

## 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.

<b>All clinical research projects</b>	
<b>Signed SSA form</b> <ul style="list-style-type: none"> <li>- The submitted SSA form must include the following prior to submission in ERM: <ul style="list-style-type: none"> <li>a. Principal Investigator for Mater</li> <li>b. Head/s of Department/s</li> <li>c. Medical Director/s or Chief Medical Officer/s</li> <li>d. General Manager/s</li> </ul> </li> <li>- For funded projects only: <ul style="list-style-type: none"> <li>c. Management Accountant</li> </ul> </li> </ul>	<input type="checkbox"/>
<i>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).</i>	
<b>HREC approval letter/s</b> <ul style="list-style-type: none"> <li>- The Mater site should be listed as Mater Misericordiae Ltd</li> <li>- All approval letters should be included (initial approval and any subsequent amendment approvals)</li> <li>- If a waiver of consent is approved, Mater requires evidence that s95A of the Privacy Act was considered</li> </ul>	<input type="checkbox"/>
<b>Protocol</b>	<input type="checkbox"/>
<b>Master PICF (for multi-site projects)</b>	<input type="checkbox"/>
<b>Mater site PICF</b> <ul style="list-style-type: none"> <li>- 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. <i>Mater PICF Version 1 dated 20 Feb 2024; based on Master PICF Version 1 dated 11 Jan 2024</i></li> <li>- Where relevant, include the Mater Research logo on the front page</li> <li>- Mater institution should be referred to as Mater Misericordiae Limited and/or the correct Mater hospital/location name/s</li> <li>- For projects approved by an external HREC, include contact details for Mater RGO - Research Governance Officer, Ph: 07 3163 3769, Email: <a href="mailto:research.governance@mater.uq.edu.au">research.governance@mater.uq.edu.au</a></li> <li>- For multi-site projects, site-specific PICFs must be tracked from the Master PICFs and a tracked and clean version provided</li> </ul>	<input type="checkbox"/>
<b>All HREC approved documents</b> All current documents: documents that have been superseded prior to SSA submission do not need to be submitted.	<input type="checkbox"/>
<b>Budget</b> Actual funding and in-kind support must be detailed, either within the SSA form or as an attached document.	<input type="checkbox"/>
<b>Other – submit if applicable to your project</b>	
<b>CTN</b> <ul style="list-style-type: none"> <li>- If externally sponsored, provide the draft/submitted CTN including Mater approving authority details. The TGA-acknowledged CTN will be required prior to authorisation.</li> <li>- If Mater sponsored, Mater RGO will submit the CTN to TGA, in consultation with the research team.</li> </ul>	<input type="checkbox"/>
<b>Early Phase Clinical Trials Risk Assessment endorsement letter</b> 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.	<input type="checkbox"/>
<b>Drug/Device Information/ Investigator's Brochure</b>	<input type="checkbox"/>
<b>Quotes and/or Service Agreements</b> Including internal services (e.g. Mater Pharmacy, Mater Pathology) and external service providers	<input type="checkbox"/>
<b>Radiation Safety Report</b>	<input type="checkbox"/>
<b>Biosafety approval and OGTR approval</b>	<input type="checkbox"/>
<b>QCAT approval letter</b>	<input type="checkbox"/>

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