NSLHD Submission Checklist for a new application to the full HREC

- 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	• 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.	☐ YES
Study Protocol	• Submission of a study protocol is mandatory. Templates are available here. • For studies in NSLHD involving drugs, it is recommended that the Clinical Trials Pharmacy is consulted during the protocol development stage. Contact: Contact: nslhd-ctpharmacy@health.nsw.gov.au	☐ YES
HREA	• 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.	☐ YES
Participant Information Sheet & Consent Form/s - as necessary	• Only the templates available on the Standard Forms section of the Research Office website are acceptable. For multi-site/interstate studies, the NHMRC templates must be used. • University PISCF templates are not acceptable for studies taking place within the NSW Health system. • For single-site studies, insert the relevant site logo in the document header. For multi-site studies, submit a master version.	☐ YES ☐ N/A

Radiation Safety Report ***Required for each site being approved**	• Required for any study involving research-specific exposure to radiation (additional to standard of care) • For radiation that is not additional to standard care, a letter from the CPI is required confirming that radiation exposure is not additional to standard care. • NSLHD Radiation Safety Officer: susan.macalpine@health.nsw.gov.au ph: 02 9926 4431	☐ YES ☐ N/A
Any other study documents	• 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. • For single-site studies, insert the relevant site logo in the document header. For multisite studies, submit a master version. • For multi-site studies, researchers should be aware of any specific State or Territory requirements when submitting to an HREC via the process of certified ethical review (e.g. a Victorian Specific Module (VSM) for sites in Victoria or Western Australian Specific Module (WSM) for sites in Western Australia.	☐ YES ☐ N/A
External researcher CVs	• Researchers external to NSLHD must provide a 2 page summary CV. Please ensure that the CV is signed and dated by the Researcher.	☐ YES ☐ N/A
Method of Payment (MoP) form	• 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.	☐ YES
Additional documents for commercially sponsored studies		**Submitted**
Protocol summary	• Mandatory for commercially sponsored studies	☐ YES
Medicines Australia or Medical Technology Form of Indemnity (HREC Review Only)	• Only required if study is **not** being conducted at a site within NSLHD (i.e. HREC is providing review only, no SSA will be submitted to NSLHD Research Office) • Must list an Australian corporate entity as the sponsor • Indemnified party details.	☐YES ☐ N/A

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

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