**Guidance to Completing a Site Specific Application to HNELHD Research Office in REGIS**

HNE Research Office is committed to continual strengthening of research governance systems and processes.

Any applicable changes to the SSA process will be informed via this document (amongst other communication methods).

All version changes will be circulated to the HNE Research Office email network and updated on the [HNE Research Office Portal.](https://www.hnehealth.nsw.gov.au/research-office/research_governance)

* This guide has been developed to assist researchers completing a Site Specific Application (SSA) for a HNELHD site.
* It contains information and advice specific to each question in REGIS.
* The more complete and succinct information you submit, the fewer questions you are likely to receive.
* Any member of the research team with admin/edit access for the project in REGIS can complete the answers in the SSA. A member of the research team with relevant research experience and expertise should review the SSA before submission.
* The HNE Principal Investigator is responsible for ensuring the Head of Departments (HOD) assigned to review this project in REGIS are consulted prior to submitting the SSA.
* The HNE Principal Investigator is responsible to make a declaration and submitting the SSA in REGIS, no other team member will have access to do this.

If you have any questions whilst completing your SSA and after you have followed this guidance, please do not hesitate to contact the HNE Research Governance team via: HNELHD-ResearchOffice@health.nsw.gov.au

As the intent of this guidance is to assist researchers in completing the SSA - the HNE Research office invite you to provide feedback on this guidance tool if you are experiencing any issues/concerns or have general feedback. All feedback and general queries relating to this document can be emailed to: HNELHD-ResearchOffice@health.nsw.gov.au Attn: Research Governance Manager

**Completing your HNE Site Specific Application in REGIS:**

The Site Specific Application (SSA) form must be submitted within the [Research Ethics Governance Information System (REGIS)](https://regis.health.nsw.gov.au/)

The following resources, together with this guidance tool, are provided to assist with the submission of HNE SSA’s:

* [HNELHD Research Governance Checklist for Researchers.](https://www.hnehealth.nsw.gov.au/research-office/research_governance/resources_a_-_z) This checklist is required to be completed and uploaded with your SSA submission and provides useful links and resources.
* [HNE Research Office Portal](https://www.hnehealth.nsw.gov.au/research-office/research_governance)

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| **Part A Study-Wide Information**  |
|  | Tip:(\*) Information in this section will prepopulate from the **project registration** and you should not edit this unless there are errors |
| A1 Project Title | (\*) |
| A2 Project Summary | (\*) |
| A3 Coordinating Principal investigator | (\*) |
| A4 HREC Name | (\*) |
| A5 HREC Code | You cannot edit this field |
| A6 Ethics Application ID | From the HREC submission  |
| A7 Study Type | Tip: * If your study type is ‘Clinical Trial’ you will proceed to A8.
* For all other study types you will proceed to Part B
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| \*\* If your project study type above is **‘Clinical Trial’** \*\* |
| A8 Clinical Trial Type | Select appropriate trial type from drop down list  |
| A9 Clinical Trial Phase | Tip: You will find this information listed within the protocol  |
| A10 Will your clinical trial be conducted under either the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) scheme? | Select from drop down list (you will find this answer within the HREA)* Refer to the [TGA website](https://www.tga.gov.au/clinical-trials) for further information
* Refer to [**HNE Clinical Trial Notification (CTN)**](https://www.hnehealth.nsw.gov.au/research-office/research_governance/research_contracts_agreements) for information that will be required for the registration of clinical trials being conducted within HNE facilities AND for the submission of clinical trials **sponsored** by HNELHD.

TIPS: * If the clinical trial is sponsored by HNELHD and requires CTN, please ensure you submit a completed CTN Submission template with your SSA in REGIS (CTN Submission template can be located within above HNE Clinical Trial Notification (CTN) link)
* If the clinical trial has an external sponsor, and a CTN is required, please ensure you upload a copy of the TGA Acknowledged CTN via site amendment before starting recruitment to the trial.
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| A11 Is NSW Civil and Administrative Tribunal (NCAT) approval required? | You will find this answer within the HREAClinical trials which seek to involve a person aged 16 years or older with decision making disability must be approved by the Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT). Further information: <https://ncat.nsw.gov.au/> . If your HREC approval stipulates your project requires this approval, please answer yes and **upload approval with your site application.**  |
| A12 Sponsor Type | Select from drop down list: Tip: You will find this information within the HREADefinitions:* **Commercial: “**Commercially sponsored trial” is a clinical trial where a pharmaceutical or device company; initiates the trial and applies the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme administered by the Therapeutic Goods Administration; is directly funding the conduct of the trial and is the primary author of the clinical trial protocol.
* **Collaborative:** A sponsored (non-commercial) research project has the following characteristics**:** The non-commercial sponsor (non-commercial) must be the primary author and custodian of the clinical trial protocol. Examples of groups that may fall under this category are; a) Research institutes external to NSW Health; b) Collaborative or cooperative research groups external to NSW Health; and c) Universities.
* **Investigator initiated:** An investigator initiated (LHD sponsored) research project has the following characteristics**:** A pharmaceutical/device company is not acting as the Sponsor for the purposes of the CTN Scheme application; a pharmaceutical/device company is not directly funding the conduct of the study; the clinical trial addresses clinical questions; the Principal Investigator and HNELHD is the primary author and custodian of the clinical trial protocol
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| A13 Sponsor Name | Enter Sponsors name here (you will find this information within the HREA).Us the drop downIf Sponsor not showing in list, add sponsor details manually  |
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| **Part B** |
| B1. Site Name | (\*) will prepopulate from the project registration (if this site populating is incorrect site, please contact HNELHD-ResearchOffice@health.nsw.gov.au Attn: Research Governance Manager |
| B2. Principal Investigator | Name of the PI at the site named above* **This PI must be listed on the HREC approval**
* This may also be the CPI
* REGIS will automatically populate this person if they have a REGIS account
* HNE health staff are employed by NSW Health
* Please upload CV for PI
* Please upload current CGP certificate for PI (if study type is clinical trial)

NOTE: if the PI is not employed by HNELHD and requires access to HNE site or identifiable HNE data (without participant consent) – please contact the HNE Research Office via HNELHD-ResearchOffice@health.nsw.gov.au before completing your SSA submission. |
| B3. Describe research activities this person will be responsible for | Note: the PI is responsible for all aspects of the project at site, and may delegate tasks to other adequately qualified staff. The PI will *retain* responsibility for those tasks.In this section:* Provide information on the research project tasks the PI will be responsible for at this named site.
* Do not state the tasks at other sites or as CPI. Do not state clinical care tasks.

**If the PI is external to HNE:*** Please contact the HNE Research Office via HNELHD-ResearchOffice@health.nsw.gov.au Attn: Research Governance Manager before submitting application.
* once discussed with HNE Research Governance Manager and if required to **come on site, access identifiable HNE patient data (without participant consent) or require HNE Clinical System access** you **must** include this information here and indicate that appointment for PROJECT SPECIFIC [HNE Research Related Contingent Worker – Contractor Appointment](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_access_-_for_external_researchers) (Position Title: Researcher) will be completed under (enter HNE Staff Member) supervision.
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| B4. Describe the person’s expertise relevant to this research project | Provide information evidencing this person’s ability to oversee a research project. Clinical or Laboratory expertise may support this, however this question addresses the PIs skills in managing a research project, not their clinical experience and expertise. |
| B5. Is the Principal Investigator a student? | (yes / no) HNE HREC requires the PI **not** to be a student. If you have HREC approval from another HREC, and the PI is a student please contact the HNE Research Office via HNELHD-ResearchOffice@health.nsw.gov.au to discuss prior to completing your SSA submission |
| B6. Is the Principal Investigator a NSW Health Staff member? | (yes / no). If yes, provide Stafflink ID |
| B7. Do you wish to provide details for an administrative contact at this site? | (yes / no). If yes, provide details here. This is **recommended** for large research teams, as this person will receive REGIS email notifications in addition to the PI. |
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| **B8 Site Team Members** |
|  | The PI is responsible for all aspects of the project at site, and may delegate tasks to other adequately qualified staff. The PI will *retain* responsibility for those tasks.* Only the Principal Investigator needs to be named on the HREC approval.
* Use the + button to add extra lines
* Add as many team members who are included in the project and will complete research / **site specific tasks** (except unnamed clinical staff who may be rostered e.g. bedside nurse, phlebotomist), broader members of the research team, who have no role at site DO NOT need to be listed on the HNE SSA.
* A page will open for each named team member seeking further details (this is dependent on the persons role in the research project)
* If you are adding team members from other HNE internal departments, please add their department as supporting department (part C) to ensure appropriate HOD approval for the staff member’s time.
* Please upload current CGP certificate **for all team members** if study type is clinical trial.
* If the team member is external to HNE and are required to **come on site, access identifiable HNE patient data (without participant consent) or require HNE Clinical System access** you **must** include this information under B8.3 below and indicate that appointment for PROJECT SPECIFIC [HNE Research Related Contingent Worker – Contractor Appointment](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_access_-_for_external_researchers) (Position Title: Research Assistant) will be completed under HNE PI (enter HNE PI name) supervision.
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| B8.1 Is this person a staff member at this NSW health site? | (yes / no) |
| B8.1.1 Stafflink number | - Add staff link number if answered yes above |
| B8.2 Will this Associate Investigator act as a substitute for the PI when unavailable? | (yes / no) |
| B8.3 Describe research activities this person will be responsible for. | Provide information for research project tasks this person will be responsible for at this named site. - If the team member is external to HNE and are required to **come on site, access identifiable HNE patient data (without participant consent) or require HNE Clinical System access** you **must** include this information here and indicate that appointment for PROJECT SPECIFIC [HNE Research Related Contingent Worker – Contractor Appointment](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_access_-_for_external_researchers) (Position Title: Research Assistant) will be completed under HNE PI (enter HNE PI name) supervision.  |
| B8.4 Describe the persons expertise relevant to this research project | Describe this persons relevant expertise to site tasks allocated |
| B8.5 Is the team member a student? | (yes / no) |
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| **Part C: Departments and Services** |
|  | Tips:* Select as many HNELHD departments as apply to this project at this site.
* Ensure you consider services like imaging, pharmacy, medical records, clinical systems and other services/depts./wards or other HNE department that’s resources are required for this project.
* Consider the example if you are employed in respiratory medicine, but need to recruit patients from ICU, you will need to add ICU as a supporting department in order to seek approval from the Manager/HOD of ICU.
* Consider the example if you are employed population health and your projects impacts another service/ward, you will need to add this service/ward as a supporting department in order to seek approval from the service/ward.
* Consider the example if your project requires additional Imaging, you will need to add in HNE Imaging as a supporting department in order to seek approval from HNE Imaging.
* NSW Health pathology (NSWHP) is not part of HNE Governance and do not need to be added as a supporting department. If NSWHP are involved in the conduct of the project, a separate SSA is required for NSWHP site. If NSWHP are providing a service for the project, please upload NSWHP quote with SSA (or indicate this is in progress)
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| C1 Department | Select from drop down If a department does not appear here, please contact HNE Research Office via HNELHD-ResearchOffice@health.nsw.gov.au Attn: Research Governance Manager |
| C2 Head of Department | This field will prepopulate with the Service research delegate name when you select the department above. It is **recommended** that you email the HOD and introduce your project prior to submission.If you believe this person is incorrect, or staff changes have occurred, please contact Research Office via HNELHD-ResearchOffice@health.nsw.gov.au Attn: Research Governance Manager |
| C3 Email | This field will prepopulate when you select department above. It is **recommended** that you email the HOD and introduce your project prior to submission. |
| C4 Resources (e.g. staff, service/s, investigations etc) you require this department to provide | If you have an ongoing or one off Service Level Agreement (SLA) with this department, note this here. Detail all resources required from this Service/Dept, consider the following categories::Non-Financial Costs: * Within Resources**:** for example : staff time (staff with research in their position description ie staff specialists/research coordinators etc)
* In-kind contribution: for example : staff time (ie staff approved by the Service to work on the research without research in their job descriptions ie )

Financial Costs:* Costs Reimbursed: for example if you have Financial Costs noted within  *E1 Are there any financial costs associated with the project* that WILL BE reimbursed via CTRA or similar research agreement
* Out of Pocket Expense:for example any out of pocket expenses the Service will incur that WILL NOT BE reimbursed via CTRA or similar research agreement

If you have listed ‘Within Resources’ or ‘In-kind contribution’ above please ensure you answer Yes to Question*: E2: Are there any non-financial costs (e.g. local resource allocations) associated with the project*If you have listed ‘Costs Reimbursed’ or ‘Out of Pocket Expense’ above please ensure you answer Yes to Question: *E1 Are there any financial costs associated with the project?* |
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| **Part D: Recruitment, Records, Tissue and Data** |
| D1 Will participants be enrolled for the research at this site? | (yes / no) If yes, you will be directed to the below questions. |
| D2 Is there a numeric site enrolment target? | (yes / no) - |
| D3 What is the minimum number of participants to be enrolled at this site? | Estimate as best you can predictFor rare disease studies, please state “0-1” |
| D4 What is the maximum number of participants to be enrolled at this site? | Estimate as best you can predict |
| D5 Please give details of the planned number of participants to be enrolled at this site | Estimate as best you can predictFor rare disease studies, please state “0-1” |
| D6 Are you planning on accessing medical records from this site before approaching participants? | Answer yes if you will access medical records before approaching participants. |
| D6.1 How many records are you proposing to review? | Please list per participant |
| D7 Are you planning on accessing tissue samples from this site? | (yes / no) |
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| **Part E: Site Costing and Funding** |
| E1 Are there any financial costs associated with the project? | (yes / no) Financial costs are any financial costs/expenses incurred by the service for the project to be conducted at this site C4-Resources of the SSA will ask you to summarise these expenses into the following categories; * Costs Reimbursed: for example if you have Financial Costs noted that WILL BE reimbursed via CTRA or similar research agreement
* Out of Pocket Expense:for example any out of pocket expenses the Service will incur that WILL NOT BE reimbursed via CTRA or similar research agreement
 |
| E1.1 What is the total estimated cost for this site in $AUD | Please provide **estimated** total financial costs for the project to be conducted at this site (please note non-financial or in-kind costs are to be estimated in Question E2). |
| E1.2 Do you have local study costings template or detailed site budget prepared? | (yes / no)If yes, please upload study costing budget * The budget must reflect the actual costs to complete all of the procedures and administrative tasks of the study.
* Please detail financial costs estimated in (E1.1).
* The budget must be signed by the relevant HNE Finance Manager E1.1 has incurred ‘Out of Pocket Expenses’ ( expenses incurred that WILL NOT BE reimbursed via CTRA or similar research agreement)
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| E1.3 Will funding be provided for the research at this site? | (yes / no) |
| E1.3.1 Is this centre the Administering Organisation for the funding? | (yes / no)- select yes if funding is being received (this will allow E.1.3.1.1 below to appear to record cost centre information) |
| E1.3.1.1 Please provide the account number and cost centre details where the funds will be deposited | This is the cost centre details within your service/dept that has agreed to receive the funds |
| E2 Are there any non-financial costs (e.g. local resource allocations) associated with the project? | (yes / no)The following are considered non-financial costs:Non-Financial Costs: * Within Resources**:** for example : staff time (staff with research in their position description ie staff specialists/research coordinators etc)
* In-kind contribution: for example : staff time (ie staff approved by the Service to work on the research without research in their job descriptions ie

C4-Resources of the SSA will ask you to summarise these expenses in these categories  |
| E3 | *REGIS is currently not populating this correctly* |
| E4 What form of Clinical Trial Agreement will this project utilise at this site? | Tips:All clinical trials are required to upload a CTRA. All research with external sponsor with payments attached are required to upload a research collaborative agreement or similar research agreement |
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| **Part F: Attachments – Site Specific Documents** |
| Tips: | * Attach all documents that will be used at this named site
* All Site Specific documentation must be uploaded as Individual files
* Winzip files will only be accepted for HREC approved documentation
* Each document will have a category to select.
* The “other” drop down option should only be used for uploading your [HNELHD SSA checklist](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_authorisation/ssa_submission) and RGO Cover Letter
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| Tips for projects with ethics approval internal to NSW/ACT HRECs: | * If this SSA is based on a research ethics approval from a NSW/ACT HREC, only attach your site specific documents.
* If the research project has had amendments since first approval, attach the documents from the most recent approval.
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| Tips for projects with ethics approval external to NSW/ACT HRECs: | If this SSA is for a research project with research ethics approval from an HREC outside of NSW/ACT, you will also need to attach all documentation including:* HREA - A copy of the most recent HREA (Human Research Ethics Application) form approved by the HREC.
* Ethics Approval Letter - and any subsequent amendment approval letters.
* HREC approved Master Participant Information Sheet(s) & Consent Form(s)
* HREC approved study documentation as listed on HREC approval letter and any other subsequent amendment approval letters
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| Tips for Site Specific Information: | The site specific information must be named consistently and in accordance with the approval letters from HREC. The site specific information should include the following information in the footer as a minimum:*Project Name, Protocol Version number and date**Master document name, Version Number and date**Site name, Document Name, Version number and date*Further information on [site specific documentation requirements can be found here](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_authorisation/ssa_submission/site_specific_documentation_-_requirements). |
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| **Part G: Declaration** |
|  | Any person with edit access may complete this governance authorisation in REGIS.If the site and supporting department (if applicable) HODs are not aware of this submission, there will be delays. We recommend you liaise with the HOD for the site and supporting departments before submission.The PI for the site must sign this REGIS submission |
|  | Once the SSA has been completed the PI signature has be recorded, REGIS automatically sends the links to all recorded Heads of Department for signature. Again, it is recommended you liaise with the site HOD and supporting departments and introduce the project (at minimum) prior to submitting the SSA. |
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| **RGO Eligibility Review** |
|  | RGO eligibility review will occur in 2 stages. * Eligibility A will focus on correct approvals and documentation.
* Eligibility B will focus on contracts, insurance, sponsors, external staff etc

The HNE Research Office will reach out to you via REGIS should any additional information be required.  |
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| **Head of Department Support** |
|  | Once all Heads of Department signatures have been recorded, this application will be submitted to the RGO for eligibility review. You do not have to progress this, it occurs automatically. |
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| **Site Authorisation** |
|  | Recommendation for Site Authorisation will only occur after the application passes HNE Research Office Eligibility A and Eligibility B reviews. To submit a high quality application and minimise return for information requests, please ensure the SSA submitted follows this guidance. |
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