



Human Research Ethics Committee (HREC)
Summary Sheet for an Amendment to an Approved Protocol (or updated Investigator's Brochure)

INSTRUCTIONS

Return this form and supporting documents with 2 complete copies to:
Ethics & Research Governance Office, Locked Bag 7017, LIVERPOOL BC, NSW, 1871

- All sections of this form must be completed; incomplete submissions will be returned.
- Provide all amended documents in both tracked changes format and a clean copy.
- Include the version number, date and page number (e.g. Page 1 of 2) in the footer of all documents.

<i>Project Title & No.</i>	
<i>HREC reference No.</i>	
<i>Name of Principal Investigator & contact details</i>	

- You are reminded that the proposed amendment can not be implemented without the prior written approval of the HREC.

1. Documents

Please list the documents (and their version number) you are submitting.

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2. Description of the amendment

Please attach separate summary page if the space provided is insufficient

3. Reason for the amendment

4. What are the ethical implications of the amendment?

5. Are there any therapeutic, efficacy or safety issues related to this Amendment?

6. Does this amendment require changes to the Patient Information Sheet and Consent Form(s)?

Yes No

*If Yes, please submit the revised documents as listed at Q1 above , which include a revised version number and date with changes: underlined and in **bold**.*

7. Additional Documentation

Please list any additional documentation that you may have attached.

8. Does the amendment require changes to the

Clinical Trial Agreement? Yes No N/A

Clinical Trial Notification Scheme form? Yes No N/A

9. Is this project sponsored?

Yes No

If Yes, please provide Invoicing details

DECLARATION

I agree that the above information is accurate, and that the project will continue in accordance with the original HREC approved protocol and any approved amendments.

.....
Signature of Chief Investigator

...../...../.....
Date

***Please attach any relevant correspondence to this sheet.
Please supply 2 copies of all documentation.***