# Site Specific Assessment Checklist & Guidance Form

(SSA REF: \_ \_ \_ \_ \_ \_)

Research Governance is required for conducting all research at Metro South Hospital and Health Service (MSHHS) sites. Research activities may include patients, staff members, interviewing/surveying staff members, hanging a poster for recruitment, clinical trials or accessing data and/or facilities at any Metro South site (e.g., service/facility).

This checklist is used to assist with the completion of the SSA and/or for tracking outstanding requirements. Refer to the work instruction for further information/clarification.

| **Applicable** | **Information to help with Site Specific Assessment Applications** |  | **Researcher Comments** | **Related Documents** |
| --- | --- | --- | --- | --- |
| 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)* | Submitting your SSA form: Create it in ERM as a sub-form to the Human Research Ethics Application (HREA).You will then be required to upload all relevant documents and select the Submit action (Note that ONLY when you select Submit does the SSA come across to Governance). The ERM User Guide and FAQs [Help - ERM Applications (ethicalreviewmanager.com)](https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/9) documents are available to assist you with accessing and using ERM.Only one SSA is required for multi-site projects. Please select all participating sites in the check box located under “*SSA 1.2 What is the name of the site/s to which this SSA Form applies?”.* |  |  |  |
| 1. **Signatures**
 | 1. The final SSA form requires an attached **Research Contracts and Study Execution (RCASE) Form,** which is used to obtain relevant signatures. Refer to MSH work instruction WI2023-302 Research contracts and study execution to determine the appropriate signatures. These signatures must include:
	1. **Principal Investigator (PI)** at the site
	2. **Business Manager (BM)/**finance delegate at each site
		1. The BM is typically the business manager for the service line.
	3. **Head of Department (HoD)** at each site.
		1. The HoD is typically considered the Manager or Director of the MSHHS Principal Investigator’s employing department.
	4. **Internal Order Number (ION):** Please provide the ION for the MSHHS site’s department - the department manager will be able to provide this (this is a mandatory requirement whether funded or unfunded).
	5. **Site Approval Contact:** Where a MSHHS site is involved in the research and is not the Princess Alexandra site, the relevant Facility or sites’ signatures must be supplied, see contacts below:

Allied Health MSHHS wide EDAH\_Metro\_South@health.qld.gov.au Metro South Addiction and Mental Health Services: MSAMHS\_Research@health.qld.gov.au or 3156 9878 for signing and internal order number.MSHHS Oral Health & Communities MSHCOH-ResearchNavigator@health.qld.gov.au Inala Indigenous Community Health: Inala\_ResearchEducation@health.qld.gov.au Palliative Care Arvind.Gunasekaran@health.qld.gov.au QEII Hospital QEII\_ResearchNavigator@health.qld.gov.au Redland Hospital baysidehealthresearch@health.qld.gov.au Logan Hospital ResearchLBHS@health.qld.gov.au  |  |  |  |
| 1. **HREC approval**
 | Where the Human Research Ethics Committee (HREC) is not the Metro South Human Research Ethics Committee (MSHREC), the approval letter should be included in the SSA submission. |  |  |  |
| 1. **HREC submission documentation**
 | A copy of the research protocol, and Participant Information and Consent Form (PICF) along with all supporting documents that will be used at site must be submitted in the initial SSA submission. Where the HREC is the MSHREC, these documents are not required to be submitted, as they can be accessed via ERM by the MSRGO. |  |  |  |
| 1. **Waiver of Consent**•

*(****Note:*** *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')*(*Note: PHA approval is a decision by Queensland Health to grant an application that permits a relevant person to give Queensland Health patient information to a person for the purposes of specified research. “Relevant person’ is defined under section 281(4) of the Public Health Act. The definition of a ‘relevant person’ is narrower than a ‘designated person’ as defined in Section 139A of the Hospital and Health Boards Act)* | Waiver approval by HREC: Considerations must be made regarding legal permissions for the lawful access of data under the *Public Health Act 2005* (PHA) or the *Hospital and Health Boards Act 2011* (HHBA) to identify if your study falls into either category, please see links below:1. **Data custodian approval** must be obtained for ***all research*** wishing to use data where consent is not being acquired, [Queensland Health and HHS Data Custodian contact list](https://www.health.qld.gov.au/__data/assets/pdf_file/0034/843199/data_custodian_list.pdf).
2. A PHA application is required when a non-Metro South Researcher seeks to be given Information held by Queensland Health [PHA Application Form| Queensland Health](https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info). If you are using the Statistical Services Branch see the [SSB PHA Companion | Queensland Health](https://www.health.qld.gov.au/hsu/ssb-pha-companion-document).
3. A PHA application may also be required if Metro South researchers, across multiple sites, are requesting access to state-wide data or data linkage.

Evidence of data custodian approval and PHA approval letter must be submitted with your SSA. |  |  |  |
| 1. **Budget**

*In-kind or funded***(Agreement/CASE form/SSA should all mirror each other with respect to the budget)** | **In-kind Study Budget,** atemplate that includes in-kind support should be used. In-kind contributions are mandatory. Only MSHHS involvement of any kind is to be calculated in the in-kind costs (e.g., hours x hourly/rate + # blood tests @ $Y/blood test = total $). Metro South facility/business managers can assist with determining study budgets. Where applicable, include funding information relating to the MSHHS site, including but not limited to, a grant application and approval letter and grant agreement.**Sponsored Funded/University Funded/Grant Funded: Provide** ***the total budget for the Metro South site*** in line with the Research Agreement or Grant. |  |  |  |
| 1. **Quotes for Services**
 | Quotes for Supporting Department Services are required with your submission from the following areas if they support the project:* Radiology/Imaging
* Pharmacy
* Biosafety approval
* Pathology
 |  |  |  |
| 1. **Radiation Safety Report**
 | Where a participant undergoes a procedure where there is use of radiation, please provide the following:* Radiation Safety Report [Home | ARPANSA](https://www.arpansa.gov.au/)
 |  |  |  |
| 1. **Agreement**

*MSH HREC & RGO Fees can be found at* [Research policy documents, forms and templates | Metro South Health](https://www.metrosouth.health.qld.gov.au/research/support-for-researchers/policy-forms-templates) | 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 MSHHS delegated authority*** can execute an agreement upon receiving a recommendation from the RGO.**Approved templates*** [Clinical Trial Research Agreements – Medicines Australia](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/)
* [Medical Technology Association of Australia Clinical Investigation Research Agreement](https://www.mtaa.org.au/clinical-investigation-research-agreements)
* [Health Translation Queensland Research Passport Agreement](https://healthtranslationqld.org.au/resources/research-ethics-and-governance/research-passport)
* [Multi-Jurisdictional Multi-Party non-Clinical Trial Collaborative Research Agreement](https://www.australianclinicaltrials.gov.au/resources/collaborative-research-agreement-template-projects-not-involving-clinical-trials)

If your research involves an external institution which falls outside of the above agreements and you are not sure what agreement is required, contact your RGO via MSH-RGO@health.qld.gov.au or via phone at 07 3443 8050/8061. |  |  |  |  | For all Commercially Sponsored studies the [Medicines Australia Standard Form of Indemnity](https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/) must be supplied with the Clinical Trial Agreement. |  |  |  |
| 1. **Indemnity**
 | For all Commercially Sponsored studies the [Medicines Australia Standard Form of Indemnity](https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/) must be supplied with the Clinical Trial Agreement. |  |  |  |
| 1. **Insurance**
 | Current Insurance certificates are required for all projects involving external parties, in particular commercially sponsored research. The certificate must be a current certificate (note on expiry it is mandatory to provide an updated certificate, any lapse will cause study suspension).  |  |  |  |
| 1. **CTN**
 | [Clinical Trials Notification (CTN) form](https://www.tga.gov.au/publication/australian-clinical-trial-handbook) is lodged online with the TGA. The CTN registration notification should be submitted via ERM. For CTN details, contact MSRGO for details of the name and email:**Approving Authority**: Metro South Hospital and Health Service**Name**: **Position**: Executive Director Research, Metro South Health**Phone Number**: 07 3443 8066 **Email**: MSH-research@health.qld.gov.au  |  |  |  |
| 1. **GCP & Research Integrity**
 | All researchers must provide evidence of accredited GCP certification and research integrity training undertaken within the previous 3 years. See MSH work instruction [WI2023-287 Research integrity](https://www.metrosouth.health.qld.gov.au/research/support-for-researchers/policy-forms-templates).* For MSH employees: all research team members must complete Research Integrity and GCP Training on [MSHLearn](https://mshlearn.birchlp.com.au/login/saml/MSHLearn).
* For external researchers: you may provide a certificate or transcript of your external training or email us to request a link to our training MSH-Research@health.qld.gov.au.
 |  |  |  |
| 1. **Clinical Trials Registry Number**
 | Section 19 of the Declaration of Helsinki (2008) & the International Committee of Medical Journal Editors (ICMJE) has made an essential criterion for publication that the trial should be publicly available in a clinical trials registry. The Registry number must be listed in the SSA 6.2a. |  |  |  |
| 1. **QCAT**
 | Queensland Civil and Administrative Tribunal (QCAT) [application form](https://www.qcat.qld.gov.au/resources/forms) and approval letter is 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 Trial under the *Guardianship and Administration Act 2000 (Qld*). |  |  |  |
| 1. **Conflict of Interest**
 | A Conflict-of-interest form attached to [WI2023-287 Research integrity](https://www.metrosouth.health.qld.gov.au/research/support-for-researchers/policy-forms-templates) must be provided signed by the PI and the Executive Director for any research project where a perceived, potential or actual conflict of interest which may compromise the research process itself and/or MSH’s processes governing research exists.For Example: researcher is performing research under both MSHHS position and University position. |  |  |  |
| 1. **Other supporting documentation**
 | Based on the research, other requirements may include,NHMRC Cellular Therapies Advisory Committee (CTAC) approval NHMRC Embryo Research Licensing Committee approvalOffice of the Gene Technology Regulator (OGTR) approval[Licence for dealings with a Genetically Modified Organism](https://www.ogtr.gov.au/about-approval-process/types-gmo-dealings) (GMO) |  |  |  |

Should you need clarification you can contact our office:

Phone:

07 3443 8050

07 3443 8061

Email: MSH-RGO@health.qld.gov.au