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

Greater than Low and Negligible Risk (LNR) Submission Checklist

All Greater than Low and Negligible Risk (>LNR) projects are to be submitted through the Research Ethics and Governance Information System (REGIS)

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)	
Q4.5 Correct pathway selected (>LNR) – if the foreseeable risks are greater than 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 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 ☐
Q1.19 Select 'People in dependent or unequal relationships' if there is a pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research.	
Q2.3.1 – Please describe and acknowledge any potential risks in regards to patient privacy	

and confidentiality, disclosure of sensitive personal information, physical harm, psychological harm, exposure of illegal activity, economic harm, discrimination, stigma or other social harm, devaluation or harassment, familial distress, harm to any member of a vulnerable population, reputational harm.	
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. SLHD Research Data Manager and REDCap Administrator can be contacted for bookings and assistance at CRGH via email or online	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 aligns with document file name	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 with their position on the project, 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	Yes ☐

fully disclosed on the front page	
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 (2020/ETHXXXX)	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 • Cultural customs and practices been taken into consideration • Expense of reimbursement has been included in the budget	Yes ☐ N/A ☐
Document name, version # and date included in the footer of the document	Yes ☐
Bio-bank studies	
Q1.18 and Q1.19 regarding participation answered correctly	Yes ☐
M2.1 the type of human bio-specimen/s collected is answered correctly including how the biospeicmens will be used	Yes ☐
Evidence of biobank certification/accreditation provided. Contact the NSW Biobank Certification program for details	Yes ☐
For studies involving genetic testing, information should be provided in the PISCF in regards to the Financial Services Council Moratorium on genetic testing	Yes ☐ N/A ☐
Information regarding sharing of bio-specimens with local and international collaborators included in the protocol and PISCF	Yes ☐ N/A ☐
Machine/device studies	
Certificate and biomedical engineering report provided	Yes ☐
Information provided in regards to the owner, supplier, manufacturer of the device and whether results are provided back to the supplier and/or manufacturer are disclosed and included in the protocol and PISCF	Yes ☐
Evidence of the machine/device listed on the Australian Register of Therapeutic Goods (ARTG) or evidence of Clinical Trial Notification (CTN) submitted to the Therapeutics Goods Administration (TGA) provided for devices considered medical machines/devices	Yes ☐
Drug and Device studies	
The TGA's online interactive decision tool used to determine whether the product is a therapeutic good	Yes ☐
ARTG certificate for indication of the use provided	Yes ☐
Evidence of Clinical Trial registration provided	Yes ☐
Investigator's Brochure or information provided which complies with the TGA's requirements for product documentation provided	Yes ☐
Product storage requirements provided	Yes ☐
Evidence of TGA's Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) provided	Yes ☐ N/A ☐
Evidence of CTN or CTX *and* Goods Manufacturing Practice (GMP) licence provided for placebo studies	Yes ☐
Data Safety Monitoring Board or Independent Board setup to monitor the trial	Yes ☐
A separate PISCF for the participant's partner is provided for studies whereby contraceptive or barrier precautions are required	Yes ☐ N/A ☐
Data stored for a minimum of 15 years	Yes ☐

The standard of care and intervention is described in the protocol and PISCF	Yes ☐
Radiation safety	
Radiation Safety Report signed by a Radiation Safety Officer submitted	Yes ☐
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 ☐
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 ☐