

NSLHD Submission Checklist for a new Low/Negligible Risk (LNR) application to the HREC Executive Committee

- The Human Research Ethics Applications (HREA) must be completed within [REGIS](#).
- All applications to the HREC must comply with the below checklist – failure to do so may result in an ineligible application.
- In the HREA, you will be required to nominate a review pathway. This is determined by a projects level of risk (i.e. low risk, negligible risk or greater than low risk). If uncertain of which pathway your research falls under please contact the Research Office.
- All additional documents to be uploaded in REGIS. Please refer to the [Quick Reference Guides](#) (Project Registration, HREA/Ethics Application – Completing and Submitting the Application).
- Please be advised that the “owner” of the ethics application is the nominated Coordinating Principal Investigator (CPI). A CPI is defined as the individual who takes on overall responsibility of a research project and submits to an HREC for ethics review.
- Please [contact](#) the Research Office if you have questions about your research project or application in REGIS, for any technical support, call REGIS Help Desk on 1300 073 447.

Documents required	Notes & guidance	Submitted
Cover letter signed by the CPI (not the study coordinator) For single-site studies, Principal Investigator and Coordinating Investigator are synonymous	<ul style="list-style-type: none"> • List all sites for which HREC approval is being sought, and indicate if they are public/private. • List all documents submitted with application, including version numbers and dates. • Indicate if this is a STUDENT PROJECT NB. Undergraduate and Medical students cannot be the CPI of a study. 	<input type="checkbox"/> YES
Study protocol	<ul style="list-style-type: none"> • Submission of a study protocol is mandatory. Templates are available here. 	<input type="checkbox"/> YES
HREA	<ul style="list-style-type: none"> • Complete the project registration and HREA on REGIS. Once the Project Registration has been completed the HREA will automatically open within the ethics application (2021/ETH000XX) • All Research Team members listed within Project Registration must be listed within the HREA and have a REGIS account. Please note that only the CPI will be able to lock the HREA and submit the Ethics application. 	<input type="checkbox"/> YES
Participant Information Sheet & Consent Form/s - as necessary	<ul style="list-style-type: none"> • Only the templates available on the Standard Forms section of the Research Office website are acceptable. • University PISCF templates are not acceptable for studies taking place within the NSW Health system. 	<input type="checkbox"/> YES <input type="checkbox"/> N/A
Any other study documents	<ul style="list-style-type: none"> • For example: investigator brochures, questionnaires, patient cards/diaries, advertisements, letters of invitation, interview/focus group questions, telephone scripts. • All study documents must have version number/date in the footer. The electronic file name should not include the version number/date. 	<input type="checkbox"/> YES <input type="checkbox"/> N/A

External researcher CVs	<ul style="list-style-type: none"> • Researchers external to NSLHD must provide a 2 page summary CV. Please ensure that the CV is signed and dated by the Researcher. 	<input type="checkbox"/> YES <input type="checkbox"/> N/A
Method of Payment (MoP) form	<ul style="list-style-type: none"> • Applications will not be authorised without a completed Method of Payment Form. • Please upload to REGIS at time of submission. Please use document type 'other' at time of upload. 	<input type="checkbox"/> YES

Please contact the Research Office for further guidance regarding your submission.

Email nsldh-research@health.nsw.gov.au or phone 02 9926 4590