UNIVERSITI MALAYA | PUSAT PERUBATAN *Medical Centre*

MEDICAL RESEARCH ETHICS COMMITTEE

I-RESEARCH ONLINE APPLICATION CHARGES GUIDELINES:

SCHEDULE OF PAYMENT CHARGES

No.	Type of application	Review charges
1.	New application: a. Industry-sponsored clinical trial b. Investigator-initiated clinical trial: • Studies that involve evaluation of interventions, procedures and diagnosticswith patients • Medical Officer, postgraduate students and UMMC/FOM staff c. Non-clinical trial d. Revision (Each round. Refer item no 4 and 5)	 RM 2000.00 RM 300.00 RM 100.00 RM 20.00
2.	Amendment to approved protocol: a. Industry-sponsored clinical trial b. Investigator-initiated clinical trial: • Studies that involve evaluation of interventions, procedures and diagnosticswith patients • Medical Officer, postgraduate students and UMMC/FOM staff c. Non-clinical trial d. Revision (Each round. Refer item no 4 and 5)	 RM 200.00 RM 100.00 RM 50.00 RM 20.00

1. It is the responsibility of the applicant to ensure that his/her application is correctly categorized according to the schedule above during the application.

2. Payment must be made prior to the final submission of each application, whether it is a new application or an amendment to an approved protocol.

3. Payment will be charged per submission, not per document, submitted for review.

4. Revision to an application in response to advice by the Secretariat will not be charged.

5. Revision to an application required by the Chair/Deputy Chair upon expedited review, or required after an MREC meeting will be charged.

6. No charges will be incurred for correction to an approval/notification letter.

7. Payment shall be made to UMMC and shall be placed under the MREC Fund.

8. Payment must be made via Credit Card or Electronic Fund Transfer (EFT). Any other mode of payment not indicated in the system will not be accepted.

9. In the event that an overpayment is made against the stated charges, the credit balance is not refundable.

10. No refund will be made for a withdrawn or rejected application.

11. The applicant is advised to retain receipts of payment for their record and for reimbursement from their research grants or research sponsors, whichever the case may be.

12. Please quote the MREC ID No. for future reference and correspondence.

13. If there is any technical error due to the system or the payment is not successful, please contact/e-mail:

    Nor 'Alia Ramlan (noraliaramlan@ummc.edu.my)
    UMMC Department of Information Technology
    603-79494939

14. Please refer **below** for a list of chargeable and non-chargeable documents for review.

Documents for MREC approval (Chargeable):

Study/trial protocol amendment
Revision/Addendum to informed consent form
Revision/Addendum to patient information sheet
Translation of ICF and PIS (Malay, Simplified Chinese, Tamil) including translation certificate
Update/Addendum to investigator brochure
Memo to investigator brochure
Additional of new sub-investigator
Changing of Principal Investigator
Insurance certificate including updates/renewal
Application for study extension
Patient retention items/materials
Patient diary card
Subject recruitment poster
Poster advertisement
Application for additional site for recruitment
Change of study title
Recruitment poster
Updated objective of the study
Revision/update of questionnaire
Increasing enrolment target
Extension of recruitment period
Subject medication tracker
Patient re-consenting
Request for patient reimbursement fee
Patient brochure & reminder card

Documents for notification to MREC (non-chargeable)

Clinical study report synopsis
Suspected unexpected serious adverse reaction (SUSAR) Report
Data and Safety Monitoring Board (DSMB) letter
Study site closure report
Interim study progress report
Annual study report
Study closure report
Serious Adverse Event (SAE) Report
Letter of study termination
Transfer of study sponsorship
End of study report
Independent Data Monitoring Committee (IDMC) letter
IDMC meeting decision
Case report form/Update case report form
Protocol deviation notification/report
Protocol violation notification/report
Local serious adverse event report
Discontinuation of recruitment
Data Monitoring Committee (DMC) Letter
Removal of sub-investigator
Investigator safety report
Development safety updated report (DSUR) line listing
Council for International Organizations of Medical Sciences (CIOMS) letter notifications
Notification of Local Sponsor Office Address
Protocol administrative letter
Important Information about SUA reports
Notification of Accidental Unblinding Issue
Notification of Local Sponsor Office Address
Development Safety Update Report (DSUR) line listing
Termination of sub-investigator
Semi-annually safety report
Study poster
Patient identification card
Protocol non-compliance
Notification of patient consent withdrawal
Patient eligibility form
Study participants communication letter
Notification on sample size re-estimation

Effective date: 1 March 2025