



Date:		Principal Investigator:	
Barwon Health Study No:		Project/Protocol No:	
Sponsor Name:		Sponsor ABN:	
Sponsor Address			
Sponsor Email:			
Project Title:			

Amendments – Ethics and/or Governance

Please note: Fees are cumulative and due on submission.

Select all applicable amendment types submitted as part of this review

Select option/s	Amendment Type	\$ Amount (ex GST)	\$ Amount (inc GST)
Commercial sponsored studies for HREC and/or Governance Review			
	Major Amendment (see overleaf for definition)	600	660
	Protocol Amendment only	600	660
	New/amended Patient Information & Consent Form (PICF) and/or patient-facing documents only	200	220
	Change to the Barwon Health Principal Investigator	200	220
	Administrative amendment (see overleaf for definition)	200	220
	Updated Investigator Brochure	200	220
Investigator-Initiated project with commercial support			
	Major Amendment (see overleaf for definition)	200	220
	Minor Amendment	100	110
Investigator-Initiated project with no commercial support			
	All Amendments (see overleaf for definition)	Nil	Nil

TOTAL FEE	\$
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Payment Methods – kindly send payment on submission

Option 1: Internal cost centre transfer (GST not applicable)

Cost centre no.	Cost centre manager	Cost centre manager signature	Amount excludes GST
			\$

Option 2: Bank Deposit / EFT Amount includes GST Email remittance to REGI@barwonhealth.org.au

Date of Transaction:	Transaction Number Details:	Payee Name (e.g. Company Name)	Amount includes GST
			\$

Barwon Health Bank Deposit / EFT Details

Bank & Branch	National Australia Bank, 49 Malop Street, Geelong 3220
BSB	083 646
Account	515 794 188
SWIFT/IBAN	NATAAU3303M
Reference	Use Barwon Health Study Number

Please email a copy of this form and your Remittance Advice to REGI@barwonhealth.org.au

All fees are payable upon submission from 1 July 2021. Once payment is made the submission will be allocated for review.

Queries can be emailed to REGI@barwonhealth.org.au

Internal Use only: Cost centre – P0904 Account Code - 58101

Fee structure

- The fees charged represent only partial recovery of the total cost of providing ethical and governance oversight. Fees have been set based on the total (human and other) resources required to review a new research project upon submission and then to monitor and manage it over its lifetime.
- Fees are payable at the time of submission.
- **Fees are cumulative:** For example if a submission received for a commercially sponsored project includes an updated Protocol (\$660 incl. GST) and Investigator Brochure (\$220 incl. GST) the total fee payable will be \$880 (incl. GST).

Definition of Amendment Type

Major Amendment	<ul style="list-style-type: none"> » Protocol amendment associated with an amended or new Participant Information and Consent Form/s (PICF); and/or » New PICF (including PICF addendums); and/or » Protocol amendment associated with patient-facing document changes; and (if applicable) Agreement amendment / New agreement (If only submitting an agreement amendment, please submit as an <i>Administrative Amendment</i>)
Minor Amendment:	<ul style="list-style-type: none"> » Amended PICF only and/or other new patient-facing docs (excluding new PICF) only; and/or » Change of Principal Investigator/ Coordinating Principal Investigator; and/or » Removal of a site
Administrative Amendment:	Minor updates to existing patient-facing documents, protocol clarification letters, advertising material, agreement amendment, single-word changes, etc.

REGI / Finance Service Use Only

Form received date..... Sent to Sundry Debtors date.....

Form processed date.....

Project entered into REGI REDA/ERM

Form from 1/7/2021