Research Governance Site Specific Application (SSA) Checklist

NSWHP_SD_049

1. The SSA form is within REGIS (NSW Health).
   *Note: mandatory questions and fields are marked in the SSA in REGIS with an asterisk * and must be completed before you can move on.*
2. NSWHP strongly encourages use of this checklist. Upload your completed checklist at Part F Attachments.
3. All supporting documents (including department approvals via email) are Uploaded at Part F Attachments.
4. The relevant Head of Department(s) must be chosen at Part C Departments and Services. Do not submit the SSA without a Head of Department, unless following specific instruction from the Research Office:
   - Senior Operations Manager (SOM) for Clinical Services; or
   - NSWHP – Forensic and Analytical Science Service (FASS); or
   - Biobank – Camperdown

   Note: To assist the Head of Department(s) (in REGIS) to support your application you MUST consult with and obtain written approval (via email) from the relevant line manager (i.e. Clinical Director, Local Pathology Director, Branch Director etc) PRIOR to submitting your site-specific application (SSA) via REGIS.
5. If NSWHP data is to be used for research, the Authority for Data Provision must also be added at Part C Departments and Services:
   - 'NSWHP – Clinical Services – Data' (Chief Medical Information Officer); or
   - 'NSWHP – Forensic and Analytical Science Service – Data (Director, Forensic and Analytical Science Service); or
   - 'Biobank – Data (Director of Biobanking)
6. If data is to be disclosed outside of NSWHP, this will require Data Custodian approval and a Disclosure of Information (DOI) agreement.
7. If you have questions about your research project or require a research agreement template (i.e. material transfer or research collaboration) please contact the Research Office (NSWPATH-Research@health.nsw.gov.au).
8. For assistance with REGIS, the SSA application process, SSA checklist or DOI agreements please contact the Research Governance Office (NSWPath-RGO@health.nsw.gov.au)

Study Information	Description	Completed
Part A: Study-Wide Information		
1. SSA Form	*Note: NSWHP must be listed as a site in the ethics approval letter and added as a site in REGIS for this SSA form to be available.*	☐
2. Coordinating Principal Investigator (CPI)	**A3.** List the CPI correctly (their email address in REGIS). The CPI has overall responsibility for the research project at all sites.	☐
3. Sponsor information	List the correct Sponsor who is responsible for, or is funding the project: **A12. Sponsor type:** *Select (drop-down)*: Commercial, Collaborative, Investigator initiated. **A13. Sponsor name:** *Select (drop-down)*: Sponsor name, or, if Sponsor is not shown in the list add the Sponsor name manually.	☐ ☐

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Part B: Site Team		
4. NSWHP site team and locations	*Note: This section relates to the NSWHP Principal Investigator and any other NSWHP site personnel.* ***Include all people and locations within NSWHP** that are involved in the research project.*	☐
5. Principal Investigator (PI)	**B2.** The person who has overall responsibility for the research project at NSW Health Pathology is the Principal Investigator (PI).	☐
6. Non-NSWHP Research personnel	Researchers not employed at NSWHP wishing to conduct research at any NSWHP site, must submit additional documentation. *Note: a contingent worker status, or clinical appointment/privileges may be required.* **Please contact** HR Support Services (students, contingent workers etc.) or Medical Workforce (JMOs or SMOs). **Upload evidence of NSWHP appointment** (see Part F, below).	☐ ☐
7. Students and their Supervisor	*Note: If applicable, students must only be listed in Section B8 Site Team Members.* If the study involves a student within a NSWHP facility, then the Student and a NSWHP Supervisor must be listed in the SSA.	☐
Part C: Departmental Approvals		
8. NSWHP department s/locations	*Note: **specify all NSWHP departments or locations where resources (staff, services, or investigations) will be used.** The NSWHP SSA is statewide and multiple NSWHP departments or locations can be listed for research projects that involve more than a single facility.*	☐
9. Relevant department approval	Approvals must be obtained in writing (email or letter) from the Line Manager (i.e. Clinical Director, Local Pathology Director, Branch Director etc) of all NSWHP departments or locations involved. *Note: obtain approval that is specific to the requirements of the research project. For example, access to biospecimens/tissue (residual leftover clinical samples, or those specially collected for research, or tissue transfer outside of NSWHP), access to use NSWHP data, requirements for sample collection, processing, packing, transport; staff time on the research project.* **Upload department approvals as an attachment** (see Part F, below).	☐ ☐

10. Head of Departments (HoDs)	The relevant Head of Department(s) must be selected *Select (drop-down):* • Senior Operations Manager (SOM) for Clinical Services; or • NSWHP – Forensic and Analytical Science Service (FASS); or • Biobank – Camperdown	☐
11. Authority for Data (HoD Data)	Access to NSWHP data, test results or any form of curated data (includes tissue pathology reports) from data assets owned by NSWHP for the research project requires relevant data authority approval: *Select (drop-down)*: • NSWHP – Clinical Services – Data, or • NSWHP – Forensic and Analytical Science Service – Data, or • Biobank – Data (NSW Health Statewide Biobank).	☐
Part D: Recruitment, Records, Tissue, and Data		
12. Biospecimens	*Note: the SSA states tissue. For the purposes of answering this section you must answer in the context of biospecimens/tissue (i.e. not only "tissue") i.e. residual leftover clinical samples.* If biospecimens are accessed from NSWHP for research this must be described: **Biospecimens – *from routine standard of care.*** Will the research project use residual, leftover, or discarded diagnostic biospecimens/tissue samples originally obtained as routine standard of care?	◯ Yes ◯ No (= Yes in D7)
	Biospecimens – *specifically collected for research.* Will this research project collect biospecimens/tissue samples specifically for this research (not part of routine standard of care).	◯ Yes ◯ No
	Biobanking. Will the research project retain or transfer biospecimens/ tissue samples into a Biobank for future research?	◯ Yes ◯ No
	If the study will collect, store, and biobank any biospecimens, then the study must meet the NSWHP Biobanking Principles of Support.	◯ Yes ◯ No
	The NSWHP representative on the Biobank Access Committee is:_____	☐
	D7. Are you planning on accessing biospecimens/tissue samples from NSWHP? (Yes / No).	☐
	If Yes, describe how many and what type, and if biospecimens will be transferred outside of NSWHP:	
	D7.1. How many biospecimens/tissue samples are you proposing to access? Describe the number and type of biospecimens.	☐
	D7.2. Will any biospecimens/tissue samples be transferred to an entity external to this site? (Yes / No).	☐
13. Consent	*Note: Patient consent is important to obtain when using their biospecimens/tissue for research.*	☐

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13. Consent (cont'd)	**Upload** the patient consent form to be used in your study, or evidence of an ethically approved waiver of consent (see Part F, below).	☐
Part E: Site Costing and Funding		
14. Financial costs	Financial costs are any costs incurred for the project to be conducted at NSWHP. This may be within the department conducting the research, or by a NSWHP service supporting the research (i.e. blood collections). **E1.** Are there any financial costs? (Yes / No). If Yes, **E1.1.** What is the total estimated cost for NSWHP in $AUD, and	☐ ☐
15. Budget	**E1.2.** Provide a detailed study budget. (Yes). You can request a quote via eResearchWithUs for NSWHP research services the study pays for. **Upload** the study budget and/or quote (see Part F, below).	☐ ☐
16. Funding	*Note: NSWHP Delegations Manual describes the delegated authority required to authorise the use of funds from cost centre accounts.* *Note: If funding is being provided by an organisation other than NSWHP, written correspondence from the organisation providing funding for the research must be provided.* If there is funding from NSWHP or an external organisation this must be described: **E1.3.** Will funding be provided for the research? (Yes / No) If Yes, specify: **E1.3.1.1.** which account number and cost centre the funds are deposited or held, and **Upload** evidence of funding approval or support (see Part F, below).	☐ ☐ ☐
17. Non-financial costs	*Note: Non-financial in-kind costs have no direct charge but are considered to be local NSWHP resource allocations. For example, staff time without any direct charge (research within a position description, or approval for staff to conduct research outside of their position description); or use of workstations, infrastructure, or any form of NSWHP equipment or facilities that do not have a direct charge involved.* Non-financial in-kind costs are important and must be accurately estimated as evidence of NSWHP's support for research. **Please calculate any in-kind support and outline resources to be used.** **E2.** Are there any **non-financial costs** (e.g. local resource allocations) associated with the project? (Yes / No).	☐

18. Data extraction costs	If Yes, describe and estimate the non-financial costs: **E2.1.** Describe the non-financial costs, and **E2.2.** What are the non-financial costs of the project at this site estimated as a dollar value? Provide a dollar value (not $0.00). If you require assistance from NSWHP IT to extract NSWHP data for research you can request this via eResearchWithUs. IT work hours required to extract data must be specified in the SSA as a financial (E1) or non-financial (E2) cost.	☐ ☐ ☐ ☐
Part F: Attachments		
Consent		
18. Participant Information Sheet(s) and Consent Form(s) (PISCF)	**Upload** a copy of the Participant Information Sheet and Consent Form, or	☐
19. Waiver of Consent (as ethically approved)	Explain what is being accessed from NSWHP without consent: _____ _____ _____ _____	☐
NSWHP investigator details		
20. CV – Investigator qualifications	**Upload** your most recent CV outlining expertise and experience to conduct activities.	☐
21. Contingent worker, or clinical appointment / privileges	**Upload** evidence of NSWHP appointment. Please contact HR Support Services (students, contingent workers etc.) or Medical Workforce (JMOs or SMOs).	☐
Study Documents		
22. HREA	A copy of the Human Research Ethcs Application (HREA) form approved by the HREC.	☐
23. Ethics Approval Letter	The Ethics Approval Letter from a Lead NSW Health (or NMA approved if outside NSW/ACT) Human Research Ethics Committee (HREC) and any subsequent amendment approval letters. *Note: the ethics approval letter or amendment letter must list NSWHP as a site.*	☐

24. Specialist HREC review and approval (if applicable)	Ethics approval letter where specialist HREC review is required for example: • AH&MRC Ethics Committee expertise in the review of Aboriginal and Torres Strait Islander research, or • Justice Health HREC research on people in custody in NSW, or • NSW Population and Health Services Research Ethics Committee data linkage studies.	☐
25. 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)	☐
Research agreements		
26. Research Agreement	When NSWHP is collaborating on a research project and is providing in-kind and/or financial contributions a research agreement is required. *Note: For a research agreement please contact NSWHP Research Office: NSWPath-Research@health.nsw.gov.au* *The research agreement does not have to be finalised for the SSA to be submitted.*	☐
27. Disclosure of Information (DOI) agreement	If NSWHP will only provide data for a research purpose to an entity external to NSWHP. *Note: for DOI please contact NSWHP Research Governance Office: NSWPath-RGO@health.nsw.gov.au*	☐
Clinical Trials		
28. ICH GCP Certificate	For a Clinical Trial **Upload**, a valid ICH GCP training certificate for the NSWHP investigators listed in this SSA (See Part B, above).	☐
29. Current Certificate of Insurance (<$20M)	A certificate issued by an insurance company or broker, verifying the existence of an insurance policy.	☐
30. Standard Form of Indemnity	Medicines Australia or MTAA (for medical devices).	☐
31. Research Agreements	For a Clinical Trial a Research Collaboration Agreement (RCA) or Medicines Australia CTRA. For RCA or Medicines Australia CTRA please contact NSWHP Research Office: NSWPath-Research@health.nsw.gov.au	☐
32. TGA eCTN	For use of unapproved drugs or devices in a clinical trial, eClinical Trials Notification (eCTN) to the Therapeutics Goods Administration (TGA).	☐
33. Radiation, Biosafety and/or GMO approval letter	Evidence that a thorough risk assessment has been performed when using genetically modified materials, radiation or organisms that cause listed human diseases under the Biosecurity Act 2015.	☐