Health
Hunter New England
Local Health District

HNELHD Research Governance Checklist for Researchers

This document has been developed to assist researchers with the submission of a HNE Research Governance Site Specific Application. It contains relevant information and hyperlinks to guidance documents and templates etc to submit a successful HNE site application.

- All HNE site applications must comply/complete this checklist, failure to do so may result in the application being deemed 'ineligible'. Please list any omissions within the RGO Cover letter
- Please contact the HNE Research Office HNELHD-ResearchOffice@health.nsw.gov.au with any questions about your research project or visit HNE Research Office - Research Governance Portal
- For REGIS technical support, call REGIS Help Desk on 1300 073 447

If you have any queries relating to this document, please contact HNELHD-ResearchOffice@health.nsw.gov.au

Section 1: SSA Application and Supporting Study Documentation

SELECT	**SSA Application form.** The Site Specific Application (SSA) form must be submitted within the Research Ethics Governance Information System (REGIS). The following resources, together with this checklist are provided to assist with the submission of HNE SSA's: • REGIS Quick Reference Guide for Applicants: Site Application - Completing the SSA • HNE Guidance to Completing a Site Specific Application to HNE Research Office in REGIS • HNE Research Office – Research Governance – Portal
SELECT	**Site Specific Participant Information Sheet(s) and Consent Form(s) (PISCF) and any other documents that require site specific information (if applicable).** These are modified versions of a Master Participant Information Sheet and Consent Form/s which includes information pertaining to the site at which the research is to be conducted. Information required for HNE Site Specific documentation can include: • local investigators details; • local research office contact details • local logos • Site footer information
SELECT Select N/A if your project was approved by a NSW Ethics Committee after 2018	**ETHICS approval:** ONLY if the project was approved by a HREC outside of NSW or if ethics pre-dates REGIS (prior to 2018), please upload the following additional documents: • HREA - A copy of the most recent HREA (Human Research Ethics Application) form approved by the HREC. • Ethics Approval Letter - The Ethics Approval Letter from the Lead Health Human Research Ethics Committee (HREC) 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: *All documents must have evidence of HREC approval*

Section 2 : Departmental Approvals, Funding & Budgets

SELECT	**Supporting Departments:** Please ensure ALL 'supporting departments' (internal to HNELHD) are nominated • Example: Medical Imaging, Pharmacy, Medical Records, other services/departments/wards • 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 sign off from the Manager/HOD of that service etc *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*

SELECT Select yes if you have listed external researchers coming on site or that will be accessing identifiable HNE data.	**Site Access and eMR Access for External Researchers:** 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.** If you selected **yes** you are committing to arranging a HNE Contingent Worker appointment and appropriate site/system access **after** site authorisation has occurred and prior to providing access. Guidance can found here. For any queries, please contact the HNE Research office
SELECT	**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. • Note: if funds are coming from the UoN please upload written commitment to your SSA. Once site authorisation has been received, please contact the HNE Research Office for the HNE/UON approved funding agreement template which will assist with the funding transactions.
SELECT	**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 HNE Finance Manager if funding is **not** being provided for the research at this site (E1.3) • The budget must be signed by the relevant service HNE Finance Manager if funding being received, does not cover the **entire** estimated financial cost (E1.1)
SELECT	**Study Budget – Resources/Non-Financial Costs (Part C4 and Part E2):** These are costs to the Service that are NOT covered in Financial Costs above. Please describe the non-financial costs to the service in Part C4 using the following categories, please add an estimated $ amount if known in E2. • **Within Resources:** example: staff time (of staff that have research within their position description ie: staff specialists etc) • **In-kind:** example: staff time (of staff approved by the Service to work on the project without 'research' roles listed within in their job descriptions etc), workstations, infrastructure etc • **Other**: if the non-financial costs don't fit into any of the above categories
Section 3 : Additional Requirements : Clinical Trials with Commercial Sponsorship ONLY	
SELECT	**Clinical Trial Research Agreement (CTRA)** – As per PD2010_056 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. Please click here for HNE Institution Details and Regulatory documents
SELECT	**Medicines Australia Form of Indemnity**- For commercially sponsored clinical trials, the sponsor must provide an executed Medicines Australia Form of Indemnity. Please click here for HNE Institution Details and Regulatory documents
SELECT	**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.
SELECT	**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. The notification form must be submitted online and accompanied by the relevant fee. Please click here for further information. Please click here for HNE Institution Details and Regulatory documents
SELECT	**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/

Section 4 : Additional Requirements **: Investigator Initiated and/or Collaborative Trials ONLY**	
SELECT	**Research Collaboration Agreement.** Written agreements for investigator-initiated applications are not usually required however in some circumstances when the research involves an external organisation, an agreement may be requested. Please use the HNELHD Research Collaborative Agreement template 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.
SELECT	**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.
SELECT Select yes if you have uploaded evidence of insurance from non-commercial external sponsor	**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. This insurance should cover a minimum amount of $10 million (AUD). For more information, see NSW Health Policy Directive - Clinical Trials – Insurance and Indemnity PD2011_006 *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.*
SELECT	**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/