

Mater Priority Trial Reviews - Submission Checklist

The following checklist is provided to assist with your submission. All items are required for authorisation, however, Items **highlighted** are **mandatory** for initial review to commence.

HREC approval for the Mater site is a prerequisite for submissions using the Mater Priority Trial Reviews service.

CHECKLIST	Yes	Pending	N/A
Site-specific Assessment (SSA)			
✓ Completed SSA Form			
✓ Protocol			
✓ Completed Patient Health Information Request Form			
✓ Master PICF			
✓ Mater site-specific PICF (tracked and clean)			
✓ Draft/submitted CTN (including Mater approving authority details)			
✓ HREC approval letter (listing Mater Misericordiae Ltd)			
✓ All HREC approved documents			
✓ Early Phase Committee approval letter if Phase 1 or 2a study			
✓ Drug/Device information			
✓ Radiation Safety Report (if applicable)			
✓ Biosafety approval and OGTR approval (if applicable)			
✓ QCAT approval letter (if applicable)			
✓ Investigator's Brochure			
✓ Copy of TGA acknowledgement of Sponsor CTN application			
✓ Clinical Trials Registry Number			
Research Agreements			
✓ Draft Clinical Trial Research Agreement (CTRA) provided by Sponsor			
✓ Draft Medicines Australia Standard Indemnity Form			
✓ Protocol (latest approved version)			
✓ Insurance/ Certificate of Currency			
✓ PICF's (if available)			
✓ Budget detail entered into Schedule 2 (if available)			

For queries, please contact:

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Mater Research Agreements Office

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