Pathology Clinical Trial & Research Overview

Austin HEALTH | Pathology

This document is intended to act as your guide when conducting a research project utilising services provided by Austin Health Pathology. This document outlines major phases of the research pathway as they relate to pathology and describes the roles of the research unit and pathology at each phase.

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	Feasibility	HREC/SSA/RGO Application	Activation (Recruitment)	Project/ Trial	Project Closure
RESEARCH UNIT	During feasibility, the research unit should engage with pathology to determine capacity to perform trial related services. The research unit may provide draft documents for review, however these may not always be available and therefore are not essential for feasibility review.	During this stage of the process the research unit will: • Engage with pathology to determine costs for services and official approval. • Supply the most up to date protocol, and laboratory manual (if applicable). • Outline required services from Austin Pathology and what services will be conducted by their team to ensure clarity of service provision.	When the research unit is ready to recruit for the project, they **must notify pathology 14 days in advance** to organise template request forms. A good time to notify pathology of intention to recruit, is upon booking and confirmation of the Site Initiation Visit (SIV).	During the project, the research unit must notify pathology of specific issues relating to pathology including but not limited to: test ordering, invoicing, and protocol amendments affecting the pathology research agreement. **Any correspondence should be identified by supplying the identifier CTX-1234, provided upon activation.**	The research unit is required to notify pathology of 'Last Patient, Last Visit' (i.e. when no further pathology services will be requested).
AUSTIN HEALTH PATHOLOGY	During feasibility review, Pathology can provide costs in the form of a 'quotation' for use within CTRA/RCA negotiations. This quote can be retained for later review by pathology which in turn may expedite Site Specific Authorisation (SSA)/RGO approval.	Pathology will: • Organise a project specific agreement outlining what tests and/or services will be conducted for the project. • Return the agreement to the research unit to support their RGO/SSA submission. This document acts as the 'master' document for pathology in relation to the research project and acts both as a 'research agreement' for the units, and a pathology guide for how the project will be facilitated within Austin Health Pathology. • Facilitate signing of the agreement by all parties upon mutual acceptance. At this stage the project will be known by its submission ID (depending on where it is submitted - eg. Research Architect, Pathology Trials Jira Portal etc).	Pathology will: • Assign a dedicated identifier to the research project as: CTX - 1234. Where X is the sites identifier assigned by pathology and 1234 is the next trial number in sequence. • Create request form/s specific to the research project, to ensure laboratory episodes are identified as being part of the project and compliant with protocol requirements. • Configure the Laboratory Information System (LIS) to ensure episodes are assigned to the correct project and invoices are addressed to the right party. • Establish an electronic site file for pathology specific documentation.	Pathology will: • Troubleshoot and resolve any issues raised by the research unit. • Audit episodes to ensure compliance with the established agreement. • Organise regular invoicing, for external research units or receipts for those who utilise internal funds transfers.	Pathology will: • ensure final episodes are correct and any outstanding invoices are sent and paid. • Archive the electronic site file within pathology • Deactivate the project specific coding in the LIS.

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