

SWSLHD Early Phase Clinical Trials Submission Guidelines

As of April 2018, The Office for Health and Medical Research - NSW Health mandated that Early Phase Clinical Trials (EPCTs) must be submitted and reviewed to Sydney Children's Health Network (SCHN) for paediatric studies or Bellberry Limited for adult studies.

The South Western Sydney Local Health District Human Research Ethics Committee is not able to provide ethics approval for EPCTs.

Participant 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.

It is recommended that researchers who are unsure of whether they are completing an EPCT to contact SCHN or Bellberry Limited directly. Contact details can be found below:

SCHN Early Phase Clinical Trials: 02 9845 3105

Bellberry Limited: 08 8361 3222

Trials involving an Investigational Product

Study Phase	Estimated study sample	Aims/Objectives	HREC submission to:
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 Limited (Adult studies) SCHN (Paediatric studies)
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. <i>Phase Ia: Single ascending dose</i> <i>Phase Ib: Multiple ascending dose</i>	Specialist HREC Bellberry Limited (Adult studies) SCHN (Paediatric studies)
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	Specialist HREC Bellberry Limited (Adult studies)

		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.	SCHN (Paediatric studies)
≥ Phase II	Typically >100	Efficacy and safety	Local HREC i.e. SWSLHD HREC

Trials involving a device

Study Phase	Estimated study sample	Aims/Objectives	HREC submission to:
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 Limited (Adult studies) SCHN (Paediatric studies)
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 Limited (Adult studies) SCHN (Paediatric studies)
Pre- or Post-Market (pivotal) study	Typically >100	Evaluate ongoing performance and safety	Local HREC i.e. SWSLHD HREC

Information for researchers:

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.