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

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| **ADMINISTRATIVE DETAILS** |
| 1. **STE ID NUMBER**
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| 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 4The Sutherland Hospital & Community Health ServiceCnr The Kingsway and Kareena Road CARINGBAH NSW 2229ABN 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** |  |