

Checklist - Site Specific Assessment (SSA) for a Multi-Centre Low/Negligible Risk (LNR) Research Application

This checklist has been designed to assist with ensuring all relevant documentation required for the submission of a Multi-Centre LNR Research SSA has been provided.

Section 1: SSA Application and Supporting Study Documentation

1 copy of each listed applicable document	<input type="checkbox"/> Completed Checklist - Showing all documents that have been provided to the site. <input type="checkbox"/> LNR Research SSA Form - The signed form, via electronic or hardcopy submission. <input type="checkbox"/> LNR Research Form - A copy of the approved LNR Form approved by the HREC. <input type="checkbox"/> Ethics Approval Letter - The Ethics Approval Letter from a Lead NSW Health Human Research Ethics Committee (HREC) and any subsequent amendment approval letters (for multi-centre LNR Projects. <i>*The letter/s must list each of the sites at which the study will be undertaken.</i>) <input type="checkbox"/> HREC Approved Master Participant Information Sheet(s) and Consent Form(s) including version number and version dates - If the project is multi-centre please ensure the Master Participant Information Sheet and Consent Form, are provided. <input type="checkbox"/> Site Specific Participant Information Sheet(s) and Consent Form(s) including version number and version dates - This is a copy of the Master Participant Information Sheet and Consent Form which includes information pertaining to the site at which the research is to be undertaken. E.g. local contact telephone numbers, local investigators, local Logo's on documentation and a local contact for complaints (e.g. RGO) etc. <input type="checkbox"/> HREC Approved study documentation: protocol, questionnaire(s), survey questions, patient diaries, recruitment advert, interview topics to be covered etc. including version no and date (If applicable) - All documents approved for use with the study; which have been listed on the Ethics Approval letter and/or any subsequent Amendment Approval letters. <input type="checkbox"/> Curriculum Vitae (CV) - A short CV is required for all Investigators listed on the SSA. Once a CV has been provided this should be kept on file and linked to all research projects being undertaken by the researcher. CV renewals will be required at a minimum of every two years (consult relevant RGO for local PHO requirements). In lieu of a CV researchers may wish to submit a declaration of the last submitted CV if this has been in the previous two years.
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Section 2: Departmental Approvals, Funding & Budgets

1 copy of each listed applicable document	<input type="checkbox"/> Relevant Departmental Approval/s – Appropriate signatories included on the SSA Form. <input type="checkbox"/> Authority for Data Provision – Appropriate signatories included on the SSA Form. <input type="checkbox"/> Funding Confirmation – A copy of written correspondence from the organisation or company providing funding for the research must be provided. If the funding is to be covered by a departmental cost centre written correspondence from the authority of the cost centre must be provided. <input type="checkbox"/> Budget – A site specific budget signed by the relevant Business Manager/Head of Department/ or delegated authority must be submitted with a research project if there is any income or expenditure generated at the local site. <input type="checkbox"/> Medical Records Budget & Approval – For any studies requiring access to participant's medical records via the Medical Records Department.
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- Please note that there are **2 Sections** to this checklist, not all sections will be relevant to all research projects.
- Application Forms, Budgets & Head of Department approvals require provision of original or scanned/mailed signatures prior to final authorisation.