Procedure

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Research application and approval

Date approved: 12/06/2020
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Purpose

The purpose of this procedure is to provide SCHHS staff with consistent processes and accountabilities for the approval of research activities being undertaken within the SCHHS.

The intended outcome of this procedure is to minimise the risks to patients, staff and the SCHHS by ensuring that:

- Research activities are conducted with appropriate approval;
- Managers of service lines are aware of research activities being conducted in their departments;
- The SCHHS has the appropriate resources to support and facilitate the research;
- Research undertaken in the SCHHS complies with Queensland Health policies and standards, legislation, and other relevant guidelines;
- The SCHHS has a record of all research activities being undertaken; and
- The SCHHS has access to all research to maximise the benefits of research outcomes and facilitate quality improvement in health services and care.

Scope

This procedure applies to:

- all staff or collaborating researchers who wish to undertake research activities within the SCHHS;
- all Service Line Managers/Heads of Departments who are responsible for a department in which research is being conducted; and
- all Business Managers who are responsible for financial approval of research being conducted in their service line, as delegated by the relevant Service Director / Chief Financial Officer.

Procedure

All information relating to the research approval process can be found on the SCHHS Research public website (Internet) and the SCHHS QHEPS Research website (Intranet). These websites contain links to resources and supplementary documentation. It is recommended that all researchers refer to these websites for additional guidance.

For research activities involving Queensland Health patients, staff, data or facilities; approval from an appropriate certified Human Research Ethics Committee (HREC) ***and*** the SCHHS Chief Executive (CE) or Delegate must be obtained ***before*** starting the project. The following sections outline the process for obtaining the necessary approvals. A detailed flowchart is also located at the end of the document to assist researchers in understanding the approval process.

Section 1 – Initial Steps for All Potential Research Activities

Section 2 – Approval from a Human Research Ethics Committee

Section 1 – Initial Steps for All Potential Research Activities

It is recommended that researchers consider the following steps before undertaking any action on a research 'idea' to ensure that the project will have the appropriate support and endorsement. Completing a research project can be resource intensive and therefore the value of the research and projected **impact** (the contribution that research makes to the world and the lives of people living in it) must be considered before any resources are allocated to develop the 'idea' into a project.

1.1. Confirm support for your project

Proposed research should be discussed with the line manager and (if applicable) the manager / director of all departments that may be required to assist with the research. Alternatively, departments may have a forum where research projects are discussed and endorsed. Your line manager will be able to confirm the appropriate forum in your department.

1.2. Confirm the project is research

Staff should refer to the document Ethical consideration for quality improvement and clinical audit activities procedure for a list of trigger questions to assist with identifying whether a project is research or a quality improvement / audit. Additional advice may be sought from the Research Governance Team or the Safety, Quality and Innovation Unit

1.3. Prepare a research protocol

A study protocol / project plan is a document which describes in detail the plan for conducting a study. Ethics committees require a research protocol or project plan to be included in all ethics submissions. It is beneficial to write this before you begin preparing the ethics application as a complete and well thought through protocol will assist in answering many of the questions contained in the ethics application form.

For further information, refer to the guide for writing a research protocol or quality assurance/clinical audit project plan *published by Mater Medical Research Institute.

Section 2 – Approval from a Human Research Ethics Committee

It is strongly recommended that you discuss your research project with the Research Governance Team prior to the development of your HREC application.

Ethical review is a process to ensure projects are ethically sound; the benefits of the research outweigh the risks; and the research methods adhere to the National Statement on Ethical Conduct in Human Research. The following steps describe the process for obtaining Human Research Ethics Committee (HREC) approval:

2.1. Identify an Appropriate HREC

It is recommended that research being undertaken in this Health Service is submitted through a Queensland Health HREC using the Ethics Review Manager (ERM) system. Other HRECs may be accepted by the SCHHS under the National Mutual Acceptance Scheme. Where questions exist regarding the most appropriate ethics committee, researchers can discuss their project with the Research Governance Team.

Once a HREC is selected, researchers should contact the committee to confirm the specific submission requirements of that committee.

2.2. Prepare Supporting Documentation

Depending on the type of study, additional supporting documents may be required. The HREC will require copies of any materials that will be given to participants (e.g. Participant Information Sheet and Consent Forms; patient questionnaires) in order to complete their review.

2.3. Prepare and Submit a HREC Application Form

The Queensland Health ethics application form can be found in the Ethics Review Manager (ERM) system. Resources are available on the Health Innovation, Investment and Research Office (HIIRO) website to support researchers in using ERM. When using an *interstate* ethics committee, researchers should use the research management system of that committee.

2.4. Address HREC Questions.

Projects are reviewed by the HREC and if approved, written notification is sent confirming this. Additional information may be required by the HREC before the research is approved.

Section 3 – Additional Approvals Required by Legislation or Policy

Depending on the type of research being undertaken, additional levels of approval may be required according to current legislation or policy. These approvals are generally obtained following HREC approval. The most common examples of additional approval are:

3.1. Registration of Research Projects

Researchers are encouraged to prospectively register all their projects with the ANZ CTR (Australia and New Zealand Clinical Trials Registry). Registration is aimed at protecting the intellectual capital, improve transparency and quality, and officially announce the study thus reducing duplication and redundancy and to encourage collaboration.

3.2. Pathology Queensland Approval

If you require access to tissue samples or other data sources held by Pathology Queensland (including data in AusLab and AusCare) you may require approval. For information on accessing tissue samples or data, consult the Pathology Queensland website or discuss the project with the local Director Pathology.

3.3. Public Health Act (PHA) Approval

If access to confidential patient health information is required and patient consent to access the information is not obtained, a PHA approval may be required. More information on obtaining PHA approval can also be obtained via the HIIRO website.

3.4. Queensland Civil and Administrative Tribunal Approval

If you are involving patients who are unable to give informed consent, approval may be required through the Queensland Civil and Administrative Tribunal (QCAT Application Form). Refer to the application form for further details on the types of research that require QCAT approval under the *Guardianship and Administration Act 2000.*

3.5. Approvals from Other Institutions

Some research will require HREC approval from other institutions, (e.g. universities). If you are unsure whether approval from another institution is required, contact the HREC or Research Office at that institution for guidance.

Section 4 – Research Governance Authorisation

Research Governance is a framework for institutions to ensure that research is conducted responsibly and safely. The process considers site suitability, legal compliance, financial management, accountability and risk management and ensures research conforms to relevant institutional, jurisdictional and national standards, and applicable laws.

Not all projects that are deemed ethically sound can be supported by the SCHHS. It is important that applicants engage in discussions with all departments involved in the research before commencing the research approval process to minimise the possibility of projects not receiving authorisation at this stage (refer to Step 1.1 above).

4.1. Prepare and Submit a Research Governance Application

*I*t is strongly recommended that you discuss your research project with the Research Governance Team prior to the development of your Site-Specific Assessment application. The SCHHS Research Guideline and corresponding Governance Documents Checklist should be utilised to ensure all required documents, evidence and signatures are included in the submission.

Applications for Research Governance are made using the Site-Specific Assessment (SSA) form within the ERM system. Further guidance on using ERM can be found on the HIIRO website. The SSA form may be commenced whilst awaiting HREC approval but must not be submitted until HREC approval has been obtained.

Key components of a complete research governance application are:

- Departmental *and* Service Group approval
- Budget *and* financial authorisation
- Additional approvals required as per Section 3 of this procedure
- Any site-specific documents generated from HREC approved Master documents
- Other documents may be required depending on the type of study.

A checklist of research governance submission requirements is available on the SCHHS internet. The SCHHS has preferred templates for obtaining Head of Department Support and preparing a budget. Contact the Research Governance Team to acquire these templates and seek further information.

4.2. Research Agreement (if applicable)

Depending on the type of research, and the collaborations that exist with external organisations, a research agreement may be required as a component of your Research Governance application.

The development and execution of a research agreement between the SCHHS and a non-Queensland Health party can be the most time-consuming aspect of the Research Governance approval process. Therefore, it is recommended that researchers discuss contract requirements with the Research Governance Team as soon as possible following submission of the HREC application.

4.3. Address Research Governance Questions

The Principal Governance Officer (Research) is responsible for reviewing the SSA application and recommending that the project be authorised by the SCHHS CE or Delegate on behalf of the institution. During review, the Principal Governance Officer (Research) may require applicants to address additional questions, or provide clarifications, prior to making their recommendation to the SCHHS CE / Delegate for authorisation to ensure that all SCHHS site specific requirements have been met.

4.4. Begin the Research

Research may commence once a letter of authorisation has been received, signed by the SCHHS CE or Delegate. Staff engaged in research activities must ensure adherence to the procedures outlined in the research application / protocol, as approved by the HREC and Research Governance and any additional site-specific conditions outlined in the authorisation letter signed by the SCHHS CE or Delegate.

All approved research must be conducted in accordance with the National Statement on Ethical Conduct in Human Research, the Australian Code for the Responsible Conduct of Research, and where appropriate, the Therapeutic Goods Administration Note for Guidance on Good Clinical Practice.

Section 5 – Ongoing Maintenance of Approved Research

All researchers are responsible for managing the ongoing approval of their research. In particular:

- **Changes to the research protocol or supporting documentation** – Changes to a research project must approved by the HREC and Research Governance prior to introducing the changes.
- **Reporting** – All research will require progress and final reports to be provided to the HREC *and* Research Governance. Additional reporting may be required for serious adverse events and safety issues as they occur. Where a study is funded or subject to additional approvals or contractual arrangements, researchers may be required to provide further reports (including financial acquittals) to external parties.
- **HREC Approval Period** – The Research Governance Authorisation is valid for the term of the HREC approval. Researchers must ensure that they maintain valid and current HREC approval in accordance with the terms of the HREC approval letter.
- **Monitoring of Approved Research** – Ethics committees and Research Governance may conduct monitoring audits on approved research. Researchers must comply with any requests from the HREC or Research Governance in relation to monitoring

References and further reading

Primary legislation, policy, standards or other authority

National Health and Medical Research Council Act (1992)

Public Health Act Application and Information for Researchers

Research Management Policy

Research Management Standard

National Health and Medical Research Council and Universities Australia – Australian Code for the Responsible Conduct of Research

National Health and Medical Research Council - National Statement on Ethical Conduct in Human Research 2007

National Health and Medical Research Council – National Approach to Single Ethical Review of Multi-centre Research

Queensland Health – Human Research Ethics Committees

Queensland Health - Research User Guide

GCP, Research Ethics and Governance Standard Operating Procedures

Ethical consideration for quality improvement and clinical audit activities procedure

Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods

National quality standards (NSQHS) or EQuIP

Clinical Governance

Partnering with Consumers

Templates, forms and other related or supporting documents

Ethics Review Manager (ERM) – Research application system

SCHHS Research Website

SCHHS guideline 001591 Research governance

Consultation

Key stakeholders who contributed to and/or reviewed this version include:

Principal Governance Officer, Research Operations Group, Research Clinical Council, Research Manager, Research Director, Principal Project Officer IQRE

Audit/ compliance strategy

Recommendation for SCHHS CE/Delegate approval to conduct research will not be made unless evidence of consultation with supporting departments has been provided and financial, legal and indemnity issues have been addressed. All research activities will be registered on ERM (Ethics Review Manager), including the outcome of the CE/Delegate's decision to authorise the research.

Level of risk	Low
Audit strategy	All research activities will be registered on ERM when approved by an ethics committee. Recommendation for SCHHS CE/Delegate approval to conduct research will not be made unless evidence of consultation with supporting departments has been provided and financial, legal and indemnity issues have been addressed. Registration of SCHHS authorised research will occur within ERM and the Research Governance and Development Unit Research Activity Database.
Audit frequency and reporting	Annually
Key elements, indicators, outcome measures	100% compliance

Document revision and approval

Version	Prepared by	Endorsed by	Authorised by	Review due
2.0	Research Governance and Development Unit	Research Clinical Council	Research Director	12/06/2024
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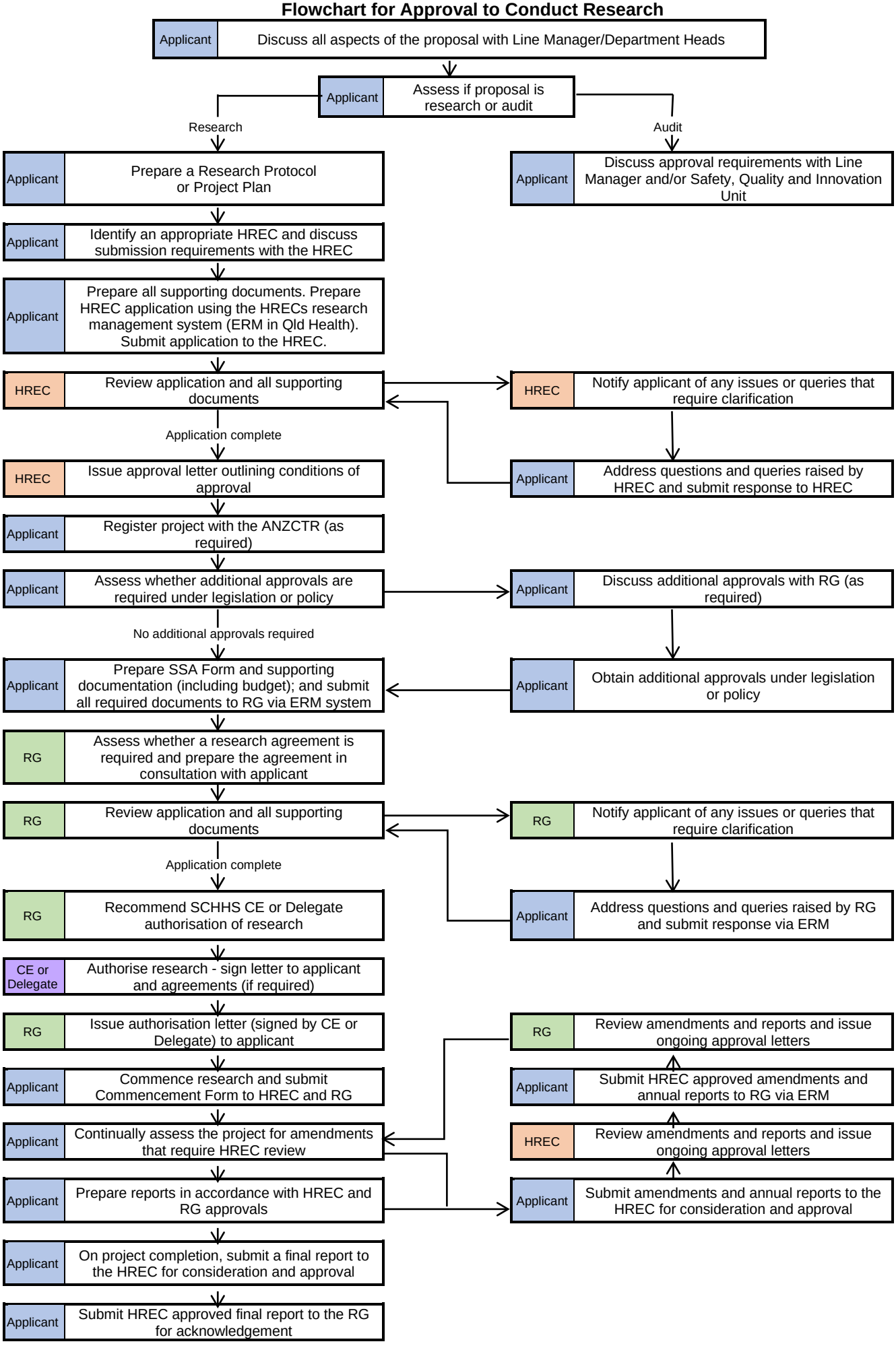
Keywords: Research, clinical audit, ethics, governance, research governance, research process, research application, conducting research, research approval, research monitoring				

Flowchart for Approval to Conduct Research



Legend			
ANZCTR	Australian and New Zealand Clinical Trials Registry	HREC	Human Research Ethics Committee
CE	Chief Executive	RG	Research Governance
ERM	Ethics Review Manager	SSA	Site Specific Assessment