FORM		
	Document Description	Version No.
RGO-FORM	**ETHICS AMENDMENT OR RENEWAL REQUEST**	**1.0**

HREC reference number	
HREC approval date	
Date of this report	
Research Title	
Sponsor	
Principal Investigator	

Amended Documents:

Document Title	Document Version	Document Date

Description of Amendments:

Declaration from Principal Investigator

The information provided is complete and correct.

I agree to conduct this clinical investigation in accordance with the design and specific provisions of this clinical investigation plan; modifications to the clinical investigation are only acceptable with a mutually agreed upon clinical investigation plan amendment as approved by the Sponsor and involved Ethics Committee(s).

I agree to await Ethics Committee approval of the clinical investigation plan and informed consent form before initiating the clinical investigation, to obtain consent from participants prior to their enrolment, to collect and record data as required by the clinical investigation plan and associated Case Report Forms, and to maintain documents related to the clinical investigation for the period required.

The product is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2023) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NMHRC, 2016).

Name	
Organisation	
Email	
Telephone	
Signature	
Date	