Murrumbidgee Local Health District

Research Governance Submission Checklist for Researchers

Clinical Trial Applications

This checklist summarises the information and documentation required from researchers before submitting a research governance Site Specific Assessment (SSA) application in REGIS for a clinical trial.

Please complete the checklist and return it to the Murrumbidgee Local Health District (MLHD) Research Office (contact details below).

If your study is a **commercially sponsored clinical trial**, please complete **Sections 1, 2 and 3**.

If your study is an **investigator initiated and/or collaborative trial**, please complete sections **Sections 1, 2 and 4**.

Section 1: SSA Application and Supporting Study Documentation				
Item	**Description**	**Yes**	**No**	**N/A**
SSA Application Form	Form generated in REGIS that contains site-specific project details.	☐	☐	
Site Specific Participant Information Sheet(s) and Consent Form(s) (PISCF) and any other documents that require site specific information, for example pamphlets, flyers, invitation emails	This is a modified version of the Master PISCF which includes information pertaining to the site at which the research is to be conducted, e.g. MLHD contact details, MLHD investigators and the MLHD logo on documentation. Documents should include site specific version numbers and dates.	☐	☐	☐

Ethics (HREC) Approval Details				
If ethics is in REGIS, these documents will be transferred automatically to your SSA application.				
Item	**Description**	**Yes**	**No**	**N/A**
HREA	A copy of the ethics application form approved by the Public Health Organisation (PHO) HREC.	☐	☐	☐
Ethics approval email and any subsequent amendment approval emails	Original ethics approval email and any subsequent amendment approval emails that list MLHD as an HREC approved site.	☐	☐	☐
HREC approved Master Participant Information Sheet(s) & Consent Form(s)	Documents should include version numbers and dates.	☐	☐	☐
HREC approved study documentation as listed on HREC approval email and any other subsequent amendment approval emails	Ensure that all HREC approved documentation is included with your SSA application.	☐	☐	☐
Aboriginal Health & Medical Research Council (AH&MRC) approval	If your research primarily concerns Indigenous people, you must obtain ethical approval from the AH&MRC HREC in addition to the PHO HREC. Site authorisation cannot be finalised until AH&MRC approval has been obtained.	☐	☐	☐

Section 2: Departmental Approvals, Service Agreements and Site Access				
Item	**Description**	**Yes**	**No**	**N/A**
Head of Department approval	It is essential that you select a Department and Head of Department (HOD) in Part C of your SSA application form. If you submit the SSA without selecting a Department and HOD, the application cannot progress to review and authorisation. We recommend that you also contact the selected HOD before submitting your application, to inform them about your project.	☐	☐	
Service Agreements from external service providers (or quotes for costs)	If you are using external service providers for any clinical trial-related activities, you need to provide a Service Agreement (or quotes for costs). Eg. external radiology or pathology services.	☐	☐	☐
Site Access or eMR Access for external researchers	Research personnel who are employed by another LHD, a university, or an external organisation, and wish to conduct research on-site at MLHD, or access MLHD eMR, must submit additional documentation. Please contact the MLHD Research Office to discuss.	☐	☐	☐

Section 3 : Additional requirements if your study is a commercially sponsored clinical trial				
Item	**Description**	**Yes**	**No**	**N/A**
Clinical Trial Research Agreement (CTRA)	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.	☐	☐	☐
Medicines Australia Form of Indemnity	For commercially sponsored clinical trials, the sponsor must provide an executed Medicines Australia Form of Indemnity.	☐	☐	☐
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.	☐	☐	☐

Section 4: Additional requirements if your study is an investigator initiated and/or collaborative trial				
Item	**Description**	**Yes**	**No**	**N/A**
Clinical Trial Research Agreement (CTRA)	Investigator-initiated or collaborative clinical trials may need a written agreement in place. Templates have been approved for use in NSW Public Health Organisations (PHOs) and can be found here.	☐	☐	☐
Research Collaboration Agreement	Written agreements for investigator-initiated applications may not be required however in some circumstances, when the research involves an external organisation, an agreement may be requested. Eg: Data Sharing Agreement. Please contact the MLHD Research Office to ascertain this requirement.	☐	☐	☐
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 contact the MLHD Research Office to ascertain this requirement.	☐	☐	☐
Certificate of Currency of Insurance	For non-commercially sponsored clinical trials, sponsors must have indemnity or insurance arrangements that are sufficient to cover their sponsor-related liabilities. This insurance should cover a minimum amount of $10 million (AUD). The Insurance Certificate must be submitted with the governance application.	☐	☐	☐

Contact the MLHD Research Office
MLHD Research Governance Manager Janelle Thomas Tel: (02) 5943 2014 MLHD-research@health.nsw.gov.au