SCHN HREC: Early Phase Clinical Trials
SUBMISSION GUIDELINES

This submission guideline provides advice on submitting an early phase clinical trial ethics application for review by the Sydney Children's Hospitals Network Human Research Ethics Committee (SCHN HREC).

It is important to note that in addition to ethical approval, Site Specific Authorisation (SSA) from the Research Governance Office of each site is required before a research project can commence at that site. For further information regarding the process of obtaining of SSA, please contact the relevant Research Governance teams.

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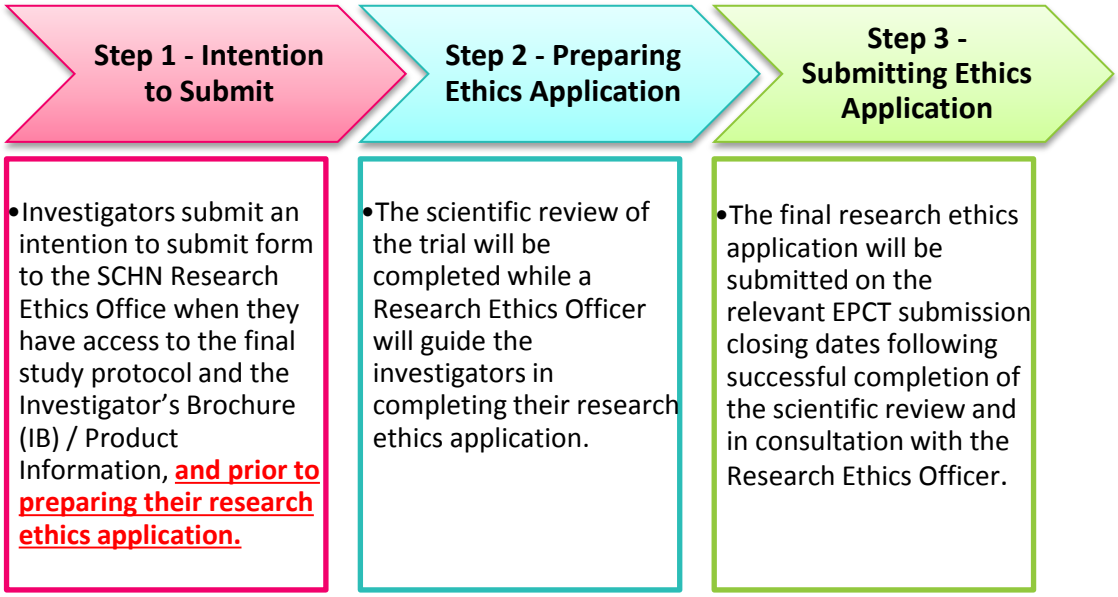
Types of Early Phase Clinical Trials

These submission guidelines apply to the types of Early Phase Clinical Trials (EPCTs) detailed in the "Early Phase Clinical Trial Framework Quick Reference Guide" available on the SCHN HREC website, and also appendix 1 of this document.

All other types of clinical trials will be reviewed as per the standard SCHN HREC greater than low risk review processes (link to submission guideline).

Overview of the Submission Processes for EPCTs



Detailed Submission Guidelines

Step 1 – Intention to Submit

Once you have access to the final study protocol and the Investigator's Brochure (IB) / Information Product and prior to preparing your ethics application, please complete the relevant EPCT Intention to Submit Form available on the SCHN Research Ethics website, and submit it via email to: SCHN-Ethics@health.nsw.gov.au.

Step 2 – Preparing Ethics Application

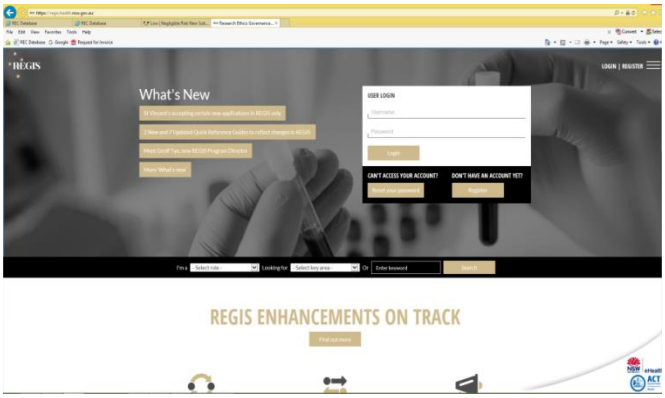
Following receipt of your Intention to Submit Form, the scientific review of your trial will be started.

While the scientific review is underway, a Research Ethics Officer will guide you in preparing your final research ethics application as per these submission guidelines.

The final submission by the investigators should be via REGIS as per the following instructions:

1. Register Project on REGIS

- The first step is to register your project on REGIS. To do this, please access the REGIS website: https://regis.health.nsw.gov.au/ (*which requires log in details. Please register for these details if you do not already have log in details).*



- Please refer to the REGIS Guide "How to Register a Project" available on the SCHN Research Ethics Website for instructions on how to register your project.

!!! Important Notes !!!

- **Ensure all details are correct before you complete registration. The project registration CANNOT be edited or changed after submission.**
- **Incorrect site selection at project registration will have a major impact on the application process. Please ensure that in part C, all the correct sites have been selected under the relevant ACT / NSW / Other tabs.**

2. Complete HREA Application Form (via REGIS)

- After project registration, REGIS will automatically generate a HREA form for completion. Please refer to the REGIS Guide "Completing & Submitting an Ethics Application (HREA)" for instructions on how to complete your HREA form on REGIS.

3. Documents Required in Addition to HREA Form

In addition to the HREA form, the following documentation is required and must be uploaded onto REGIS for your application before it is submitted. **Please note that incomplete applications will be rejected requiring a full resubmission.**

- **Protocol including a data management plan as per the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), section 3.1.45.**
  Note: It is mandatory that the SPIRIT Protocol Template is utilised for investigator initiated studies. Please refer to the SCHN Research Ethics website for a copy of the template.

- **Investigator Brochure/Product Information (if applicable)**

- **Master Participant/Parent Information Sheets and Consent Forms (link to NHMRC templates)**

- **A one page executive summary for Participant/Parent Information Sheets longer than 10 pages.**

- **All Research Tools that will be used (for example, participant diaries / questionnaires)**

- **All Advertising Materials that will be used (if applicable)**

- **For applications involving radiation in excess of Clinical Care, a report from the Radiation Safety Officer at each site requiring ethical review and approval from SCHN HREC.**

- **Invoicing Authorisation Form (if applicable)**
  Please refer to the fee schedule on page 6 for further information. The Invoicing Authorisation Form is to be downloaded from the SCHN Research Ethics Website.

- **For all Victorian sites** - The Victorian Specific Module

- **For all Western Australian sites** - Western Australian Specific Module (WASM) via RGS website

- **For commercially sponsored, multi-centre studies that involve non-SCHN sites - Medicines Australia Form of Indemnity (HREC review only)**

Please refer to this link for Medicines Australia indemnity forms and guidelines: https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/. The indemnity form must be provided by an Australian corporate entity. This may be:

  - An Australian company; or
  - An Australian company that is subsidiary of an overseas parent company; or
  - An Australian contract research organisation (CRO) that has been engaged by an overseas or Australian company to conduct the trial in Australia.

The indemnified party details must be completed as per the following:

"**The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)**, ABN: 53 188 579 090; a Statutory Health Corporation incorporated under the *Health Services Act* 1997 of Hawkesbury Rd and Hainsworth St, Westmead, NSW, 2145 ("**the Health Service**")."

- **Submission Checklist including signatures on the declaration pages from both the CPI/PI and Head of Department**

NOTE: If your submission checklist is incomplete (including missing endorsements, versions and dates, etc.) then your application will be considered invalid and will require a full resubmission.

Step 3 – Submitting Ethics Application

Final applications that are prepared in consultation with the Research Ethics Officer will be submitted via REGIS following successful completion of the scientific review, and on the relevant submission closing date for EPCT applications (link to submission closing dates).

Fees for Review of EPCT Research Ethics Applications

Type of Application	Sponsor / Financial Support	Amount (Incl. GST*) *GST is applicable for external payments
New Application	Full Industry Sponsorship	$6,600
New Application	Investigator initiated with industry funding	0.5 % of total (funding) contract value up to $6,600
New Application	Collaborative group sponsored or other funded trials	$3,000 (for internal applicants - GST exempt) $3,300 (for external payments)
Amendments	Full Industry Sponsorship	$1,100
Amendments	Investigator initiated with industry funding	$550
Amendments	Collaborative group sponsored or other funded trials	$500 (for internal applicants - GST exempt) $550 (for external payments)

Appendix 1 – EPCT Quick Reference Guide

Investigational Product Study Phase	Typical study size	Objectives	HREC
Phase 0: Human pharmacology (micro-dosing)	≈10-15 Involves dosing a limited number of participants with a limited range of doses for a limited period of time.	**Assess pharmacokinetics** Gather preliminary data on pharmacokinetics and bioavailability to determine if an investigational product behaves as expected from preclinical 'Micro-dosing' studies	**Specialist HREC;** Bellberry (Adult) SCHN (Paediatric)
Phase 1: Human pharmacology	≈ 10-100 May involve the first administration to humans, usually to small numbers of healthy volunteers or to participants	**Safety and tolerance** Define pharmacokinetics and pharmacodynamics, determine dosing. Explore drug metabolism and drug interactions. Identify preferred administration route. *Phase Ia*: Single ascending dose *Phase Ib*: Multiple ascending dose	**Specialist HREC;** Bellberry (Adult) SCHN (Paediatric)
Study with a Phase I component	≈10-100	**Safety, efficacy and Maximum Tolerated Dose** Phase I/II, or other variant with a phase I component, clinical trials test how well a certain type of disease responds to a new treatment. In the later phase component of the clinical trial, participants usually receive the highest dose of treatment that did not cause harmful side effects in the phase I part of the clinical trial.	**Specialist HREC;** Bellberry (Adult) SCHN (Paediatric)
≥ Phase II	Typically >100	**Efficacy and safety**	Local HREC
Device Study Phase	**Typical study size**	**Objectives**	**HREC**
Early feasibility/ pilot study/ First in Human	≈10-30 Usually involves a small group of human participants	A limited clinical investigation of a device early in development, typically before the device design has been finalised, for a specific indication, including marketed devices for a NOVEL clinical use. Exploratory investigations to determine preliminary safety and performance information to plan design modifications or provide support for a future pivotal study.	**Specialist HREC;** Bellberry (Adult) SCHN (Paediatric)
Traditional feasibility study	≈30-100	A clinical investigation commonly used to capture preliminary safety and effectiveness information on a near-final or final device design to adequately plan an appropriate pivotal study.	**Specialist HREC;** Bellberry (Adult) SCHN (Paediatric)
Pre- or Post- Market (pivotal) study	Typically >100	Evaluate ongoing performance and safety	Local HREC

Additional Guidance

- If an EPCT HREC submission has been made **PRIOR TO 29April19**, the ethics review and approval will be accepted by a NSW PHO site without requiring another ethics application to the appointed NSW Health EPCT HRECs. These applications will not be affected by this Scheme.
- **ON** and **AFTER 29April19**, all EPCT HREC applications should be submitted to one of the two NSW Health EPCT HRECs for review and approval before it can be accepted by a NSW PHO site, unless under current arrangements of the Scheme involving paediatric EPCTs.

NMA Exemption:

- **Adult EPCTs in NSW:** NSW Health is excluding all adult early phase clinical trials from the National Mutual Acceptance (NMA) model. NSW Public Health Organisation (PHOs) sites will no longer accept interstate HREC reviews for ADULT EPCTs from this date. All new ADULT EPCTs proposed to be conducted in an NSW PHO site, must be submitted to Bellberry HRECs for ethical review.
- **Paediatrics EPCTs in NSW:** NSW Health recognises that there is a small community of practice and high collegiality amongst paediatric clinical trial sites nationally. For multi-centred paediatric EPCTs, if an HREC hosted in a specialist paediatric tertiary hospital outside NSW has approved a paediatric EPCT, NSW PHO sites will continue to accept interstate HRECs' approval in these instances. However, it is important to note that paediatric EPCTs with an NSW PHO lead site are required to be submitted to SCHN HREC for ethics review.

Age Group within the Scope:

Bellberry HRECs:

- Trials involving adults equal to and greater than the age of 18 years; or
- Combined paediatric and adult trials involving young people and adults equal to and greater than 16 years.

SCHN HREC:

- Trials involving only children and young people under the age of 18; and
- Combined paediatric and adult trials involving children and young people under the age of 16 and young adults up to the age of 25.