Research application policy and procedure

A stakeholder-oriented overview of the Southern Cross Healthcare research application process.

Southern Cross Healthcare actively supports quality improvement and research activities that improve patient experience and outcomes.

This document describes the policy and procedure for research applications at our hospitals, from proposal through to acceptance. Each stage of this process is owned by a different stakeholder. The responsibilities of each stakeholder are detailed below.

This information will be helpful for General Managers (GMs) and other hospital staff when dealing with research applications.

Contents

---

1. Principal Investigator (PI)

Conditions for the acceptance of research proposals

Southern Cross Healthcare (SCH) only accepts research proposals when the following conditions are met:

- Equivalent Indemnity for trial participants where they are not eligible for ACC.
- The research is phase 3 or phase 4 trial.
- Health and Disability Ethics Committee approval has been granted where required.
- Confirmation that where DHB or ACC Contract patients may become participants of this research, these entities have been informed.
- Confirmation that the written patient consent will be completed in full prior to admission to hospital.
- A robust data management plan is in place compliant with the requirements of the Privacy Act 2020 and Health Information Privacy Code 2020 (and any other relevant legislation), including the management and reporting of any form of data loss.
- Confirmation of compliance with this policy.

- A written summary or report of the outcomes of the research and the implications for patient care and/or further research (even if the study findings were negative or non-conclusive) must be shared with SCH.

Documentary evidence required

If these conditions are met, documentary evidence must be provided, and the following submitted to the General Manager(s) of the relevant Southern Cross Hospital(s):

- A 300-word précis of the research proposal.
- A patient information sheet (PIS).
- A patient consent form.
- A data management plan including processes to mitigate, manage and report and form of data loss.
- An estimate of any additional time and resource (human and equipment) that the research entails.
- An estimate of the duration of the research.
- Contact details of the PI and any co-investigators.

---

2. SCH Hospital General Manager

The GM should complete the first section of the Research application checks form and confirm with the PI:

- That the hospital(s) concerned can accommodate the intended research.
- That a copy of this policy has been provided.
- That the resource consumption estimates for the hospital provided are reasonable.
- That patients admitting surgeon/s and or anaesthetist/s are supportive of the study.
- That relevant documentation (above) is in order.

The application is then submitted to the Chief of Quality and Risk (CQR).

---

3. Chief of Quality and Risk

The CQR will discuss and confirm with the GM the following:

- Medsafe approval if appropriate.
- Compatibility with Researched Medicines Industry guidelines.
- Confirmation that the PI and any associates who will be accessing the hospital are eligible for or already credentialled with SCH.

If there are no issues the application is referred to the National Clinical Governance Committee (NCGC) with a recommendation to approve.

---

4. National Clinical Governance Committee

The NCGC receives the application and confirms it after consideration of:

- The potential value of the research to SCH.
- The relevance of the research to the wider medical and private surgical hospital sector.
- The cost to SCH of supporting the research.
- Implications for the patients and Southern Cross hospitals if complications arise.
- Implications for the patients and SCH if the study includes a no treatment arm and the patient requires subsequent treatment.
- The potential for subsequent re-admission for treatment which would not have occurred but for the patient participating in the study.
- Study treatment and clinical considerations including a risk benefit analysis.
- The research applicant generally including the potential for conflicts of interest and the relationship with SCH.
- The background and financial stability of the sponsor and the local research individuals or organisation.

The NCGC Chair informs the applicant of the NCGC decision (including any conditions) and notifies the GMs and Chief Operating Officer. The decision is minuted in the NCGC records and the Research application checks form completed.

Associated documents

Research application checks form

This checklist is to be completed as part of an application to conduct research or a quality improvement study.

CONTENT CONTROL

Published Date: **22 Jan 2022**
Version: **25**
Site: **Network**

Content Owner: **Victoria Aliprantis**
Authorised By: **Chief of Quality & Risk**

WATCH THIS CONTENT