Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Low and Negligible Risk (LNR) Submission Checklist

All Low and Negligible Risk (LNR) projects are to be submitted through the Research Ethics and Governance Information System (REGIS) https://regis.health.nsw.gov.au/

Quick Reference Guides are available to assist researchers to submit their ethics applications: Ethics Completing and Submitting the Application

The checklist below is designed to assist researchers to complete the required application documentation for ethical review. Incomplete applications may be deemed ineligible for review which will delay the progress of an application.

Consults to discuss research proposals and pre-review of applications is available. Please email the Concord Research Office for pre-review requests.

Please contact the Concord Research Office for further information regarding submitting research applications:
E: SLHD-ConcordEthics@health.nsw.gov.au
T: 02 9767 5622

Project Registration	
All sites listed	Yes ☐
Correct Human Research Ethics Committee selected	Yes ☐
Human Research Ethics Application (HREA)	
Correct pathway selected LNR or >LNR - LNR is where the only foreseeable risks are discomfort or inconvenience.	Yes ☐
Q1.9.10 Only one person nominated as the Co-ordinating Principal Investigator (CPI), the person who takes overall responsibility for the research project, and this person is listed first in the study team.	Yes ☐
Q1.9.11 is selected as 'Yes' for the CPI only.	Yes ☐
Supervisors should be listed as the CPI for student projects	Yes ☐
Institutional emails nominated for the CPI and Principal Investigator (PI) of each site	Yes ☐
Q1.15 All sites are listed are also listed in the protocol	Yes ☐
Q1.19 If "Aboriginal and Torres Strait Islander Peoples" is selected and the proposed study specifically involves the collection and analysis of the medical record data of Aboriginal or Torres Strait Islander (ATSI) peoples, or if the researchers wish to collect information on ATSI status and report findings for this group separately from the rest of the study population, the research proposal will also need to be submitted to the HREC of the Aboriginal Health & Medical Research Council of NSW for review and approval. Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research	Yes ☐ N/A ☐
Q1.19 If "People highly dependent on medical care who may be unable to give consent" or "People with a cognitive impairment, intellectual disability or mental illness" is selected the research proposal should consider and make reference to all sections of the National Statement Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness.	Yes ☐ N/A ☐
Q3.1 and 3.2 the difference between **collecting** and **using** data is answered correctly	Yes ☐
Q3.3 and Q3.4 unless using a completely anonymised data set, most research will collect, use and store re-identifiable (coded) information. Data should be kept in re-identifiable form (for auditing and monitoring purposes) for the requisite time	Yes ☐ N/A ☐

Q3.8 In most instances, data would have been collected for clinical purposes	Yes ☐ N/A ☐
All questions answered and HREA submitted by the CPI to declare certification of study documents	Yes ☐
Protocol	
Aims, hypothesis, outcomes and objectives clearly defined in line with the National Statement Chapter 3.1: The elements of research	Yes ☐
Background information based on current literature, relevant information and referenced appropriately	Yes ☐
Designed to ensure respect for the participant is not compromised by the aims of the research, by the way research is carried out, or by the results and that the research is designed to minimise the risk of harm or discomfort to participants	Yes ☐
Benefits and risks are described	Yes ☐
Recruitment method is appropriate to the study type and the sample size is listed	Yes ☐
Inclusion/Exclusion criteria clearly defined	Yes ☐
Statistical plan included. It is suggested that researchers consult with a statistician regarding the statistical analysis plan.	Yes ☐ N/A ☐
Data management is in accordance with Element 4 of the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*	Yes ☐
For best practice data storage and management, it is suggested that the SLHD software licence for REDCap (Research Electronic Data Capture) should be used to capture and store research data as this is a secure web-based data management tool designed for research purposes.	Yes ☐ N/A ☐
Ethical considerations are described with reference to the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018*	Yes ☐
Safety considerations and contingency plans provided	Yes ☐
Investigator obligations defined	Yes ☐
Funding and/or conflicts of interests disclosed	Yes ☐
Document name, version # and date included in the footer of the document	Yes ☐
Research Data Management Plan (RDMP)	
Contact the SLHD Research Data Manager for enquiries regarding completing the RDMP	Yes ☐
Participant Information Sheet and Consent Form (PISCF)	
SLHD template used • For multicentre studies, a Master Version PISCF should be created in which all local sites can prepare their own version.	Yes ☐ N/A ☐
All Investigators listed, including international collaborators	Yes ☐
Simplified terminology used and descriptions are in laymen terms	Yes ☐
Benefits and risks to the participant are described	Yes ☐
Data management described including storage, access, location, archive and destruction	Yes ☐
Study procedures clearly described, including time required to conduct study procedures and location of study procedures	Yes ☐
Funding, conflicts of interests, external interested parties and commercialisation interests are fully disclosed on the front page	Yes ☐
Process of withdrawal including what will happen to information already collected, clearly outlined • Participants should be able to verbally withdraw from a study as a withdrawal form is not a mandated requirement of the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018*	Yes ☐
Approving HREC contact details and ethics reference number listed	Yes ☐
Reimbursement: the following have been considered in regards to reimbursing participants: • Reimbursement can potentially coerce participants to provide favourable responses • Reimbursement is proportionate to the time and risk involved in participant	Yes ☐ N/A ☐

• Cultural customs and practices been taken into consideration • Expense of reimbursement has been included in the budget	
Document name, version # and date included in the footer of the document	Yes ☐
Other applicable documents	
Please provide a copy of the REDCap Project Codesheets with your variables listed for review and approval. If REDDcap has not been set-up, please submit the following: 1) Master Code Sheet and Data Collection Form • Contains identifiable participant information and study ID to link participants with their data • Document name, version # and date in footer 2) Data Collection Sheet • Data collection sheet with non-identifiable data and study ID to link data with the participant • Document name, version # and date in footer	Yes ☐ N/A ☐
For studies requesting a waiver of consent: SLHD Privacy Compliance Form	
Completed SLHD Privacy Compliance Form for requesting a waiver of consent. Please provide a strong argument for a waiver of consent in terms of why the research is in the public interest and arguments for impracticality of obtaining consent.	Yes ☐ N/A ☐
The justification for a waiver of consent is in accordance with Chapter 2.3 of the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018*	Yes ☐ N/A ☐
The data and number of records is listed and aligns with the protocol	Yes ☐ N/A ☐
The Waiver of Consent has been completed in accordance with the relevant Act: - *Health Records and Information Privacy Act 2002 (NSW) – Statutory Guidelines on Research* - *Guidelines approved under Section 95 of the Privacy Act 1988* - *Guidelines approved under Section 95A of the Privacy Act 1988* Note: Further Information can be found at *Privacy Act 1988* and *Australian Privacy Principles Guidelines*	Yes ☐ N/A ☐
Focus group/interview/workshops guidelines	
• Disclosure of whether sessions will be recorded and transcribed • If sessions will be recorded, where the recordings will be stored • If sessions will be transcribed, who will be transcribing sessions. If recordings will be externally transcribed, who and where this will be performed • Contingency plans are described for participants who do not want to be recorded • Tentative dates and times of sessions are provided • Document if participants be in sessions with their managers or supervisors • Document name, version # and date included in the footer of document • Scripts provided, including prompt/follow-up questions	Yes ☐ N/A ☐