**SOUTH EASTERN SYDNEY RESEARCH OFFICE – GOVERNANCE APPLICATION CHECKLIST**

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| **ADMINISTRATIVE DETAILS** | |
| 1. **STE ID NUMBER** |  |
| 1. **Principal Investigator** | Please enter your name |
| 1. **Have you completed ICH-GCP training** | YES ☐ NO☐ (If yes, please upload certificate with submission) |
| 1. **PARTICIPANT DELEGATED RISK PATHWAY** | Enter the Provided Risk Pathway |
| 1. **]blank]** |  |
| 1. **Have you spoken to each relevant HoD:** 2. **That the request has been sent to the correct HoD** 3. **ensure that the HoD has had the opportunity to ask questions re the study** 4. **that the HoD agrees and they will receive an email from REGIS requiring their formal approval.** | **YES  NO**  **YES  NO**  **YES  NO** |
| 1. **SPONSOR TYPE** | Please enter Sponsor Type from STE A12 |
| 1. **SPONSOR NAME** | Please enter Sponsor Name from STE A13 |
| 1. **IS THE SPONSOR AN AUSTRALIAN ENTITY** | **YES  NO**  *If no, the SSA must be returned to the Investigator. Research must be Sponsored by an Australian entity* |
| **[blank]** | **YES  NO** |

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

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| **FEE INFORMATION** | |
| **Fee category** | Please select the appropriate fee schedule |
| **MoP attached** | Please select the appropriate fee schedule |

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

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| **HREC details** | |
| **PROPOSED SESLHD SITE** | Please enter Site Name from STE B1 |
| **IS THE SITE LISTED IN THE HREC APPROVAL LETTER?** | **YES  NO**  (if no- please submit an amendment to the lead HREC) |
| **WAS STUDY APPROVED UNDER THE NMA SCHEME**? Check list on the following link: https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research | **YES  NO  N/A** (If no – please submit an Ethics application with NMA cert. HREC) |
| **DATE OF HREC APPROVAL** | Click or tap to enter a date. |
| **ARE ADDITIONAL APPROVALS REQUIRED?** | **YES  NO**  Please select the requisite approval |

**COMMENTS:**

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| **STUDY PERSONNEL** | | | | | | | |
| **INVESTIGATORS ON SITE** | **NSW HEATLH EMPLOYEES** | | **EXTERNAL PERSONNEL4,5** | | **STUDENT** | | **GCP TRAINING PROVIDED6** |
| **NAME** | **SESLHD** | **OTHER LHD2 OR UNSW3** | **INSURANCE PROVIDED** | **CV PROVIDED** | **SESLHD STAFF** | **EXTERNAL, INSURANCE PROVIDED5** |
|  |  | **-** | **-** | **-** | **-** | **-** | **YES  NO** |
| Click to enter AI’s Name |  |  | **YES  NO** | **YES  NO** |  | **YES  NO** | **YES  NO** |
| Click to enter AI’s Name |  |  | **YES  NO** | **YES  NO** |  | **YES  NO** | **YES  NO** |
| Click to enter AI’s Name |  |  | **YES  NO** | **YES  NO** |  | **YES  NO** | **YES  NO** |

*1 The Principal Investigator must be a SESLHD employee*

*2 Evidence of Contingent Worker status required*

*3 UNSW staff members are authorised to be on site as per the Memorandum of Understanding*

*4 Check if external personnel will require site access, if yes, request evidence of Honorary Appointment or Contingent Worker status. Visiting Medical Officers are required to have a signed services contract and contract of liability coverage for the period of the trial. In the absence of any of these items, evidence of personal Medical Defence Organisation coverage is required.*

*5 Employees of Universities or other private organisations, including students, must provide evidence on insurance and indemnity to conduct research for their employer.*

*6 For clinical trials only*

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| **SUPPORTING DEPARTMENTS** | | | | | |
| **DEPARTMENT NAME** | **HEAD OF DEPARTMENT** | **HOD ADDED** | **HOD APPROVAL GRANTED** | **IS THE HOD A STUDY TEAM MEMBER** | **HOD’S LINE MANAGER ASSIGNED** |
| Click to enter Department’s name | Click to enter HoD’s name | **YES  NO** | **YES  NO** | **YES  NO** | **YES  NO  N/A** |
| Click to enter Department’s name | Click to enter HoD’s name | **YES  NO** | **YES  NO** | **YES  NO** | **YES  NO  N/A** |
| Click to enter Department’s name | Click to enter HoD’s name | **YES  NO** | **YES  NO** | **YES  NO** | **YES  NO  N/A** |
| Click to enter Department’s name | Click to enter HoD’s name | **YES  NO** | **YES  NO** | **YES  NO** | **YES  NO  N/A** |

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| **STUDY DESIGN DETAILS** | |
| **PARTICPANT & RECRUITMENT DETAILS** | |
| **PATIENT RECRUITMENT TARGET** |  |
| **WILL THE STUDY RECRUIT MINORS?** | **YES  NO** |
| **IF YES, DOES THE STUDY COMPLY WITH LOCAL AGE OF ADMISSION POLICY?** | **YES  NO** |
| **IS AN NCAT APPROVAL REQUIRED? (STE A11)**  *Clinical trials recruiting participants over 16 without the capacity to consent and/or require consent from a responsible person (e.g., parent or guardian)* | **YES  NO** |
| **IF YES, WAS RELEVANT THE NCAT APPROVAL PROVIDED?** | **YES  NO** |
| **MATERIALS** | |
| **WILL TISSUE BE EXPORTED FROM THE LHD? (STE D7 & STUDY PROTOCOL)** | **YES  NO** |
| **IS AN MTA REQUIRED?**  *An MTA is not required for commercially sponsored clinical trials* | **YES  NO  N/A** |
| **WAS AN MTA PROVIDED?** | **YES  NO  N/A** |
| **WILL DATA BE EXPORTED FROM THE LHD?** | **YES  NO** |
| **WILL THE DATA BE DE-IDENTIFIED BEFORE LEAVING THE DISTRICT?** | **YES  NO** |
| **HAS THE APPROVAL FOR DATA ACCESS AND EXPORT BEEN GRANTED BY THE SESLHD DATA CUSTODIAN ?** *If not, please seek advice with the SESLHD Corporate and Legal team* | **YES  NO  N/A** |
| **COMPLIANT DATA EXTRACTION PROCESS?**  *e.g. REDCap or Accellion KiteWorks* | **YES  NO  N/A** |
| **DATA COLLECTION METHOD** | **PROSPECTIVE COLLECTION**  **RETROSPECTIVE COLLECTION** |
| **RETROSPECTIVE COLLECTIONS: DATA CUSTODIAN APPROVAL PROVIDED**  *If no, only* ***conditional authorisation*,** *may be issued whereby Data Custodian approval is required prior to extraction* | **YES  NO  N/A** |
| **IS THIS A DATA LINKAGE PROJECT?** | **YES  NO** |
| **STATE-WIDE DATABASES**  [*http://www.cherel.org.au/data-dictionaries*](http://www.cherel.org.au/data-dictionaries) | **YES  NO  N/A** |
| **FEDERAL DATABASES**  [*https://www*](https://www)*.aihw.gov.au/our-services/data-linkage/data-collections* | **YES  NO  N/A** |
| **STATE-WIDE DATABASES: NSW POPULATION & HEALTH SERVICES HREC APPROVAL PROVIDED** | **YES  NO** |
| **FEDERAL DATABASES: AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE or SERVICES AUSTRALIA APPROVAL PROVIDED** | **YES  NO** |
| **WILL THE STUDY INTEND TO COLLECT/ANALYSE FIRST NATION’S PEOPLE’S DATA?** | **YES  NO** |
| **OTHER DESIGN RELATED APPROVALS** | |
| **RADIATION SAFETY REPORTS**  *Required for studies involving the use of radiation. The report will usually be completed by the site’s Radiation Safety Officer* | **YES  NO  N/A** |
| **BIOSAFETY COMMITTEE APPROVAL**  *For studies involving the use of recombinant DNA* | **YES  NO  N/A** |
| **CLINICAL TRIALS REGISTRY**  *If a clinical trials registry number is not provided, the PI is aware that clinical trials must be registered prior to commencing recruitment. This will not prevent site authorisation proceeding* | **YES  NO  N/A** |

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| **FINANCIAL INFORMATION** | |
| **IS THE PROJECT FUNDED?** | **YES  NO  N/A**  If Yes, Name Funding Body. Enter “Department Funds” if internal funds will be used |
| **EVIDENCE OF EXTERNAL FUNDING PROVIDED**  *If no, evidence must be provided. Note: this will likely be within the CTRA* | **YES  NO  N/A** |
| **DO IN-KIND OR FINANCIAL COSTS EXCEED $10,000**  *If yes, GM approval is required* | **YES  NO  N/A** |

**COMMENTS:**

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| **CLINICAL TRIALS ONLY** | |
| **CONTRACT** | Please select the contract type |
| **FIRST PAGE HAS CORRECT SESLHD DETAILS LISTED** | **YES  NO**  South Eastern Sydney Local Health District  District Executive Unit, Level 4  The Sutherland Hospital & Community Health Service  Cnr The Kingsway and Kareena Road CARINGBAH NSW 2229  ABN 70 442 041 439 |
| **SCHEDULE 1 – HREC AND STUDY DETAILS MATCH SSA** | **YES  NO** |
| **SCHEDULE 2 – FUNDING/BUDGET DESCRIBED** | **YES  NO  N/A** |
| **SCHEDULE 3 – CRG AGREEMENT**  **SCHEDULE 6 – OTHER CTRA**  **STUDY PROTOCOL IDENTIFICATION IS CORRECT** | **YES  NO** |
| **SCHEDULE 4 – CRG AGREEMENT**  **SCHEDULE 7 – OTHER CTRA**  **MATCH SEBS APPROVAL**  *If no, SEBS approval must be provided.* | **YES  NO  N/A** |
| **SIGNED BY PI AND SPONSOR** | **YES  NO** |
| **INSURANCE**  *Collaborative Research Group Trials: $10 million*  *Commercially Sponsored Trials: $20 million, named Australian Sponsor, ≤$25,000 excess* | **YES  NO** |
| **INDEMNITY**  *Commercially Sponsored Trials Only* | **YES  NO  N/A** |
| **INDEMNITY FORM** | Please choose Indemnity Form |
| **CORRECT STUDY TITLE** | **YES  NO** |
| **CORRECT SESLHD DETAILS (INC. ABN)** | **YES  NO** |
| **CORRECT PI NAME** | **YES  NO** |
| **SIGNED BY SPONSOR** | **YES  NO** |

**COMMENTS:**

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| **DOCUMENT VERSION QUALITY CONTROL (DELETE IF NOT APPLICABLE)** | | | | | |
| **DOCUMENT** | **MASTER** | | **SITE-SPECIFIC** | | **REFERENCED CORRECTLY** |
| **VERSION** | **DATE** | **VERSION** | **DATE** |
|  | Please enter HREC approved version | Enter approved document date | Please enter HREC approved version | Enter approved document date | **YES  NO** |
|  | Please enter HREC approved version | Enter approved document date | Please enter HREC approved version | Enter approved document date | **YES  NO** |
|  | Please enter HREC approved version | Enter approved document date | Please enter HREC approved version | Enter approved document date | **YES  NO** |
|  | Please enter HREC approved version | Enter approved document date | Please enter HREC approved version | Enter approved document date | **YES  NO** |

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| **DOCUMENTS** |  |  | |
| **DOCUMENT TITLE** *(please ensure that document versions and titles match HREC approval letter)* | **VERSION** | | **DATE** |
|  | Please enter HREC approved version | | Enter approved document date |
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|  | Please enter HREC approved version | | Enter approved document date | Please list the problem with the document e.g. wrong version uploaded: V1.0 provided |

**FOR OFFICE USE ONLY:**

**COMMENTS:**

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| **GOVERNANCE RECOMMENDATION** | |
| **IS THIS GOVERNANCE APPLICATION ELIGIBLE TO PROCEED** | **YES  NO** |
| **QUERIES TO THE INVESTIGATOR** | *Please list the response to the Investigator here (to be copied and pasted into REGIS eligibility email):* |
| **COMMENTS** |  |