

Memorandum

To:	All Clinical Trial Coordinators/ Researchers/ Principal Investigators		
CC:			
From:	Prof. Beena Kumar	Sender Fax No: Tel. No:	(03) 9594 6502 (03) 9594 3459
Department : Monash Health Pathology Date :		Date:	13 Oct 2025
Subject:	Pathology Testing for Clinical Trial Participants		

Dear Colleagues,

Please be advised that effective from 01 Nov 2025:

- 1. Any pathology tests requested for participants enrolled in a clinical trial are now considered above Standard of Care (SOC), as the frequency of tests done in patients enrolled into clinical trials is more than what would be done in a patient as part of routine management.
- 2. All pathology requests for clinical trial participants must include a pathology referral form with the trial sticker/details.
- 3. The trial sponsor or relevant cost centre is responsible for covering the cost of all pathology tests requested for clinical trials participants.
- 4. A price adjustment for laboratory tests is being implemented, as fees have not been reviewed for an extended period. Details will follow shortly.

Please note: Pathologists provide clinical input as to the clinical teams as in-kind contributions to support clinical trials as an additional service. These contributions are voluntary and are not built into standard test pricing for clinical trials.

We appreciate your cooperation in ensuring that clinical trial pathology requests are processed according to these updated guidelines. This approach helps maintain clarity, transparency, and compliance with regulatory requirements.

Any question regarding this variation can be directed to: <u>Sasika.Somaweera@monashhealth.org</u>, Sasika Somaweera, Clinical Trials and Research Manager, Monash Health.

Thank you for your attention and support.

Beena Kumar

Program Director

Monash Health Pathology