

General guidance for research ethics submissions

- Prior to starting please review the Research Office [website](#) and [pre-submission guide](#). This is a detailed reference for all aspects of research ethics and governance applications.
- Additional support
 - **Q&A drop-in sessions**, times and link on our [website](#).
 - Email SESLHD-RSO@health.nsw.gov.au.
- Ethics applications must be completed and submitted within [REGIS](#) (Research Ethics Governance Information System, operated by NSW Health)
 - REGIS How-To guides and videos can be accessed [here](#).
 - For REGIS technical issues (i.e. cannot upload/submit/login) please contact the REGIS Help Desk on 1300 073 447.
- **Investigator team** – the role of Coordinating Principal Investigator (CPI, primary responsibility for conduct of the study) and Principal Investigator (PI) at each study site (responsibility for the conduct of the study at the site) must be nominated. For SESLHD sites the PI must be a permanent SESLHD employee. If the CPI is also a PI, both roles should be clearly indicated in the study documents.
- Please nominate a **review pathway** (low risk or greater than low risk) when completing the Human Research Ethics Application (HREA) form completed in REGIS.
 - Low risk projects will be reviewed by the Low Risk Committee. Greater than low risk will be reviewed by the full HREC.
 - Please see this [low risk research guideline](#) and contact the Research Office if unsure.
- Please see [meeting dates and deadlines](#) dates on our website. All new submissions to the full HREC will undergo pre-review, please ensure they are submitted by the **pre-review deadline**.

Submission checklist – All ethics applications
All study documents must have [version number/date](#) in the footer.

Document	Notes & guidance	Submitted
Cover letter	<ul style="list-style-type: none"> • See template on SESLHD Research Office (RO) website • Please list sites where research is taking place • Nominate a CPI and a PI for each site (see note on these roles above) 	<input type="checkbox"/> Yes
Study Protocol	<ul style="list-style-type: none"> • Templates available on RO website. • Please ensure CPI / PI are clear and match the HREA. 	<input type="checkbox"/> Yes
HREA	<ul style="list-style-type: none"> • Complete the Project Registration in REGIS to generate Ethics application (reference 2024/ETHXXXXX) and HREA. • REGIS How-To guides and videos can be accessed here. • Please ensure the CPI and PI names and roles are consistent with protocol. 	<input type="checkbox"/> Yes
(Master) PISCFS	<ul style="list-style-type: none"> • Templates on RO website • Master version – do not include site logos. Placeholders for site logos or sites names only. • It is recommended that you use a tool like SHeLL Editor for your documents to ensure readability prior to submission 	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
CVs	<ul style="list-style-type: none"> • The CPI and PI must provide a short CV, signed and dated, that includes research experience and list Good Clinical Practice (GCP) training. 	<input type="checkbox"/> Yes
Data Collection / Sheet	<ul style="list-style-type: none"> • All variables to be collected must be listed in the application If applicable, a separate data collection sheet should be submitted 	<input type="checkbox"/> Yes <input type="checkbox"/> N/A



Other study documents	<ul style="list-style-type: none"> Questionnaires, patient cards/diaries, recruitment materials, letters of invitation, interview/focus group questions, telephone scripts, social media tiles. 	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Radiation Safety Report	<ul style="list-style-type: none"> Required for <u>each study site</u> where ionising radiation is additional to standard care (SC) For SESLHD sites contact: SESLHD-RadiationSafetyOfficer@health.nsw.gov.au If radiation is not additional to SC please provide a statement from CPI that it is in accordance with SC. 	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Specific Modules (VIC/WA)	<ul style="list-style-type: none"> For studies with sites in Victoria or Western Australia Victorian Specific Module (VSM) Western Australian Specific Module (WSM) 	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Additional documents required for Clinical Trials		
Method of Payment (MoP) Form	<ul style="list-style-type: none"> Submission of completed form is mandatory for all clinical trials Please note all review of all clinical trials with an external non-commercial or commercial sponsor will incur a fee according to NSW health policy. 	<input type="checkbox"/> Yes
Investigator's Brochure	<ul style="list-style-type: none"> for experimental drugs/devices (or product information / ARTG listing for registered goods). 	
Industry sponsored research		
Form of Indemnity (HREC review Only)	<ul style="list-style-type: none"> Medicines Australia Standard form for HREC Review Only (Note: required only if SESLHD does not have a participating site) <p>SESLHD Legal Entity details: Name: South Eastern Sydney Local Health District Address: District Executive Unit, Level 4 The Sutherland Hospital & Community Health Service Cnr The Kingsway and Kareena Road CARINGBAH NSW 2229 ABN: 70 442 041 439</p>	<input type="checkbox"/> Yes <input type="checkbox"/> N/A