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

**PLEASE NOTE:** **To avoid delays to your timelines please ensure that you have prepared the following WITHIN YOUR SUBMISSION**:

* Attached relevant agreements partially executed (all signatures are completed except for the signature of the Research Director on behalf of SESLHD)
* If required, your request for data custodian brief approval signed from the CE. **The request should be sent through email (****SESLHD-RSO@health.nsw.gov.au****) and signed prior to uploading into your STE within REGIS.**
* You have received your Contingent worker status and submitted within your application

Only upload relevant documents to your STE application. Triaging through long lists of unnecessary files or zip folders and or incorrectly titled files will lengthen the process.

Applications that are delayed in providing a response to more information requests from the Research office will be withdrawn after 30 days and a new application will be required.

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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 discussed the study with 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** [ ]  **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 HoD 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**
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| 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 and SESLHD staff member as Principal Investigator for that 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 check with the HREC that they are certified to approve studies conducted within SESLHD public hospitals) |
| 1. **DATE OF HREC APPROVAL**
 | Click or tap to enter a date. |
| 1. **ARE ADDITIONAL APPROVALS REQUIRED?**
 | **YES** [ ]  **NO** [ ] Please select the requisite approval |

**For more information:** Please see the SESLHD Research website: https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home

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| 1. **STUDY PERSONNEL – from 1 July 2023 – all study team members must have GCP certificates included in submission**
 |
| *1***INVESTIGATORS ON SITE** | **NSW HEATLH EMPLOYEES** | **EXTERNAL PERSONNEL2,3** | **STUDENT** | **GCP TRAINING Certificate PROVIDED** |
| **NAME** | **SESLHD** | **OTHER LHD2** | **Contingent Worker Status** | **CV PROVIDED** | **SESLHD STAFF** | **EXTERNAL, INSURANCE PROVIDED** |  |
|  | [ ]  | **-** | **-** | **-** | **-** | **-** | **YES** [ ]  **NO** [ ]  |
| Click to enter AI’s Name |[ ] [x]  **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 and culture – position maintenance, if coming on site*

*3 Check if external personnel will require site access, if yes, request evidence of 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.*

Please ensure that you are familiar with using the Ministry of Health led state-wide platform REGIS to manage your study throughout its duration for amendments and annual reports as well as applications.

 Training, IT help and how to guides are available: <https://regis.health.nsw.gov.au/>

Please ensure that you have engaged with the head of department providing the resources (in-kind or financial) to ensure:

* You have the correct HoD
* The HoD has the opportunity to ask questions regarding the study.

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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)**

*NCAT is for 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 no, please see the template/ guide on the seslhd research website)* **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. **DATA CUSTODIAN APPROVAL PROVIDED FOR DATA LEAVING SESLHD?**

*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? (if yes, 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** [ ]  |

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| 1. **CLINICAL TRIALS ONLY**
 |
| 1. **CONTRACT**
 | Please select the contract type |
| 1. **IS THE STUDY UPLOADED ON CTMS?**
 | **YES** [ ]  **NO** [ ] Code:  |
| 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.**

**\*Please ensure that you have correctly created a site specific (with logo and correct footer) participant facing document from the master copy approved by the lead HREC. Please see example in the first row.**

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| 1. **DOCUMENT VERSION QUALITY CONTROL (DELETE IF NOT APPLICABLE)**
 |
| 1. **DOCUMENTS**
 | **MASTER** | **\*SITE-SPECIFIC** | **REFERENCED CORRECTLY** |
| **VERSION** | **DATE** | **VERSION** | **DATE** |
| PISCF[Please ensure that all documents are titled correctly -dated/correct version and consistent with footer information for example: *PISCF Prince of Wales Hospital version 1 dated 04/09/2023**Based on Master Version 2.0 dated 05/04/2023*  | **example: PISCF Master Version 2.0** | 5-Apr-23 | **Example: PISCF POWH version 1.0** | 4-Sep-23 | **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** |  |