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

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| 1. **ADMINISTRATIVE DETAILS**
 |
| 1. **REGIS “STE” ID NUMBER**
 | (year/STExxxxx) |
| 1. **Principal Investigator**
 | (must be a permanent SESLHD staff member or visiting medical officer) |
| 1. **Have you completed ICH-GCP training**
 | YES ☐ NO☐ (please upload certificate with submission)**Please note: In July 2023 this will be a mandatory requirement of all investigators conducting research in SESLHD. Please see details for course info on the “SESLHD Research” website homepage.**  |
| 1. **PARTICIPANT DELEGATED RISK PATHWAY**
 | Enter the Provided Risk Pathway |
| 1. **Check that HoD is not a study team member?**
 | YES ☐ NO☐ Study team members cannot sign off as a HoD for the project. Their next line manager must sign off as HoD for the study.  |
| 1. **Does your study have non-financial costs?** (in-kind)
 | **YES** [ ]  **NO**[ ] Please submit with your SSA application a cover letter stating the “in kind“ or non-financial costs involved**.** |
| 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**[ ] **YES** [x]  **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* |
| 1. **Has the Principal Investigator’s direct line manager approved the project and is added to the HoD list in REGIS**
 | **YES** [ ]  **NO**[ ] **A HoD is signing approval for the resources required for the study on behalf of their remit.** **Therefore a HoDs who is participating within the study requesting resources cannot sign off the approval for their own study- the next line manager must be then added as the HoD.**  |
| 1. **Fee category**
 | Please select the appropriate fee schedule |
| 1. **MoP attached**
 | Please select the appropriate fee schedule  |

**Please be sure to check the lead HREC is certified to approve a study conducted within a NSW public Hospital.**

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| 1. **HREC details**
 |
| 1. **PROPOSED SESLHD SITE**
 | Please enter Site Name from STE B1 |
| 1. **IS THE SITE LISTED IN THE HREC APPROVAL LETTER?**
 | **YES** [ ]  **NO** [ ]  (if no- please submit an amendment to the lead HREC to add a site) |
| 1. **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) |
| 1. **DATE OF HREC APPROVAL**
 | Click or tap to enter a date. |
| 1. **ARE ADDITIONAL APPROVALS REQUIRED?**
 | **YES** [ ]  **NO** [ ] Please select the requisite approval |

**COMMENTS:**

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| 1. **STUDY PERSONNEL – from 1 July 2023 – all study team members must have GCP certificates included in submission**
 |
| **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** [x]  **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** [ ]  |
| 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 from SESLHD people assist hub/Workforce Operations if coming on site*

*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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| 1. **SUPPORTING DEPARTMENTS**
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| **DEPARTMENT NAME** | **HEAD OF DEPARTMENT** | **HOD ADDED** | **HOD APPROVAL GRANTED** | **IS THE HOD A STUDY TEAM MEMBER** | **HOD’S LINE MANAGER ASSIGNED** |
| **PIs direct line manager or workplace HoD** | 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** [ ]  |
| 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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| 1. **STUDY DESIGN DETAILS**
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| 1. **PARTICPANT & RECRUITMENT DETAILS**
 |
| 1. **PATIENT RECRUITMENT TARGET**
 |   |
| 1. **WILL THE STUDY RECRUIT MINORS?**
 | **YES** [ ]  **NO** [ ]  |
| 1. **IF YES, DOES THE STUDY COMPLY WITH LOCAL AGE OF ADMISSION POLICY?**
 | **YES** [ ]  **NO** [ ]  |
| 1. **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** [ ]  |
| 1. **IF YES, WAS RELEVANT THE NCAT APPROVAL PROVIDED?**
 | **YES** [ ]  **NO** [ ]  |
| **MATERIALS Material Transfer Agreements are used for both data and tissue**  |
| 1. **WILL TISSUE BE EXPORTED FROM THE LHD? (STE D7 & STUDY PROTOCOL)**
 | **YES** [ ]  **NO** [ ]  |
| 1. **IS AN MTA REQUIRED?**

*An MTA is not required for commercially sponsored clinical trials* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **WAS AN MTA PROVIDED?**
 | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **WILL DATA BE EXPORTED FROM THE LHD?**
 | **YES** [ ]  **NO** [ ]  |
| 1. **WILL THE DATA BE DE-IDENTIFIED BEFORE LEAVING THE DISTRICT?**
 | **YES** [ ]  **NO** [ ]  |
| 1. **HAS THE APPROVAL FOR DATA ACCESS AND EXPORT BEEN GRANTED BY THE SESLHD DATA CUSTODIAN**
 | **YES** [ ]  **NO** [ ]  **?** *If not, please seek advice with the Research Business Manager* **N/A** [ ]  |
| **13. COMPLIANT DATA EXTRACTION PROCESS?***e.g. REDCap or Accellion KiteWorks* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **DATA COLLECTION METHOD**
 | **PROSPECTIVE COLLECTION** [ ] **RETROSPECTIVE COLLECTION** [ ]  |
| 1. **RETROSPECTIVE COLLECTIONS: DATA CUSTODIAN APPROVAL PROVIDED**

*If no, only* ***conditional authorisation*,** *may be issued whereby Data Custodian approval is required prior to identifiable extraction* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **IS THIS A DATA LINKAGE PROJECT? (respond below)**
 | **YES** [ ]  **NO** [ ]  |
| 1. **STATE-WIDE DATABASES**

[*http://www.cherel.org.au/data-dictionaries*](http://www.cherel.org.au/data-dictionaries) | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **FEDERAL DATABASES**

[*https://www*](https://www)*.aihw.gov.au/our-services/data-linkage/data-collections* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **STATE-WIDE DATABASES: NSW POPULATION & HEALTH SERVICES HREC APPROVAL PROVIDED**
 | **YES** [ ]  **NO** [ ]  |
| 1. **FEDERAL DATABASES: AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE or SERVICES AUSTRALIA APPROVAL PROVIDED**
 | **YES** [ ]  **NO** [ ]  |
| 1. **WILL THE STUDY INTEND TO COLLECT/ANALYSE FIRST NATION’S PEOPLE’S DATA?**
 | **YES** [ ]  **NO** [ ]  |
| **OTHER DESIGN RELATED APPROVALS** |
| 1. **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** [ ]  |
| 1. **BIOSAFETY COMMITTEE APPROVAL**

*For studies involving the use of recombinant DNA* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **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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| 1. **FINANCIAL INFORMATION**
 |
| 1. **IS THE PROJECT FUNDED?**
 | **YES** [ ]  **NO** [ ]  **N/A** [ ] If Yes, Name Funding Body. Enter “Department Funds” if internal funds will be used |
| 1. **ARE THE COSTS LISTED WITHIN THE CTRA CONSISTENT WITH THE COSTS QUOTED IN THE SSA?**
 | **YES** [ ]  **NO** [ ]  ***(if not, PI can provide a brief cover letter demonstrating the link between total and cost per patient)* N/A** [ ]  |
| 1. **EVIDENCE OF EXTERNAL FUNDING PROVIDED**

 *Evidence must be provided. Note: this will likely be within the CTRA* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **DO IN-KIND OR FINANCIAL COSTS EXCEED $10,000**

*If yes, GM approval is required, please provide budgetary evidence* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |

**COMMENTS:**

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| 1. **CLINICAL TRIALS ONLY**
 |
| 1. **CONTRACT**
 | Please select the contract type |
| 1. **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 |
| 1. **SCHEDULE 1 – HREC AND STUDY DETAILS MATCH SSA**
 | **YES** [ ]  **NO** [ ]  |
| 1. **SCHEDULE 2 – FUNDING/BUDGET DESCRIBED**
 | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **SCHEDULE 3 – CRG AGREEMENT**
2. **SCHEDULE 6 – OTHER CTRA**
3. **STUDY PROTOCOL IDENTIFICATION IS CORRECT**
 | **YES** [ ]  **NO** [ ]  |
| 1. **SCHEDULE 4 – CRG AGREEMENT**
2. **SCHEDULE 7 – OTHER CTRA**
3. **MATCH SEBS APPROVAL**
 | **YES** [ ]  **NO** [ ] *If no, SEBS approval must be provided.***N/A** [ ]  |
| 1. **SIGNED BY PI AND SPONSOR**
 | **YES** [ ]  **NO** [ ]  |
| 1. **INSURANCE**

*Collaborative Research Group Trials: $10 million**Commercially Sponsored Trials: $20 million, named Australian Sponsor, ≤$25,000 excess* | **YES** [ ]  **NO** [ ]  |
| 1. **INDEMNITY**

*Commercially Sponsored Trials Only* | **YES** [ ]  **NO** [ ]  **N/A** [ ]  |
| 1. **INDEMNITY FORM**
 | Please choose Indemnity Form |
| 1. **CORRECT STUDY TITLE**
 | **YES** [ ]  **NO** [ ]  |
| 1. **CORRECT SESLHD DETAILS (INC. ABN)**
 | **YES** [ ]  **NO** [ ]  |
| 1. **CORRECT PI NAME**
 | **YES** [ ]  **NO** [ ]  |
| 1. **SIGNED BY SPONSOR**
 | **YES** [ ]  **NO** [ ]  |

**PLEASE NOTE: How you title and version your uploaded documents within REGIS will determine the populated list within your authorisation.**

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| 1. **DOCUMENT VERSION QUALITY CONTROL (DELETE IF NOT APPLICABLE)**
 |
| 1. **DOCUMENTS**
 | **MASTER** | **SITE-SPECIFIC** | **REFERENCED CORRECTLY** |
| **VERSION** | **DATE** | **VERSION** | **DATE** |
| [Please ensure that all documents are titled correctly -dated/correct version and consistent with footer information]  | 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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| 1. **DOCUMENTS**
 |  |  |
| 1. **DOCUMENT TITLE** *(please ensure that document versions and titles match HREC approval letter)*
 | **VERSION** | **DATE** |
|  | Please enter HREC approved version | Enter approved document date |
|  | Please enter HREC approved version | Enter approved document date |
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| 1. **REGIS**
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| **Regis is the ministry of health led statewide platform for which you will manage and monitor your project for the duration of your study.**  |
| 1. **Have you been on the REGIS website to understand how to submit applications through the state-wide Ministry of Health (OHMR) platform REGIS**
 | **YES** [ ]  **NO** [ ]  | ***REGIS QUICK REFERENCE GUIDES:*** ***https://regis.health.nsw.gov.au/how-to/*** |
| 1. **Do you know how to submit post approval documents and manage your study within REGIS (annual reports, amendments, safety reports)**
 | **YES** [ ]  **NO** [ ]  | ***REGIS RESEARCHER TRAINING:*** [***https://regis.health.nsw.gov.au/content-resources/***](https://regis.health.nsw.gov.au/content-resources/) |
| Declaration:As the PI, I have completed the above checklistI have personally contacted the relevant HoDs regarding my study’s resource requirements including my own line managerI understand that I have 30 days to respond to a request for information from the research office. I understand that my study may be withdrawn if the 30 days has been breached without providing the requested information.**YES** [ ]  |

**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** |  |