

HUMAN RESEARCH ETHICS COMMITTEE

Annual/Final Report Form

Project No: **Chief Investigator:**

Title:

Date of Approval: **Date of this Report:**

Expiry Date of Project Approval:

[Researchers are reminded that a written request for an extension is necessary where the project is expected to extend beyond the initial/ extended period of approval. An explanation for the required extension and the expected date of completion, are to be included in the request for extension.]

1. Status of the project (please tick)

- Completed ⇒ Completion Date ___/___/___
- In progress
- Abandoned ⇒ Reason: _____
- Not Commenced ⇒ Reason: _____

2. Recruitment of subjects

- No. of subjects recruited: _____
- No. currently participating: _____
- No. of subjects who have dropped out: _____
- Reason: _____
- Have any complaints been received from any of your participants? Yes No

3. Compliance

- Have you complied with the conditions of ethical approval, including security of records, procedures for consent, approved protocol and any conditions of approval? Yes No
- (If **no**, please explain) _____
- _____
- _____

4. Adverse events

- Have there been any adverse events of the project on subjects? Yes No
(If **yes**, what steps have been taken to deal with this?)
- _____
- _____
- Have any of these events occurred within RRCS? Yes No
- Have all these adverse events been reported to the RRCS HREC? Yes No

5. Changes in research protocol

- Have there been any substantial changes in the research protocol? Yes No
(If **yes**, what are the changes and what are the ethical implications of the changes?)
- _____
- _____

Were these changes reported to the RRCS HREC? Yes No

6. Unforeseen events

Were there any unforeseen events that you believe the RRCS HREC should be made aware of? Yes No
(If **yes**, please attach details of these events)

7. Publications

Have any abstracts of publications been accepted as a result of this research? If they have, please list and/ or attach. Yes No

8. Patient information sheet and consent form

Have there been any changes to the patient information sheet or consent form since the protocol was approved? If so, please attach a copy. Yes No

9. Attachments

Please attach any necessary documentation.

10. Please provide a brief paragraph outlining your results/ progress to date:

Please return to: Secretary, RRCS Ethics Committee, PO Box 6 Ryde NSW 1680.

The information I have given above is true and my research had not contravened either the NHMRC Statement on Human Experimentation or the privacy principles (as outlined in the guidelines). I have respected the personality, rights, beliefs, consent and freedom of the individual subject in the conduct of my research.

Chief Investigator's Signature: _____ Date: _____

Co-Investigator's Signature: _____ Date: _____

It is my belief that the protocol, with any amendments approved by the RRCS HREC, are being adhered to by all staff involved in this study.

Chief Investigator's Signature: _____ Date: _____