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

**PLEASE NOTE:** **To avoid delays to your timelines please ensure that you have**:

* 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**](mailto:SESLHD-RSO@health.nsw.gov.au)**) and signed prior to uploading into your STE within REGIS.**
* 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Applications that are delayed in providing a response to more information requests from the Research office will be withdrawn after 30 days and a new application will be required.

|  |  |  |
| --- | --- | --- |
| 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.**

|  |  |
| --- | --- |
| 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 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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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** | **INSURANCE PROVIDED** | **CV PROVIDED** | **SESLHD STAFF** | **EXTERNAL, INSURANCE PROVIDED** |
|  |  | **-** | **-** | **-** | **-** | **-** | **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** |
| 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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **SUPPORTING DEPARTMENTS** | | | | | |
| **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** |

|  |  |
| --- | --- |
| 1. **STUDY DESIGN DETAILS** | |
| 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** |

|  |  |
| --- | --- |
| 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** |

|  |  |
| --- | --- |
| 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 4  The Sutherland Hospital & Community Health Service  Cnr The Kingsway and Kareena Road CARINGBAH NSW 2229  ABN 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.**

**\*site specific documents must each have the appropriate hospital logo.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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** |

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |
|  | Please enter HREC approved version | | Enter approved document date |
|  | Please enter HREC approved version | | Enter approved document date |
|  |  | |  |
|  |  | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. **REGIS** |  |  | |  | | |
| **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 checklist  I have personally contacted the relevant HoDs regarding my study’s resource requirements including my own line manager  I 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:**

|  |  |
| --- | --- |
| **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** |  |