Procedure

Site Specific Assessment and Authorisation of Research

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Executive sponsor	Executive Director Medical Services			**Effective date**	23/08/2021
Author/custodian	Research Governance Officer			**Review date**	23/08/2024
Supersedes	Nil				
Applicable to	All staff employed by CHQ (permanent, temporary, casual) within all facilities and services conducting research at or in collaboration with CHQ.				
Authorisation	Executive Director Clinical Services				

Purpose

Children's Health Queensland Hospital and Health Service (CHQ) is committed to the highest standards and practices in the assessment, authorisation, oversight and conduct of research. This procedure describes the Site Specific Assessment (SSA) authorisation processes for research being conducted at or in collaboration with CHQ.

Adherence to this procedure will ensure all research conducted at CHQ or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

Scope

This procedure applies to CHQ or Queensland Health employees whose usual reporting line is through a CHQ facility or service, who conduct human research at or in collaboration with CHQ, or through access to CHQ participants, health records or data.

Failure to comply with this procedure may amount to professional misconduct, or research misconduct on the part of the researcher. This procedure must be read in conjunction with other relevant CHQ policies and procedures.

Key Principles

The following key principles guide CHQ in the assessment, authorisation, and oversight of research submissions:

- SSA is a framework through which CHQ is accountable for the research it authorises to be conducted at any of its facilities (e.g. Queensland Children's Hospital (QCH), Centre for Children's Health Research (CCHR) or CHQ Community Facilities). It addresses financial accountability and transparency, intellectual property, mandated legal obligations, site resource utilisation/implication and site suitability.

- SSA involves co-operation and communication between the research project principal investigator, coordinating principal investigator and the CHQ Research Governance Office (RGO).
- SSA ensures research project documentation is appropriate, so that an informed decision can be made to approve or reject conduct of the research at CHQ.
- Information contained within relevant CHQ policies, procedures and frameworks applies to all research projects conducted at/within or by CHQ.
- SSA application must be submitted in parallel with the Human Research Ethics Committee (HREC) submission using the Ethics Review Manager (ERM) Applications portal.
- Research is only permitted to commence when both HREC clearance and SSA authorisation from the Health Service Chief Executive (HSCE, or delegate) has been provided by RGO, and financial, legal and indemnity issues have been addressed.

Responsibilities

Health Service Chief Executive (or delegate)

- Provide authorisation on SSA applications and contracts according to the CHQ Finance Management Practice Manual and the Contract Management Framework.

CHQ Director of Research

- Execute HSCE-delegated duties as they pertain to research, according to the CHQ Finance Management Practice Manual and the Contract Management Framework.
- Provide leadership and consultative advice to the CHQ Research Governance Officer on research matters, including those pertaining to SSA.
- In instances where the CHQ Director of Research has a Conflict of Interest (e.g., is an investigator for the research being assessed) or is unavailable, the CHQ Business Manager, Research is authorised to execute HSCE-delegated duties as they pertain to research, according to the CHQ Finance Management Practice Manual and the Contract Management Framework

Executive Leadership Team

- Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical, scientific and SSA review of research of all research conducted within CHQ.
- The Executive Director, Medical Services (EDMS) executes HSCE-delegated duties as they pertain to research, according to the CHQ Finance Management Practice Manual and the Contract Management Framework, on occasions when the CHQ Director of Research has a Conflict of Interest or is unavailable and the CHQ Business Manager, Research is also unavailable. The EDMS also sponsors Briefs for HSCE approval as they pertain to SSA authorisation.

CHQ Human Research Ethics Committee (CHQ HREC)

- Provide oversight of the ethical and scientific review of human research by keeping abreast of international, national and state-wide legislation, regulations and guidelines.
- Promote CHQ strategic requirements and ethical and responsible decision-making which respects the rights of CHQ participants.

CHQ Research Governance Officer (RGO)

- The CHQ Research Governance Officer provides oversight and completes due diligence in line with state legislation, regulation, guidelines and in accordance with CHQ SSA requirements. Due diligence may include consultation and/or review by CHQ Legal Services, CHQ Health Information Services and CHQ Finance as required.
- All research agreements and confidentiality agreements are managed by the Research Governance Office, and must be submitted to the RGO directly, who will coordinate relevant approval/execution.
- Provides a recommendation and Brief for Approval for authorisation by the Health Service Chief Executive or delegate as appropriate.

Coordinating principal investigator/principal investigator - responsible officer

- Conduct research in accordance with national guidelines and the CHQ Research Governance Framework (in development).
- Ensure research practices reflect current professional (ethical and legal) standards for research, including promptly responding to reporting and monitoring requirements.
- Ensure compliance with the approval given by a HREC, legislative and policy requirements for participant contact, consent and confidentiality of participant information.
- Only conduct clinical intervention studies with the essential approved credentialing privileges and clinical experience.
- Ensure all Investigators listed on the Human Research Ethics Application/SSA are appropriately credentialed
- Are required to be aware of and comply with this procedure when conducting research.

Employees, researchers, supervisors and students

- Adhere, be aware of and comply with all relevant policies, procedures, guidelines, research protocols and Standing Operating Procedures (SOPs) when conducting research.

Procedure

SSA PRE-AUTHORISATION

Applications for SSA are to be made using ERM. Completion of the SSA form, via ERM, may be commenced whilst awaiting HREC approval.

Step 1: Study preparation for parallel review of the SSA and HREA

CHQ Research recommends compilation and submission of the SSA documentation, at the same time as the Human Research Ethics Application (HREA) submission process. Please see Ethical and Scientific Review of Human Research Procedure (in development) for more information.

Step 2: Commencing the SSA - conflicts of interest

If any person believes they may have a conflict of interest in relation to an SSA, the conflict must be declared and detailed preceding submission of SSA documentation. Please see CHQ-PROC-90004 Conflicts of Interest in Research for more information.

Step 3: Preparing the SSA - specific components

In order to fulfil SSA requirements the following specific components must be prepared.

SSA created in ERM

Note:

- The Principal Investigator is only required to sign when assuming full responsibility for the conduct of the research project at the site and ownership of the research contract/agreement (if applicable).
- The head of department in which the research project is to be conducted, is normally the director/head of the department or service. This delegate must not be a member of the research team. Their signature indicates that they support the conduct of the research project within the department or service. Additional support may be required if the research involves more than one department.
- The signature of the research management accountant is sought if the study funding or expected expenditure is above $10,000. The Research Management Accountant's signature provides confirmation that there are sufficient resources available to conduct the research project.

Step 4: Preparing the SSA – supporting documents

Based on research project requirements the following associated supporting documents may also be required. It is important to note that the online SSA form can be saved and updated throughout the preparation process. All supporting documents must be prepared and uploaded against the research project's online SSA form available on ERM.

For document control purposes, all supporting documents must have version control number and date in the footer. For example:

- *Site Specific Version x dated XX*
- *Based on Master Version x dated XX*

(1) HREC clearance/approval letter

The HREC clearance/approval letter is a mandatory requirement and must be provided prior to SSA authorisation. Queensland Children's Hospital (or the relevant CHQ site) must be listed as the approved as a site on the HREC approval letter.

Research projects that are approved by an external HREC (ie non-CHQ HREC) require the following additional supporting documents:

- Research protocol
- HREA available on ERM
- Patient Information and Consent Form (PICF):
  - master PICF for multi-centre research projects only; or
  - site specific PICF which contains site contact details and site logo;
  - For single centred projects, the site specific PICFs are same as the PICFs approved by the HREC.
  - For multi-site projects, a site-specific version should be created based on the HREC approved master version.
- confirmation of Good Clinical Practice (GCP) certification for clinical trials (certification completed within past three years)
- any relevant supporting documents.

(2) Research contract/agreement (as applicable)

Research contract/agreements are typically required when a third-party entity (commercially sponsored study/non for-profit organisation) is involved in the collaboration or when a University student is undertaking a research under their University affiliation as part of the research team. Please see Research Governance Framework (in development) for more information.

Researchers are encouraged consult with the RGO via email CHQ_RGO@health.qld.gov.au or booked appointment to ascertain the required research contract/agreement.

(3) Medicines Australia clinical trial agreement and standard indemnity

Researchers must provide the relevant Medicines Australia Clinical Trial Agreement for commercially sponsored research projects along with the Medicines Australia Standard Indemnity and relevant valid Insurance Certificate.

(4) Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) radiation Risk Assessment

A copy of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Risk Assessment is required for research projects involving ionising radiation as a specific component of the Research Protocol.

(5) Quotes and approvals

Quotes and approvals from services/departments providing a service to support the research project (ie Pharmacy, Radiology and Pathology etc) must be included and be reflected in any contract provided for the study.

(6) Budget

All research projects must include a budget to confirm the costs associated with the research projects and specify the type of costs to be covered (e.g revenue, expenses and in-kind contributions).

(7) Clinical Trial Notification (CTN) Form

A trial of any medicine or device (or its software) that is not listed on the Australian Register of Therapeutic Goods (ARTG), including any new formulation of an existing product or any new route of administration, must be conducted under the CTN Scheme.

All CTNs must be submitted using the online form via the TGA business services website. A copy of the Therapeutic Goods Administration acknowledgment of receipt of a CTN should be provided as part of the SSA submission for CHQ records as soon as it is available.

(8) Invoicing details

Invoicing details are required for research projects that attract a fee.

(9) Health Support Queensland (HSQ) Pathology or Coronial Material Approval

Depending on the research project, researchers seeking access to HSQ resources (eg data, equipment, biospecimens, biological materials, tissue blocks and slides, etc) are required to seek approval from the relevant director or delegate. Forensic and Scientific Service (FSS) approval is required where studies require access to coronial material held by FSS, please refer to the following link - (Research using material from coronial autopsies | Queensland Health), and further assistance can be provided by contacting the Research Governance Office.

(10) *Public Health Act 2005* (Qld) approval

The *Public Health Act 2005* (Qld) (PHA) applies to all researchers (internal and external to Queensland Health) who are undertaking research using identifiable or potentially re-identifiable health information for which the researchers are unable to obtain participant consent to use their personal or identifying information for a clearly specified research study.

The relevant data custodian must be contacted and the PHA Application form to be completed. Researchers must ensure any PHA approval is received and upload it in the ERM.

If the study involves the use or disclosure of identifiable or potentially re-identifiable patient information where the disclosure will occur with or between non-designated persons (refer to the Hospital and Health Boards Act 2012 (Qld)). Contact the Research Governance Office for further information if you require guidance regarding the legislative requirements of the research.

(11) Aboriginal and Torres Strait Islander considerations

The NHMRC has published ethical guidelines on research involving Aboriginal and Torres Strait Islander peoples. The guidelines provide a set of principles to ensure research is safe, respectful, responsible, high quality, of benefit to Aboriginal and Torres Strait Islander people and communities and of benefit to research. The Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders defines six core values — spirit and integrity, cultural continuity, equity, reciprocity, respect, and responsibility. Applying these values and other ethical principles will ensure that research conducted with or for Aboriginal and Torres Strait Islander people and communities, or their data or biological samples, is ethically conducted. The following guidelines should be applied when undertaking any research involving Aboriginal and Torres Strait Islander peoples or Indigenous Cultural and Intellectual Property:

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities; Guidelines for researcher's stakeholders 2018; and
- Keeping research on track II 2018.

These documents should be read alongside:

- the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Guidelines for Ethical Research in Australian Indigenous Studies 2012
- the Queensland Health Aboriginal and Torres Strait Islander Cultural Capability Framework 2010-2033.
- additional resources published by the Lowitja Institute and the Queensland Aboriginal and Islander Health Council.

For any research requiring an Indigenous Elders Support as indicated in the above guidelines, the evidence must be provided with the submission of the SSA. For further guidance or information, please contact the Research Governance Office.

(12) Additional documentation

The research protocol/study plan and additional documents used for the study are provided for information reference only, enabling the RGO to determine any additional requirements. If more than one version of the protocol has been approved by the HREC, please provide the governance office with most recent approved versions.

Step 5: Submitting the completed SSA

Researchers should review the CHQ-PROC-90008-1 Site Specific Assessment and Authorisation Checklist regarding documentation that may be required for governance approval.
Once the SSA submission is completed online and submitted electronically via ERM, an SSA reference number is generated. This will be the five (5) digit number in ERM. Once submitted it will be immediately accessible for review by the RGO.

SSA Authorisation

Step 1: Authorisation and review

Recommendation of authorisation of the research project will not occur until all regulatory, legislative and institutional (CHQ) requirements are met including legal review (as required) and acceptance of indemnity provisions. Only research projects approved by a NHMRC certified HREC will be considered for SSA authorisation.

It is not permissible to commence research until all SSA requirements are met. The RGO will review all submitted documentation and request further information if/when required via email correspondence.

Step 2: Acknowledgement

Formal acknowledgment/confirmation of receipt will be sent from the RGO when relevant supporting documents are received. Relevant SSA documentation will be uploaded to the relevant Research Governance database and ERM for record keeping purposes.

Step 3: Health Service Chief Executive (or delegate) review

All SSA documents requiring Health Service Chief Executive (or delegate) review and/or authorisation will be forwarded by the RGO to the authorised delegate, together with a Brief for Approval. This includes CHQ sponsored research projects.

Step 4: Approval

Researchers will be formally notified by the Research Governance Office that SSA authorisation has been obtained, via correspondence to the Principal Investigator and nominated contact person. The time to reach approval will not take more than the twenty-five (25) day (stop-clock days*) benchmark as set by the NHMRC.

Registration of the RGO authorisation of the research is documented within ERM. The research project may only proceed upon receipt of advice/confirmation from the RGO. Researchers are responsible for ensuring research project activities do not commence prior to receiving SSA authorisation.

**The clock starts when the completed SSA application is submitted via ERM. The clock stops when a request for further information or clarification is requested from the applicant. The clock recommences when the requested information or clarification has been received. The clock is stopped when the RGO formally notifies the applicant of the final decision.*

Step 5: Notification of commencement

Following SSA authorisation, CHQ requires that the RGO is provided the start date of the research project, via ERM as a sub-form to the SSA, prior to commencing research.

SSA POST-AUTHORISATION

Researchers must ensure adherence to the procedures outlined in the research application/research protocol, as approved by the HREC and the RGO.

Step 1: Annual reporting

Principal Investigators and research teams are required to submit a CHQ-FORM-90010 Health Research Ethics Committee/Research Governance Officer Progress Report for each research project on the anniversary of the HREC approval each year that the project is active.

Step 2: Suspension or termination of a research project

If a decision is made by the Principal Investigator to either suspend or cease a research project (prior to the expected date of completion) a completed CHQ-FORM-90010 Health Research Ethics Committee/Research Governance Officer Progress Report and a CHQ-FORM-90013 Data and Materials Management Plan must be forwarded to both the HREC Office and the RGO via CHQ_RGO@health.qld.gov.au and CHQEthics@health.qld.gov.au.

Step 3: Amendments to research protocols

Any changes to the research project, in respect of aims, design and anticipated outcomes, which have been approved by the relevant HREC, and which impact on the ongoing site acceptability, the documents, must be formally submitted as an amendment for review by RGO via ERM SSA sub-form process:

- Post Authorisation Notification form in the ERM acts as a cover letter,
- the rationale for the changes,
- any implications for the ongoing conduct of the research project at CHQ.

Researchers must ensure a copy of the HREC Approval Letter for the amendment is included with the amendment submission. Amendment submissions must include relevant supporting documentation which has been changed as a result of the amendment. Examples of amendments may include:

- updated insurance certificates,
- variations to research contracts/agreements including changes to the legal name of the third (3rd) party entity,
- changes to the Clinical Trial Exemption Form (CTX) or Clinical Trial Notification Form (CTN),
- Pathology/Radiology/Pharmacy costing changes,
- research project budget updates or other changes which may have financial or other resource implications for CHQ,
- principal investigator or change in research personnel involved in the research project/s,

- any other matters which may impact on the conduct of the research project in CHQ.

The following documents must be submitted electronically to the RGO via ERM:

- HREC approval letter,
- supporting documentation – updates/changes to relevant documents.

Note: There is no specific deadline for amendments but all amendments require Research Governance acknowledgement prior implementing those changes

Further assessment/more information may be required by the RGO. Principal Investigators will be formally advised by the RGO when the research project amendments have been approved. Whilst the PI is awaiting for the amendment to be approved, there may be circumstances where the study must be suspended until the amendment has been approved. In instances where the amendment is only for an administrative change, the previously approved protocol version will remain in place and can be used whilst the study continues; however in other instances, including (but not limited to) the amendment changing the safety profile of the study, the research must be suspended whilst awaiting approval. The RGO should be contacted for any instances where there may be uncertainty or require further clarification whilst the amendment is being considered.

Step 4: Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Report

Researchers must report Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reactions (SUSAR) to the Sponsor.

Step 5: Completion of study

Upon completion of the research on the expected completion date, a completed CHQ-FORM-90010 Health Research Ethics Committee/Research Governance Officer Progress Report and CHQ-FORM-90013 Data and Materials Management Plan must be forwarded to the relevant RGO via the ERM SSA sub-form process.

Supporting documents

Authorising Policy and Standard/s

- Health Service Directive: Research Ethics and Governance HSD-035:2016
- *Public Health Act 2005* (Qld)
- Research Governance Framework (in development)

Procedures, Guidelines and Protocols

- CHQ-PROC-90004 Conflicts of Interest in Research
- Contract Management Framework
- Ethical and Scientific Review of Human Research Procedure (in development)
- Finance Management Practice Manual
- National Health and Medical Research Council, Australian Code for the Responsible Conduct of Research
- National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research, 2018

Forms and Templates

- CHQ-PROC-90008-1 Site Specific Assessment and Authorisation Checklist
- CHQ-FORM-90010 Health Research Ethics Committee/Research Governance Officer Progress Report
- CHQ-FORM-90012 Research Close Out Checklist
- CHQ-FORM-90013 Data and Materials Management Plan
- CHQ-FORM-90011 Notification of Commencement of Research Project
- CHQ-PROC-90004-1 Research Conflicts of Interest Disclosure Form

Consultation

Key stakeholders who reviewed this version:

- CHQ Legal Services
- CHQ Research Governance Officer
- Business Manager Research
- Director of Research

Audit/evaluation strategy

Level of risk	Medium
Strategy	Observe practice, file/matter review
Audit/review tool(s) attached	Nil
Audit/Review date	Annually
Review responsibility	Business Manager, Research
Key elements / Indicators / Outcomes	Self-assessment of compliance with obligations

Procedure revision and approval history

Version No.	Modified by	Amendments authorised by	Approved by
1.0 30/06/2021	Research Governance Officer	Business Manager Research	Director of Research

Keywords	Site Specific Assessment, SSA, authorisation, research, 90008
Accreditation references	NSQHS Standards (1-8): 1: Clinical Governance and 2: Partnering with Consumers ISO 9001:2015 Quality Management Systems: (4-10): Meet regulatory requirements and ensure continuous improvement