

Memorandum

To:	Monash Health Researchers	
CC:	A/Prof Anjali Dhulia, Chief Medical Officer Prof Bill Sievert, Director Clinical Research	
From:	Deborah Dell, Director Research Operations	Sender Tel No: 9594 4605
Department:	Research Support Services	Date: 21 December 2021
Subject:	Monash Health Human Research Ethics & Governance Fee Schedule	

Monash Health is committed to maintaining its high standing with respect to the review of Human Research Ethics proposals and management of research governance matters. This has been recognised at both the state and national levels. Monash Health holds certification of multi-centre review with both the NHMRC through the Harmonisation of Multi-Site Ethical Review (HoMER) Initiative and the National Mutual Acceptance Scheme.

The current fee schedule has been in place since January 2019 and in order to facilitate ethics and governance review of investigator-initiated research, collaborative research and commercially sponsored research, a revised fee structure will take effect from 01 February 2022.

Overall, there are no changes to the submission fees for new studies except for external studies where Monash Health is providing Human Research Ethics Review. The main changes reflect the growing complexity and workload associated with post-approval items.

The changes are:

- The post approval Human Research Ethics & Governance fee for protocol amendments will increase from \$715 (including GST) to \$880 (including GST). The fee for of \$220 (including GST) for revised IBs and administrative changes will remain unchanged.
- The post-approval governance fee for protocol amendments will increase from \$220 (including GST) to \$440 (including GST). The fee for of \$220 (including GST) for revised IBs and administrative changes will remain unchanged.
- If a Clinical Trial Research Agreement is modified due to a request from the sponsor for commercially sponsored studies. e.g. change in study budget, change of address of the sponsor this will incur a fee of \$110 (including GST).
- For external studies (non-clinical trial) being conducted by a non-profit organisation, where Monash Health is being requested to provide Human Research Ethics review, the fee will increase from \$330 (including GST) to \$550 (including GST).
- For external practitioners requesting the Monash Health Human Research Ethics Committee endorsement of Authorised Prescriber Applications, a fee of \$110 (including GST) will apply.
- For Collaborative Group and Investigator-initiated studies, where sites are being added to the HREC post approval a fee of \$110 per (including GST) will apply.

In the event that a researcher is submitting a multicentre study for both HREC and governance approval at Monash Health, a HREC review fee will be charged but no governance fee will apply.

Memorandum

Human Research Ethics & Governance Fees

Bold and Italics denotes changes that come into effect from 01 February 2022

Ethics/Governance New Research Project Fee for:	Amount incl. GST
Commercially Sponsored study- Phase I single site study	\$7700
Commercially Sponsored study- Phase I multiple site study (+ charge per site)	\$7700
Commercially Sponsored study- single site study	\$6600
Commercially Sponsored study- multiple site study (+ charge per site)	\$6600
Commercially Sponsored study Number of additional sites:	\$550 per site
Commercially Sponsored - Sub studies	\$3300
Non-commercial external sponsor- e.g. collaborative group studies	\$605
External studies (non-clinical trials) for profit entity	\$605
<i>External studies (non-clinical trials) not for profit entity</i>	<i>\$550</i>
In-house studies (including clinical research studies, low risk research studies conducted by Monash Health staff, which are funded)	\$220
Ethics/Governance Post Approval Fees for:	Amount incl. GST
<i>HREC & Gov review of Protocol amendments and changes to Participant information and Consent Form as part of the protocol amendment – commercially sponsored studies.</i>	<i>\$880</i>
<i>Gov review only of Protocol amendments and changes to Participant information and Consent Form as part of the protocol amendment – commercially sponsored studies.</i>	<i>\$440</i>
HREC & Gov review of Admin changes, updated IB, addition of investigator only, updated Participant Information and Consent Form – commercially sponsored studies.	\$220
Gov review only of Admin changes, updated IB, addition of investigator only, updated Participant Information and Consent Form – commercially sponsored studies.	\$220
Addition of a site to an existing commercially sponsored study (charge per additional site) – commercially sponsored studies.	\$550
<i>Addition of a site to collaborative/investigator-initiated study following HREC approval (charge per additional site)</i>	<i>\$110</i>
Post Approval amendments to collaborative group, investigator driven studies and external studies for not-for-profit entities.	No fee
<i>External Practitioner requests for HREC Endorsement of Authorised Prescriber</i>	<i>\$110</i>
<i>Changes to the Clinical Trial Research Agreement initiated by the Commercial sponsor</i>	<i>\$110</i>

PLEASE NOTE THAT THESE FEES ARE CUMULATIVE:

Example: The fee for submitting a multi-site commercially sponsored trial with 2 sites will be \$6,600 for the ethics/governance review + 1 x \$550 per extra site to give a total fee of \$7,150 inc GST. Please note that each study will only be charged once. A study will be charged for either for the ethics submission or governance submission.

Payment Methods

Fees are payable in FULL at the time of the initial submission of a project or amendment and are non-refundable. All payments that are submitted to Research Support Services must be completed using the New Fee Form or Amendment Fee Form.

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Dandenong Hospital
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Dandenong
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Casey Hospital
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Berwick
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**Community-based
services across
the South East**