NSW Health Site Specific Assessment (SSA) Roles and Responsibilities

This document outlines roles and responsibilities of key staff when assessing and authorising a site specific assessment (SSA) in line with NSW Health PD2010_056: Research – Authorisation to commence human research in NSW Public Health Organisations.

All human research that takes place in NSW Health Organisations must be reviewed in accordance with PD2010_056 and authorised by the Chief Executive or their delegate before commencement. Authorisation is conditional upon ethical and scientific approval of the research project that has been granted in line with NSW Health PD2010_055: Ethical and scientific review of human research in NSW Public Health Organisations. Human research projects must not commence until the applicant has received written notification of authorisation by the Chief Executive or their delegate.

SSA Section	Roles and Responsibilities			
	Principal Investigator (PI)	**Research Governance Officer (RGO)**	**Head of Department (HOD) (including Clinical HOD and Supporting HOD)** [i]For definitions, please see footer located on page 7.	**Other (as specified)**
Overarching SSA Responsibility	√ It is the responsibility of the PI to submit an SSA application for research that is to be conducted under the control of a NSW Health Organisation. PIs should start to prepare the SSA application at the earliest possible opportunity.	√ It is the responsibility of the RGO to: • Provide advice to investigators seeking to undertake human research within NSW Health Organisations, in accordance with policy directives; • Review applications for site authorisation; and • Provide recommendation to the	√ It is the responsibility of the Clinical HOD responsible for the PI to: • Discuss the research project with the PI; • Assess whether the project meets appropriate governance requirements; and • Promptly provide a declaration of	**Chief Executive or Delegate** √ It is the responsibility of the Chief Executive or their delegate responsible for the site where the research is to be conducted to promptly provide site authorisation (or promptly reject site

	It is the responsibility of the PI responsible for the site where the research is to be conducted to: • Proactively discuss their research project with their Clinical HOD; • Proactively discuss their research project with each Supporting HOD. Responsibility for the content and quality of the application remains with the PI even when the administrative responsibility of submitting the application has been delegated.	Chief Executive or their delegate.	support/no support for the project. It is the responsibility of each Supporting HOD listed on the project to: • Be available to discuss the project with the PI; • Assess whether the project requires additional resourcing (through either financial or in-kind support) or whether the Department can support the project through existing resources; and • Promptly provide a declaration of support/no support for the project.	authorisation) following recommendation from the RGO.
Part A: Study-Wide Information				
A1. Project title A2. Project Summary A3. Coordinating Principal Investigator A4. HREC Name A5. HREC Code A6. Ethics Application ID A7. Study Type A8. Clinical Trial Type A9. Clinical Trial Phase A10. CNT/CTA Scheme A11. NCAT Approval	√ It is the responsibility of the PI to ensure this section is completed truthfully and accurately, reflecting the details of the research project.	√ It is the responsibility of the RGO to assess and confirm that all relevant questions on the form have been completed. The RGO should also check all classifications have been		

A12. Sponsor Type A13. Sponsor Name	PIs are responsible for making themselves aware of the intent of the questions and seek advice if they are unsure of what answers are appropriate for each section.	entered correctly into REGIS.		
Part B: Study-Wide Information				
B1: Site Name B2. Principal Investigator B3. Research Activities person will be responsible for B4. Expertise relevant to the research project B5. Principal Investigator a student B6. Principal Investigator a NSW or TAS Health staff member B7. Administrative contact B8. Site Team Members	√ It is the responsibility of the PI to ensure this section is completed truthfully and accurately, reflecting the details of the research project. PIs are responsible for making themselves aware of the intent of the questions and seek advice if they are unsure of what answers are appropriate for each section.	√ It is the responsibility of the RGO to assess and confirm that all relevant questions on the form have been completed. **NOTE:** X It is not the responsibility of the RGO to assess the competency of the research team by requesting curriculum vitae (CVs). Assessments of competency of the research team are the responsibility of the relevant Clinical HOD/s. It is not the responsibility of the RGO to be satisfied of the content of any discussion between the PI	√ It is the responsibility of the Clinical HOD/s to review the expertise of investigators and be satisfied they have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision have been arranged.	

		and Clinical or Supporting HOD, or even that a discussion has taken place. The HOD signature provided in SSA: Part G is sufficient evidence for the RGO to fulfil their responsibility.		
Part C: Departments and Services				
C1. Department C2. Head of Department C3. Email C4. Resources	√ It is the responsibility of the PI to ensure this section is completed truthfully and accurately, reflecting the details of the research project.	√ It is the responsibility of the RGO to assess and confirm that all relevant questions on the form have been completed and verify that all relevant HOD/s are listed.		
Part D: Recruitment, Records, Tissue and Data				
D1. Participant Enrolment D2. Numeric Site Target D3. Minimum number of participants to be enrolled at site D4. Maximum number of participants to be enrolled at site D6. Access to medical records D7. Access to tissue samples	√ It is the responsibility of the PI to ensure this section is completed truthfully and accurately, reflecting the details of the research project.	√ It is the responsibility of the RGO to assess and confirm that all relevant questions on the form have been completed.		
Part E: Site Costing and Funding				
E1. Financial costs associated with the project E2. Non-financial costs associated with the project E3. Site Funding	√ It is the responsibility of the PI to ensure this section is completed	√ It is the responsibility of the RGO to assess and confirm that all relevant questions	√ It is the responsibility of the Clinical and Supporting HOD/s to:	

E4. Form of Clinical Trial Agreement	truthfully and accurately, reflecting the details of the research project.	on the form have been completed. **NOTE:** X It is not the responsibility of the RGO to review the budget or financial details of the project.	• Review the costs of the research and to ensure there are sufficient funds to cover conducting the research at the site; and • To determine there are suitable and adequate facilities and resources for the research to be conducted at the site as proposed, and they are available for the duration of the project. Supporting HOD/s may support research with a budget in deficit, if they are satisfied there is benefit to the NSW Health Organisation and the costs can be sufficiently covered by the relevant department.	
Part F: Attachments – Site Specific Documents				
Participant Information Sheet Consent Form Research Protocol Ethics Application Decision Notification Certificate of Currency of Insurance Budget Indemnity	√ It is the responsibility of the PI to provide all documents relevant to the conduct of the research at the site.	√ It is the responsibility of the RGO to confirm that: 1. All required supporting documents have been submitted;	√ It is the responsibility of the Clinical and Supporting HOD/s to read the relevant project documents to inform	

Research agreement Other project-related documentation		2. All research documents to be used at the site comply with the requirements of the NSW Health Organisation (see note below); and 3. That there is ethical and scientific approval for the project and research documents. **NOTE:** X The RGO will not undertake ethical and scientific review of the project and associated documents. RGO's are recommended to only read the Human Research Ethics Application (HREA) if there is a need to further understand the project (above and beyond the information provided in the SSA). RGO's should only check the participant information sheet-consent form for three things:	their knowledge of the project.	

		1. Correct logo is used (NSW Health logo recommended) 2. Correct site study investigators are listed 3. Local contact details are provided If the RGO has the capacity to update logos and correct minor administrative issues (such as header/footer errors) this will reduce the turnaround time and improve the level of support provided to the researcher.		
Part G: Declaration				
Principal Investigator Declaration Head of Department Support	√ It is the responsibility of the PI to sign the declaration outlined in SSA: Part G. This declaration includes a statement that the information provided is truthful and accurate and they take full responsibility for the conduct of the research project in accordance with the NHMRC National Statement on Ethical Conduct in Human Research, the Australian	√ It is the responsibility of the RGO to check the SSA contains the signatures of: the PI, the HOD/s of the site; and, where applicable, heads of supporting departments and the nominated authority for data provision.	√ It is the responsibility of the Clinical and Supporting HOD/s to list their decision to either support or not-support the research project in SSA: Part G. It is the responsibility of the Clinical and Supporting HOD/s to declare they are not a member of the research team, have read the relevant project documents to inform	

	Code for the Responsible Conduct of Research, and where applicable, Note for Guidance on Good Clinical Practice. Responsibility for the content and quality of the application remains with the PI even when the administrative responsibility of submitting the application has been delegated.		their knowledge of the project and that they have discussed the research project and resource implications with the PI. Where the CPI and/or PI is a Clinical or Supporting HOD they will need to seek suitable alternate sign off for this section.	

Following review of the SSA, the RGO will make a recommendation to the Chief Executive or delegate regarding authorisation of the project and indicate whether authorisation:

1. is recommended;
2. is not recommended; or
3. requires consideration by the Chief Executive or delegate.

[i] Definitions:

- **Clinical HOD**: Clinical HODs are responsible for the operational and financial management of the department, service or site where human research is to be conducted within the NSW Health Organisation. Clinical HODs are usually divisional directors or other nominated authorities.
- **Supporting HOD**: Supporting HODs are responsible for providing additional support or services to the human research project conducted at the NSW Health Organisation. Examples of supporting departments include pharmacy, medical imaging, medical records and treatment units providing care.