www.health.qld.gov.au/ohmr/documents/Schedule_7_Clauses.pdf

### Parties to a contract

The 'State of Queensland' is the contracting party for all QH agreements. The various state government departments (including QH) are not separate legal entities and cannot enter into contracts. Any wording which follows "The State of Queensland" is descriptive only and intended to assist the parties in identifying the relevant part/area/department within the State involved in the contract.

QH should be described on all research contracts as: "The State of Queensland acting through Queensland Health (*name of hospital/district*) of (*Address of Institution)*".

## 16. Intellectual property considerations

The provision of this information enables the RGO to consider whether the intellectual property arrangements for the research project are consistent with QH Intellectual Property Policy.

## 17. Biosafety, chemical and radiation safety

To enable the RGO to ensure that biosafety, drug committee and radiation safety approvals have been obtained where necessary.

Some types of research projects (such as research involving gene therapy), necessitate review and/or approval by an Institutional Biosafety Committee (IBC), and the NHMRC Cellular Therapies Advisory Committee (CTAC).

Where a project requires compliance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code, a physicist report will be required. Section 2.1.6 of the ARPANSA Code on Exposure of Humans to Ionizing Radiation for Research states that a researcher must obtain an independent assessment or verification by a Medical Physicist. For QH the relevant contact person is the Radiation Safety Officer.

## 18. Resources and Budget Information

### Section 18.1: Departments & services involved in the research

The provision of this information enables the RGO to consider whether the department and services involved in the research are identified and the Head of Department has been involved in any negotiations.

### Section 18.2: Study Budget at the Site

The provision of this information enables the RGO to identify the essential source of funding for a research project and the annual or participant costs associated with the study. This also provides data for the annual QH Chief Scientist report.

### Section 18.3: Site Finance Management

The provision of this information enables the RGO to identify if all research costs are covered by the sponsor or if not covered how the institute will benefit from the non funded research, and from which cost centre those costs will be recovered.

Adequacy of the local facilities available for the research and to ensure the additional time and resources spent by the researchers have been identified and are appropriate:

- Consider the budget for the research to proceed at the District/site is identified, is appropriate, adequate and available.
- Cost implication – services provided within operating budget or at a stated/agreed cost.
- Any additional costs to the District/site from participating in the new research project.
- Availability of any extra support required by research participants, for example, reimbursement of transport costs, etc.
- Consider whether the HSD site has the appropriate resources to recruit the targeted population.

### Section 18.4: Finance Authorisation

The provision of this information enables the RGO to determine if the local Director of Finance or delegate has reviewed and approved the study budget. This requirement is consistent with the obligations of financial management under the Financial Accountability Act 2009.

Where there are resource demands for a QH facility department – the researcher is to discuss what the funding and resource requirements are and cost these accordingly. The Director of Finance or delegate must sight and consider the implications for the site budget before giving authorisation.

It is not a RGO responsibility to obtain the signature of the Finance Officer.

## 19. Funds management

The provision of this information enables the RGO to streamline its financial accounting processes in line with the Financial Accountability Act 2009. Details of the designated Queensland Health Cost Centre and or Internal order number when the funding for the project is being managed by the Department. Where funds are being managed from another site e.g. university, cost centre or account name is required so when invoicing the organisation in order to recoup cost, – reference may be made to the specific account.

Details should include:

- Cost centre and/or internal order number where research funds are managed in accordance with the financial management guidelines of the QH Research Management Policy and local financial management practices.
- Details of the organisation that will receive and manage the funding for the study;
- Account details for external funding organisations and CRA details.

## 20. Database of Research Activity (DORA)

### 20.1 Purpose

The Database of Research Activity is a publicly accessible, searchable internet web site which takes an automatic download of research data from the AU-RED system and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health.

The searchable database covers all Queensland Health human research (not just clinical trials) and is designed to facilitate greater collaboration and communication between researchers, improve patients' access to research information and raise awareness about the benefits of health and medical research.

### 20.2 Specific Guidance

Sections 20.1 – 20.10 will be auto populated from previous sections of the SSA Form. Researchers will be asked if they have the authority to consent for the release of the data and if so, give consent for the release of the data. The Research Ethics and Governance Unit will follow up those researchers who do not consent for the data to be released for DORA.

## 21. Declarations

### Section 21a: Declarations from investigators and site coordinator

#### 21.1aPurpose:

The provision of this information enables the RGO and / or delegate to determine if all the researchers and site coordinators are aware of their roles and responsibilities in regards to the conduct and completion of research at the site.

### Section 12.1b: Declarations from Head of Department or delegate where the research project will be conducted

#### 21.1b Purpose:

The provision of this information enables the RGO to determining if the research is supported within an institution

Researchers should have a signed declaration from the Head of Department or Services area where resources are required, prior to submission of the SSA. It is not a RGO responsibility to obtain the signatures of the Finance Officer, Head of Department or Head of Supporting Department.

### Section 21c: Declarations from Head of Department or delegate providing support and/or services to the research project

#### 21.1c Purpose:

The provision of this information enables the RGO to determine under what conditions institutional departments can provide support for the research project. It is highly recommended that researchers contact the relevant supporting departments within an institution (eg Pathology, Pharmacy, Radiology, Allied Health etc) prior to HREC submission, to ensure that the services, can be provided by the department.

## SECTION 2: SITE-SPECIFIC ASSESSMENT (SSA) APPLICATIONS

### New Applications

2.1 A completed SSA form is submitted by the Site Principal Investigator responsible for the overall conduct of the research project at the site.

2.2 It is the responsibility of the Site Principal Investigator that the completed SSA form contains all the essential elements when submitted to the RGO. This includes all attachments as listed in the SSA Checklist

2.3 All new applications for SSA review must be submitted using the Qld Health on line SSA Form accessed through http://www.ethicsform.org. All data from the QH SSA Form and the supporting documents must be uploaded into AU-RED by the RGO.

2.4 Site-specific information should be included in the local version of the participant information sheet for the study

- The address and telephone number of the site
- Contact details for the local investigator(s) and, if applicable, other staff such as:
  - Research nurses;
  - Emergency contacts if appropriate;
  - Contact information for complaints.
- The research content of the participant information sheet may not be changed after HREC approval, by the researcher or RGO, unless this is first submitted to the HREC as an amendment.

2.5 It is the responsibility of the site principal investigator to make arrangements for notifying other pertinent health care staff, who may be caring for the participants, about the proposed research.

2.6 For research involving adults with impaired capacity to consent:

- The site principal investigator is required to obtain approval from the Queensland Civil and Administrative Tribunal (QCAT) in circumstances where the participants of the trial may be, by reason of physical or mental incapacity, incapable of giving informed consent to participation
- Where a person is over the legal age of consent but is unable to give consent, a written application to QCAT must be submitted after HREC approval is obtained.
- The RGO should ensure that a QCAT approval is submitted with the completed SSA form if the research involves adults with impaired capacity to consent

## *Entry of applications on AU-RED*

(See appendix A for 'cheat sheet' on processing an SSA Form)

2.7 On registering a SSA form application you will be asked to enter the HREC Reference Number, which is on the SSA form under Section 1. Once you have entered the HREC Ref. No. you can then register the SSA application. Following registering of an application on AU-RED, a unique identifying number will be generated by the AU RED database.

## *Uploading applications to AU RED*

2.8 The researcher will have completed a Qld Health SSA on the online form. Click on the 'Upload online form data' button on the 'Details' page of the application on AU RED and enter the 'Submission Code' on the bottom right hand side of the SSA application. If there is no 'Submission code' on the SSA Form you will need to contact the researcher and ask them to create a Submission Code their SSA Form and inform you of the 'Submission Code'.

2.9 Researchers should be requested to electronically 'upload' all supporting documentation (eg participant information sheets, CTN, CTX, contracts, insurance documentation etc) through the online site when completing their SSA application. This ensures that the RGO receives and has a record of all the supporting documentation sent.

***SF2: Site-Specific Assessment (SSA) Form and Checklist AU-RED ALERT***

## *Uploaded supporting documents*

### *All Studies*

2.10 If the applicant has attached electronic copies of their supporting documentation to their online application form (www.ethicsform.org/au), these documents will automatically be uploaded to the Application when you import the online form.

2.11 To view the uploaded document, click on the magnifying glass icon next to the document in the 'Uploaded Documents' column.

2.12 If the applicant uploads a newer version of an electronic supporting document to their online form application at www.ethicsform.org/au, they should notify the RGO that the revised version is available. The revised version can then be uploaded to the Application − Checklist page simply by clicking the refresh version icon next to the current version of that document in the list of 'Documents checked in'. AU RED will keep a copy of all document versions uploaded.

2.13 If the researcher uploads an entirely new document into the Online Forms Document tab after the RGO has uploaded the SSA application , the RGO will need to upload the online form data again (using the same submission code unless the form itself has been modified) in order to pull in the new document.

## Site-Specific Assessment Validation

2.14 A valid SSA form is one which is deemed complete by the RGO (including all relevant signatures and supporting documentation).

2.15 As a general guide, the SSA form is accepted as valid if it meets all the following criteria:

- All relevant sections and questions in the SSA form have been completed;
- A copy of the HREC recommendation and approved protocol have been attached;
- The application has been signed by the PI;
- The application has been signed by supporting Heads of Department;
- A Copy of the study protocol and a short Curriculum Vitae have been submitted for all site investigators;
- Other attachments that may be applicable: CTN/CTX, Contractual Agreements, Biosafety/chemical and/or radiation safety approvals have been attached.

2.16 If the SSA Form is valid, the RGO acknowledges receipt by writing to the site investigator.

***SL1: SSA Acknowledgement and validation*** ***AU-RED ALERT***

2.17 If the application is invalid (the SSA form not submitted or the SSA form is not complete), the PI is notified of the reason.

***SL2: Invalid SSA Notification*** ***AU-RED ALERT***

2.18 When an invalid SSA form is received by the RGO, the Site Principal Investigator is requested to supply the missing information. The 25 day clock does not begin until a valid application has been received.

## Withdrawal of Applications

2.19 Where the Site Principal Investigator decides not to proceed with the research project at that site, he/she may withdraw the SSA form. Requests to withdraw the research project from site-specific assessment, is made in writing to the RGO.

***SL3: Acknowledgement of withdrawal of SSA*** ***AU-RED ALERT***

## SECTION 3: SITE-SPECIFIC ASSESSMENT AND HREC APPROVAL

### General Policy

Neither the authorising HREC nor the local institutional HREC will be required to review or note the SSA form prior to granting ethical approval.

The SSA form will be submitted to the RGO including an attached copy of the HREC approval letter and HREC approved research protocol. As such, approval of the SSA by the District CEO or delegate is contingent upon HREC approval of the research.

The RGO may communicate any concerns regarding any identified local circumstances relevant to the ethical review to the authorising HREC.

# SECTION 4: GRANTING INSTITUTIONAL AUTHORISATION TO CONDUCT RESEARCH

## General Policy

4.1 Only the QH District CEO or Delegate can give authorisation for a research project to commence within, or in association with, their HSD. This cannot be delegated to the HREC or RGO.

4.2 Once the RGO has completed their assessment of site-specific factors, they will provide a recommendation to the District CEO or Delegate, along with the additional documentation attached as outlined in the SSA checklist. This may include the following documents, the HREC approval, CTN/CTX form (sign by the HREC Chair), insurance and indemnity forms and Clinical Trials Agreement (if applicable) to authorise commencement of the project at the HSD site.

4.3 Any conflict of interest pertaining to researchers, institutions, HREC members & all other stakeholders should be considered in accordance with QH Standard 5: Conflict of Interest in Research 2010 and the QH Research Management Policy 2010.

## Research Governance Office/r Authorisation

4.4 It is expected that the RGO will conduct their assessment in an efficient and timely manner. A 25 day (calendar day) review clock, that commences when a valid SSA form is received, is recommended for the completion of site-specific assessment and authorisation.

The RGO should forward the SSA Form for the next stage of authorisation when:

- the SSA form is complete and;

- the RGO has provided their recommendation on the SSA Form – including clearance from the District Lawyer / QH Legal Unit if a non standard contract has been used.

## District CEO or Delegate Authorisation

4.5 The QH District CEO or Delegate may either sign authorisation to commence the research project or reject the application on site specific grounds.
http://qheps.health.qld.gov.au/pl/corp_governance/delegations/contract_signing.htm

4.6 The signed authorisation is returned to the RGO. This is accompanied by the signed section of the CTN/CTX Form (if applicable) and the Study Agreement (if applicable).

## Notification of the Decision to the Site Principal Investigator and reviewing HREC

4.7 The RGO is responsible for notifying the Site Principal Investigator of the District CEO or Delegate decision. This is in the form of a standard letter noting the decision, accompanied by the signed CTN/CTX Form (if applicable) and the Study Agreement (if applicable).

***SL4: Research Authorisation AU-RED ALERT***

***SL5: Research not Authorised AU-RED ALERT***

4.8 Initial District CEO or Delegate approval notification to the researcher may be via email.

4.9 The RGO is required to enter the decision of the District CEO or Delegate in the QH AU-RED tracking and management system (that is, whether or not the project has been authorised to commence at the site). All documentation relating to the SSA for each research project (including, evidence of final ethical opinion of authorising HREC, final protocol, copy of CTN form, clinical trial agreement etc.) must be kept on file in a secure and confidential manner, by the relevant RGO.

## Exceptional Circumstances Review

### *All studies*

4.10 There may be wholly exceptional circumstances where as a matter of public policy, and in the national interest, it is essential that an application should be reviewed urgently to allow a health-related research study to commence as quickly as possible. Such circumstances could include the urgent need for research data in a field that is currently the subject of major public anxiety, or where there is an urgent threat to public health. There could also be a need to capitalise on a unique opportunity for significant research where there is only a limited time to consider participation.

4.11 Note that application for review under exceptional circumstances is never justifiable solely on the grounds of a researcher's claim to the need for urgent review of their project based on failure to meet deadlines. The onus is on the researchers to ensure the timely submission of their application to a HREC and completion of site-specific requirements.

### *Procedure*

### *Single Site Studies*

4.12 Applications submitted for review under exceptional circumstances should contain:

- Completed NEAF or original submission if not on NEAF and time factor does not allow time for NEAF to be completed;
- Study protocol and supporting documentation;
- A request for exceptional circumstances review in writing and containing the reason for requesting review under exceptional circumstances and justification for the request by aligning the protocol with the above categories

4.13 The application will be checked by the HREC Administrator for compliance with application procedures and recorded on AU – RED.

4.14 The application will be reviewed by the HREC Chairperson and one or more HREC members. The Chairperson and additional HREC member/s will be blinded to the other's decision in the initial review. One of these two reviewers should be a 'layperson' or other member not affiliated with the institution. The reviewers will be given the opportunity to seek clarification from the investigator or from other HREC members, if required, prior to making a decision.

4.15 If the decision of the Chairperson and additional HREC member is unanimous that the application qualifies for exceptional circumstances review, the HREC Chair will advise the District CEO or Delegate, through the local RGO, of the recommendation to conduct the research and monitoring responsibilities.

4.16 In such circumstances, the Principal Investigator may be exempt from completing an SSA form, subject to local administrative research governance requirements. All approval documents should be signed off by the District CEO or Delegate in accordance with normal approval procedures. At this stage the research may commence.

4.17 If there is disagreement between the Chairperson and the additional HREC member, the protocol will not receive exceptional circumstances review and will be reviewed at a full meeting of the HREC.

4.18 The HREC reserves the right to ratify the previous decision, request amendments or clarification, or reject the protocol.

### *Multi-centre Studies*

4.19 Applications submitted for review under exceptional circumstances should be submitted to the local RGO as per the normal single ethical review process for multi-centre research and should include:

- Completed NEAF or original submission if not on NEAF and time factor does not allow time for NEAF to be completed;
- Evidence of a certified HREC approval;
- Study protocol and supporting documentation

4.20 The RGO will review the application and make a recommendation to the District CEO or Delegate

4.21 The District CEO or Delegate may grant approval, under exceptional circumstances for a study where:

- A certified HREC has approved the application and it appears to conform to the requirements of the institution / district and
- Clinical need necessitates urgent approval of the application.

## SECTION 5: AMENDMENTS TO RESEARCH GIVEN AUTHORISATION

### General Policy:

5.1 This section refers to amendments (including requests for time extensions) to those research projects which have been granted authorisation by a QH District CEO or delegate. Where an amendment to a research project is proposed, the following procedures should be followed

### Amendments to the research project which may affect the ongoing ethical acceptability of the project

#### *Multi-centre studies*

5.2 For multi-centre studies, as a condition of ethical approval, the authorising HREC requires the Coordinating Principal Investigator to request approval for proposed amendments to the research project which may affect its ongoing ethical acceptability. Examples of amendments requiring approval by a HREC include changes to the following:

- The safety, physical and/or mental integrity of the participants in the trial;
- The scientific value of the trial;
- The quality or safety of any investigational medicinal product used in the trial.

5.3 Amendment requests approved by the HREC may commence upon receipt of an HREC approval letter, provided they do not affect the information provided in the SSA Form. Where the amendment request does alter the SSA Form, each local Site Principal Investigator must notify the RGO, in writing.,. The amendment may not be implemented at that site until authorisation has been granted by both the RGO and the authorising HREC.

5.4 Only those amendments which affect the ethical acceptability of the research project require submission to, and review by the authorising HREC.

#### *Single site studies*

5.5 As a condition of ethical approval, the authorising HREC requires the local Site Principal Investigator to request approval for proposed amendments to the research project which may affect its ongoing ethical acceptability. Examples of amendments requiring approval by a HREC include changes to the following:

- The safety, physical and/or mental integrity of the participants in the trial;

- The scientific value of the trial;
- The quality or safety of any investigational medicinal product used in the trial.

5.6 Amendment requests approved by the HREC may commence upon receipt of an HREC approval letter, provided they do not affect the information provided in the SSA Form. Where the amendment request does alter the SSA Form, each local Site Principal Investigator must notify the RGO in writing. The amendment may not be implemented at that site until authorisation has been granted by both the RGO and the authorising HREC

5.7 Only those amendments which affect the ethical acceptability of the research project require submission to, and review by the authorising HREC.

***SL7: Favourable Opinion of Post Authorisation Amendment (HREC review only)***
***AU-RED ALERT***

5.8 The outcome of the HREC review and any revised documentation pertaining to the research project must be submitted by the site investigator to the relevant Research Governance Office/r for the District/site record.

## Amendments to the research project which only affect the ongoing site acceptability of the project

### *All studies*

5.9 Only those amendments to the research project which may impact upon the suitability of the research to be conducted at that site will necessitate a submission, in writing, to the RGO.

5.10 Amendment requests for an authorised research project may be submitted directly to the RGO (by-passing the HREC) only when the amendment requires:

- No change to the authorised NEAF; and
- A change to one or more of the following sections of the QH SSA Form:
  - Section 4 – Training
  - Section 6 – Anticipated start and finish dates
  - Section 8a(ii), b(ii) or c(ii) – Medicines Australia standard indemnity form
  - Section 8a(iii) b(iii) or c(iii) – Evidence of adequate insurance cover
  - Section 8d - Medicines Australia Standard Clinical Trial Agreement;
  - Section 11 – Departments and services involved in the research
  - Section 13 – QH account number(s) / cost centre details
  - Section 14 – Finance Authorisation

- Section (a – f) – Declarations and authorisations

5.11 The RGO will determine whether authorisation from the District CEO or Delegate is required to implement the amendment at that site. This is at the discretion of the RGO.

- Should the RGO be of the opinion that authorisation from the District CEO or Delegate is not required, the RGO will notify the site principal investigator, in writing, that authorisation is granted for the amendment to be implemented at the site.
- Should the RGO be of the opinion that authorisation from the District CEO or Delegate is required; the RGO will forward the relevant documentation to the District CEO or Delegate for authorisation. The RGO will then notify the site principal investigator as to whether or not authorisation has been granted by the District CEO or Delegate for the amendment to be implemented at that site.

5.12 It is the responsibility of the site principal investigator to ensure they have received notification of authorisation of the amendment by the RGO, prior to commencement of the amendment at that site.

5.13 If, in the course of reviewing an amended SSA form, the RGO is of the opinion that amendments to the research project may impact on the ongoing ethical acceptability of the project (for example, amendments to the recruitment process), and an amendment request has not been submitted to the HREC, the RGO will notify the site principal investigator that HREC review of the amendment will be required before the proposed amendment can be authorised and therefore implemented at the site. The RGO may discuss aspects of the proposed amendment with the HREC and vice versa. For multi-centre studies approved under the single ethical review process, the local principal investigator will then notify the Coordinating Principal Investigator of the requirement for ethical review by the authorising HREC

***AU-RED ALERT***

***SL6: Request for HREC Amendment approval prior to Authorisation***

***SL8: Favourable opinion of post authorisation SSA amendment***

***SL9: Unfavourable Opinion of Post Authorisation SSA amendment (with options for further review***

5.14 The RGO will record the outcome of the amendment review in the QH AU-RED application tracking and management system.

5.15 The RGO must keep all documentation relating to the amended SSA form for each research project on file in a secure and confidential manner, at the relevant HSD site.

## Amendments to the Research project which may affect both the ethical acceptability and site acceptability of the project

### *Multi-centre studies*

5.16 Where a proposed amendment to the research project may affect both the ethical acceptability and site suitability of the project, the CPI must submit an amendment request to the (authorising) HREC. The HREC will review the amendment request according to standard procedures and will notify the CPI in writing of its decision.

5.17 Once HREC approval has been given for the amendments, copies of the HREC approval letter, revised SSA form, a cover letter and all relevant updated documents with track changes must be uploaded onto the online forms by the local principal investigators prior to submission to each RGO for authorisation to implement the amendment at the site.

5.18 Amendments which may affect both the ethical acceptability and site acceptability of the project are considered major amendments and should be reflected in a cover letter from the coordinating principal investigator, stating the changes and reasons for changes, and accompanied by all relevant updated documents (which have been uploaded onto AuRED by the coordinating principal investigator). Hard copies of the cover letter and all relevant updated documents with track changes must be submitted to the HREC coordinator, as per normal HREC procedure.

5.19 Substantial amendments (as per glossary) should normally be reviewed at meetings of both the scientific sub-committee of the HREC and the HREC. They may not be reviewed by the Chair acting alone.

5.20 The amendment cannot proceed until site authorisation is granted.

### *Single site studies*

5.21 Where a proposed amendment to the research project may affect both the ethical acceptability and site suitability of the project, an amendment request must be submitted in writing to the HREC and RGO by the local principal investigator.

5.22 The site principal investigator must make an amendment request to the HREC prior to informing the RGO

5.23 The HREC will review the amendment request according to the standard procedures (Refer to QH HREC SOPs) and notify, in writing, the site principal investigator of the outcome of its review. The site investigator will be required to send a copy of this letter to the RGO, to notify them of the outcome of the HREC review of the amendment.

5.24 Upon receipt of the amendment request, the RGO will review the amendment and determine whether District CEO or Delegate authorisation is required to implement the amendment at the HSD site.

5.25 The RGO will notify the site investigator as to whether or not authorisation has been granted for the amendment to be implemented at that site. Authorisation to implement the amendment will only be granted when evidence has been provided of HREC approval.

***AU-RED ALERT***

***SL8: Favourable opinion of post authorisation SSA amendment;***

***SL9: Unfavourable Opinion of Post Authorisation SSA amendment (with options for further review)***

5.26 The site principal investigator may not implement the amendment until the RGO has provided written notification that the amendment has been authorised at the HSD site.

## Minor amendments to the Research Project which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors, addition to study team)

### *Multi-centre studies*

5.27 Amendments which do not affect either the ethical acceptability or site acceptability of the project should be submitted in hard copy to the authorising HREC administrator by the CPI. These should include a cover letter from the CPI, stating the changes and reasons for changes, and all relevant updated documents with tracked changes. All altered documents should have updated version numbers and/or dates. All submitted documents, including the cover letter, should be uploaded into AuRED by the CPI prior to submission.

5.28 The amendments should also be submitted to the local RGO by the local site principal investigators. These should include a cover letter from the local PI, stating the changes and reasons for changes, and all relevant updated documents with tracked changes. Again, all submitted documents should be uploaded by the site P.I. and attached to the original SSA.

### *Single site studies*

5.29 Amendments which do not affect either the ethical acceptability or site acceptability of the project should be submitted in hard copy to the HREC administrator and RGO by the local PI. These should include a cover letter from the PI, stating the changes and reasons for changes, and all relevant updated documents with tracked changes.

5.30 All submitted amendments must be uploaded onto the online forms by the local P.I. prior to submission.

## Extension of a research project to an additional site

### *All studies*

5.31 For those studies conducted under CTN/CTX conditions, the TGA and authorising HREC must be notified of the new site/s by completion of the appropriate paperwork.

### *Multi-centre studies*

5.32 If the original approving HREC is not certified to approve multi-centre research in the study field, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the Central Coordinating Service at QH REGU to determine which HREC will review the application.

5.33 Where a multi-centre study has been approved by a certified HREC in the study field and originally approved the study after 1 July 2010, and is to be extended to include additional site/s, the CPI will apply for approval from the approving HREC for the addition. This ensures that the approving HREC has the relevant information to correctly monitor the study.

5.34 For studies approved prior to 1 July 2010, the study will need to be submitted through the Central Coordinating Service for allocation to a suitable HREC (this is to ensure that the original reviewing HREC is certified in the study field to approve the research study)

5.35 The reviewing HREC will notify the CPI once HREC approval is granted.

5.36 The CPI will notify the local PI who will then apply to the local RGO for district authorisation.

5.37 The research will not be able to commence at each additional site until each respective district/ site has granted authorisation.

### *Single site studies*

5.38 Where a single site study is to be extended to additional site/s, the local PI will take on the role of the CPI.

5.39 If the original approving HREC is not certified to approve multi-centre research in the study field, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the Central Coordinating Service at QH REGU to determine which HREC will review the application.

5.40 If the original approving HREC is certified to approve multi-centre research in the study field, and originally approved the study after 1 July 2010, the CPI will submit an amendment to the original approving HREC.

5.41 In all cases, for studies approved prior to 1 July 2010, the study will need to be submitted through the Central Coordinating Service for allocation to a suitable HREC (this is to ensure that the original reviewing HREC is certified in the study field to approve the research study)

5.42 The approving HREC will notify the CPI once HREC approval is granted.

5.43 The CPI will notify the local PI who will then apply to the local RGO for district authorisation.

5.44 The research will not be able to commence at each additional site until each respective district/ site has granted authorisation.

5.45 For those studies conducted under CTN/CTX conditions, the TGA must be notified of the new site/s by completion of the appropriate paperwork.

## Urgent Safety-Related Measures:

5.46 Where it is necessary to eliminate an immediate hazard to the project's participants, deviations from, or changes to the research project, may be implemented without prior HREC review and authorisation from the District CEO or Delegate (if necessary). As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted to the HREC and RGO (if the amendments affect the SSA Form).

## SECTION 6: SITE-SPECIFIC ASSESSMENT OF LOW RISK RESEARCH

### General Policy:

6.1 A low risk reviewing body that reviews research involving only low or negligible risk, has the authority to waive, in consultation with the RGO, the need for an SSA Form on the basis of a review. Local administrative requirements will be implemented.

6.2 If a SSA is required, the site principal investigator must complete a separate SSA for each site and submit the completed SSA Form(s) and all other relevant documentation to the RGO as per usual.

### Uploading negligible and low risk research to AU RED

6.3 It is highly recommended that all "Low & Negligible Risk" protocols be uploaded on AU-Red. This allows for noteworthy reports to be developed, with relation to the substantiation of your workload and tracking of the types of research types. If negligible and low risk research is processed through the RGO please upload the research onto AU RED manually.

6.4 (Online submission of negligible and low risk research will be available in 2010)

### Process

- Create a 'new application'.
- Select 'other' as the "*Study type"*
- Enter 'Low / negligible risk research' in "Study Type description"
- Enter the rest of the details and click 'register application'
- On the 'Details' tab screen enter the details manually, and tick the "Low Risk Review" box
- Follow through registering the application as normal.

# SECTION 7: MONITORING OF RESEARCH GIVEN INSTITUTIONAL AUTHORISATION

## General Policy:

7.1 As a condition of ethical approval for research, the site principal investigator must immediately report to the authorising HREC anything which might warrant review of the approval of the project, including serious and unexpected adverse events. Such events must be reported to the HREC in the format specified in the HREC SOPs, Section 8 and review outcomes should be forwarded by the Site Principal Investigator to the RGO.

## Progress Reports

### *All studies*

7.2 Institutions are responsible for the ongoing monitoring of the ethical conduct of research projects for which they have granted ethical approval (National Statement 5.5). As a minimum, the institution will require at regular periods, at least annually, progress reports from investigators on matters including:

- Progress reports to date or outcome in the case of completed research;
- Maintenance and security of records;
- Compliance with the approved protocol; and
- Compliance with any conditions of approval.

7.3 The authorising HREC recommends the frequency, type and format of reporting and monitoring which reflects the degree of risk of the research.

### *Single site studies*

7.4 The site principal investigator will send a progress report to the reviewing HREC. The HREC will send written notification of the HREC review outcomes of the progress report to the Site Principal Investigator who will then forward a copy of the progress report review outcomes to the RGO.

7.5 In very specific cases of high risk research, the HREC may communicate directly to the RGO that the local institution coordinates on-site monitoring at recommended intervals or randomly throughout the research project. The RGO will provide such on-site monitoring reports to the HREC. These monitoring requirements will also be detailed in the HREC approval letter. If a district/ site considers that it cannot comply with the monitoring

recommendations made by the HREC, then it should not grant authorisation of the research at the site / district.

7.6 The coordination of on-site monitoring by the RGO involves making the necessary arrangements for appropriate personnel (internal and external to QH) to conduct the monitoring activity within the given timeframe.

7.7 On-site monitoring, coordinated by the RGO, may include attention to:

- auditing / inspection of research conduct in compliance with the agreed protocol and conditions of approval, including consent documentation, current number of recruits, commencement / completion / withdrawal dates;
- auditing / inspection of research conduct in accordance with ICH GCP;
- auditing / inspection of data storage and security
- Interviews (or other forms of feedback) with research participants.

### *Multi-centre studies*

7.8 The local site principal investigators will send a progress report to the Coordinating Principal Investigator and local RGO. The CPI will coordinate the reports and send them to the reviewing HREC. The HREC will send written notification of the HREC review outcomes of the progress report to the CPI.

7.9 In very specific cases of high risk research, the HREC may recommend in its letter of approval that the RGO coordinate on-site monitoring at recommended intervals or randomly throughout the research project. The RGO will provide such on-site monitoring reports to the HREC. If a district/ site considers that it cannot comply with the monitoring recommendations made by the HREC, then it should not grant authorisation of the research at the site / district.

7.10 The coordination of on-site monitoring by the RGO involves making the necessary arrangements for appropriate personnel (internal and external to QH) to conduct the monitoring activity within the given timeframe.

7.11 On-site monitoring, coordinated by the RGO, may include attention to:

- auditing / inspection of research conduct in compliance with the agreed protocol and conditions of approval, including consent documentation, current number of recruits, commencement / completion / withdrawal dates;
- auditing / inspection of research conduct in accordance with ICH GCP;
- auditing / inspection of data storage and security
- Interviews (or other forms of feedback) with research participants.

## Tracking of Medical Devices:

7.12 Tracking of medical devices will be as per the TGA requirements and Australian Medical Devices Guidelines.

7.13 Medical Device TGA SAE Forms and guidelines:
http://www.tga.gov.au/docs/pdf/forms/iris_mdir03b.pdf and
http://www.tga.gov.au/docs/pdf/forms/iris_udir03c.pdf
http://www.tga.gov.au/docs/pdf/devguid11.pdf

7.14 Device identifiers are placed into patients medical notes and manufacturers are required to maintain a tracking system

## Serious Adverse Events (including serious unexpected):

7.15 The local principal investigator/researcher must capture and report AEs, including SAEs, which occur at their site to the sponsor in accordance with the study protocol.

7.16 The local principal investigator/researcher must report all SAEs to the sponsor immediately (within 24 hours of finding out about the event) in accordance with the study protocol and GCP guidelines as adopted by the TGA.

7.17 For multi-centre studies the local PIs will send all AE & SAE reports as per the Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products MAY 2009 for reporting requirements to the CPI who will collate and submit these to the authorising HREC for review.

7.18 Refer to the HREC SOPs. The table of requirements for adverse event reporting to HRECs by Investigators from the Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products MAY 2009 for reporting requirements can be found at:
http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

7.19 It is the responsibility of the RGO to ensure that the institution is aware of any updates to the NHMRC Alerts.

## Suspension or Withdrawal of Authorisation for a research project:

## Suspension or Withdrawal of HREC approval

### *Single site studies*

7.20 Where the authorising HREC considers it appropriate that the adverse event/s and/or progress reports requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the Site Principal Investigator and RGO. This should be followed by a notice in writing, within 3 working days.

7.21 An investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC.

7.22 Upon receipt of the HREC decision to suspend or withdraw ethics approval, the RGO must promptly advise the QH District CEO or Delegate to suspend or withdraw authorisation to conduct the research at the HSD site. In such circumstances, the RGO will be required to immediately notify the site principal investigator. This notification must be confirmed in writing within three working days.

### *Multi-centre studies*

7.23 Where the authorising HREC considers it appropriate that the adverse event/s and/or progress reports requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the CPI who will notify the local Site Principal Investigators, who will then notify the local RGO. This should be followed by a notice in writing, from the authorising HREC, within 3 working days.

7.24 An investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC.

7.25 Upon receipt of the HREC decision to suspend or withdraw ethics approval, the RGO must promptly advise the QH District CEO or Delegate to suspend or withdraw authorisation to conduct the research at the HSD site. In such circumstances, the RGO will be required to immediately notify the site principal investigator. This notification must be confirmed in writing within three working days.

***AU-RED ALERT***

***SL10: Suspension/Withdrawal of District Authorisation to conduct research.***

## Suspension or withdrawal of authorisation by the site at which the research is being conducted

7.26 Where the QH District CEO or Delegate is satisfied that circumstances have arisen as such that is no longer appropriate to conduct a research project at the site/district, the HSD may suspend or withdraw its authorisation to conduct the research at that District/site.

7.27 In such circumstances, the RGO is required to immediately notify both the site principal investigator and HREC. The RGO must consult with the HREC first to ensure the safety and welfare of research participants that may be involved in the research. This notification must be confirmed in writing within three working days.

7.28 For multi centred studies the local PI must notify the CPI of the date and reason for the suspension or withdrawal of authorisation by the site. The CPI must then notify the authorising HREC.

***AU-RED ALERT SL10: Suspension/Withdrawal of District Authorisation to conduct research.***

7.29 An investigator cannot continue with the research if the District CEO or Delegate has suspended or withdrawn authorisation for the research to be conducted at that site.

7.30 It is the responsibility of the RGO to update the AU-RED application tracing and management system accordingly.

## Study Closure/Termination at a site:

7.31 Where an authorised research project is to be closed at a site, the site principal investigator must notify the authorising HREC in writing. The investigator will also be required to notify, in writing, the RGO.

7.32 AU -RED must be updated accordingly by both the HREC and RGO.

7.33 Where a research project at a site is terminated or suspended by the site principal investigator prematurely, the HREC and RGO should be promptly informed and provided with a detailed written explanation of the circumstances.

## SECTION 8: LEVY FOR SITE SPECIFIC ASSESSMENT

### Schedule of Fees:

8.1 Site-specific assessments by an RGO of industry sponsored protocols are subject to a fee.

***SF3: Schedule of Fees for Ethics and Research Governance Review of Commercially Sponsored Research.*** ***AU-RED ALERT***

8.2 Fees may also be levied by other QH departments such as the QH Forensic and Scientific Services to recover costs associated with ethical review and monitoring of research projects from applicants external to QH.

### Background:

8.3 In 2007, the revisions of the NHMRC "National Statement on Ethical Conduct in Human Research" (2007) and the NHMRC and Universities Australia "Australian Code for the Responsible Conduct of Research" (2007) have clearly identified the roles and responsibilities of institutions, researchers and review bodies in the conduct of research. In particular, these documents charge institutions to take a clearer overall responsibility for research governance.

8.4 The revised National Statement and Code advise institutions to have appropriate research governance processes in place to allow the ethical review of research to be undertaken well.

8.5 QH has implemented a policy of charging for HREC review, independent expert review and site-specific assessments of research protocols (unless exempt). These fees should be applied consistently throughout Queensland by QH districts.

### Payment of Fees:

8.6 It is the responsibility of the Site Principal Investigator to provide the RGO with details of the sponsor organisation to whom the invoice will be sent.

8.7 Invoices will normally be sent to the sponsor organisation / CRO by the district / site Finance Department as per usual practice.

8.8 The District CEO or delegate may withhold final research authorisation until the invoice has been paid.

8.9 If cheques are received by the RGO they to be recorded on the Money Received Register and promptly forwarded to Finance Department in line with local administrative procedures.

## What does the Fee for Site-specific assessment by a RGO Cover?

8.10 The QH SSA Fees enables the RGO to fulfil their duties as follows:

- Funding and managing the RGO, including the costs for equipment, furniture and stationary
- Assessing the completeness and appropriateness of the research project based on the information provided in the standard SSA form
- Provide timely recommendation to the District CEO or Delegate on the authorisation of research projects at the HSD
- Liaising with other District sites, authorising HRECs and District Administration on SSA matters
- Liaising with researchers regarding SSA submissions, requests for clarifications, responses and incomplete submissions
- Training researchers in submission of SSA forms
- Coordination for the monitoring of authorised research protocols, requesting reports, organising audits and contacting non compliant researchers
- Invoicing sponsors for SSA fees, receipting, reconciliation, follow up of unpaid invoices
- Facilitating and participating in meetings of the RGO group. This group consists of RGO personnel from other QH Districts. The groups focus is to disseminate information, to provide assistance if requested in the establishment of Research Governance and to enhance the education and role of Research Governance.

## Creating an invoice for industry sponsored studies

8.11 See Appendix A for 'cheat sheet' on creating a memo / invoice for finance

- The contact details for the study sponsor and CRA will need to be entered in the 'Contacts' section of the application prior to an invoice being generated.
- Click 'Add a new invoice'
- Insert the details (the GST component is % not $) and save
- A memo can now be printed and sent to the relevant department (usually the finance department) for the company to be invoiced.
- A receipt notification can also be entered onto AU RED by clicking 'edit' and submitting the receipt details.
- The invoice / receipt details will be recorded under the 'History' tab.

## SECTION 9: HANDLING COMPLAINTS

### General Policy:

9.1 A framework for dealing with allegations of research misconduct is outlined in The Code for the Responsible Conduct of Research (2007). A number of people within a site/district have responsibility for investigating and resolving allegations of research misconduct, such as, the District CEO or Delegate, Head of Departments, research supervisors and researchers. The site/district should ensure that all personnel are aware of their responsibilities.

9.1 Sites/districts must make public the process for receiving and resolving allegations of research misconduct. This should be consistent with the Code, the QH General Principles for Handling Research Complaints and QH – Complaints Process for Research Misconduct.

***AU-RED ALERT***

***SF4: General Principles for Handling Research Complaints***

***SF5: Complaints Process – Research Misconduct***

### Procedure for handling complaints concerning the RGO review process, including the District CEO or Delegate rejection of an application:

9.2 The site principal investigator may appeal the decision of the site-specific assessment.

9.3 Any concern or complaint about the RGO's review process should be directed to the attention of the RGO, detailing it in writing.

9.4 The RGO will notify the institutional CEO of any complaints received by him/her, as soon as possible. The institutional CEO will inform the RGO of any complaints received by him/her as soon as possible.

9.5 The RGO will investigate the complaint and its validity, and make a recommendation to the institutional CEO or delegate on the appropriate course of action.

9.6 If the complainant is not satisfied with the outcome of the RGO's, then he/she can refer the complaint to the District CEO, or his/her nominee, or request the institutional CEO to do so.

9.7 The RGO will provide to the District CEO all relevant information about the complaint/concern.

9.8 The District CEO will determine whether there is to be a further investigation of the complaint.

9.9 If it is decided there is to be a further investigation, then the District CEO will convene an investigating committee to review the complaint, ensuring that both the complainant and the RGO are afforded the opportunity to make submissions. In conducting its review, the panel shall be concerned with ascertaining whether the RGO acted in accordance with the National Statement, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

9.10 The decision of the investigating committee will be final

9.11 Appeals against HREC decisions will be dealt with as specified in the HREC SOPs

## Procedure for handling complaints about the conduct of an authorised research project:

9.12 As per the Australian Code for the Responsible Conduct of Research 2007 the institution will nominate 'advisers in research integrity' to advise possible complainants about research conduct issues and explain the options open to persons considering, making, or having made an allegation.

9.13 As per the Australian Code for the Responsible Conduct of Research 2007 the institution will nominate a 'designated person' for handling research complaints, including research misconduct.

9.14 Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the authorising HREC institution's designated person for handling research complaints, including research misconduct.

9.15 Any complaints received must also be forwarded to the secretariat of the authorising HREC who will enter the complaint details on AU RED and to the local site RGO where the complaint applies.

9.16 Initially, complaints should be forwarded by the designated person to the relevant department to be dealt with at departmental level.

9.17 The departmental decision will be reported back to the 'designated person', the HREC secretariat and the local RGO.

9.18 The 'designated person' will review the departmental decision and make a recommendation to the HREC on the appropriate course of action.

9.19 If the complainant is not satisfied with the outcome of the 'designated person's' investigation, then he/she can refer the complaint to the institution's Chief Executive Officer (CEO) or his/her nominee.

9.20 For allegations not resolved at departmental level and appeals, the authorising HREC's institution's CEO or his/her nominee will establish an investigating committee; nominating three independent individuals, who do not have any conflict of interest in the case and have appropriate expertise to evaluate the research issues, to review the case.

9.21 The decision of the investigating committee will be final.

9.22 Participant Information Sheet and Consent forms must include contact details to allow such complaints to be made.

9.23 All complaints will be acknowledged within seven (7) days.

9.24 The complainant will be advised of the decision within 30 days.

## SECTION 10: EDUCATION AND TRAINING OF DISTRICT RESEARCH GOVERNANCE OFFICE/RS (RGO/rs)

### Essential Reading:

- NHMRC *"National Statement on Ethical Conduct in Human Research" (2007)*
- NHMRC and Universities Australia *"Australian Code for the Responsible Conduct of Research" (2007)*
- Therapeutic Goods Administration "*Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)" (2000)*
- *Public Health Act (Qld)* 2005, Part 4 Division 1 s280
- Guidelines under Section 95 of the Privacy Act
- Guidelines under Section 95A of the Privacy Act
- Queensland Health Information Standard 42A
- Queensland Health Research Management Policy and Guidelines 2008
- Finance Management Practice Manual
- Coroners Act 2003, s.53

# SECTION 11: STORAGE AND RETENTION OF RGO RECORDS AND DOCUMENTATION

## General Policy

The Queensland Health Strategic Records Management Team have advised that until such a time that the *Retention Disposal Schedule* has been approved by Queensland State Archives, that all Site-specific records and associated documentation should be held by Districts/sites indefinitely.

Further information can be obtained from the Queensland Health Strategic Records Management Team on 07 3239 0928.

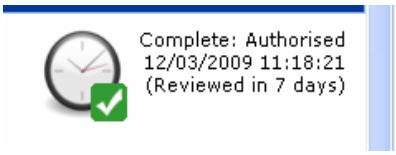
## APPENDIX A: CHEAT SHEET FOR PROCESSING A SSA APPLICATION

### Registering an SSA Application on AU-Red

1. Select the Application Tab from the "blue banner" at the top of screen
   - Select **NEW**
   - Enter the Study type
   - In the Application Type select **SITE SPECIFIC APPLICATION** from the drop down box
2. Once Site Specific Application is selected, the box to enter HREC reference number appears. Enter this number (the HREC number is found at the top of the SSA print out)
3. Select **CONFIRM**
4. Select **REGISTER APPLICATION**. (This will take you to the next page with all the processing tabs)
5. Enter Submission Code (From SSA Application Form) & Click on the **GET ONLINE FORM**. The page will flip over to the "Details" page
6. The uploaded details from the SSA will be visible. Check details and select **NEXT**
7. The Reference for HREC & SSA will be visible. Check details and select **CONTINUE**
8. Click on the **CONTACTS** tab
   - Check that details here are correct
   - Enter any new details if required
9. Click on the **CHECKLIST** tab
   - Select **SSA APPLICATION**
10. Click **ENTER SELECTED ITEMS**
11. Put in a date into the **DATE RECEIVED** box and select **SAVE ITEMS** (☝*Other documents maybe checked "recorded" here. Only documents entered under the "CHECKLIST tab" will appear in the letter. The History Tab enables the "true" copy to be up-loaded in pdf/word format. Documents that are uploaded into the History Tab do not appear on your letter. The History tab keeps a record of all documents for future retrieval eg: If someone were asked to retrieve correspondence relating to a particular SSA, the History Tab will have this "actual" document (if it were up-loaded))*

12. Click on **VALIDATE/START**
    - Select **VALID** (or Invalid if the case arises)(
    - Put in the date and click **UPDATE**
13. **PRINT** SSA Valid/Invalid Letter (save to desktop and modify with district pertinent details before posting) Upload the modified letter by clicking the **HISTORY TAB and then 'Upload Files'**.(☝ *the comments that are entered into Au-RED for Invalid Applications will transfer over into the Letter that is generated once the PRINT button is selected*)
14. Select the **MEETING** tab
15. Enter **RGO RECOMMENDATION** by clicking on the down arrow and selecting the appropriate selection
16. Next select the **PRINT/PREVIEW** button for the Memo for District CEO (save the Memo to the desk and modify with district pertinent details. Upload into the History Tab)
17. Once a decision is received back from the District CEO, retrieve the SSA from the **WORKAREA**. Click on the **MEETINGS** tab and assign the CEO decision by clicking on the down arrow.

- **SAVE DECISION** ,
- **PRINT/PREVIEW** the letter
- Click on the **LETTER SENT, STOP CLOCK**
- The clock will show a **BIG GREEN TICK**

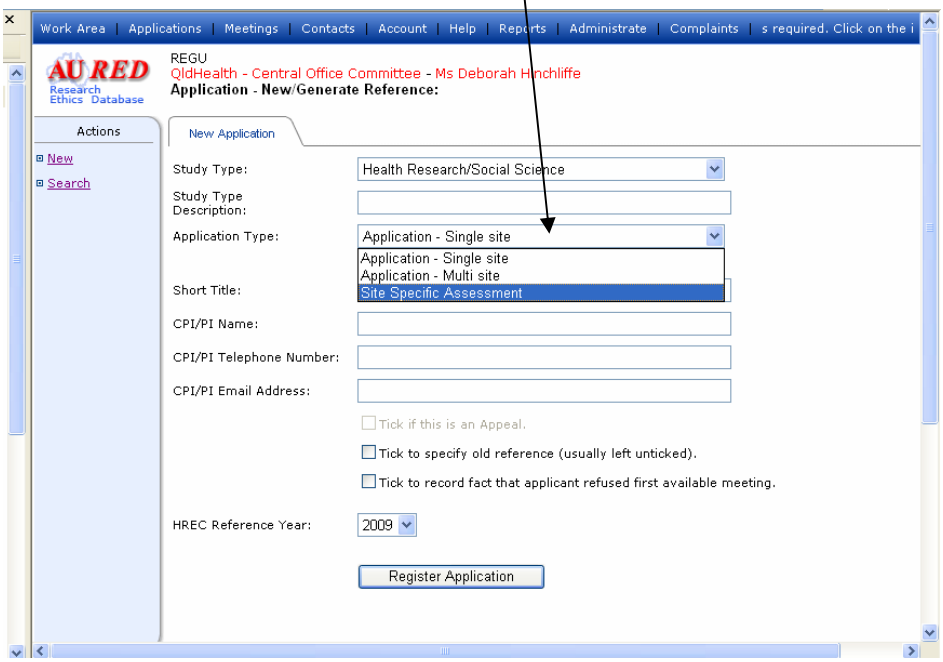



❖❖❖❖❖❖❖❖

Select the Application Tab from the “blue banner” at the top of screen

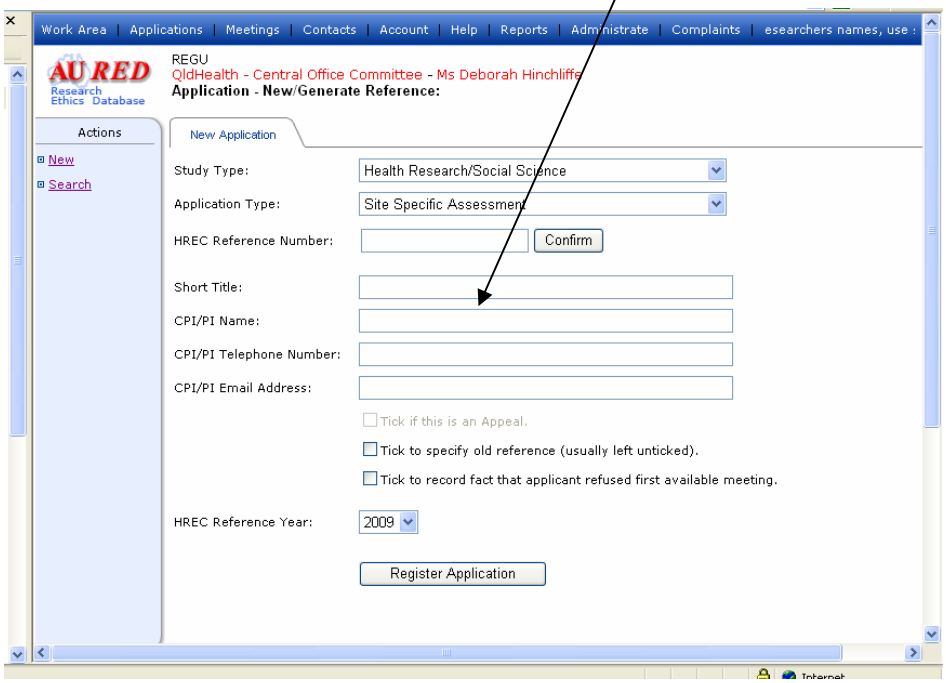
- Select **NEW**
- Enter the Study type
- In the Application Type select **SITE SPECIFIC APPLICATION** from the drop down box

1



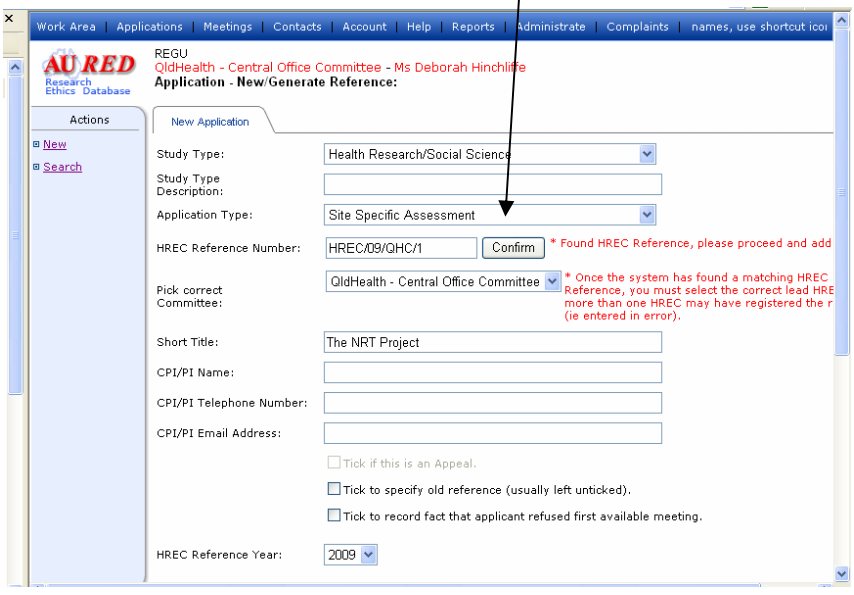
Once Site Specific Application is selected, the box to enter HREC reference number appears

2

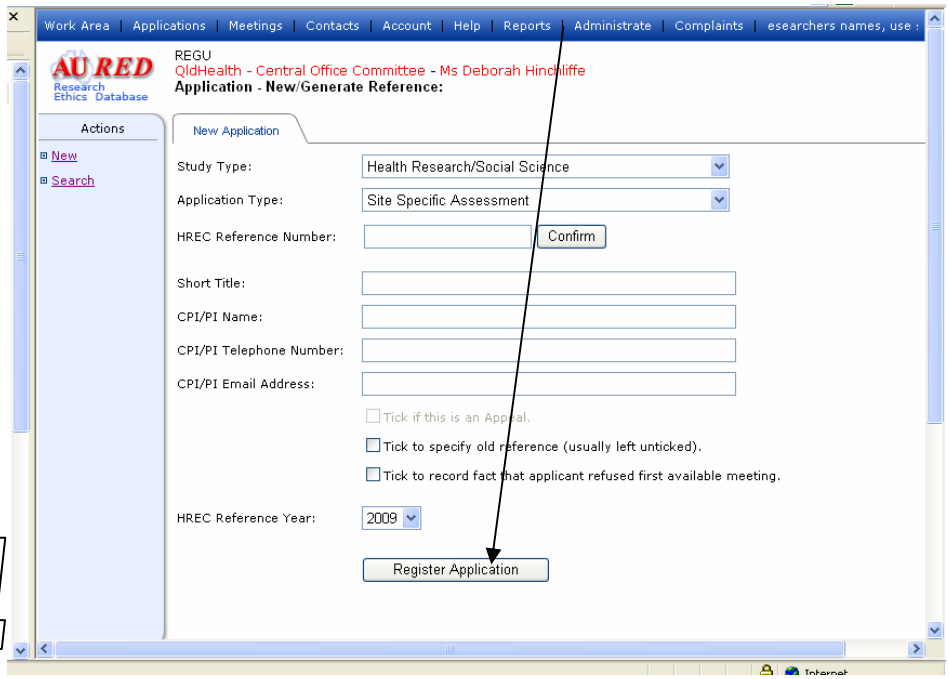



3

Select **CONFIRM**



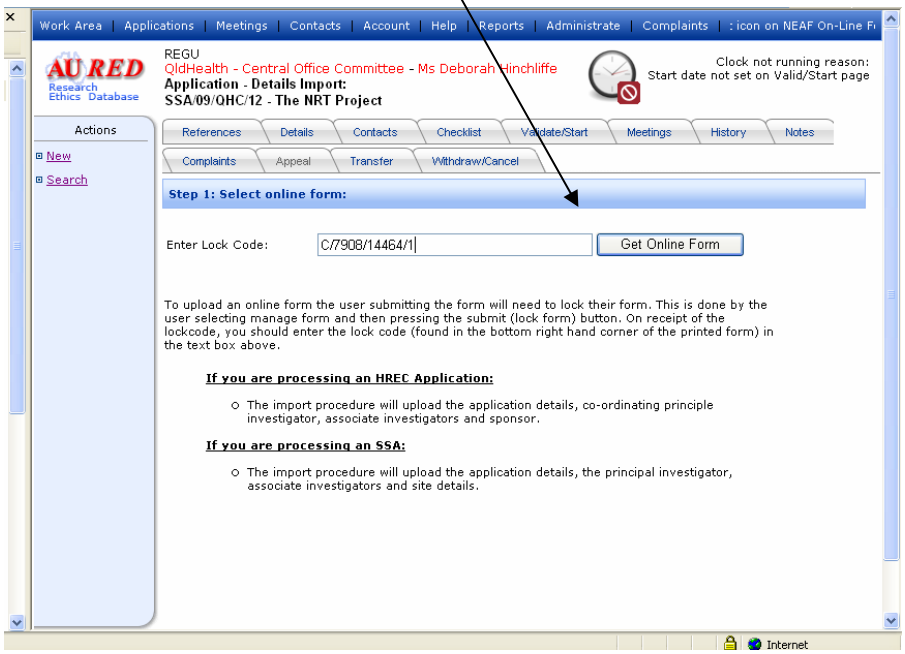
Select **REGISTER APPLICATION**



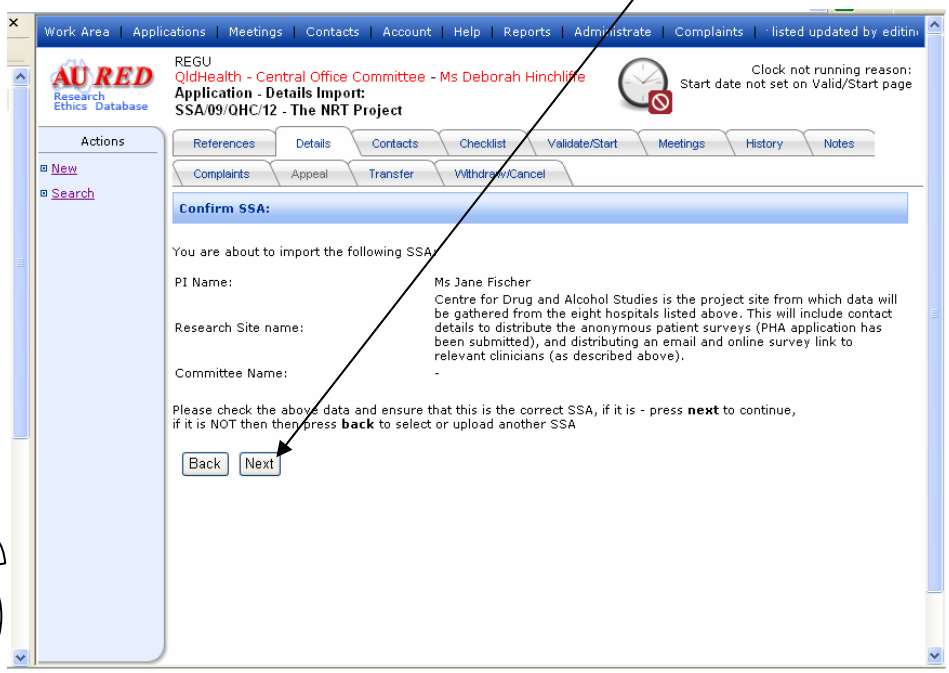

4

Enter Submission Code (From SSA Application Form)

5

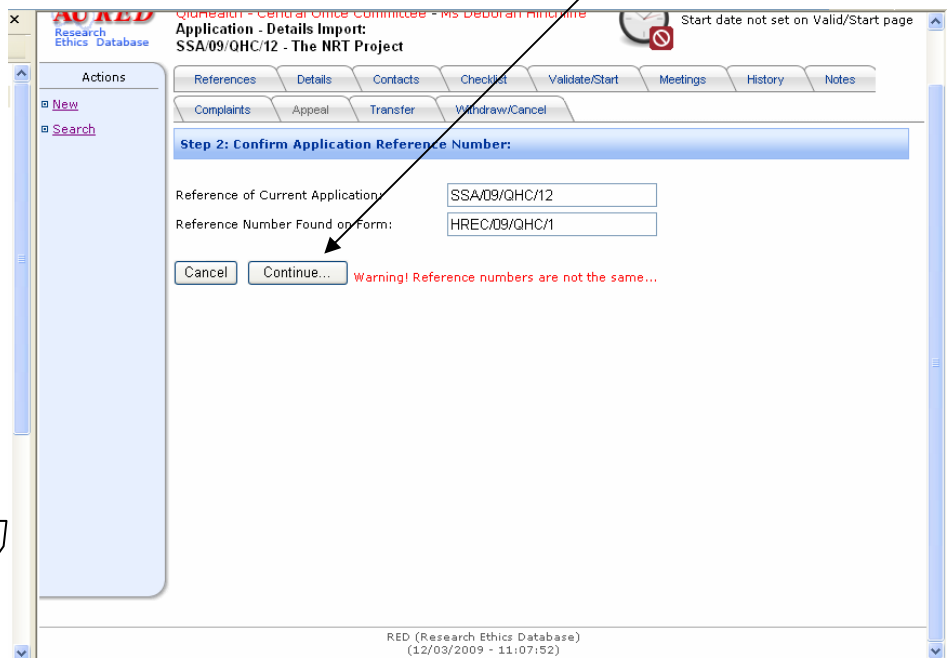


Check Details and select **NEXT**




6

Check details and select **CONTINUE**

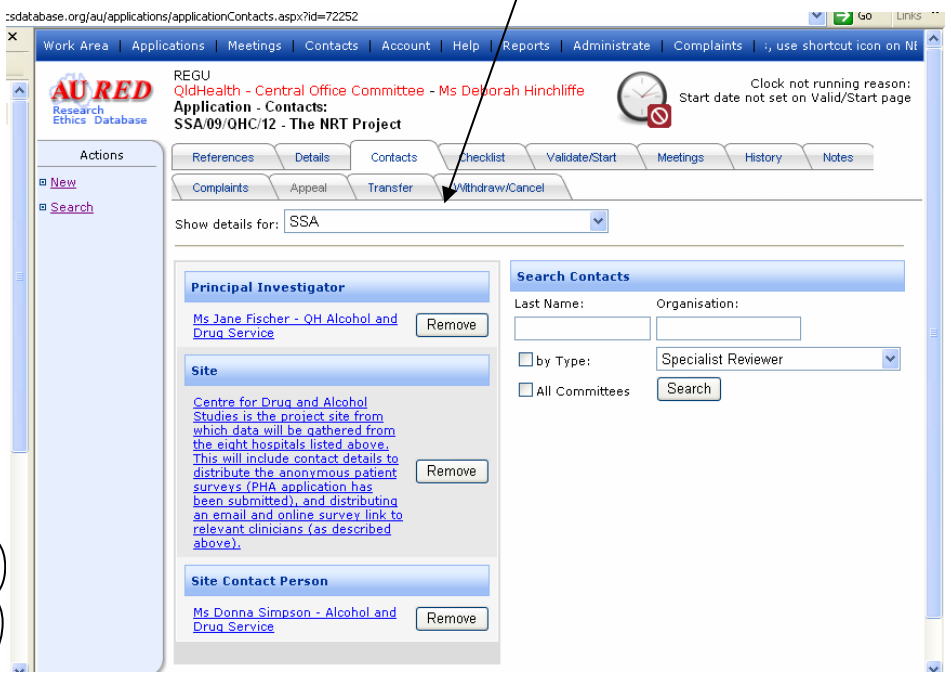



7

Click on the **CONTACTS** tab

Check that details here are correct

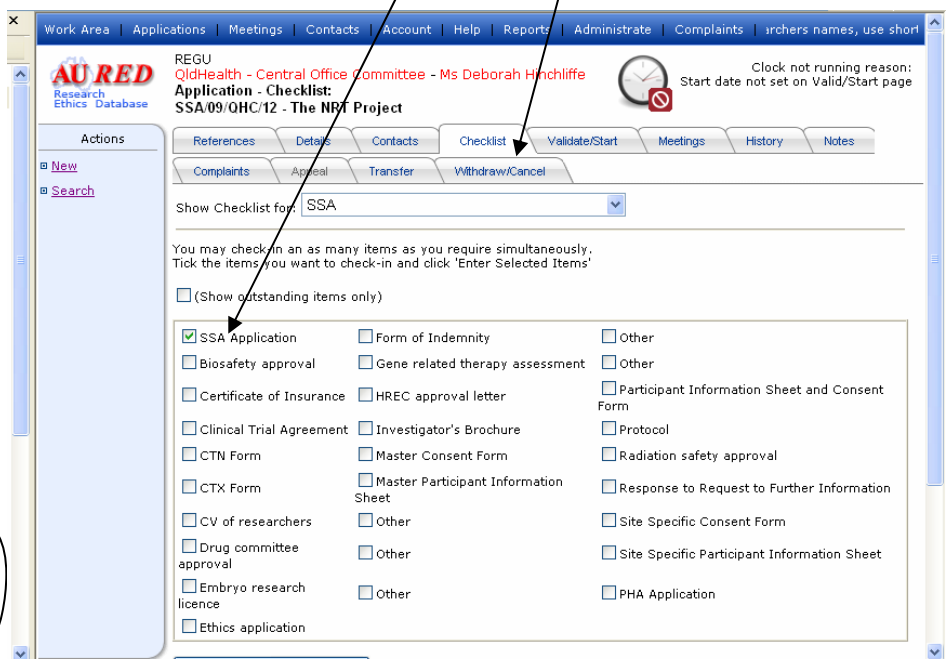
Enter any new details if required




8

Click on the **CHECKLIST** tab

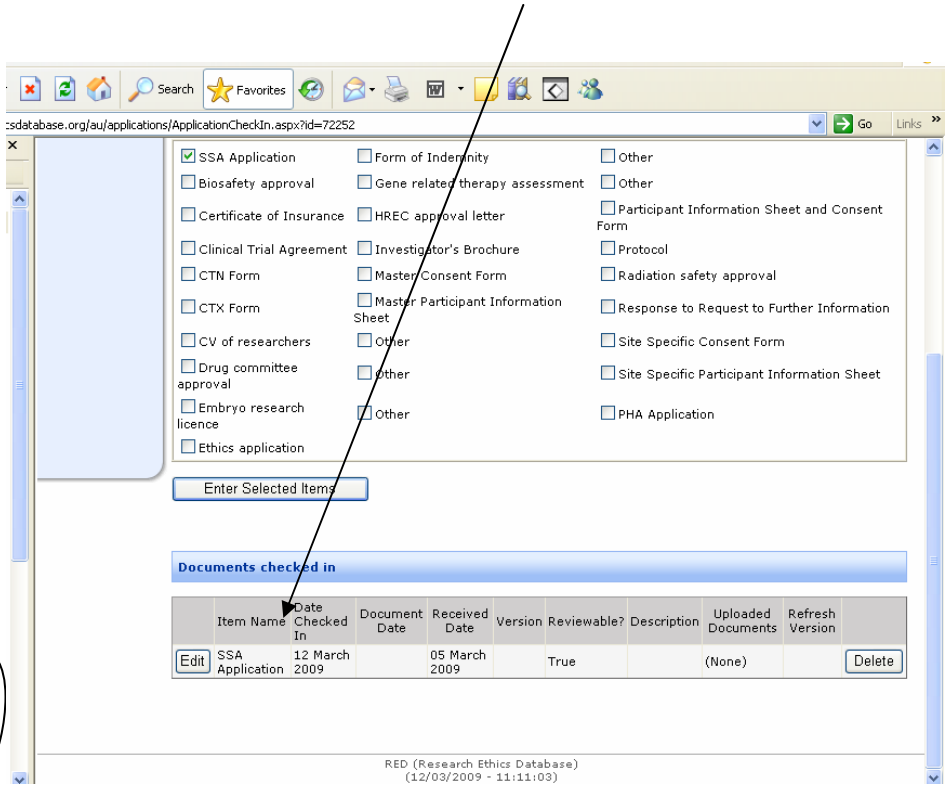
Select SSA **APPLICATION**




9

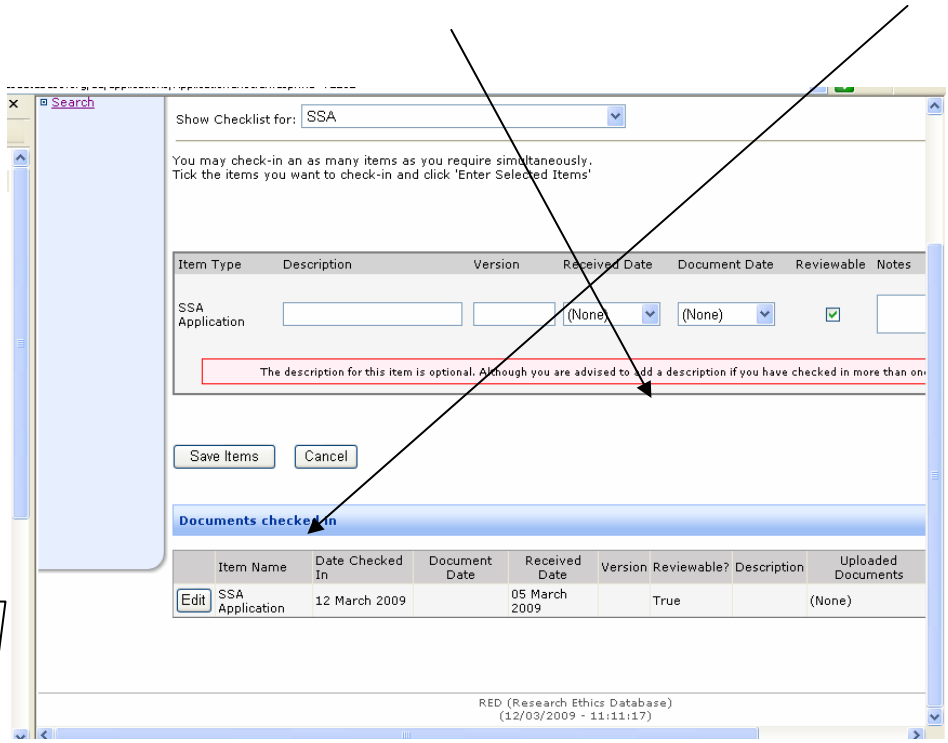
Click **ENTER SELECTED ITEMS**

10




Put in date into the **DATE RECEIVED** box and select **SAVE ITEMS**

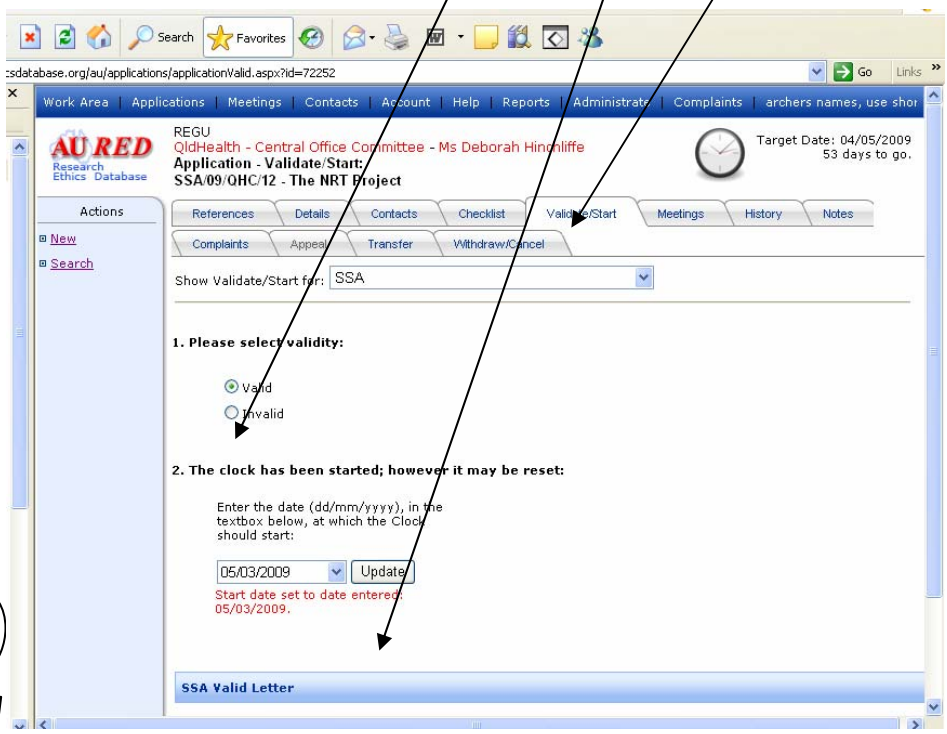
11



Click on **VALIDATE/START**

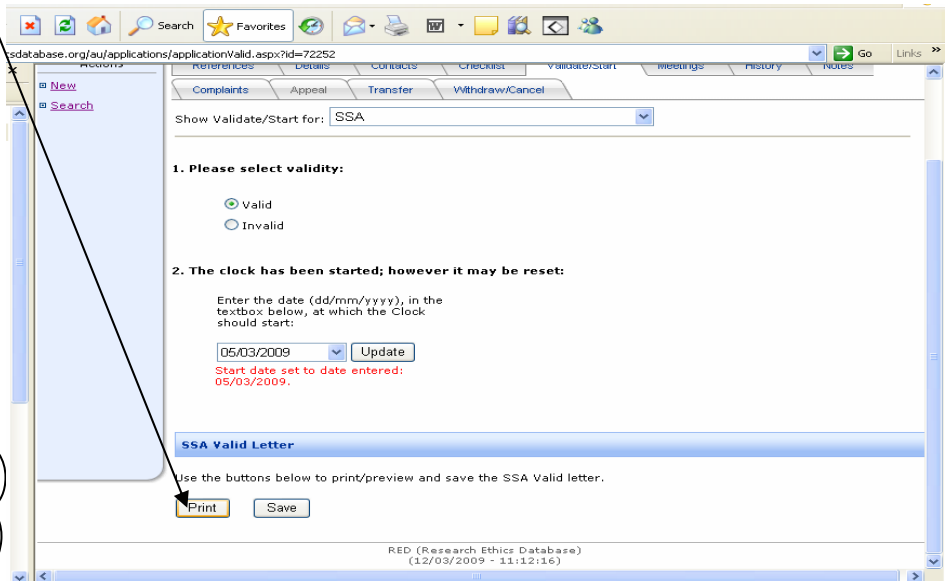
Select **VALID**

Put in the date and click **UPDATE**



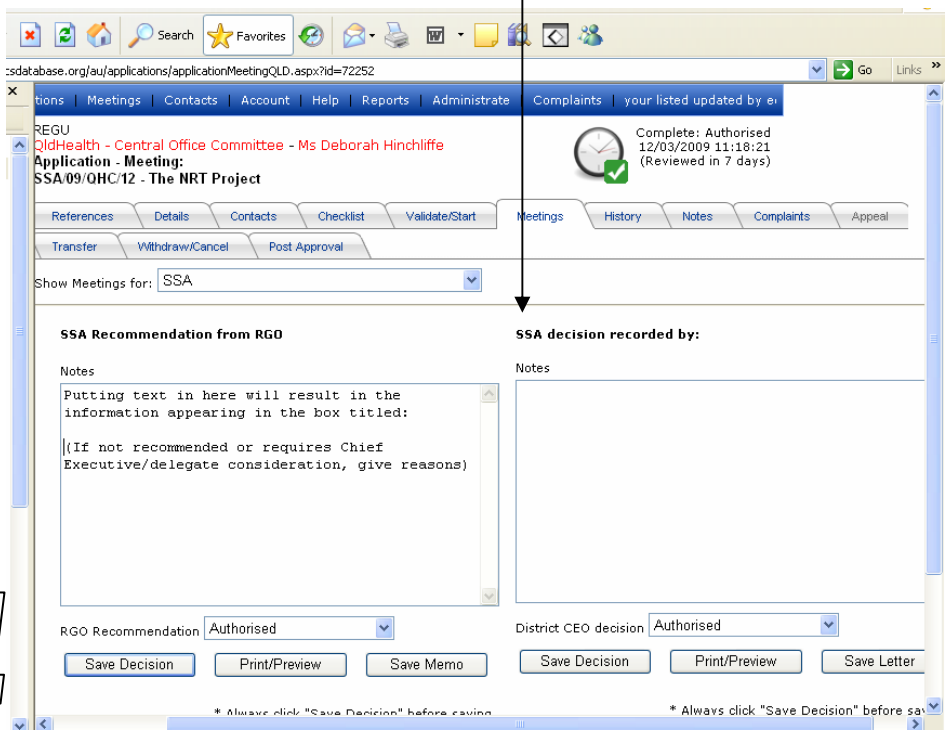

12

**PRINT** SSA Valid Letter (save to desktop and modify with district pertinent details) (Upload finished letter to your **HISTORY** tab



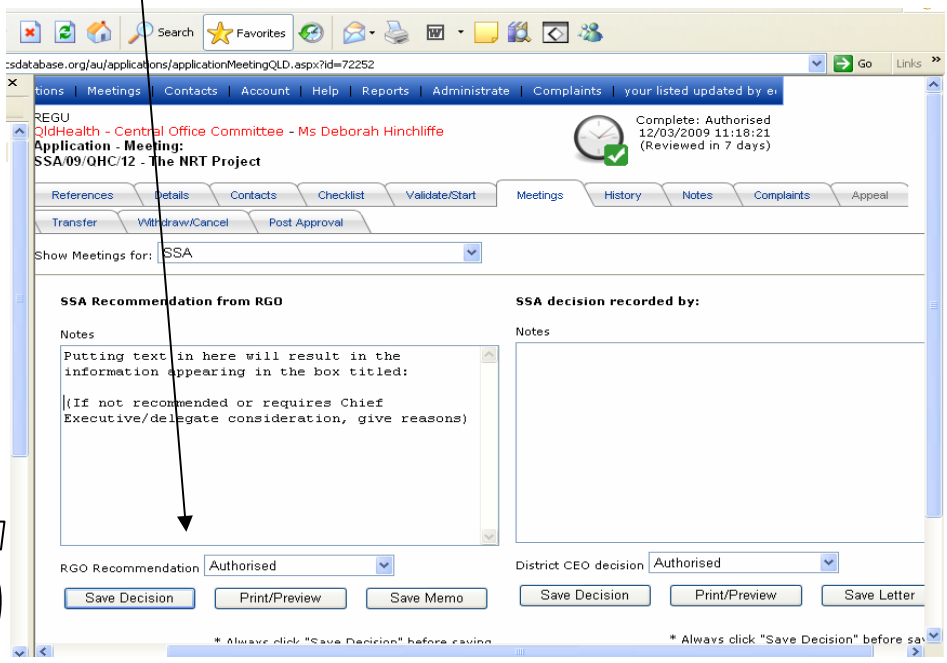

13

Click on the **MEETINGS** tab




14

Enter **RGO RECOMMENDATION** by clicking on the down arrow and selecting the appropriate selection

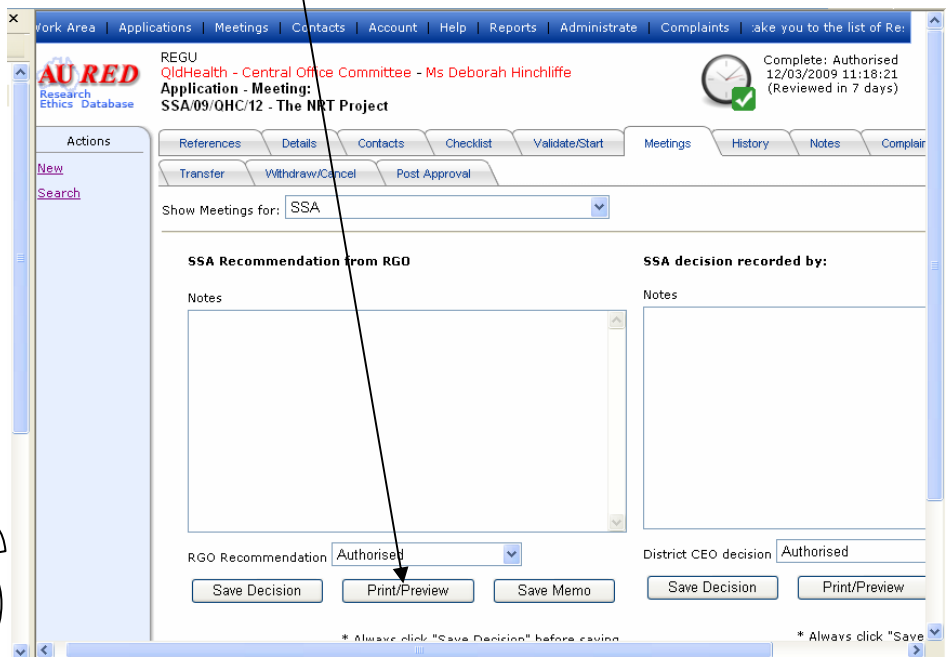



15

Next select the **PRINT/PREVIEW** button for the Memo for District CEO

(send letter to District CEO)

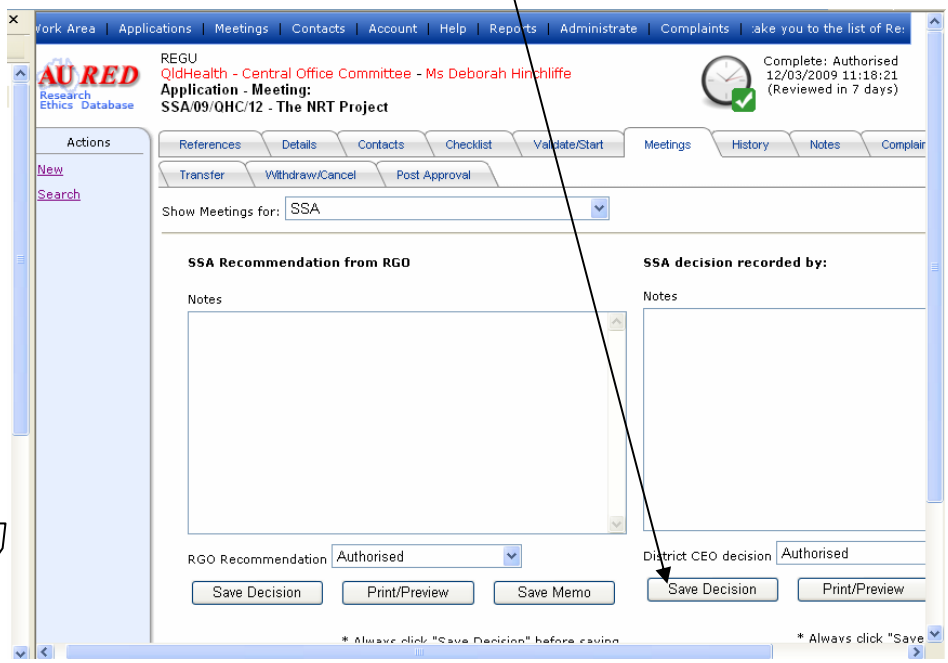
16




Once a decision is received back from the District CEO, retrieve the SSA and assign the decision by clicking on the down arrow.

**SAVE DECISION**

17



**PRINT/PREVIEW** the letter

District Research Governance

Enquiries to:

12 March 2009

Phone: **[Phone]**

Fax: **[Fax]**

Our Ref: **SSA/09/QHC/12**

E-mail **[Email]**

CPI
Address

Dear CPI

**HREC reference number: HREC/09/QHC/1**
**SSA reference number: SSA/09/QHC/12**
**Project title: Evaluation of Component 2 of the Queensland Health smoking management policy: Managing inpatient nicotine withdrawal with nicotine replacement therapy (NRT) and/or brief interventions.**
**Protocol number: Protocol Ref N/A**

Thank you for submitting the Site Specific Assessment (SSA) Form to conduct research as the Site Principal Investigator at [Insert District/Site Name]. I can confirm that the submission was received on 05 March 2009.

The Research Governance Office will make an assessment of the suitability of this project.

**Please note, you cannot commence this project at this site until you receive authorisation from the [District CEO or Delegate].**

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

District Research Governance

| | |
|---|---|
| | Enquiries to: |
| 19 March 2009 | Phone: **[Phone]** |
| | Fax: **[Fax]** |
| | Our Ref: **SSA/09/QRBW/42** |
| | E-mail **[Email]** |

Dear

**HREC reference number: HREC/09/QRBW/5**
**SSA reference number: SSA/09/QRBW/42**
**Project title: ACE Inhibition: A Potential New Therapy for Peripheral Arterial Disease**
**Protocol number: Protocol Ref N/A**

Thank you for submitting the Site Specific Assessment (SSA) Form to conduct research as the Site Principal Investigator at Royal Brisbane & Women's Hospital, Brisbane. I can confirm that the submission was received on 27 January 2009.

Unfortunately the application is not valid for the following reason(s):

- The Site Specific Assessment form is not complete.

Section 8d has not been completed. Please explain why a clinical trial contract has not been submitted for this study.

*[List any other reasons for incompletion]*

You are welcome to re-submit the SSA form, taking into account the above points.

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

**Recommendation by the Research Governance Office/r at the site:**

**HREC Application Reference number:** SSA/09/QHC/12

**Project Title (in full):** Evaluation of Component 2 of the Queensland Health smoking management policy: Managing inpatient nicotine withdrawal with nicotine replacement therapy (NRT) and/or brief interventions.

**Principal Investigator or Contact Person:** Ms Jane Fischer

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

SSA authorisation is: Recommended ☐

Not recommended ☐

Requires Chief Executive/delegate consideration ☐

If not recommended or requires Chief Executive/delegate consideration, give reasons.

Update form with pertinent district details

Delegated Research Governance Office/r …….

Signature ……... Date……

Queensland Government
Queensland Health

# MEMORANDUM

**To:** Professor Robin Mortimer
Senior Director, Office of the Health & Medical Research

**Copies to:**

**From:** Deborah Hinchliffe — Contact No: 323 0034
Research Ethics & Governance Unit — **Fax No:** 3405 6131

**Subject:** **Site Specific Assessment (Approval)**

**File Ref:** **SSA/09/QHC/12**

**Recommendation by the Research Governance Officer at the site**

**HREC Application Reference number:** SSA/09/QHC/12

**Project Title (in full):** Evaluation of Component 2 of the Queensland Health smoking management policy: Managing inpatient nicotine withdrawal with nicotine replacement therapy (NRT) and/or brief interventions.

**Principal Investigator or Contact Person:** Ms Jane Fischer

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

SSA authorisation is: Recommended ✓

Not recommended ☐

Requires Chief Executive/delegate consideration ☐

If not recommended or requires Chief Executive/delegate consideration, give reasons.

**This study has received full HREC approval on 26 February 2009**

Delegated Research Governance Officer: Deborah Hinchliffe

Signature: _____Date: _____

## APPENDIX B: STANDARD LETTERS AND FORMS

**Standard Letters:**

SL1: SSA Acknowledgement and validation
SL2: Invalid SSA notification
SL3: Acknowledgement of withdrawal of SSA
SL4: Research Authorisation
SL5: Research not Authorised
SL6: Request for HREC amendment approval prior to Authorisation
SL7: SSA Acknowledgement and validation of amendment.
SL8: Favourable opinion of post authorisation SSA amendment
SL9: Unfavourable opinion of post authorisation SSA amendment (with options for further review)
SL10: Suspension/Withdrawal of District Authorisation to conduct research.
SL 11: Acknowledgement of study completion

**Standard Forms:**

SF1: Guidance in using the Site-specific Assessment (SSA) Form – online document: http://www.health.qld.gov.au/ohmr/documents/ssa_full_suite_docs.pdf
SF2: Site-specific Assessment (SSA) Form and Checklist – online form: https://ethicsform.org/au/SignIn.aspx
SF3: Schedule of Fees for Ethics and Research Governance Review of Commercially Sponsored Research
SF4: General Principles for Handling Research Complaints
SF5: Complaints Process – Research Misconduct

**SL1: SSA Acknowledgement and validation.**

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

Thank you for submitting the Site Specific Assessment (SSA) Form to conduct research as the Site Principal Investigator at [Insert District/Site Name]. I can confirm that the submission was received on [Insert Date].

The Research Governance Office will make an assessment of the suitability of this project.

**Please note, you cannot commence this project at this site until you receive authorisation from the District CEO or their delegate.**

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

**SL2: Invalid SSA Notification.**

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

Thank you for submitting the Site Specific Assessment (SSA) Form to conduct research as the Site Principal Investigator at [Insert District/Site name]. I can confirm that the submission was received on [Insert Date].

Unfortunately the application is not valid for the following reason(s):

[The Site Specific Assessment form is not complete. [List reasons for incompletion] or;
[The Site Specific Assessment form has not been submitted]

You are welcome to re-submit the SSA form, taking into account the above points.

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

**SL3: Acknowledgement of withdrawal of SSA**

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

The above Site Specific Assessment (SSA) to conduct research as the Site Principal Investigator at the [Insert District/Site name] was received on [Insert Date].

I wish to acknowledge that the SSA has been withdrawn by the [Choose either Researcher / Research Governance Office/r or Cancelled as main study not approved by HREC on the [Insert Date].

The SSA has been registered as withdrawn on the Research Ethics Database and if you wish to re-submit the SSA, it will be treated as a new submission.

Should you require any additional information, please contact the [Insert District/Site Name] Research Governance Office, [Insert name, phone number and email].

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL4: Research Authorisation

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following site(s):

[List each site at which the research project has been granted approval separately]

The following conditions apply to this research proposal. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval.

1. [Insert any special conditions of approval imposed by the site];
2. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the HREC for review, are copied to the research governance officer;
3. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted to the research governance officer;
4. Proposed amendments to the research protocol or conduct of the research which may affect both the going ethical acceptability of the project and the site acceptability of the project are to be submitted to the research governance offer after a HREC decision is made.

Yours sincerely

[Insert Name]
District Authorisation Delegate
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL5: Research not Authorised

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:**

Thank you for submitting an application for authorisation of this project. I regret to inform you that authorisation has not been granted for the reasons outlined below:

[Insert reasons]

Should you wish to discuss this review of your project, please contact the [Insert District/Site Name] Research Governance Office, [Insert name, phone number and email].

Yours sincerely

[Insert Name]
District Authorisation Delegate
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL6: Request for HREC amendment approval prior to Authorisation

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

Thank you for submitting the amended Site Specific Assessment (SSA) form for the above project for [Insert District/Site name] authorisation. I can confirm the amended SSA was received on [Insert Date].

It is considered that this amendment will require prior review and approval from the HREC before [District/Site name] authorisation can be granted for the following reasons:

[Insert reasons for decision]

The Research Governance Office will make an assessment of the suitability to implement the amendment for this project after HREC consideration.

**Please note, you cannot commence the amendment for this project at this site until you receive authorisation from the District CEO or their delegate.**

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL7: SSA Acknowledgement and validation of amendment.

District Research Governance

| | | |
|---|---|---|
| | Enquiries to: | |
| [date] | Phone: | [Phone] |
| | Fax: | [Fax] |
| | Our Ref: | [SSA Reference] |
| | E-mail | [Email] |

[PI Name]
[PI Address]

Dear [PI Name]

**HREC reference number: [HREC reference number:]**
**SSA reference number: [SSA reference number:]**
**Project title: [Project title:]**
**Protocol number: [Protocol number:]**

Thank you for submitting the amendment to the Site Specific Assessment (SSA) Form for the above project. I can confirm that the submission was received on [SSA Application Received Date].

The Research Governance Office will make an assessment of the suitability of this amendment.

**Please note, you cannot commence the amendment to the project at this site until you receive authorisation from the District CEO or their delegate.**

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL8: Favourable Opinion of Post Authorisation SSA Amendment.

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

Thank you for submitting the amended Site Specific Assessment (SSA) form for the above project for [Insert District/Site name] authorisation. I can confirm the amended SSA was received on [Insert Date].

[List authorised documents and version nos.]

I am pleased to inform you that authorisation is granted for this study amendment to take place at the following site(s):

[List each site at which the project amendment has been granted authorisation separately]

It should be noted that all conditions of the original [Insert District/Site name] authorisation still apply.

Yours sincerely

[Insert Name]
District Authorisation Delegate
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

**SL9: Unfavourable Opinion of post authorisation SSA amendments (with options for further review)**

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**

**[SSA reference number:]**

**[Project title:]**

**[Protocol number:]**

Thank you for submitting the amended Site Specific Assessment (SSA) form for the above project for [Insert District/Site name] authorisation. I can confirm the amended SSA was received on [Insert Date].

Unfortunately the amendment was not granted authorisation for the following reasons:

[Insert reasons/comments]

The study should continue in accordance with the documentation previously authorised by the [Insert District/Site Name]. You may modify or adapt the amendment taking into account the concerns outlined above and re-submit a revised SSA Form and supporting documentation.

Should you wish to discuss this review of the project amendment, please contact the Research Governance Office, [Insert name, email and contact].

Yours sincerely

[Insert Name]

District Authorisation Delegate

[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL10: Suspension/Withdrawal of District Authorisation to conduct research.

Research Governance

Enquiries to:

[date]

Phone:

Fax:

Our Ref: [prot no]

E-mail

[name and address of pi]

Dear [surname]

**[HREC reference number:]**
**[SSA reference number:]**
**[Project title:]**
**[Protocol number:]**

The above project was granted authorisation to commence by the [Insert District/Site Name] HSD on [Insert Date].

The [Insert Name/Delegate, title, position] has decided to [Suspend / Withdraw ] authorisation of your project for the following reasons.

[List reason/s separately]

[List any conditions that may restore authorisation for the Research to proceed (if applicable)].

**You are not authorised to continue with this research.**

Should you wish to discuss this decision, please contact [Insert name and contact details of District Research Governance personnel].

Yours sincerely

[Insert Name]
District Research Authorisation
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

## SL11: Acknowledgement of study completion

District Research Governance

| | |
|---|---|
| | Enquiries to: |
| [date] | Phone: [Phone] |
| | Fax: [Fax] |
| | Our Ref: [SSA Reference] |
| | E-mail [Email] |

[PI Name]
[PI Address]

Dear [PI Name]

**HREC reference number: [HREC reference number:]**
**SSA reference number: [SSA reference number:]**
**Project title: [Project title:]**
**Protocol number: [Protocol number:]**

Thank you for sending notification of the completion of the above study, dated [Report Date], at the [Insert site]

The Research Governance Office would like to congratulate you and the investigating team on the successful outcome of the study.

We have now closed and archived our file.

Yours sincerely

[Insert Name]
Research Governance Officer
[Insert District/Site Name]

cc. [Name and address of research assistant if applicable]

**SF3: Schedule of Fees for Ethics and Research Governance Review of Commercially Sponsored Research.**

## Schedule of Fees for Ethics and Research Governance Review of Commercially Sponsored Research

1. The following fees apply to all applications to review commercially sponsored research made to all Queensland Health Districts, commencing 17 October 2008. That is, it applies to all HREC applications and all site specific assessment applications lodged with a Queensland Health District/Site after 17 October 2008.

**Table 1: Fees for review of commercially sponsored research by Human Research Ethics Committees and Governance Review (site specific assessments)**

| Fee | Value |
|---|---|
| HREC fees for application for research project with full industry sponsorship | $3300 |
| HREC fees for amendments to research projects with full industry sponsorship* | $550 |
| HREC fees for addition of sub-studies to research projects with full industry sponsorship# | $1665 |
| Independent Review Fee | Cost Recovery Only |
| Site-Specific Assessment (SSA) Fee | $3300 per site |

* Amendments include changes to the protocol excluding minor administrative changes

# Sub-studies will be reviewed and fees determined on a case-by-case basis.

The HREC may request that the sub-study be submitted as a new application and charge the full fee. All figures are inclusive of GST.

## SF4: General Principals for Handling Research Complaints

### GENERAL PRINCIPLES OF HANDLING RESEARCH COMPLAINTS

**STANDARDISED:**

- Consistency in process and decision making;
- Enhance public and staff acceptance of process;

**ACCOUNTABLE:**

- Ensure people with appropriate experience and expertise provide guidance and advice on complaint cases;
- Complaint process is complete and demonstrates accountability by the Health Service District;

**TRANSPARENT:**

- Take appropriate steps to maintain public confidence in the research;
- Take appropriate steps to avoid conflicts of interest in managing complaint cases;
- Decide who should be informed and how.

**ACCESSIBLE:**

- Ensure appropriate personnel are identified and easily accessible for a complaint to be made;
- Informing the complainant of the complaint management process;

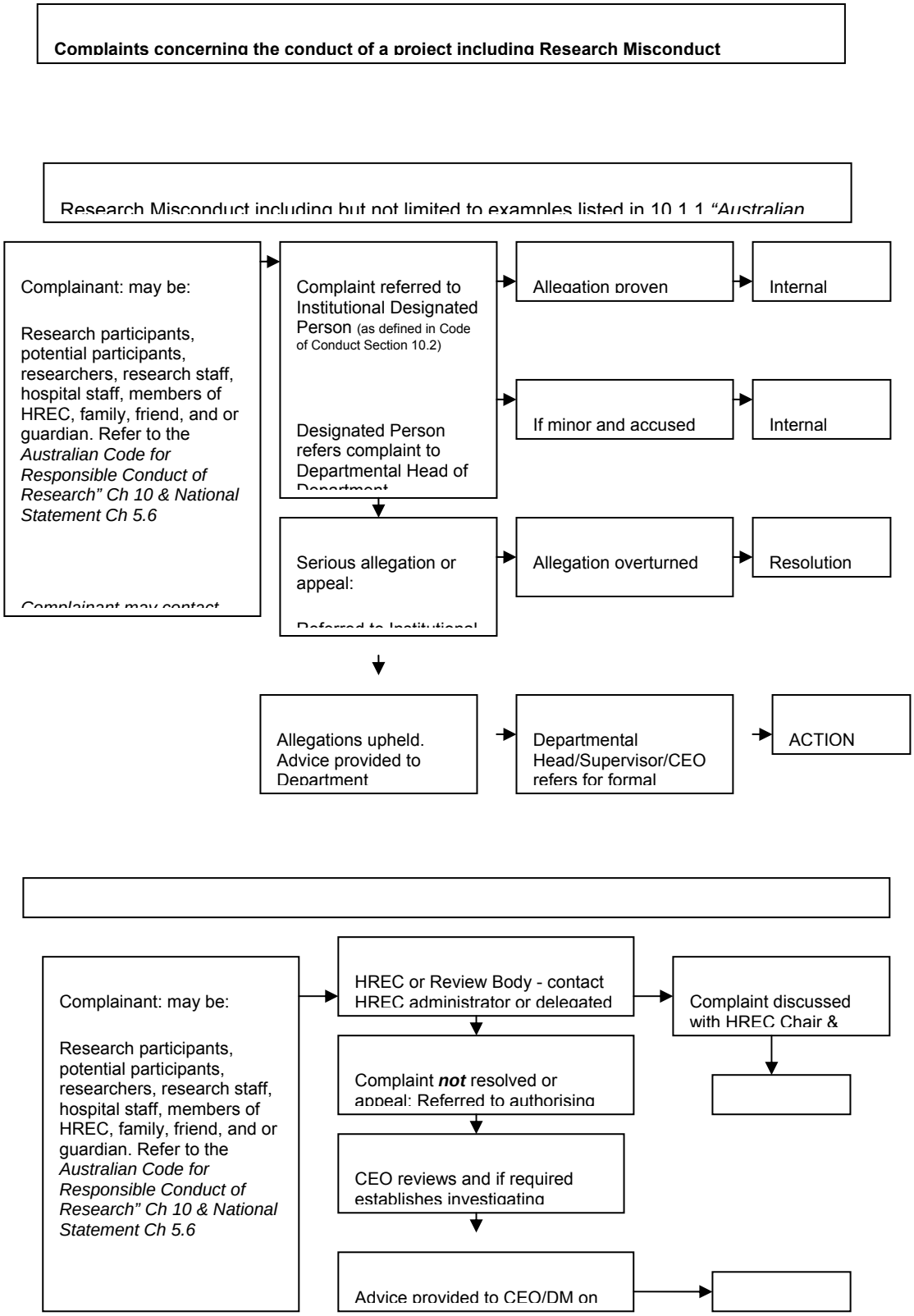
**TIMELINESS:**

- Acknowledgement of complaint, recorded and investigated in a timely manner in the best interest of all parties;
- Ensure prompt and effective response in each complaint case;

**PROCEDURAL FAIRNESS:**

- All affected parties must be treated in a way that supports natural justice;
- Allegations of research misconduct or complaints concerning a HREC/Review Body should be made in writing;
- Person facing allegations has a right to be heard;
- Personnel investigating complaint must be free from bias or preconception;
- Findings/Outcomes of complaint should be provided in writing and stating reasons for findings/outcomes;
- Person who makes allegations must be treated fairly;
- Provide an avenue for appeals.

## SF5: Research Complaints Process



**Complaints concerning the District CEO or delegate's review process including the rejection of an application**