**SOUTH EASTERN SYDNEY RESEARCH OFFICE – ETHICS ELIGIBILITY CHECKLIST**

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| **CPI/PI DETAILS** |
| **ETHICS ID NUMBER** | Click and enter ETH Code |
| **CPI**  |   |
| **PI** |  |
| **SUBMISSION DATES HAVE BEEN CHECKED ON WEBSITE FOR RELEVANT MEETINGS: *seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/committee-details*** | **YES ☐ NO ☐** |
| **PI DECLARES TO HAVE CONFIRMED WITH THE RELEVANT HEAD/S OF DEPARTMENT/S THE REQUIRED RESOURCE REQUIREMENTS FOR THE STUDY?** | **YES** [ ]  **NO** [ ] *(PLEASE ENSURE THAT YOU HAVE THE CORRECT HEAD OF DEPT. BEFORE SUBMITTING A SUBSEQUENT SSA)* |

***REGIS RESEARCHER TRAINING: https://regis.health.nsw.gov.au/content-resources/***

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| **ADMINISTRATIVE REVIEW** |
| *Answering No to any of the following questions will result in an ineligible application* |
| **CPI/PI AND RESEARCH TEAM NOMINATED MATCH ACROSS DOCUMENTS: REGIS REGISTRATION/HREA/PROTOCOL ETC.** *(PLEASE NOTE ONCE YOU HAVE CREATED THE REGIS REGISTRATION, IT CANNOT BE EDITED AND A NEW APPLICATION WILL BE REQUIRED IF THERE IS AN ERROR)* | **YES** [ ]  **NO** [ ]  |
| **“RESEARCH TYPE” WAS CORRECTLY ENTERED** *(i.e.: CLINICAL RESEARCH)* | **YES** [ ]  **NO** [ ]  |
| **CONTACT DETAILS** |  |
| *Answering No to any of the following questions will result in an ineligible application* |  |
| **EACH SITE HAS A NOMINATED PRINCIPAL INVESTIGATOR THAT IS A STAFF MEMBER of SESLHD** | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **INSTITUTIONAL EMAIL ADDRESSES PROVIDED IN HREA**  | **YES** [ ]  **NO** [ ]  |
| **MOBILE CONTACT NUMBER PROVIDED IN HREA** | **YES** [ ]  **NO** [ ]  |

***REGIS QUICK REFERENCE GUIDES: https://regis.health.nsw.gov.au/how-to/***

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| **NATIONAL MUTUAL ACCEPTANCE – OTHER APPROVALS** |  |
| **HREA – Q1.13 – HAS ETHICS BEEN APPROVED OR UNDERWAY ELSEWHERE** | **YES** [ ]  **NO** [ ]  |
| ***If Yes, please commit the following items*** |  |
| **APPROVAL FROM NHMRC LEAD HREC**  | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **STUDY QUALIFIES FOR NMA APPROVAL***If yes, the study is ineligible. If no, please continue to the next question*  | **YES** [ ]  **NO** [ ]  |
| **HREA – Q1.14:***If yes:***RESEARCH IN FIRST NATIONS PEOPLE HAS AHMRC LISTED****RESEARCH IN PERSONS (THOSE IN CUSTODY/STAFF) IN THE JUSTICE HEALTH DEPARMENTS HAS NSW JUSTICE HEALTH HREC LISTED****RESEARCH REQUIRING ACCESS TO STATE-WIDE DATA COLLECTIONS (NSW HEALTH/CANCER INSTITUTE) HAS NSW POPULATION & HEALTH SERVICES RESEARCH HREC LISTED** | **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |

***FREQUENTLY ASKED QUESTIONS: https://regis.health.nsw.gov.au/help-desk-faqs/frequently-asked-questions-for-researchers-and-applicants/***

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| **RISK PATHWAY REVIEW** |
| *Answering Yes to any of the following questions will require the application to be reviewed by the full HREC. If yes is selected for the vulnerable groups only; there may be recourse for the study to proceed to LNR. Please contact the Research Ethics and Governance Manager/HREC Executive Officer if you are unsure.*  |
| **IS THE STUDY REQUESTING A WAIVER OF CONSENT?** FOR PERSONAL/SENSITIVE INFORMATION, BIOSPECIMENS, INTENSIVE CARE RESEARCH, OR THE TRANSFER OF GENETIC MATERIAL | **YES** [ ] *(ANSWER NEXT QUESTION)* **NO** [ ] *(SKIP NEXT QUESTION)* |
| **HAVE YOU VERIFIED YOU ARE ASKING FOR A WAIVER OF CONSENT ACCORDING TO THE NATIONAL STANDARDS:** *(Q 2.2.8) Asking for a “waiver of consent” will require a full HREC meeting review, please ensure that you are clear whilst filling in the HREA questions regarding consent* [*https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1) *(PAGE 19)* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **OPT-OUT CONSENT MODEL USED** | **YES** [ ]  **NO** [ ]  |
| **STUDY IS TESTING INTERVENTIONS** | **YES** [ ]  **NO** [ ]  |
| **STUDY INVOLVES EMBRYONIC CELL LINES/STEM CELLS** | **YES** [ ]  **NO** [ ]  |
| **STUDY INVOLVES BIOSPECIMEN COLLECITON, BIOBANKING, OR EXPORT** | **YES** [ ]  **NO** [ ]  |
| **BIOSPECIMEN COLLECTION MAY REVEAL IMPORTANT INFORMATION** | **YES** [ ]  **NO** [ ]  |
| **STUDY INVOLVES VULNERABLE GROUPS****ABORIGINAL & TORRES STRAIT ISLANDER PEOPLES****PREGNANT WOMEN AND/OR THE FOETUS****HIGHLY DEPENDENT PARTICIPANTS/PARTICIPANTS UNABLE TO CONSENT****PARTICIPANTS WITH COGNITIVE IMPAIRMENT/MENTAL ILLNESS****PARTICIPANTS IN DEPENDENT OR UNEQUAL RELATIONSHIPS****RESEARCH AIMS TO EXPOSE ILLEGAL ACTIVITY****RESEARCH PLANS TO USE ACTIVE CONCEALMENT OR DECEPTION** | **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **FORESEEABLE RISK OF DISTRESS (HREA Q M8.5)** | **YES** [ ]  **NO** [ ]  |

***WHO DO I CONTACT?*** [***https://regis.health.nsw.gov.au/help-desk-faqs/who-and-***](https://regis.health.nsw.gov.au/help-desk-faqs/who-and-)

***when-to-contact/***

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| **SUPPORTING DOCUMENT REVIEW** |
| *Answering No to any of the following questions will result in an ineligible application** *Please ensure that all your documents are titled: title-version-date*
 |
| **ENSURED THAT THE TITLE OF EACH SUPPORTING DOCUMENT UPLOADED IN REGIS IS TITLED ARE CORRECT AND INCLUDE TITLE/VERSION/DATE:** *(i.e.: Protocol-V1.0-16-01-2022 and include (clean) or (tracked) if relevant).***STUDY PROTOCOL****PROTOCOL VERSION IN FOOTER****PROTOCOL DOCUMENT DATE IN FOOTER****PAGE NUMBERS IN FOOTER****SESLHD PROTOCOL TEMPLATE USED** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **PATIENT INFORMATION AND CONSENT FORM****PISCF VERSION IN FOOTER****PISCF DOCUMENT DATE IN FOOTER****PAGE NUMBERS IN FOOTER****CONSENT FORM PROVIDED** *(may be a separate document)***WITHDRAWL OF CONSENT FORM PROVIDED** *(may be a separate document)***PISCF TEMPLATE USED** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **MASTER PISCF – MULTI-SITE RESEARCH****PLACE HOLDER FOR LOGO PRESENT****PLACEHOLDER IN COMPLAINTS SECTION FOR STE/PID CODE** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **SINGLE SITE PISCF****SESLHD LOGO PRESENT****COMPLAINTS SECTION LISTS THE RO AND PID/ETH/STE CODE LISTED** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **QUESTIONNAIRES & SURVEYS****VERSION IN FOOTER****DOCUMENT DATE IN FOOTER****PAGE NUMBERS IN FOOTER** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **RECRUITMENT MATERIALS (E.G. FLYERS)** **PLACE HOLDER FOR LOGO PRESENT/SESLHD LOGO PRESENT****VERSION IN FOOTER****DOCUMENT DATE IN FOOTER** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [x]  |
| **DATA COLLECTION SHEET****VERSION IN FOOTER****DOCUMENT DATE IN FOOTER** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |

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| **TO ATTEND INFORMATION WEBINARS, PLEASE SEE DETAILS ON THE SESLHD RESEARCH WEBSITE:** |
| https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research |

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| **PRINCIPAL INVESTIGATOR OR DELEGATE DECLARATION THAT ALL INFORMATION IN THIS CHECKLIST IS CORRECT AND COMPLETE** |
| **YES** [ ]  |