Policy, procedure and guidelines for research and quality improvement activities

Southern Cross Healthcare accepts the importance of medical and clinical research and supports appropriate research involving Southern Cross Healthcare Limited (SCHL) facilities, patients or other parties on the proviso that it is:

- in the best interests of SCHL; and
- consistent with the Health and Disability Commissioner's Code of Consumer Rights[1] and considering the special nature of private hospital care means that patients' expectations may differ from those in the public sector[2].

Southern Cross Healthcare acknowledges the evolving scope of Ethics Committees under the Ministry of Health Standard Operating Procedures for Health and Disability Ethics Committees (May 2012)[3].

Research policy and process

All research applications must follow the process outlined in this policy.

All research involving SCHL patients must be approved by the Chief Executive Officer (CEO) and National Clinical Medical Committee (NCMC) and confirmed in writing prior to the study commencing (refer Delegated Authority Policy).

Applications may be received from SCHL employees, credentialed practitioners or other parties who may be eligible to be credentialed. Applicants must comply with Southern Cross Healthcare' Credentialing and Defining Scope of Practice Guide and other Southern Cross Healthcare' policy and any employment agreement/s.

All applicants must follow the process and should contact the General Manager for assistance in the first instance (refer pp 3-4 Procedure).

SCHL management and or employees will not accept any form of inducement to support research applications, including funding for staff activities.

The General Manager recommends the application to the Chief of Quality & Risk. The Chief of Quality & Risk will work with the General Manager and the applicant to progress the application to the NCMC (Refer pp 3-4 Procedure and the Research checklist).

Research participants in clinical trials must **be potentially eligible for ACC cover** in the event of injury as a result of the research. This means that any research conducted principally for the benefit of the manufacturer or distributor of a medicine, device or item being trialed, (as determined by an Ethics Committee)[4] will not usually be approved for Southern Cross Healthcare.

SCHL approves only **Phase 3 and 4 trials.** Only in exceptional circumstances will Phase 1 or 2 trials be considered.

Gaining informed consent from a patient for being a research study participant is the responsibility of the principal researcher or co-investigator/researchers and this **must take place prior to the time of admission** in the hospital.

The approval of patient's admitting practitioner (usually the surgeon) and anesthetist is required.

Where the patient is admitted under a DHB or ACC contract, the approval of the DHB or ACC is also required**.** The applicant will liaise with the DHB/ACC to obtain the approval.

In order for the application to progress an ethics committee approval process may need to be undertaken.

The NCMC and makes a considered decision to approve or decline the application or to postpone its consideration until further information is obtained. The Chair NCMC informs the research applicant of NCMC's decision including any conditions.

Correspondence and communications concerning research will be via the Chief of Quality & Risk. Except as otherwise agreed to or instigated by the NCMC, the research applicant will not have direct contact with members of the NCMC.

Locality Authorisation can only be provided by NCMC.

Where the application is approved the applicant requests Locality Authorisation via NZ Online Forms, the NQCRM completes the authorization process on behalf of the NCMC.

Where an applicant is not using NZ forms online, a hard copy Locality Authorisation form is signed by the Chairman of NCMC with removal of the statement related to indemnity insurance (please ask for the Locality Authorisation Example Form requested from victoria.aliprantis@schl.co.nz).

SCHL does not carry indemnity insurance for this purpose. Note: Locality approval does not bind SCHL to approve an application after having been reviewed by the Ethics Committee.

Scope of this policy

Includes any:

research that aims to generate knowledge for the purpose of improving health and independent outcomes that involves:

- human participants recruited in their capacity as consumers of health or disability support services, relatives or caregivers of consumer of health and disability support services or volunteers in clinical trials,and or employees and or credentialed practitioners)
- the use, collection or storage of human tissue
- the use or disclosure of health information (refer exceptions point 27.3 MoH SOPs for Health and Disability Ethics Committees May 2012)
- applications approved by an Ethics Committee (full and expedited review) including amendments or extensions to existing studies
- written confirmation from the Ethics Committee to the researcher that the research study does not require their review, (for the purposes of future publication a researcher can write to the Ethics Committee to request an opinion on whether their review is required)
- student research

Does not include (except where <u>any</u> of the above factors are present):

- general business surveys (e.g. Southern Cross Healthcare patients, specialists and employee survey) for the purpose of business improvement;

- audit and related activities - external or internal audits, or collection of data from clinical notes and files for the purpose of audit review and clinical practice improvement activities. Please use Toward Clinical Excellence, An Introduction to Clinical Audit, Peer Review and Other Clinical Practice Improvement Activities (Ministry of Health, Wellington, 2002) as a guide for these situations to determine the difference between research and audit; or
- also outside of the scope of this policy may be a situation where a patient is booked for admission to a Southern Cross Healthcare and is identified as being a participant on an Ethics Committee approved DHB or ACC and or another external clinical organisation's research that is not directly related to the purpose of the patient's admission to the Southern Cross Healthcare; in this situation the patient's admitting specialist (usually a surgeon) and anesthetist need to consider any risks and agree the surgery is in the patient's interests.

The applicant provides the General Manager with a copy and or confirmation of:

- Study Application and attachments, for example:
    - study protocol
    - patient informed consent and information sheets
- Locality Authorisation via the New Zealand Online Forms for Research request to victoria.aliprantis@schl.co.nz
- Ethics Committee approval or confirmation from Ethics Committee that ethics review is not required
- the process the applicant will follow to manage approval of patient's admitting medical specialist/s
- the process the applicant will follow to ensure patient informed consent occurs prior to admission

Where applicable:

- confirmation of the applicants undertaking to comply with the Researched Medicines Industry (RMI) guidelines is required.
- confirmation of the DHB/ACC approval where the study participants include DHB and or ACC contract patients
- an insurance certificate supplied by the Sponsor

The General Manager

- provides the research Applicant with a copy of the SCH Research Policy;
- makes an initial assessment of implications to hospital operations, e.g. additional hospital resources such as costs and staff involvement (Refer App;
- completes Research Checklist, Section A, forwards the complete application documents with summary of initial assessment and working Checklist to the Chief of Quality & Risk and
- informs the Chief Operating Officer

Post approval and where applicable:

- confirms consent procedures are being completed prior to admission
- communicates with relevant clinical and administrative staff
- checks credentialing and compliance with SCH Credentialing and Defining Scope of Practice Guideline
- monitors compliance to approved SCHL procedures and conditions
- informs Chief of Quality & Risk when completed

The Chief of Quality and Risk:

- provides support and or information to the
    - General Manager
    - Applicant
    - CEO and NCMC
- coordinates the process
- closes the file

The National Clinical Medical Committee

- where participants are not entitled to ACC the NCMC considers:
    - the risks and benefits of the study in the context of SCH facilities
    - the insurance certificate supplied by the sponsor
    - a signed New Zealand Association of Clinical Research Standard Indemnity and Compensation Agreement (SIA) between the sponsor and Southern Cross Healthcare (which requires no modification).
- considers the application and responds

References

- Health and Disability Commissioners Code of Consumer Rights
- Southern Cross Healthcare Credentialing and Defining Scope of Practice Guide, page 13
- Health Research Council of NZ: Section 32 (6) Injury Prevention Rehabilitation and Compensation Act 2001
- Health and Disability Ethics Committees (HDECS): Standard Operating Procedures for Health and Disability Ethics Committees (May 2012)
- New Zealand Online Forms for Research
- Ministry of Health: Toward Clinical Excellence, An Introduction to Clinical Audit, Peer Review and Other Clinical Practice Improvement Activities (Wellington, 2002)
- Australian regulatory guidelines for medical devices
- Medicines New Zealand: Researched Medicines Industry (RMI) guidelines
- MEDSAFE: Guideline on the Regulation of Therapeutic Products in New Zealand (Dec 2017)
- Southern Cross Healthcare: Delegated authority policy
- Australia New Zealand Clinical Trials Registry (ANZCTR)
- Health Research Council of NZ
- New Zealand Health & Disability Ethics Committee
- Standing Committee on Therapeutic Trials (SCOTT)
- The Researched Medicines Industry Association of New Zealand
- International Review Board
- MEDSAFE: Use of unapproved medicines and unapproved use of medicines
- Auckland District Health Board: research
- JAMA: What makes clinical research ethical?
- RACS/ASERNIP-S: A review of policies and processes for the introduction of new interventional procedures, July 2007, (PDF)
- RACS/ASERNIP-S: General Guidelines for Assessing, Approving & Introducing New Surgical Procedures into a Hospital or Health Service (PDF)
- MoH ACC Compensation for injuries caused as a result of participation in a clinical trial and the role of ethics committees – Guidelines – December 1993

- Ministry of Health/ACC, Guidelines, *Compensation for Injuries Caused as a Result of Participation in a Clinical Trial and the Role of Ethics Committees* (Wellington, 1993).
- Southern Cross Healthcare Limited Clinical Research, HARC 2002, NCMC 2007 and 2008
- National Ethics Advisory Committee: Streamlined ethical guidelines for health and disability research

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