Mater Priority Trial Reviews

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1. Information

Mater Research is pleased to offer a fee-for-service Research Governance and Agreements express review model to expedite initial site authorisation or review of post-authorisation amendments for clinical trials conducted under a Clinical Trial Research Agreement (CTRA) only. This service is not applicable to non-clinical trial research.

Key features of the model include:

- ✓ Initial Research Governance and Agreements review within 5 business days of submission
- ✓ Dedicated Primary Research Governance and Agreements Officers for the review
- ✓ Parallel review by Research Governance and Agreements

GOAL: complete review and authorisation process to allow authorisation within 2-4 weeks of submission.

This process outlines both Research Governance and CTRA reviews for eligible clinical trials. In some instances, CTRA review may commence prior to submission of a SSA or amendment under the Mater Priority Trial Review service.

MATER PRIORITY TRIAL REVIEWS - FEES

SSA - First in human/Phase 1 clinical trial	$10,000 + GST
SSA - all other trials	$9,000 + GST
Major Amendment	$1,150 + GST
Minor Amendment	$350 + GST

2. Workflow

Research Team	Research Governance/Research Agreements
START	
❶ **SSA Submission** *Submit the SSA in ERM, ensuring **you select the option to request review under the Mater Priority Trials Review service, and include** all required documents in **accordance** with the Mater Priority Trial Reviews Submission Checklist.*	
	❷ **Pre-review** *Discussion of application to determine eligibility and identify primary reviewers for eligible applications.* ***NOTE:** Research Governance and Research Agreements reserve the right to accept or decline applications for Priority Review. If declined, a written explanation will be provided.*
	❸ **Outcome of pre-review** *Notification of acceptance or non-acceptance will be sent to the research team within 2 business days of submission.*
	❹ **Initial Review** • *Research Governance – Initial feedback/queries issued within 5 business days of acceptance* • *Agreement – Initial feedback/queries issued within 5 business days of acceptance*
❺ **Response to queries** *Respond to all queries as completely and promptly as possible*	
	❻ **Subsequent Reviews** *Review of resubmissions and provision of responses within 2–5 business days, depending on complexity and quality*
Steps ❺ and ❻ will repeat as required until all requirements are met.	
FINISH	
Site authorisation within 2-4 weeks of submission. This is subject to adherence to internal review timeframes and the absence of external delays (e.g. sponsor/research team responses, contract negotiations, or incomplete documentation).	

3. Submission Checklist

All items on the submission checklist are required for application authorisation. Additional requirements may be identified and communicated during the review process. Items **highlighted** on the checklist must be provided before the initial review can begin.

CHECKLIST	Yes	Pending	N/A
SSA – all trials			
✓ **SSA Form including all relevant approvals**			
✓ **Protocol**			
✓ **Master PICF - clean**			
✓ **Mater site-specific PICF - tracked and clean**			
✓ **Draft/submitted CTN with correct Mater site and Approving Authority**			
✓ **All HREC approval letters (including approval of Mater Misericordiae Ltd)**			
✓ **All HREC approved documents**			
SSA – if applicable			
✓ **Drug/Device information**			
✓ **Mater site-specific Radiation Safety Report**			
✓ **Institutional Biosafety Committee (IBC) approval and OGTR approval**			
✓ **QCAT approval letter**			
If not already provided to Research Agreements			
✓ **Draft Clinical Trial Research Agreement (CTRA) provided by Sponsor**			
✓ **Draft Medicines Australia Standard Indemnity Form**			
✓ **Insurance/ Certificate of Currency (clinical trial and public/product)**			
✓ **Quotes for external service providers**			
✓ TGA Acknowledged CTN with correct Mater site and Approving Authority			
✓ Clinical Trials Registry Number			