NSW Health Early Phase Clinical Trial HRECs Scheme
Quick Reference Guide

The Framework applies to early phase clinical trials proposed to be conducted at NSW Public Health Organisations, and includes trials involving products which are defined as therapeutic goods, including medicines, biologicals, and medical devices. Please refer to the guidance below:

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** i.e; Phase I/II study, or other variant with a phase I component, such as dose escalation/dose expansion studies. These clinical trials typically test how well a certain 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 earlier phase.	**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

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.

Applications that include both paediatric and adult populations:

- Please contact either specialist HREC to discuss the review of this application as a single combined review.