|  |
| --- |
| 1. **CPI/PI DETAILS**
 |
| **a. ETHICS ID NUMBER** | Click and enter ETH Code |
| **b. CPI (Coordinating Principal Investigator) the roles need to be consistent in the registration/protocol/ ethics and governance applications etc.**  | *(Please check the role definitions:* [**https://www.medicalresearch.nsw.gov.au/app/uploads/2018/04/ACTJWG-resp-investigator.pdf**](https://www.medicalresearch.nsw.gov.au/app/uploads/2018/04/ACTJWG-resp-investigator.pdf) *)* |
| **c. PI (Principal Investigator/s) and corresponding site/s** ***Please ensure that each site is listed*** | *PI-* *SITE 1**SITE 2 ((+ MORE)* |
| **d. SUBMISSION CUT-OFF DATES HAVE BEEN CHECKED ON WEBSITE FOR RELEVANT MEETINGS:**  | **YES ☐ NO ☐*****seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/committee-details*** |
| **e. PI DECLARES TO HAVE CONFIRMED WITH THE RELEVANT HEAD/S OF DEPARTMENT/S, RESOURCE REQUIREMENTS FOR THE STUDY?** | **YES** [ ]  **NO** [ ] *(PLEASE ENSURE THAT YOU HAVE THE CORRECT HEAD OF DEPT.* ***BEFORE*** *SUBMITTING A SSA)* |
| **f. YOUR STUDY HAS BEEN REVIEWED BEFORE SUBMISSION TO REGIS?**  | **YES ☐ NO ☐ (***BY YOUR SUPERVISOR/MANAGER/RESEARCH MANAGER or SUBJECT MATTER EXPERT?)* |
| **g. HAS THE PROJECT HAD STATISTICAL REVIEW?** | **YES ☐ NO ☐** *(IF THIS IS A COLLABORATIVE PROJECT, PLEASE SEEK REVIEW FROM A STATISTICIAN WIITHIN THE TERTIARY INSTUTION)* |

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

|  |
| --- |
| **2. ADMINISTRATIVE REVIEW** |
| *Answering No to any of the following questions will result in an ineligible application* |
| **a. 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)***THE INTENDED SITES ARE LISTED CORRECTLY IN THE REGISTRATION** | **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **b. “RESEARCH TYPE” WAS CORRECTLY ENTERED** *(i.e.: CLINICAL RESEARCH)* | **YES** [ ]  **NO** [ ]  |
| 1. **CONTACT DETAILS**
 |  |
| **a. EACH SITE HAS A NOMINATED PRINCIPAL INVESTIGATOR THAT IS A STAFF MEMBER of SESLHD** | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **b. INSTITUTIONAL EMAIL ADDRESSES PROVIDED IN HREA**  | **YES** [ ]  **NO** [ ]  |
| **c. MOBILE CONTACT NUMBER PROVIDED IN HREA** | **YES** [ ]  **NO** [ ]  |

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

|  |  |
| --- | --- |
| 1. **NATIONAL MUTUAL ACCEPTANCE – OTHER APPROVALS**
 |  |
| **a. HREA – Q1.13 – HAS ETHICS BEEN APPROVED OR UNDERWAY ELSEWHERE** | **YES** [ ]  **NO** [ ]  |
| ***If Yes, please commit the following items*** |  |
| **i. APPROVAL FROM NHMRC LEAD HREC**  | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **ii. STUDY QUALIFIES FOR NMA APPROVAL***If yes, the study is ineligible. If no, please continue to the next question*  | **YES** [ ]  **NO** [ ]  |
| **b. HREA – Q1.14:***If yes:***i. RESEARCH IN FIRST NATIONS PEOPLE HAS AHMRC LISTED****ii. RESEARCH IN PERSONS (THOSE IN CUSTODY/STAFF) IN THE JUSTICE iii.HEALTH DEPARMENTS HAS NSW JUSTICE HEALTH HREC LISTED****iv. 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/***

|  |
| --- |
| 1. **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. For risk pathway reference please see: (https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)* |
| **a. 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)* |
| **b. 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** [ ] *(answering incorrectly, may result in the application requiring extra time to process for correction and submission to meeting)* |
| **c. OPT-OUT CONSENT MODEL USED** | **YES** [ ]  **NO** [ ]  |
| **d. STUDY IS TESTING INTERVENTIONS** | **YES** [ ]  **NO** [ ]  |
| **e. STUDY INVOLVES EMBRYONIC CELL LINES/STEM CELLS** | **YES** [ ]  **NO** [ ]  |
| **f. STUDY INVOLVES BIOSPECIMEN COLLECITON, BIOBANKING, OR EXPORT** | **YES** [ ]  **NO** [ ]  |
| **g. BIOSPECIMEN COLLECTION MAY REVEAL IMPORTANT INFORMATION** | **YES** [ ]  **NO** [ ]  |
| **h. STUDY INVOLVING VULNERABLE GROUPS *check risk pathway: https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2010\_055.pdf*****i. ABORIGINAL & TORRES STRAIT ISLANDER PEOPLES****ii. WOMEN AND/OR THE FOETUS****iii. DEPENDENT PARTICIPANTS/PARTICIPANTS UNABLE TO CONSENT****iv. PARTICIPANTS WITH COGNITIVE IMPAIRMENT/MENTAL ILLNESS****v. PARTICIPANTS IN DEPENDENT OR UNEQUAL RELATIONSHIPS****vi. RESEARCH AIMS TO EXPOSE ILLEGAL ACTIVITY****vii. RESEARCH PLANS TO USE ACTIVE CONCEALMENT OR DECEPTION** | **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **i. FORESEEABLE RISK OF DISTRESS (HREA Q M8.5)** | **YES** [ ]  **NO** [ ]  |
| 1. **IF your project is deemed Low/Negligible Risk – are you requesting a QA/QI determination?**
 | **YES** [ ]  **NO** [ ]  **protocol template available on ‘seslhd research” website** |

***REGIS IT HELP?*** [***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/***

|  |
| --- |
| **7. SUPPORTING DOCUMENT REVIEW** |
| *Answering No to any of the following questions will result in an ineligible application* |
| **ENSURED THAT THE TITLE OF EACH SUPPORTING DOCUMENT UPLOADED IN REGIS IS TITLED ARE CORRECT AND INCLUDE TITLE/VERSION/DATE:** *[i.e.: PID No./Document type / Version no. /date and include (clean) or (tracked) if relevant].***a. STUDY PROTOCOL PRESENTED (protocol template on seslhd research website)****i. PROTOCOL VERSION IN FOOTER****ii. PROTOCOL DOCUMENT DATE IN FOOTER****iii. PAGE NUMBERS IN FOOTER****iv. SESLHD PROTOCOL TEMPLATE USED****v. SITES LISTED IN PROTOCOL** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **b. PATIENT INFORMATION AND CONSENT FORM PRESENTED****i. PISCF VERSION IN FOOTER****ii. PISCF DOCUMENT DATE IN FOOTER****iii. PAGE NUMBERS IN FOOTER****iv. CONSENT FORM PROVIDED** *(may be a separate document)***v. WITHDRAWL OF CONSENT FORM PROVIDED** *(may be a separate document)***vi. PISCF TEMPLATE USED** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **vii. MASTER PISCF – MULTI-SITE RESEARCH****viii. PLACE HOLDER FOR LOGO PRESENT****ix. PLACEHOLDER IN COMPLAINTS SECTION FOR STE/PID CODE** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **x. SINGLE SITE PISCF****xi. SESLHD LOGO PRESENT****xii. COMPLAINTS SECTION LISTS THE RO AND PID/ETH/STE CODE** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **c. QUESTIONNAIRES & SURVEYS PRESENT****i. VERSION IN FOOTER****ii. DOCUMENT DATE IN FOOTER****iii. PAGE NUMBERS IN FOOTER** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **d. RECRUITMENT MATERIALS (E.G. FLYERS)** **i. PLACE HOLDER FOR LOGO PRESENT/SESLHD LOGO PRESENT****ii. VERSION IN FOOTER****iii. DOCUMENT DATE IN FOOTER** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ] **YES** [ ]  **NO** [ ]  |
| **e. DATA COLLECTION SHEET PRESENTED****i. VERSION IN FOOTER****ii. DOCUMENT DATE IN FOOTER** | **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ] **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| **8. METHOD OF PAYMENT FORM:** |
| **i. METHOD OF PAYMENT (MoP) FORM ATTACHED, COMPLETE AND CORRECT**? **YES** [ ]  **NO** [ ]  **(please complete)** |
| **TO ATTEND INFORMATION WEBINARS, PLEASE SEE DETAILS ON THE SESLHD RESEARCH WEBSITE:** |
| <https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research>\*Please respond to research office requests for more information within the given time limit (30 DAYS) to avoid application withdrawal. |
| **9. PRINCIPAL INVESTIGATOR OR DELEGATE DECLARATION THAT ALL INFORMATION IN THIS CHECKLIST IS CORRECT AND COMPLETE** |
| **PLEASE NOTE: you MUST obtain a Site Specific Authorisation from the LHD site/s before commencing your study. Applications are made through REGIS (**[**https://regis.health.nsw.gov.au/**](https://regis.health.nsw.gov.au/)**) YES** [ ]  |