Site Specific Assessment (SSA) Guidance Note & Checklist

Research governance is required for conducting research at Metro North Health (MNH). Such research activities may include Metro North patients, staff members, interviewing/surveying staff members, hanging a poster for recruitment, clinical trials, accessing Metro North data and/or facilities at any Metro North site.

Use this guidance note and checklist to assist with the completion of a Site-Specific Assessment application to Metro North Research Governance.

Mandatory	Required for all SSA applications	
1. Site Specific Application (SSA)	To submit your SSA form, create it in ERM as a sub-form of the Human Research Ethics Application (HREA). You will then be required to upload all relevant documents and click the Submit action. The ERM User Guide and FAQs documents are available to assist you with accessing and using ERM. Additional guidance is available if required through our combined HREC and Governance clinics available each Monday and Thursday. **Single SSA –** Only one SSA for MNH is required, regardless of how many sites are involved at MNH. For example, if the research project is being conducted at RBWH and Redcliffe Hospital, one SSA is required. Please tick all participating sites in the tick box located in the SSA form. Please obtaining each participating sites Principal Investigator, head of department and business manager approvals.	☐
2. **Signatures**	The final SSA form must include the signatures of the: **a. Principal Investigator (PI)** at the site b. **Business Manager (BM) or finance delegate at each site** **c. Head of Department (HoD) at each site** The Head of Department is typically considered the Manager or Director for the MNHHS Principal Investigator's employing department. The Business Manager is typically the business manager for the Service Line. The name, date and position of the signatory are required. Electronic signatures, wet ink signatures or email approval(s)are permitted.	☐
3. Approvals	If your study goes across departments, uses the services of Queensland Pathology and/or includes use of coronial material, the following is required: a. Supporting 'Head(s) of Department' must also give their approval for any research conducted in their department. Evidence of Supporting Head(s) of Department is required with your submission. b. The Director, Pathology Queensland needs to give approval if results or data are required from Pathology Queensland (even if the pathology results are located within the patient's medical records). Information contained in pathology reports is owned by Pathology Queensland and not the HHS. c. Director, Radiology/Medical Imaging needs to give approval if patient radiology data are required for use in research.	☐

	d. Forensic and Scientific Services (FSS) approval is required where studies require access to coronial material held by Queensland Health FSS.	
4. HREA & HREC approval*	The Human Research Ethics Application (HERA) and the Human Research Ethics Committee (HREC) approval letter should be included in the SSA submission. Where amendments to the study have occurred following the initial approval, all HREC amendment approval letter(s) should also be included in the submission and listed in the cover letter.	☐
5. **HREC approved documentation***	The Human Research Ethics Committee (HREC) approval letter will generally include a list of documents that have been approved (including the version number and date of the document). You will need to submit all of the **current** documents listed in the HREC letter for RGO approval. For example, documents that have been superseded prior to your SSA submission do not need to be submitted as part of the SSA application. Please ensure that the versions of documents submitted are the same version number and date as that approved by the HREC. Use this section to list documents approved by HREC that are not listed elsewhere on this Checklist. All other material approved by the HREC and relevant to the site - this may include any other material supplied to participants (e.g. identification cards and diaries) or recruitment/promotional material (e.g. advertisement material such as posters), study tools (questionnaires, advertisements, diaries completed etc). Where appropriate, other correspondence from HREC which reflects the history of the project, discussion between the investigator and HREC (in particular requests for further information from the HREC and the responses), and any amendments made to the project should also be provided in the ERM SSA submission.	☐
6. Protocol*	If more than one version of the Protocol has been approved by the HREC, provide the most recent approved version.	☐
7. Budget (funding & in-kind)	A budget template that includes in-kind support should be used (excluding clinical trials), such as the MNHHS research budget template. In-kind contributions should be quantified in order for the health service to calculate the actual cost of research. For example, if you anticipate spending 20 hours on a research project during work hours as a Principal Investigator and MNHHS employee, you need to quantify the in-kind contribution (e.g. 20 hours x $35.50 hourly/rate = $710) for the SSA study budget. Facility and research business managers can assist with determining salary costs or with other queries relating to study budgets. Please discuss your research budget with the relevant departmental business manager or hospital director of finance. Where applicable, include funding information, including but not limited to a grant approval letter and grant agreement. For commercially sponsored clinical trials, the budget is outlined in the Clinical Trial Research Agreement (CTRA).	☐
Other, if applicable	**Required where applicable to your specific study**	
8. Waiver of Consent	Where a HREC has granted a waiver of consent, consideration of the legal permissions for the lawful access of data under the *Public Health Act 2005* (PHA) or the *Hospital and Health Boards Act 2011* (HHBA) or is required. 1. A PHA application is required when a researcher seeks to be given Information held by Queensland Health where **both** of the following apply: • valid consent by, or, where relevant, on behalf of the individual about whom the Information relates has not been obtained for the disclosure and/or use of the Information for the purposes of approved research	☐

	• the disclosure is not between 'designated persons' as defined in s139A HHB Act for use in research 'for evaluating, managing, monitoring or planning health services' under s150(a) HHB Act If a Public Health Act (PHA) application is applicable, please visit the Department of Health website. A data custodian may also request a PHA grant be obtained prior to disclosing the Information to provide assurance of valid authorisation to disclose. Please submit the PHA grant approval with the SSA. 2. Permission under Section 150 of the *Hospital and Health Boards Act 2011* ("Section 150 Permission") • Section 150 of the Hospital and Health Boards Act 2011 provides that a 'designated person' may disclose 'confidential information' to another 'designated person' if the disclosure is for the purpose of 'evaluating, managing, monitoring or planning health services'. Evidence of data custodian approval is required to be provided with your SSA. Data custodian approval is provided via the local facility Director Health Information Services (*or equivalent*) Contact the Research Governance Office or the local data custodian for further information if you require guidance regarding the legislative requirements of the research.	
9. PICF master*	Participant Information, Consent and Withdrawal Forms (PICFs) are required for research projects in which the research team is seeking participant consent. The version details must match the most recent HREC approval letter. Templates are available via the NHMRC website. For single-site studies, the Master PICF will be the same as the Site Specific PICF (refer to below). For multi-site projects, the HREC will approve a Master PICF from which Site Specific PICFs will be generated for each site involved in the research. The PICF Master is submitted with your SSA application.	☐
10. PICF site specific	For single-site projects, the Site Specific PICF should be the same as the PICF approved by the HREC. For multi-site projects, a Site Specific PICF should be created based on the most recent HREC approved master version. Site Specific PICF should contain • the site version and date • the version and date of the Master PICF which it is based on (multi-site only) e.g. *MNH Site PICF Version 2 dated 13-12-2023; based on Master PICF Version 2 dated 14-11-2023* • details of the Site Principal Investigator • details of the approving HREC Committee should the participants have any concerns about the project • details of the relevant Research Governance Manager for complaints Name: Research Governance Manager Position: Metro North Office of Research Ph: 07 3647 9550 Email: MetroNorthResearch-RGO@health.qld.gov.au	☐

	• the Queensland Government logo on the front page, to demonstrate to the participants that the research project has received Queensland Health endorsement. Where a Site Specific PICF is being provided, a tracked version is required.	
11. Agreement	A research agreement is required for all research in which an external organisation is involved in the research. This includes sponsored, collaborative and student research (e.g. Research Higher Degree). Only the MNHHS Chief Executive or delegated authority can authorise an agreement upon receiving a recommendation from the RGO. **Approved templates** – Medicine Australia's Clinical Trial Research Agreements – Medical Technology Association of Australia Clinical Investigation Research Agreement. – Health Translation Queensland Research Passport Agreement – Metro North Collaborative Research Agreement (contact the RGO) – Metro North Data and Materials Transfer Agreement (contact the RGO) Refer to Clinical Trial Agreement Information Sheet	☐
12. Quotes for Services	Quotes for services are required with your submission from the following areas if they support the project: • Radiology • Pharmacy • Biosafety approval • Radiation Safety Report • Herston Imaging Research Facility	☐
13. GCP	Principal Investigators (PI's) of **clinical trials** must provide evidence of accredited GCP certification undertaken within the previous 3 years. Evidence of GCP certification will form a requirement for Site-Specific Assessment (SSA) authorisation. The site PI is then responsible for ensuring respective members of the research team undertake GCP training prior to the commencement of the study.	☐
14. Indemnity	Medicines Australia Standard Form of Indemnity (for commercially sponsored clinical trials)	☐
15. Insurance	Insurance Certificates are required for all projects involving external parties, in particular commercially sponsored research. For commercially sponsored research, insurance details or a copy of the current insurance certificate must be inserted into the appropriate Schedule of the Agreement.	☐
16. CTN	Clinical Trials Notification (CTN) form is lodged online with the TGA. Once the notification process has been completed, the approval letter should be submitted to the Research Governance Office via ERM. The CTN lodgement may occur after governance authorisation for the study has been issued. If this occurs, the CTN registration notification should be submitted via ERM as a post-authorisation notification. For CTN details please refer to the CTN Information Sheet.	☐
17. Investigator Brochure	The Investigator Brochure (for clinical trials) and product information are required for all drug and/or device trials. If more than one version of the IB has been approved by the HREC, provide the most recent approved version.	☐

18. QCAT	Queensland Civil and Administrative Tribunal (QCAT) application form and approval letter are required for clinical and/or interventional research where patients have impaired capacity to consent (usually a Person Responsible PICF is used), and the research project meets the definition of Clinical Research under the *Guardianship and Administration Act 2000 (Qld*).	☐
3. Other supporting documentation	Depending on the study, other documents may be required. This can include Radiation Safety Report, NHMRC Cellular Therapies Advisory Committee (CTAC), NHMRC Embryo Research Licensing Committee, Office of the Gene Technology Regulator (OGTR) Licence for dealings with a Genetically Modified Organism (GMO); Institutional Biosafety Committee (IBC) approval.	☐

*If the approving HREC is MNH A or MNH B you do not need to upload to ERM the HREC approved documents; RGO only require the site specific/research governance documents (e.g. site-specific PICF, approvals/signatures, budget, agreement, quotes for services.)

Contact details

- Contact Us - Metro North Health
- MetroNorthResearch-RGO@health.qld.gov.au
- Research governance and site authorisation - Metro North Health