The Sydney children's Hospitals Network

Data Registries

Research Ethics Guidelines

The Sydney Children's Hospitals Network Human Research Ethics Committee (SCHN HREC)

Research Ethics and Registries

Ethical review and approval is required for all of the following scenarios involving registries and human research:

1. Establishing a registry (pages 2 – 6)
2. Contributing data to a registry e.g. an international registry (page 7)
3. Accessing data from a registry for an individual project (page 8)

Whilst the fundamental elements of the ethics application are the same for the above three scenarios, there are a few variations according to the nature of your research and the involvement of the registry. This document provides a summary of these variations.

Hint: *For detailed instructions on how to submit your ethics application, please refer to the SCHN Submission Guidelines accessed via the following link:* http://www.schn.health.nsw.gov.au/research/ethics-governance/ethics/resources-templates

What is a Registry?

A 'registry' can be difficult to define as there is no standard definition available and it may be referred to in various terms. However, for the purposes of this guideline and the types of registries established and contributing to research under the jurisdiction of the SCHN HREC, registries are defined as:

"an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical or policy purposes".[1]

[1] Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. http://www.effectivehealthcare.ahrq.gov/registries-guide-3.cfm.

1. Establishing a Registry

Whether a registry is to be open access or closed access will impact on the type of information required in the research ethics application to establish the registry.

Closed Access Registry

If the registry is only to be accessed by a single research team, it is considered a closed access registry.

The aim of the registry may include addressing single or multiple research questions. For the latter scenario, one research ethics application may still be suitable if all research questions are outlined in the initial application and the research personnel, methodology etc. remain the same.

Alternatively, if the registry is to be used for multiple, related sub projects to be prospectively added to the initial ethics approval, a 'Program of Research' framework may be more suitable for your research.

Please refer to the *SCHN Programs of Research Guideline* and liaise with the SCHN Ethics Office to identify whether a program framework is more suitable for your research.

Hint: *If you wish to start the registry as 'closed access' and potentially open it at a future date to external researchers, it is recommended that you obtain consent for the use of the participant's data in future research in the initial Participant Information Sheet and Consent Form.*

Then, when you wish to open the registry, submit an amendment application to the Ethics Office and address the requirements below for 'open access' registries.

Open Access Registry

If the registry is to be accessed by researchers external to those establishing the registry, additional components are required to be included in the ethics application. This is highlighted in the requirements outlined on the following page.

What do I need to include in my ethics application?

When establishing an **open access** registry, it is important to design a governance framework for the effective functioning of the registry. This framework should include the following:

❖ Access Procedure

An access protocol is required which outlines the following:

- Who will be the custodian/s of the registry
- Who will have direct access to the registry and in what format (i.e. identifiability)
- The process for external researchers to request access to the registry data
- Who will assess requests to access the data, for example an Access Committee
- The criteria for the assessment of the access requests
- The condition that evidence of ethics approval from the applicant's local site is provided when applying to access the data.

Hint: *For ease of review, provide the access protocol in a separate document to the study protocol.*

❖ Terms of Reference

If the Data Custodian or entity assessing access requests is a committee, consider drafting a Terms of Reference which outlines:

- The composition of the committee
- Process of member appointment and the terms of the appointment
- Meeting details

For both **closed access** and **open access** registries, the following aspects are important to consider:

❖ Participant Information Sheets and Consent Forms (PISCFs)

In addition to the usual information, the following details should be reflected in the PISCFs;

- The format of the data to be stored in the registry (i.e. identifiable / re-identifiable (coded))
- The format of the data to be accessed and used for research i.e. identifiable, non-identifiable etc.
- Examples of the type of data to be collected e.g. demographic data, information from medical records etc.
- If photos are to be collected and stored in the registry and used for research.
- A statement outlining that ethically approved future research projects will access the data (applicable for open access registries).
- The scope of the future research e.g. national and international projects (applicable for open access registries).

❖ Data Management Plan

As identifiable health information is collected for registries, a strong data management plan is required which outlines the security arrangements for the data e.g.

- The platform for the registry database e.g. REDCap
- Restricted access to the data e.g. restricted personnel access, password protection etc.
- If data is being transferred between sites, the data should be anonymised by each site prior to being sent or uploaded to the central registry site. Additionally, the re-identifying code is usually held at the local site as an additional security measure for the participant's data.
- Please refer to section 3.1.44 of the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018) for further guidance in designing your data management plan.

Hint: *If the registry (central site) wishes to hold the re-identifying key, this detail needs to be reflected in the Participant Information Sheet i.e. "your identifiable data will be sent to the registry" etc.*

What are some considerations for consent?

❖ Prospective Data Collection

For prospective data collection, obtaining informed written consent from participants is the preferred option.

However, if this is not feasible for your study e.g. due to the scale of the registry, an opt-out method may be accepted by the Committee. To propose an opt-out method, *refer to sections 2.3.5 -2.3.6 of the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)* to develop an appropriate consent strategy. Key elements of this section include:

- Proposing a reasonable timeframe between distributing information to prospective participants and the inclusion of their data in the registry.
- Describing how reasonable attempts will be made to provide information to prospective participants which explains the nature of the information to be collected, the purpose of collecting it, and the procedure to decline participation or withdraw from the research.
- Highlighting how public interest in the proposed activity substantially outweighs the public interest in the protection of privacy.

❖ Retrospective Data Collection

For retrospective data collection, a waiver of consent may be considered by the Committee on a case by case basis. To pursue this option, it is recommended that you contact the Ethics Office to discuss whether it may be suitable for your research. Also, refer to section *2.3.10 of the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018).*

Hint: *Please refer to the SCHN Submission Guidelines and templates for further guidance in designing your study documents and ethics application.*
http://www.schn.health.nsw.gov.au/research/ethics-governance/ethics

2. Contributing data to a registry

If your project involves contributing data to a registry that has been established under a separate ethics approval e.g. an international registry, there are certain elements required to be considered in your application.

- **Secure Transfer of Data:** As personal health information is being transferred from the local site to the registry (central site), the data should be anonymised by each site prior to being sent or uploaded to the central site / registry. Additionally, the re-identifying code is usually held at the local site as an additional security measure for the participant's data. These measures are to ensure the secure transfer of data and these details are required to be conveyed in your application.

Hint: *If the registry (central site) wishes to hold the re-identifying key, this detail needs to be reflected in the Participant Information Sheet i.e. "your identifiable data will be sent to the registry" etc.*

- **International Registries:** In most cases, the international protocol does not provide sufficient detail regarding local processes for the Ethics Committee to review the project. Prior to submitting your application, review the international protocol. If it does not sufficiently cover the following aspects in regards to the local process, please provide a brief local protocol which outlines the following:

  - *Aims / objective of the study*
  - *Sample size (local)*
  - *Methodology*
  - *Recruitment Methods*
  - *Distribution of results*
  - *Data management plan including how the data will be securely transferred to the international registry.*

- **Participant Information Sheets:** should include a statement highlighting that the participant's data will be accessed by future researchers and describe the format of the data e.g. non-identifiable, re-identifiable etc.

Hint: *Please refer to the SCHN Submission Guidelines and templates for further guidance in designing your study documents and ethics application.* *http://www.schn.health.nsw.gov.au/research/ethics-governance/ethics*

3. Accessing a Registry

When accessing a registry for the purposes of your research, there are certain considerations for your ethics application including:

- **Does the registry need to be added as a research site for accessing purposes?**

  If your project involves accessing information stored in a registry, the registry may need to be listed formally as a research site. Factors contributing to this determination include whether the registry is public or private and the specific requirements of the registry.

Hint: *Prior to submitting your research ethics application, liaise with the registry to ascertain their requirements to be listed as a research site.*

- When outlining in your application the proposed activity to access a registry, it is recommended that you also note that the participant's data will be used in accordance with the requirements of the registry.

Hint: *Please refer to the SCHN Submission Guidelines and templates for further guidance in designing your study documents and ethics application.* *http://www.schn.health.nsw.gov.au/research/ethics-governance/ethics*

Queries?

Contact the SCHN Research Ethics Team at:

SCHN-Ethics@health.nsw.gov.au / (02) 98451253