**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** |
| **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** |