SOP 1: Concerns or complaints about the conduct of a research project

University of New South Wales Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 010 Date: February 18, 2010

Subject: Concerns or complaints about the conduct of a research project

Purpose: To describe the mechanism for receiving, handling and responding to concerns or complaints about the conduct of a project approved by the HREC

The National Statement specifies that “An institution or organisation with an HREC will establish mechanisms for receiving and promptly handling complaints or concerns about the conduct of an approved research project.” The following procedures apply in order to deal with concerns or complaints about the nature or conduct of research, and are formulated to be consistent with the University Research Code of Conduct (see http://www.gs.unsw.edu.au/policy/documents/researchcode.pdf)

1. The HREC will nominate the Ethics Secretariat as the venue to which concerns/complaints from research participants, researchers, or other interested persons about the conduct of approved research projects, should be made in the first instance. The contact details of the person nominated by the HREC to receive concerns/complaints must be included in the Participant Information Sheet and/or Consent Form for each project. Members of UNSW who have concerns about possible research misconduct can obtain advice from the office of the Deputy Vice Chancellor (Research).

2. Any possible breach of the UNSW Research Code of Conduct is to be referred immediately by the Presiding Member to the Deputy Vice Chancellor (Research), for resolution as dictated by the Code.

3. The following points relate to concerns/complaints where there is no possible breach of the UNSW Research Code of Conduct.

4. Any other concern or complaint received by the Ethics Secretariat about the conduct of a research project approved by the HREC should be directed to the attention of the Executive Officer, who will record details in the Complaints Log (Attachment 13). The Executive Officer or nominee is responsible for obtaining, either verbally or in writing, the grounds of the concern/complaint and will notify the Presiding Members immediately after a concern/complaint is received. If the complainant provides consent, their contact details are to be recorded in the Project File so that the outcome of the investigation can be reported to the complainant.

5. The Presiding Member(s) will review the concern/complaint and its validity, and make a recommendation to the Executive of the HREC on the
appropriate course of action. This initial review will take no longer than two weeks from the time of notification of the concern/complaint, unless exceptional circumstances exist, and will include a full written explanation of the circumstances surrounding the concern/complaint solicited from the chief investigator of the project. If the concern/complaint is substantiated, the ensuing actions may include:

- a requirement for amendments to the project, including changes to the Participant Information Statement or increased monitoring by the HREC;
- temporary suspension of the project, pending resolution of the concerns/complaints;
- termination of the conduct of the project;
- referral to the Deputy Vice Chancellor (Research) as a potential breach of the *UNSW Research Code of Conduct*;
- application of the UNSW Staff Complaint Procedure or the UNSW Student Complaint Procedure; or
- other action to resolve the concern/complaint.

6. The complainant will be informed by telephone or in writing of the outcome of the Presiding Member’s review. This communication will be recorded in the Complaints Log.

7. Concerns/complaints designated as serious by the Presiding Member(s), and the planned resolution, will also be referred immediately to the Deputy Vice-Chancellor (Research). Serious complaints include, but are not restricted to, those associated with: significant injury to a research participant or researcher; significant damage to property.

8. If the complainant is not satisfied with the outcome of the Presiding Member’s review, then he/she can refer the concern/complaint to the Deputy Vice-Chancellor (Research), or request the Presiding Member to do so.

9. Should this occur, the Presiding Member of the HREC will provide the Deputy Vice-Chancellor (Research) with all relevant information about the complaint/concern, including:
   a. the complaint;
   b. material reviewed in the Presiding Member’s review;
   c. the results of the Presiding Member’s review; and
   d. any other relevant documentation.

10. The Deputy Vice-Chancellor (Research) will consider the concern/complaint. Where no further investigation is deemed necessary, the Deputy Vice-Chancellor (Research) will inform the complainant and the Presiding Member of this. Alternatively, the Deputy Vice-Chancellor (Research) will notify the complainant and the Presiding Member of the outcome of any further investigation.