Research Governance Site Specific Application (SSA) Checklist

NSWHP_SD_049

1. The SSA form must be completed within REGIS.
2. All site-specific applications must comply with the below checklist – failure to do so may result in delays or an ineligible application determination.
3. All additional documents (including department approvals via email) to be uploaded in REGIS.
4. Authority for Data Provision must be added as 'Department Head' if you require NSWHP data.
   - '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)
5. If data is to be disclosed outside of NSWHP, this will require Data Custodian approval and DOI agreement (CMIO or CE)
6. 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**).
7. 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**)

Supporting Document	Description	Required
Section 1: SSA Application and Supporting Study Documentation		
1. SSA Form	NSW Health REGIS	☐
2. Site Specific Participant Information Sheet(s) and Consent Form(s) (PISCF) uploaded	Include version number and version dates, a copy of the Master Participant Information Sheet and Consent From and site specific (if applicable).	☐
Section 2: Departmental Approvals, Funding & Budgets		
3. Relevant departmental approval	Line manager (i.e. Clinical Director, Local Pathology Director, Branch Director etc) approval/s should be obtained via email and uploaded into REGIS as an attachment.	☐
4. Authority for Data Provision *(if applicable)*	Applicable for research activities involving access to paper medical records and/or research projects accessing a data asset owned by NSWHP. Add the relevant data authority (CMIO, Director Forensic and Analytical Science Service, Director of Biobanking) as a 'Department Head' in REGIS.	☐
5. Funding Confirmation	If funding is being provided by an organisation other than NSWHP, written correspondence from the organisation providing funding for the research must be provided. *Please note funding confirmation is not required when a Collaborative Research Agreement is being submitted for the study.*	☐

6. Budget	The budget must reflect the actual costs to complete all of the procedures and administrative tasks of the study. Please include all direct, indirect, and in-kind costs. Outline all in-kind funding – estimated time for investigators and NSWHP staff as well as consumables etc.	☐
7. Non-NSWHP Research personnel	Researchers not employed at NSWHP wishing to conduct research at any NSWHP site, must submit additional documentation. A contingent worker, non-clinical or clinical appointment may be required.	☐
Section 3: For projects that have had ethics approved; • **Prior to REGIS implementation; or** • **outside NSW and ACT (i.e. not via REGIS)**		
8. HREA	A copy of the Research application form approved by the HREC.	☐
9. 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 (for multi-centre LNR Projects. *The letter/s must list each of the sites at which the study will be undertaken.	☐
10. HREC Approved Master Participant Information Sheet(s) and Consent Form(s)	Including version number and version dates.	☐
11. 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)	☐
Section 4: For projects that are: • **Clinical Trials;** • **Greater than low risk**		
12. CV – Investigator qualifications	Outlining expertise and experience to conduct activities and evidence of valid ICH GCP training certificate for clinical trials and honorary research appointments for external personnel.	☐

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13. Current Certificate of Insurance (<$20M)	A certificate issued by an insurance company or broker, verifying the existence of an insurance policy	☐
14. Standard Form of Indemnity	Medicines Australia or MTAA (for medical devices)	☐
15. Research Agreements	CTRA, research collaboration agreement (RCA) or material transfer agreement (MTA).	☐
16. TGA eCTN	For use of unapproved drugs or devices in a clinical trial, eClinical Trials Notification (eCTN) to the Therapeutics Goods Administration (TGA).	☐
17. 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.	☐