RESEARCH - ETHICAL REVIEW OF PROGRAMS OF RESEARCH

POLICY©

DOCUMENT SUMMARY/KEY POINTS

- This Policy sets out the requirements for the establishment, scientific and ethical review of Programs of Research at the Sydney Children's Hospitals Network.
- For further information please contact the Executive Officer, Research Ethics by:
  - Email – SCHN-Ethics@health.nsw.gov.au
  - Telephone – (02) 9845 3066

READ ACKNOWLEDGEMENT

- All staff undertaking Human Research should read the Policy Directive

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	31/05/2016	**Review Period**: 3 years
Team Leader:	Executive Officer	**Area/Dept**: Research Governance

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Introduction

The Sydney Children's Hospitals Network (SCHN) Human Research Ethics Committee (HREC) and the Research Office promotes streamlined ethical review processes for the various types of research that occur within the Network. In response to the growing number of research programs, as well as a rise in the number of bio-banks and data-registries being established, the SCHN HREC has established a "Program of Research" framework for ethical review of these activities.

A Program of Research is defined under this framework as one of the following:

1. *A single research theme using a variety of methodologies;*
2. *A single methodological approach used to address a series of related research questions by either the same research group or a team of researcher from various disciplines;*
3. *A research bio-bank from which future research projects may / may not be conducted; or,*
4. *A research data registry from which future research may / may not be conducted.*

It is acknowledged that on submission not all project methodologies may be known, but will evolve throughout the lifespan of the project.

Examples of a Program of Research may include, but are not limited to:

- A Principal Investigator identifies a research question and independent aspects of that question will be investigated by a series of research students as part of their Independent Learning Project (ILP).
- There exists a common methodology, for example, a standard genetic test being used to address independent research questions across multiple disciplines.
- A longitudinal project that will develop over a number of years using different cohorts and research methodologies.
- A longitudinal project that will be replicated over a number of years across different cohorts.

1 When should a Program of Research be submitted?

Investigators are required to consult the Executive Officer or delegate prior to any submission. Applications received where the Investigator has not consulted with the Research Ethics Office will not be accepted for review.

When to submit a Program of Research instead of a standard research project application may be obvious in some situations, for example in the establishment of a Bio-bank or Registry, but not in others.

2 What documentation is required for a Program of Research?

When submitting a Program of Research to the Research Ethics Office the following documentation is required:

National Ethics Application Form (NEAF)

Investigators should pay particular attention to the following sections:

1. Section 1 - Title and Summary of Project

   Clearly state at *"Description of the project in plain language"* in the first line that the application is for a Program of Research. Outline in the description how the proposed program fits within the definitions as above as well as enough relevant information to enable the HREC to understand the scope of the project. This should include the proposed timeframe / flowchart for the Program of Research, if known.

2. Section 2 - Researchers / Investigators

   List the Principal Investigators only. These are the Investigators who will ultimately be responsible for the conduct of the Program.

   At Section 5, "Other personnel relevant to the research project", state the following – *"Each project submitted under the approved Program of Research will have a Principal Investigator and Associate Investigators responsible for the conduct of that individual project and will be advised accordingly"*

Master Protocol

NOTE - For bio-banks and data registries, the Protocol should include collection and consenting processes.

Terms of Reference (for certain Programs of Research only)

Terms of Reference should be established outlining the obligations of each of the parties (i.e. the Program Principal Investigator and the sub-project Principal Investigators) including, but not limited to, the use of the Master Protocol; Participant Information Sheets and Consent Form; annual reporting requirements; data custodians; application process and criteria for inclusion on the Program of Research; and, authorship.

Terms of Reference should also be established for bio-bank and data registry review Committees.

'Access' Governance Procedures

For bio-bank and data registries, access protocols for obtaining samples/data from the bank/registry are required.

Included within this must be a condition that evidence of ethics approval from the applicant's local site is provided when applying to access samples / data.

Master Participant Information Sheet and Consent Form

Any other supporting material relevant to the ethical review of an application including, but not limited to:

- Questionnaires / Surveys

- Focus Group Questions
- Invitation Letters
- Advertising Materials

3 Approval Process for a Program of Research

The Program of Research will be reviewed by the Human Research Ethics Committee through normal review processes of the NEAF.

Where scientific review of a Specific Project is required, a member of the Scientific Advisory Committee will review.

4 Sub-Project Approval

New projects under the Program of Research will be termed sub-projects. Sub-projects must be submitted through the SCHN Research Ethics Office amendment process using the "Program of Research Sub-Project Notification Form". For Research Ethics Office administrative purposes, the sub-project will be an amendment to the Program of Research, but for all intents and purposes will be a sub-project of the main Program.

The sub-project will be reviewed by the appropriate sub-committee according to the level of risk of the project.

5 Bio-Banks and Data Registries

Minutes from Bio-Bank and Data Registry Access Committees must be provided to the HREC for review by that Committee's scheduled Submission Closing dates.

6 Research Governance Requirements

All human research that takes place in Public Health Organisations must be reviewed through site specific assessment or access request review, and authorised by the Chief Executive or their delegate before commencement.

Human research taking place in NSW Public Health Organisations means research that is conducted at sites under the control of Public Health Organisations; and / or involving participants, tissue or data accessed through Public Health Organisations.

Investigators submitting a Program of Research must submit an SSA for all sites participating in the Program. Where a sub-project is submitted that involves a site that does not have SSA Program approval, that site cannot be approved until this has been obtained.

Some sites under which the Program will operate may require a local Principal Investigator be named on the Program before they will provide Site Specific Authorisation. It is recommended that Investigators liaise with each site's Research Governance Office to confirm requirements ahead of submitting the Program for ethics approval.

The Research Ethics Office will liaise with the Research Governance Office at each site on receipt of an application to confirm that this discussion has taken place before review occurs.

6.1 Sub-Project Approvals

Each Research Governance Office processes amendment applications differently and applicants of sub-projects may be required to submit documents in addition to the Specific Project Notification Form in order to obtain Site Specific Authorisation for the sub-project.

Across all sites at which the sub-project is being conducted, any Investigators not approved under the Program must submit to the relevant Research Governance Office documentation necessary for them to be approved; for example, CV, Certificate of Insurance.

It is the Investigators responsibility to confirm the requirements of the local Research Governance Office and obtain Site Specific Authorisation before any conduct on the research commences.

7 Annual Reporting and Monitoring

7.1 Program of Research Monitoring

In accordance with any ethics approval, the Principal Investigator of the Program of Research is responsible for providing an annual progress report on the conduct of the study. The Principal Investigator is also responsible for monitoring the conduct of all sub-projects that have been approved as part of the Program.

For biobanks and registries which operate with a Committee to manage access and use of samples / data, the minutes of those Committee meetings are considered as progress reporting.

7.2 Sub-Project Monitoring

Whilst the responsibility for sub-project monitoring rests with the Chief Principal Investigator of the Program of Research, it is expected that the Sub-Project Principal Investigator provide the Program of Research with an annual report using the SCHN Research Ethics Office Annual Report template. The Program Principal Investigator is then required to submit a consolidated report through Minutes.