



FAMILY PLANNING VICTORIA

FAMILY PLANNING VICTORIA HUMAN RESEARCH ETHICS COMMITTEE

ADVERSE EVENT REPORT

Date of report:	Date of Adverse Event:
FPV HREC Project No. and title:	
Principal Investigator:	
Contact telephone No:	E-mail:
1. Provide details of the adverse event (<i>attach separate page if required</i>).	
2. How does the adverse event relate to the project:	
<input type="checkbox"/> Unrelated <input type="checkbox"/> Possibly related <input type="checkbox"/> Probably related <input type="checkbox"/> Definitely related	
3. How does the adverse event affect research participants and/or the project?	
4. What ethical issues are raised by the occurrence of this adverse event?	

5. Will any amendments to any documents approved by FPV HREC be required as a result of this adverse event?

Yes (provide details. Note: you may be required to apply for Approval of Amendments) No

6. Provide details of any remedial action already undertaken (when, what, who).

ACTION RECOMMENDED BY PRINCIPAL RESEARCHER

I have considered the information and circumstances regarding this adverse event and recommend the following action:

- | | |
|---|----------|
| • Protocol be amended | Yes / No |
| • Participant Information & Consent Form be amended | Yes / No |
| • Participants be notified | Yes / No |
| • Study be stopped | Yes / No |
| • No action | Yes / No |

Principal researcher's comments on action recommended:

Principal Investigator's Signature:

Date:

COMMITTEE USE ONLY:

Action recommended by FPV HREC

- Changes to protocol.....Y / N
- Changes to Participant Information & Consent Form.....Y / N
- Notify participants.....Y / N
- Suspend studyY / N
- Stop study.....Y / N
- No action required.....Y / N

Date FPV HREC was first advised of adverse event:

...../...../.....

- phone
- email
- letter
- person

Received by :