

Application Form for an Amendment to an Approved Research Project

Please submit a clean version of the amendment document with either:

- Summary of changes listed; or
- Tracked changes version of the amended document/s.

Note: Requests for *scientific/ethical* review and approval of amendments must only be submitted to the HREC that approved the study. You are reminded that the proposed amendment must not be implemented without prior written approval from both the HREC and local Research Governance Officer (for studies reviewed after 1 July 2007).

- Research Proposal Number :
- Coordinating / Principal Investigator:
- Study Title:
- Multi-site (within NSW Health): Yes / No
If yes list sites approved by Royal Rehab HREC:
- Is this study Industry sponsored: Yes / No
Protocol Amendment and/or Investigator Brochure Update –
Please complete Ethics/Research Governance Fee Payment Form and attach cheque or payment advice for \$550 for each document (only if industry sponsored).

If the Protocol Amendment is a Sub-study (contact Ethics/Research Office for advice), please complete Ethics/Research Governance Fee Payment Form and attach cheque or payment advice for \$1665(only if industry sponsored)

1. Description of amendment

(Examples of types of amendments: Protocol amendment, Investigator Brochure Update, Participant Information Sheet and Consent Form changes, or change to other study documentation/study conduct)

2. Reason for requesting amendment

3. What are the ethical implications of the amendment?

4. Does this amendment require changes to the:

- **Clinical Trial Agreement:** **Yes / No / NA**
- **Clinical Trial Notification Scheme form:** **Yes / No / NA**

5. Are any changes to the Patient Information Sheet and Consent Form?

Yes No

If yes, please attached the revised documents which include a revised version number and date

6. Additional Documentation

Please list any additional documentation including version and dates that you may have attached.

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.

For projects reviewed by the HREC after 1 July 2007 a copy of the amendment approval letter must be forwarded to all Principal Investigators at every site conducting the project for submission along with a copy of the approved documents to the relevant Research Governance Officer.

Signature of Coordinating/Principal Investigator/Co Investigator

Date