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| HNELHD Submission checklist – research governance – site specific assessment | |
| This document has been developed to assist researchers with the submission of a HNE Research Governance Site Specific Application within REGIS. It contains relevant information and hyperlinks to guidance documents and templates to ensure that an eligible application has been submitted for review by the HNELHD Research office.   * For REGIS technical support, call **REGIS Help Desk on 1300 073 447** * Please contact the [HNE Research Office](mailto:HNELHD-ResearchOffice@health.nsw.gov.au) with any questions about your research project before submission. * Please contact [HNE Research Office](mailto:HNELHD-ResearchOffice@health.nsw.gov.au) if you have any queries relating to this document. | |
| **Section 1: SSA Application and Supporting Study Documentation – for all SSAs** | |
|  | **Complete Cover Letter** – addressed to the Research Governance Officer (RGO) which   * lists all **site** documents being submitted including versions and dates, * indicates if the application is a student project, * indicates if contract is to be signed and the signature type (ie Adobe/Docusign) * addresses any application specific items that you wish to bring to the attention of the RGO   The cover letter must be signed by the Principal Investigator. Click here to view a [sample cover letter](https://www.hnehealth.nsw.gov.au/research-office/research_governance/resources_a_-_z) |
|  | **Complete SSA Application form -** The Site Specific Application (SSA) form must be submitted within the Research Ethics Governance Information System [(REGIS).](https://regis.health.nsw.gov.au/media/1728/qrg-resapp-site-application-completing-and-submitting.pdf) The following resources, together with this checklist are provided to assist with the submission of HNE SSA’s:  • [HNE Research Office – Research Governance – How to Submit: Site Specific Application (REGIS)](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_authorisation/ssa_submission) |
|  | **If required: Site Specific Participant Information Sheet (s) and consent form (s) –** These are ethics approved Master Participant Information Sheet and Consent form (s) which has included information pertaining to the site at which the research is to be conducted. They must meet the [HNELHD Site Specific Document requirements.](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_authorisation/ssa_submission/site_specific_documentation_-_requirements) |
|  | **CV** required for HNELHD PI (if it has not been included in the shared ethics documents) |
| **For projects where the ethics application has been approved outside of REGIS (prior to REGIS implementation or by an HREC outside of NSW and ACT), please also upload the following:** | |
|  | **HREA** - A copy of the Research application form approved by the HREC. |
|  | **Ethics Approval Letter -** The Ethics Approval Letter from approving NMA Health Human Research Ethics Committee (HREC) and any subsequent amendment approval letters. |
|  | **HREC Approved Master Participant Information Sheet(s) and Consent Form(s)** including version number and version dates (if applicable) |
|  | **ALL HREC Approved study documentation:** protocol, questionnaire(s), survey questions, patient diaries, recruitment advert, interview topics to be covered etc. including version number and date (If applicable)  All documents intended for use at a HNELHD site must be submitted with evidence of ethics approval. |
| **Section 2 : Departmental Approvals, Funding & Budgets** | |
|  | **Relevant Departmental Approval/s** – Please ensure ALL ‘supporting departments’ (internal to HNELHD) are nominated   * 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)   [Site Application - Completing, Requesting Head of Department Support and Submitting](https://regis.health.nsw.gov.au/media/1728/qrg-resapp-site-application-completing-and-submitting.pdf)  Please ensure all resources you require from each department (eg: to provide staff, service/s, investigators etc) have been discussed with the unit in advance, and are well described in Part C: Departments and Services (C4) Resources for each department listed  If the department you are conducting research in is not listed on REGIS, please contact HNELHD Research Office on [HNELHD-ResearchOffice@health.nsw.gov.au](mailto:HNELHD-ResearchOffice@health.nsw.gov.au) and advise us of the department name and head of department contact person. |
|  | **Authority for Data Provision** – For projects involving access to paper medical records and/or research projects accessing a database owned by HNELHD, please ensure appropriate data custodian is added as a supporting department (or approval is uploaded to the SSA). [HNE Research Data Lead](mailto:Shaun.Grady@health.nsw.gov.au) can assist with data custodian connection, and compliance of policy [*PD2018-001 Releasing LHD* ***Unit*** *data for Research or contractor purposes*](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2018_001.pdf)if required |
|  | **Funding Confirmation –**  If funding is being provided by an organisation other than HNELHD, written correspondence from the organisation providing funding for the research must be provided/uploaded   * Funding confirmation is not required when a Collaborative or Clinical Trial Research Agreement (or similar) is being submitted for the study that includes the funding confirmation. |
|  | **Study Budget** – Financial Costs (Part E1): Please upload a study budget for this site that details financial costs estimated in (E1.1). • The budget must be signed by the relevant service Finance Manager if funding being received, does not cover the **entire** estimated financial cost (E1.1) |
|  | **External Researcher Information** – Please make sure you have nominated within the Study Team on your SSA Application all external researchers that are coming on site or that will be accessing identifiable patient data/HNE clinical systems.  If selected, the PI is committing to arranging a research project specific HNE Contingent Worker appointment and appropriate site/system access **after** site Authorisation prior to providing access. Guidance can [found here](https://www.hnehealth.nsw.gov.au/research-office/research_governance/site_access_-_for_external_researchers). For any queries, please contact the HNE Research office |
| **Section 3 : Additional Requirements : Clinical Trials with Commercial Sponsorship ONLY** | |
|  | **GCP** **certificates** are required to be uploaded for all site team members listed on the SSA. |
|  | **Clinical Trial Research Agreement (CTRA)** – As per [PD2010\_056](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2010_056.pdf) all clinical trials with an external sponsor must have a written agreement in place. Five CTRA templates have been approved for use in NSW Public health organisations (PHOs) and can be [found here](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/). Please click here for [HNE Institution Details](https://www.hnehealth.nsw.gov.au/__data/assets/pdf_file/0008/428660/HNE_Institution_Details_HNELHD_Research_Office_Governance.pdf) and [Regulatory documents](https://www.hnehealth.nsw.gov.au/research-office/research_governance/research_contracts_agreements) |
|  | **Medicines Australia Form of Indemnity**- For commercially sponsored clinical trials, the sponsor must provide an executed [Medicines Australia Form of Indemnity](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/).  Please click here for [HNE Institution Details](https://www.hnehealth.nsw.gov.au/__data/assets/pdf_file/0008/428660/HNE_Institution_Details_HNELHD_Research_Office_Governance.pdf) and [Regulatory documents](https://www.hnehealth.nsw.gov.au/research-office/research_governance/research_contracts_agreements) |
|  | **Certificate of Currency of Insurance** - For all commercially sponsored clinical trials, an Insurance Certificate must be submitted with the governance application. The insurance certificate should: Cover a minimum of $20 million (AUS); have an Australian-named sponsor; and an excess/deductible or self-insured retention amount not greater than $25,000 for each and every claim. For more information, see [NSW Health Policy Directive - Clinical Trials – Insurance and Indemnity PD2011\_006, section 2.2.](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_006.pdf) |
|  | **If the study requires: Clinical Trial Notification (CTN) Form** – The Australian clinical trial sponsor must notify the TGA of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good prior to commencement of the use. If the clinical trial has an external sponsor, and a CTN is required, please ensure you upload a copy of the TGA Acknowledged CTN with your site application – or via site amendment before starting recruitment to the trial. You will find relevant details for HNE for CTN [here](https://www.hnehealth.nsw.gov.au/research-office/research_governance/research_contracts_agreements) |
|  | **If the study requires NSW Civil and Administrative Tribunal (NCAT) approval, please obtain this approval prior to submission**. Under Part 5 of the Guardianship Act 1987 (NSW), clinical 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/> |
| **Section 4 : Additional Requirements : Investigator Initiated and/or Collaborative Clinical Trials ONLY** | |
|  | **GCP** **certificates** are required to be uploaded for all site team members listed on the SSA. |
|  | **Research Collaboration Agreement.** Written agreements for investigator-initiated applications are not usually required however in some circumstances when the research involves an external organisation, or payments are being transferred, an agreement may be requested. Please use the [HNELHD Research Collaborative Agreement template](https://www.hnehealth.nsw.gov.au/research-office/research_governance/research_contracts_agreements) where possible.  Please contact the HNE Research Office before submitting your SSA if you are unsure, or require review of a non-standard research collaborative agreement before arranging the sponsor and HNE PI signatures. |
|  | **Material Transfer Agreement (MTA).** If your research involves a transfer of data, materials or samples (such as cell lines, blood, tissue, CT and MRI scans and other clinical data) to an external site and does not require a CTRA or other collaboration agreement a MTA may be required. Please select the yes box if you have uploaded a MTA. Please contact the HNE Research Office before submitting your SSA if you are unsure, or require review of a MTA before submitting your SSA. |
|  | **Certificate of Currency of Insurance For non-commercially external sponsored** research, sponsors must provide indemnity or insurance arrangements that are sufficient to cover their sponsor-related liabilities. For more information, see [NSW Health Policy Directive - Clinical Trials – Insurance and Indemnity PD2011\_006](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_006.pdf)  NOTE: HNE Research Office is collecting and storing on file certificate insurances from non-commercial sponsors, so that researchers are not repeatedly required to obtain and provide this. You will be asked to obtain and provide evidence of insurance when a certificate has expired, or the insurance cannot be located in the HNE Research Office file. |
|  | **If your study requires Clinical Trial Notification (CTN)** –  [HNELHD CTN application form](https://www.hnehealth.nsw.gov.au/research-office/research_governance/therapeutic_goods_administration_clinical_trial_notification_ctn) is to be completed for studies in **which HNELHD is the sponsor and CTN is required** (you can find this answer in the HREA). The CTN will be lodged by the Research Office on behalf of the Sponsor (ie. HNELHD), however it is the responsibility of the investigator to provide the information required for the CTN and the payment to TGA for processing of CTN. If this applies to your clinical trial, please upload the HNE CTN application form with your SSA  If the clinical trial has an external sponsor, and a CTN is required, please ensure you upload a copy of the TGA Acknowledged CTN with your site application – or via site amendment before starting recruitment to the trial. You will find relevant details for HNE for CTN [here](https://www.hnehealth.nsw.gov.au/research-office/research_governance/research_contracts_agreements) |
|  | **If your study requires NSW Civil and Administrative Tribunal (NCAT) approval, please obtain this approval prior to submission**. Under Part 5 of the Guardianship Act 1987 (NSW), clinical 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/> |