Site-specific Assessment (SSA) Checklist

The following checklist/guidance information is provided to assist with your SSA application; it is not required for submission.
Please note: For applications submitted via the Mater Priority Trials Review service, refer to separate checklist.

All clinical research projects	
Signed SSA form - The submitted SSA form must include the following prior to submission in ERM: a. Principal Investigator for Mater b. Head of Department/s - For funded projects only: c. Management Accountant - For greater than low risk projects only: d. Director of Medical Services e. General Manager	☐
If the Mater Misericordiae Ltd HREC is the approving HREC, you do not need to upload HREC approvals or approved documents in the SSA. RGO only require additional site-specific documents (e.g. site-specific PICFs, site level approvals/letters of support, budget, quotes).	
HREC approval letter/s - The Mater site should be listed as Mater Misericordiae Ltd - All approval letters should be included (initial approval and any subsequent amendment approvals) - If a waiver of consent is approved, Mater requires evidence that s95A of the Privacy Act was considered	☐
Protocol	☐
Master PICF (for multi-site projects)	☐
Mater site PICF - Footer details - the site version and date. For multisite projects, include the version and date of the Master PICF on which it is based, e.g. Mater PICF Version 1 dated 20 Feb 2024; based on Master PICF Version 1 dated 11 Jan 2024 - Where relevant, include the Mater Research logo on the front page - Mater institution should be referred to as Mater Misericordiae Limited and/or the correct Mater hospital/location name/s - For projects approved by an external HREC, include contact details for Mater RGO - Research Governance Officer, Ph: 07 3163 3769, Email: research.governance@mater.uq.edu.au - For multi-site projects, site-specific PICFs must be tracked from the Master PICFs and a tracked and clean version provided	☐
All HREC approved documents All *current* documents: documents that have been superseded prior to SSA submission do not need to be submitted.	☐
Budget Actual funding and in-kind support must be detailed, either within the SSA form or as an attached document.	☐
Other – submit if applicable to your project	
CTN - If externally sponsored, provide the draft/submitted CTN including Mater approving authority details. The TGA-acknowledged CTN will be required prior to authorisation. - If Mater sponsored, Mater RGO will submit the CTN to TGA, in consultation with the research team.	☐
Early Phase Clinical Trials Risk Assessment endorsement letter Phase 1 and 2a clinical trials: A separate 'Mater Early Phase Clinical Trial Risk Assessment' application must be submitted in ERM. The SSA review can commence prior to endorsement but cannot be authorised until this is received.	☐
Drug/Device Information/ Investigator's Brochure	☐
Quotes and/or Service Agreements Including internal services (e.g. Mater Pharmacy, Mater Pathology) and external service providers	☐
Radiation Safety Report	☐
Biosafety approval and OGTR approval	☐
QCAT approval letter	☐

For queries, please contact the Mater Research Governance Office - Email: research.governance@mater.uq.edu.au