Standard Operating Procedures

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Standard Operating Procedure (SOP)

Title: Accepting and processing new applications for ethical review

Date: March 2015

Purpose: To describe the procedure for accepting and processing new applications.

1.1 Submission of new applications
- Upon submitting new applications by the relevant closing date and time (as advertised on the Human Ethics website), the HREC Secretariat will review the application for compliance and completeness per the submission requirements outlined on the UNSW Human Ethics website.
- Applications will only be accepted if completed using the UNSW Human Research Ethics Form, and all relevant study tools, recruitment materials and Participant Information Statement and Consent Forms are received.

1.2 Compliance check
- The HREC Secretariat will refer applications not meeting the minimum requirements to the HREC Executive.
- The HREC Executive will complete a review of these applications and decide whether it can be accepted onto the agenda.
- In circumstances where applications are not accepted onto the agenda, the researcher will be provided with recommendations to revise their project in order for it to be accepted onto the agenda.
- The applicant may request a phone or ace to face meeting with the HREC Executive to discuss their application.
- Depending on the nature of the changes, applicants may be asked to resubmit their application at the next available meeting date.

1.3 Allocation to HREC meeting agenda
- Applications that have met the submission requirements will be allocated to the agenda of the next available HREC meeting.
- Applicants will receive an acknowledgement email advising them of:
  (a) their project reference number;
  (b) the meeting date where their application will be reviewed;
  (c) when they can expect notification on the outcome of the review.
Standard Operating Procedure (SOP)

Title: SP0002: Preparation of agendas

Date: March 2015

Purpose: To describe the procedure and format of agendas for the HREC

2.1 Preparation of Agenda

- Upon receiving completed paperwork, the HREC Secretariat will prepare agendas for:
  
a. HREC Main Agenda
   (1) Attendance & apologies
   (2) Minutes of previous HREC Main Meeting & HREC Executive meetings;
   (3) Business arising from previous meetings;
   (4) Conflicts of interest;
   (5) HREC Training;
   (6) General Correspondence;
   (7) Adverse Incidents (including SAEs, protocol deviations & protocol violations);
   (8) Complaints;

b. HREC Committee A Agenda
   (1) Attendance & apologies
   (2) Minutes of previous Committee A meeting;
   (3) Business arising from previous meetings;
   (4) Conflicts of interest;
   (5) Deferred/rejected applications previously reviewed by this committee;
   (6) New applications;
   (7) Any other business;
   (8) Close and next meeting;

c. HREC Committee B Agenda
   (1) Attendance & apologies
   (2) Minutes of previous Committee B meeting;
   (3) Business arising from previous meetings;
   (4) Conflicts of interest;
   (5) Deferred/rejected applications previously reviewed by this committee;
   (6) New applications;
   (7) Any other business;
   (8) Close and next meeting;

d. HREC Executive Agenda
   (1) Attendance & apologies
   (2) Subject To - New Applications which have previously been reviewed by the HREC;
   (3) Modifications;
   (4) Adverse Incidents (including SAEs, protocol deviations & protocol violations);
   (5) General Correspondence;

2.2 Delivery of Agenda

- The HREC Secretariat will prepare the HREC Committee A, B and Main Agendas at least two weeks prior to the meeting date.
- The HREC Secretariat will prepare the HREC Executive Agenda on the submission date.
- Documentation received after the closing date will be included on the agenda at the next available meeting. The Presiding Chair can use their discretion to decide if a late agenda item can be added to the agenda or tabled at the meeting.
2.2 Confidentiality of Agendas
   • The agendas and all documentation will remain confidential;
3.1 HREC & HREC Executive Meetings
- The HREC will meet on a monthly basis, except in January. Meeting dates and agenda submission deadlines will be published on the Human Ethics website.
- The HREC Executive will meet weekly, except for the week of the HREC meeting.

3.2 Member Attendance
- Members are to attend HREC meetings in person. If they are unable to attend the meeting, in order to remain quorate they will be asked to provide written comments prior to the scheduled meeting or to dial in via teleconference.
- The Presiding Chair may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the HREC will convene within five working days from the date of the cancelled meeting.
- The HREC meetings will be conducted in private, to ensure confidentiality and open discussion.
- The Presiding Chair may agree to the presence of visitors or observers to a meeting. Visitors or observers will sign a confidentiality agreement and conflict of interest declaration prior to attending the meeting.
- A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum will exist when the following are present:
  a. 1 x Presiding Chair or Deputy Presiding Chair
  b. 1 x Layman
  c. 1 x Laywoman
  d. 2 x Researchers
  e. 1 x Lawyer
  f. 1 x Professional Care
  g. 1 x Pastoral Care
- The HREC will endeavor to reach a decision concerning the ethical acceptability of all applications by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. All minority views will be recorded in the minutes.
- The HREC may invite expert reviewers to the HREC meeting to discuss projects in their area of expertise.
- Any person who attends a HREC meeting who has any actual, potential or perceived interest, financial or otherwise, in a project or other related matter(s) considered by the HREC will declare their conflict of interest.
Standard Operating Procedure (SOP)

Title: SP0004: Preparation of minutes  
Date: March 2015

Purpose: To describe the process and format for taking minutes of meetings of the HREC

- The HREC Secretariat will prepare the minutes to be a true and accurate record of the meeting. The minutes will maintain a record of:
  a. Attendance and apologies;
  b. Absence of a quorum if relevant;
  c. Confirmation of minutes of previous meetings;
  d. Declarations of conflicts of interest relating to agenda items;
  e. Business arising since the previous meeting(s) that the HREC indicated it wished to reconsider;
  f. Minutes of meetings and any issues for noting and/or approved from the HREC Executive Committee, subcommittees and external expert reviewers;
  g. Reports of adverse incidences;
  h. HREC deliberations and decisions on new applications, whether in the main text of the minutes or in attachments;
    (1) Submission of written comments by members;
    (2) Summaries of the advice given by expert of primary spokesperson;
    (3) Summaries of main issues considered;
    (4) Decisions of the HREC on the applications;
    (5) Formal dissent from the decision of the HREC by a member and the reason for it and/or any significant minority views
  i. Correspondence;
  j. Other business;
  k. Close and next meeting details;

- The minutes should include the recording of decisions taken by the HREC or HREC Executive. A summary of relevant discussion may be included if requested by the Presiding Chair. This may include reference to views expressed by absent members or independent experts.

- In relation to the review of new applications or amendments, the minutes will record a summary of the main ethics issues considered, including any requests for additional information, clarification or modification of the project.

- In recording a decision made by the HREC, if a consensus cannot be reached, all minority views will be recorded in the minutes.

- To encourage free and open discussion and to emphasise the collegiate character of the HREC, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections are recorded.

- Declarations of conflicts of interest by any member of the HREC or by other interested parties, and the absence of the member concerned during the HREC consideration of the relevant application will be minuted.

- The minutes will be produced as soon as practicable following the relevant meeting. The minutes will first be checked by the Presiding Chair for accuracy. The DVC(R) or its delegate will provide final approval of the HREC’s recommendations. Once DVC(R) approval has been granted, letters to researchers will released. Verbal or written communication cannot be given until DVC(R) has been granted.

- Written correspondence will be signed off by the HREC Presiding Chair as delegated by the DVC(R).

- The minutes will be circulated to all members of the HREC as an agenda item for the next
meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be formally ratified at the next HREC meeting.

- The original copy of each meeting’s minutes will be retained in a confidential ‘Minutes’ file for a length of time as required by relevant UNSW policy and stat record keeping acts.
5.1 HREC Executive Membership
   • The HREC will establish an Executive, consisting of Presiding Chair (or in their absence the Deputy Presiding Chair).

5.2 HREC Executive Review of New Applications
   • Responses to projects marked as ‘subject to’ at the HREC meeting will be reviewed by the HREC Executive. If an adequate response has been received, the HREC Executive can provide approval for the project per the approval of the minutes as outlined in SDP0004.
   • The Executive cannot provide expedited review of new applications between scheduled HREC meetings.
   • Projects approved by the HREC of another institution which involve UNSW staff, students or facilities require notification to the UNSW HREC Executive. The original complete application, Lead HREC approval letter and UNSW noting cover sheet should be provided by the Chief Investigator. The HREC Executive will allocate a UNSW identifier and keep a registry of all projects approved by another HREC.
   • To facilitate the review of multi-Centre research the HREC Executive may:
     a. Communicate with any other HREC;
     b. Accept a scientific or technical assessment of research by another HREC;
     c. Accept the ethical assessment of another HREC;
     d. Share its scientific or technical assessment of the research with another HREC;
     e. Share its ethical assessment of the research with another HREC.

5.3 HREC Executive Review of Modifications and/or Correspondence
   • The HREC Executive will undertake review of requests for modification to an existing HREC approved project. All requests for modifications must outline the nature of the proposed changes, reason/s for the request and an assessment of any ethical implications arising from the modification.
   • All amended documents must have tracked changes, including the application form if applicable.
   • All modifications to approved research projects should be requested in writing by the Chief Investigator. Requests from researchers other than the Chief Investigator should include a copy of the correspondence to the Chief Investigator.

5.4 HREC Executive Review of Adverse Incidents
   • Adverse Incidents must be reported in writing by the Chief Investigator per the reporting requirements outlined in adverse incident SOP.
   • The HREC Executive will delegate the review of adverse incidents to a professional care member on the HREC Executive or relevant expert reviewer.
   • Once the delegated member has reviewed the adverse incident, the HREC Executive will provide final review at the next available HREC meeting.

5.5 HREC Executive Review of Complaints
   • The HREC Executive will review complaints per the HREC complaint process, and will endeavor to resolve the complaint in a timely manner.
   • Complaints will be minuted, and once resolved will be communicated at the next available HREC
meeting.

5.6 HREC Executive Minutes
- The HREC Executive Minutes will be written and approved per SOP0004.
- The minutes of the HREC Executive meetings will be tabled for ratification at the next available HREC meeting.
6.1 HREC Executive Minutes

- The HREC Executive Minutes will be written and approved per SOP0004.

- The HREC will establish a number of Human Research Ethics Advisory Panels (HREAPs). These will be discipline-based panels of researchers with a nominated convenor, as well as at least two additional members with expertise in the relevant discipline, and locally-based administrative support. HREAP will review low risk projects. Low risk research is where the only foreseeable risk is discomfort (National Statement on Ethical Conduct in Research, 2007 (revised 2014)).

- Low risk research may include, but is not limited to the following:
  - a. Questionnaires on non-controversial, non-personal issues;
  - b. Studies which do not involve an intervention that could result in significant harm to participants;
  - c. Studies which do not involve participants who are vulnerable;
  - d. Observational studies in public situations which focus on non-sensitive areas;
  - e. Studies of existing re-identifiable (coded) or non-identifiable data, documents, records, pathological or diagnostic specimens;
  - f. Collection of certain biological specimens, for example hair, nail clippings, or saliva.

- The HREAPs will have administrative support provided by Deans of Faculties or Heads of Schools/Centres as required to carry out their activities in a timely and efficient manner.

- Low risk research applications must be submitted on the approved paperwork to the HREAP Administrator, by the relevant submission deadline and application forms and templates published on the Human Ethics Website.

- HREAP approvals are valid for up to five years.

- Details about HREAP membership will be published on the Human Ethics Website.
7.1 New Applications Requiring Modifications and/or Clarifications

- The HREC at their meeting will determine if further information, clarification or modification is required for the project to meet the requirements of the National Statement and any other relevant UNSW, State or Federal guidelines and policies.
- At the meeting the HREC will assign one of the following decisions:
  a. **Recommended for approval** - no items for clarification, to be sent to the DVC(R) for final approval;
  b. **Subject to** - Outstanding items must be completed before approval can be given. Responses are reviewed by the HREC Executive. If the response is complete, it will then be sent to the DVC(R) for final approval;
  c. **Deferred** - Due to major ethical issues, the applicant must resubmit their revised application to meet the requirements of the National Statement and/or other relevant guidelines and legislation. Deferred applications must be resubmitted for review at the next HREC meeting;
  d. **Rejected** - The application does not meet the minimum requirements of the National Statement and/or the application did not contain the relevant detail in order for a full ethical review to be conducted.

- Whilst awaiting a response to correspondence requesting further information, clarification or modification of a project, no further consideration will be given to the application.
- The HREC will endeavor to communicate openly with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant or invite the applicant to attend the relevant HREC meeting.
- The Deputy Vice Chancellor (Research) (DVC(R)) delegates the authority to the Presiding Chair or Human Research Ethics Advisory Panel (HREAP) Convenor to sign the letters regarding the outcome of ethics review.

7.2 New Applications Approved

- After the DVC(R) has approved the HREC or HREC Executive minutes, an approval letter can be sent to the Chief Investigator.
- The Deputy Vice Chancellor (Research) (DVC(R)) delegates the authority to the Presiding Chair or Human Research Ethics Advisory Panel (HREAP) Convenor to sign the approval letters.
8.1 Reporting of SAEs when the UNSW HREC is the lead/primary HREC
   a) As a condition of UNSW HREC approval, researchers must report SAEs to the
      UNSW HREC within 72 hours of becoming aware of the event.
   b) SAEs must be submitted for review when the event happened at UNSW and/or at
      UNSW affiliated and/or non-affiliated participating sites.
   c) Researchers should use the latest SAE template available for download from the
      UNSW human ethics website.

8.2 Reporting of SAEs when the UNSW HREC has provided ratification of
   another HREC approval
   a) The SAEs should only be reported to the UNSW HREC if the event occurred at
      UNSW or an UNSW affiliated institution participating in the study and/or if
      UNSW is providing indemnification for the project.
   b) SAEs for ratified projects that meet the above condition must be reported
      within 72 hours of becoming aware of the event.
   c) Researchers should use the latest SAE template available for download from the
      UNSW human ethics website.

8.3 Review of SAEs
   a) The HREC Secretariat will allocate SAEs to a Professional Care member of the
      UNSW HREC for initial review.
   b) The professional care member will determine the appropriate recommendations
      for the HREC Executive. These recommendations may include:
      - Request for further information
      - Notation on file of the occurrence;
      - Increased monitoring of the project;
      - Request for an amendment to the protocol and/or Participant Information
        Statement and Consent Form;
      - Recommendation to the HREC Executive that approval be immediately
        suspended on ethical grounds;
      - Recommendation to the HREC Executive that approval be immediately
        terminated on ethical grounds;
      - Referral to the HREC Executive as a possible breach of the UNSW Research
        Code of Conduct
   c) The HREC Executive will review the recommendations provided from the
      Professional Care and if required, will forward recommendations of suspension,
      termination, or breaches to the Deputy Vice Chancellor (Research) for action.
   d) The HREC Executive will provide notice to the investigator that it has received
      notification of the SAE, and the course of action it has deemed necessary to take.
   e) The HREC Executive will require researchers to provide regular follow-up reports
regarding participants who have experienced an SAE until the event is resolved. Any such events will be reported to the HREC at the next available meeting.
Standard Operating Procedure (SOP)

Title: SP0009: Monitoring of approved research projects

Date: March 2015

Purpose: To describe the procedure for monitoring research projects approved by the HREC to ensure compliance with ethical approval.

1. The HREC will monitor approved projects to ensure compliance with its ethical approval. In doing so it may request information on any relevant aspects of the project with the investigators at any time. In particular, the HREC will require applicants to provide a report at least annually, and at completion of the study. Continuing approval of the research will be subject to the Chief Investigator submitting an annual report.

2. The HREC will require the following information (Attachment II) in the annual report:
   - status of the project;
   - progress to date or outcome in the case of completed research;
   - compliance with the general conditions included in the National Statement;
   - compliance with the approved protocol;
   - compliance with any conditions of approval;
   - maintenance and security of records;
   - number of participants recruited in the project;
   - description of any new or additional information which may impact approval of the project;
   - other information as may be required from time to time for reporting purposes.

3. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as random inspections of research sites, data and signed consent forms.

4. In the case of clinical trials, depending on the perceived risk to participants the HREC may require researchers to establish independent data safety monitoring boards, with the frequency of independent monitoring to be determined by the HREC; and if there are implantable devices, the researcher must establish a system for tracking the participants with implantable devices for the lifetime of the device (with consent) and report any device incidents to the TGA.

5. The HREC will require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:
   - adverse events;
   - proposed changes in the protocol;
   - any unforeseen events that might affect continued ethical acceptability of the project; and
   - new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the protocol.
6. The HREC will require, as a condition of approval of each project, that investigators inform the HREC and other relevant institutions, giving reasons, if the research project is discontinued before the expected date of completion. Wherever possible, the researcher should inform participants as well. For multi-site research, or where there has been multiple ethical review, the researcher must advise how this will be communicated before the research begins.

7. In the event that the annual report is not provided after two requests, the approval will be suspended by the Deputy Vice Chancellor (Research) and the Chief Investigator and Head of School notified (Attachment 12). If information comes to light during the research project (such as an SAE, a complaint or other information that arises through monitoring or other means) that may alter the level of risk faced by participants, then the Presiding Member will immediately advise the Chief Investigator to discontinue the project, pending review or investigation (Attachment 1B). If approval is suspended or withdrawn, the research must be discontinued (refer previous point on discontinuation and next point on withdrawal of approval).

8. Where the HREC is satisfied that circumstances have arisen such that a research project is not being, or cannot be, conducted in accordance with the approved project, the Deputy Vice Chancellor (Research) may withdraw approval. This process should ensure that researchers and others involved in the project are treated fairly and with respect. In such circumstances:
   • the researcher, the Head of School, other relevant institutions and, where possible, the participants should be informed of the withdrawal (Attachment 12). If a grant is associated with the project, the Grants Management Office will be notified.
   • the Head of School must ensure that the researcher promptly suspends the research and makes arrangements to meet the needs of participants; and
   • the research may not be resumed until the approval is reinstated (Attachment 16) i.e. unless either
      — the researcher subsequently establishes that continuance will not compromise participants’ welfare; or
      — the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved.

9. In determining the frequency and type of monitoring required for approved projects, the HREC will give consideration to the degree of risk to participants in the research project.
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 Human Ethics Coordinator 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.

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 Human Ethics Coordinator about the conduct of a research project approved by the HREC should be directed to the attention of the Ethics Coordinator, who will record details in the Complaints Log. The Ethics Coordinator or nominee is responsible for obtaining, the grounds of the concern/complaint and will notify the Presiding Members immediately after a concern/complaint is received.

5. The Presiding Member(s) will review the concern/complaint and its validity, and make a recommendation to the HREC/HREP Executive on the appropriate course of action. The initial review will be placed on the next available Executive Meeting agenda, 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 Members 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.
SOP 11: Complaints concerning the HREC’s review process

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

Reference Number: SOP 011  Date: February 16,

2010  Subject: Complaints concerning the HREC’s review process

Purpose: To describe the procedure for receiving and handling concerns or complaints from investigators about the HREC’s review process.

The National Statement specifies that “An institution or organisation will … establish procedures for receiving and promptly handling concerns or complaints from researchers about the consideration of their research protocol by an HREC.” The following procedures apply in order to deal with complaints about the review process:

A researcher with a concern or complaint about the HREC’s review of their application should make a complaint in accordance with the UNSW Staff Complaint Procedure or the UNSW Student Complaint Procedure available respectively at http://www.gs.unsw.edu.au/policy/documents/staffcomplaintproc.pdf and http://www.gs.unsw.edu.au/policy/documents/studentcomplaintproc.pdf.

Where complaints are made by non-UNSW staff or non-UNSW students, the UNSW Staff Complaint Procedure is followed.

Where either of these UNSW complaint procedures refers to a supervisor, Head of School, Department Head or Student Conduct and Appeals Officer (SCAO), either one of the HREC Presiding Members may perform that role if the complainant chooses and it is appropriate. Any role ordinarily performed by the Deputy Vice-Chancellor (Academic) under the relevant complaint procedure, will continue to be performed by the Deputy Vice-Chancellor (Academic).

Complaints regarding the HREC review process will be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference and Standard Operating Procedures, or if it acted in an unfair or biased manner.

In addition to complying with the relevant UNSW procedure, the HREC will perform the following steps:

1. Any concern or complaint received by the Ethics Secretariat about the HREC’s review process should be directed to the attention of the Executive Officer, who will record details in the Complaints Log (Attachment 13). The Human Ethics Coordinator or nominee is responsible for obtaining, either verbally or in writing, the grounds of the complaint and will notify the Presiding Members immediately after a 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 process can be reported to the complainant.

2. The Presiding Member will comply with the timeframes set out in the relevant complaint procedure, however may endeavour to resolve the complaint within a shorter period of time such as 10 days.

3. If the complainant has provided their contact details, they will be informed by telephone or in writing of the outcome of the complaints process. This communication will be recorded in the Complaints Log.
Outright rejection of an application to the HREC is a rare occurrence and the *National Statement* is silent on mechanisms to deal with this circumstance. The following mechanisms apply to complaints arising from rejection of an application:


Where complaints are made by non-UNSW staff or non-UNSW students, the UNSW Staff Complaint Procedure is followed.

Where either of these UNSW complaint procedures refers to a supervisor, Head of School, Department Head or Student Conduct and Appeals Officer (SCAO), either one of the HREC Presiding Members may perform that role if the complainant chooses and it is appropriate. Any role ordinarily performed by the Deputy Vice-Chancellor (Academic) under the relevant complaint procedure, will continue to be performed by the Deputy Vice-Chancellor (Academic).

“Complaint” includes any objection to a decision of the HREC. Such an objection might result from a flaw in the process used to reach the decision or from a dispute about the substance of the decision.

Complaints regarding the HREC review process will be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference and Standard Operating Procedures, or if it acted in an unfair or biased manner.

In addition to complying with the relevant UNSW procedure, the HREC will perform the following steps:

1. Any concern or complaint received by the Ethics Secretariat about the rejection of an application should be directed to the attention of the Human Ethics Coordinator, who will record details in the Complaints Log (Attachment 13). The Human Ethics Coordinator or nominee is responsible for obtaining, either verbally or in writing, the grounds of the complaint and will notify the Presiding Members immediately after a 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 process can be reported to the complainant.

2. The Presiding Member will comply with the timeframes set out in the relevant complaint procedure, however may endeavour to resolve the complaint within a shorter period of time such as 10 days.
3. If the complainant has provided their contact details, they will be informed by telephone or in writing of the outcome of the complaints process. This communication will be recorded in the Complaints Log.
SOP 13: Conflicts of interest

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

Reference Number: SOP 013 Date: February 10,

2010 Subject: Conflicts of interest

Purpose To describe the procedure for the handling of conflicts of interest

The Independent Commission Against Corruption (ICAC) guidelines on Conflict of Interest state that: “There is nothing unusual or necessarily wrong in having a conflict of interest. How it is dealt with is the important thing.” ICAC has defined conflict of interest in the following terms, based on the OECD (Organisation for Economic Cooperation and Development) definition: “A conflict of interest involves a conflict between the public duty and private interests of a public official, in which the public official has private interests which could improperly influence the performance of their official duties and responsibilities.”

Conflicts of interest can be actual, perceived, or potential:
- actual: involves a direct conflict between current duties and responsibilities and existing private interests;
- perceived: conflict exists where it could be perceived, or appears, that private interests could improperly influence the performance of duties — whether or not this is in fact the case;
- potential: arises where private interests could conflict with official duties.

A conflict of interest can be pecuniary (involving financial gain or loss) or non-pecuniary (based on enmity or amity). A conflict of interest can arise from avoiding personal losses as well as gaining personal advantage, financial or otherwise.

As the complexity and diversity of relationships and perspectives at universities is extensive, the most effective means to address unavoidable conflicts of interest is to establish a system under which interested parties disclose potential conflicts, so that these can be managed appropriately. These parties include members of the HREC, external reviewers and experts, researchers, institutions, including UNSW (for example, where it is required to act as a sponsor of investigator-initiated research), other institutions’ researchers and others involved in the HREC process, such as research participants, advocates and interpreters.

1. Prior to reviewing any application, external expert reviewers will be required to sign a declaration that they have no actual, perceived or potential conflict of interest concerning the application they are being asked to review.

2. The Presiding Member will at the outset of each HREC meeting invite HREC members to declare any actual, perceived or potential conflicts of interest (as defined above) in a project or other related matter(s) to be considered by the HREC. HREC members will inform the Presiding Member of their conflicts of interest. Where an institution has an actual, perceived or potential conflict of interest concerning the outcome of HREC review, the Presiding Member will seek such a declaration from the institution’s Delegated Officer prior to the HREC meeting.
3. The HREC will determine how the declared conflict of interest will be managed. In the case of an HREC member, the member will withdraw from the meeting until the HREC’s consideration of the relevant matter has been completed. The member will not be permitted to adjudicate on the research. In the case of external expert reviewers, the expert’s advice may not be sought or only written advice may be accepted. In the case of institutions or their researchers, they and relevant review bodies will be notified.

4. All declarations of conflict of interest and the absence of the member concerned or any other measures to manage the declared conflict of interest will be minuted.

7. Individuals and representatives of institutions may be required to complete
   a. a Declaration of the absence of a conflict of interest and a confidentiality agreement (Attachment 2); and in some cases
   b. a Disclosure of a conflict of interest (Attachment 19). It is rare that a disclosure will be needed as any conflict of interest will usually preclude participation in the review process.

   ▪ UNSW staff members disclose general conflicts of interest annually as part of normal university procedure. If any other disclosure is required in relation to the HREC process, UNSW staff should complete the disclosure statement (www.hr.unsw.edu.au/employee/disclosure.rtf) which is part of the UNSW conflict of interest policy (www.hr.unsw.edu.au/employee/conflict.html).
   ▪ Non-UNSW staff members disclose conflicts of interest using Attachment 19, which is based on the UNSW conflict of interest disclosure statement. The completed disclosure should be sent to the Ethics Secretariat for review by the HREC Presiding Member, for filing in the Ethics Secretariat’s HREC file and/or Project file, and for notification of relevant review bodies.
1. The Ethics Secretariat will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.

2. In accordance with the National Statement and to ensure appropriate record keeping of each application the Ethics Secretariat will prepare and maintain a confidential electronic and paper Project File for each application received and reviewed and will record the following information:
   - unique project identification number;
   - date of meeting;
   - project title;
   - submitted to other HREC;
   - will submit to other HREC;
   - other HREC name;
   - primary ethics committee;
   - chief investigator name/title;
   - email;
   - address;
   - other investigator/s;
   - applied for funding;
   - funding body/application number;
   - category of research;
   - participant information sheet;
   - consent form;
   - privacy;
   - commercial entity;
   - approval / status as of ……;
   - approval date / expiry date;
   - comments;
   - monitoring sent in ……(dates) / status in ……..(dates);
   - involvement of Aboriginal or Torres Strait Islanders as participants.

The paper Project File will contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the HREC, all approved documents, and other material used to inform potential research participants. If there is other correspondence, such as between the Deputy Vice Chancellor (Research) and the Chief Investigator, a copy of this correspondence (or a reference to it, including date and a brief summary), should be included in the file (e.g. date that the project was suspended).
3. All relevant records of the HREC, including applications, membership, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the Commonwealth and State Privacy Acts or as required by the UNSW Record Keeping Policy and the State Records Act, whichever is longer.

4. To ensure confidentiality, all documents provided to HREC members, which are no longer required, are to be disposed of in a secure manner. Members who do not have access to secure disposal should leave their documents with the Ethics Secretariat for disposal.

5. Project files and HREC files are stored on-site at the Grants Management Office for 3 years, after which they are archived off-site. Movements of records will be recorded by the Ethics Secretariat. The Ethics Secretariat has access to all records, both on and off-site, and may provide access to the following parties, who may be required to sign Confidentiality or Conflict of Interest declarations (Attachment 2) and in some cases a Conflict of Interest disclosure statement (Attachment 19) prior to access:
   a. HREC Presiding Members and members
   b. Office of the Deputy Vice-Chancellor (Research)
   c. Office of the Deputy Vice-Chancellor (Academic)
   d. Legal Office
   e. Director Grants Management Office
   f. Grants Management Office staff (for approval letter only)
   g. Researchers
   h. or in exceptional circumstances other parties as approved by the Deputy Vice Chancellor (Research).
SOP 15: HREC reporting requirements

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

Reference Number: SOP 015       Date: January 12,

2010 Subject: HREC reporting requirements

Purpose: To describe the reporting requirements of the HREC

1. The minutes of each HREC meeting will be forwarded to the Deputy Vice Chancellor (Research), following confirmation.

2. The HREC will provide an annual report to the Deputy Vice Chancellor (Research) and thence to the UNSW Council, at the end of each year on its progress, including:
   - HREC composition;
   - number of projects reviewed, approved and rejected, or managed by expedited review;
   - time to final approval for all projects;
   - enumeration of any complaints received and their outcome;
   - approvals by Human Research Ethics Advisory Panels; and
   - general issues raised.

3. The HREC will provide reports to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC.

4. The HREC will provide reports to the NSW Privacy Commissioner and to the Commonwealth Privacy Commissioner in accordance with the relevant Acts.

5. Other reports will be generated as required by other authorities from time to time.

6. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the University website.
SOP 16: Applications from non-UNSW affiliated researchers

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

Reference Number: SOP 016  Date: June 1, 2007

Subject: Applications from non-UNSW affiliated researchers

Purpose: To describe the processing of applications from researchers who have no affiliation with UNSW

1. The UNSW HREC will consider ethics applications from researchers who have no affiliation with UNSW, but who wish to conduct research involving or impacting upon humans.

2. Such applications will be accepted on either the Ethics and Privacy Application Form for Research Involving Humans, or the National Ethics Application Form (NEAF). Both are available via the University website on: http://research.unsw.edu.au/human-research-ethics-committee-hrec
   and handled in accordance with the procedures set out in SOPs 001-015.

3. Such applications will incur a fee for the initial review, and subsequent fees for each and every modification to the project. The fee must be paid at the time of submission and prior to consideration of the application thus ensuring payment, whether or not approval is given.

   Researchers and their institution/organisation will be required to sign the HREC Agreement with Non-affiliated Researchers. The proforma is available at http://research.unsw.edu.au/human-ethics-forms-and-proformas
   (Refer also attachment 2). This Agreement will set out the UNSW Terms & Conditions for consideration, approval and indemnification arising from the review of such projects.

5. The Risk Management Unit will be advised of such applications by the Ethics Secretariat as required by UNSW for indemnity and insurance purposes.
SOP 17: HREC education and training activities

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

Reference Number: SOP 017  Date: February 10,

2010 Subject:  HREC education and training activities

Purpose: To describe the requirements for education and training of members of the HRECs, the Ethics Secretariat, HREA Panels as well as researchers.

The University has an obligation to provide education and training in ethical research conduct, not only for the members serving on the HREC and the ethics secretariat, but also for HREA Panel members and the university research community in general (see Attachment 14).

1. Members newly appointed to the HRECs will be provided with:
   - an opportunity for an informal meeting with Presiding members and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures;
   - an opportunity to sit in on HREC meetings as an observer before their appointment takes effect;
   - copies of the HREC Operations Manual and the National Statement

2. HREC Members and Ethics Secretariat staff will receive the following training during the course of the year:
   - A presentation will be held at the beginning of most HREC meetings. At a minimum, there will be eight 45 minute presentations each year on a relevant topic. HREC meeting minutes will record the topic, discussion and presentation pack.
   - Emails of relevant information will also be sent periodically.
   - Equitable access to education sessions, conferences, workshops and training related to technology relevant to the work and responsibilities of the HRECs, at the expense of the University.

3. Members newly appointed to the HREA Panels will be provided with:
   - an expectation that they sit in on HREC presentations and meetings as an observer before their appointment takes effect;
   - opportunities to attend lectures, seminars and workshops made available by the HREC as needed for the education and training of Panel members;
   - opportunities to interact with members of the HREC for provision of advice and support.

4. Researchers at the University will be provided with:
   - comprehensive instructions, guidelines and linked access to education materials regarding human research ethics via the University website
   - an opportunity to attend introductory sessions for new researchers targeting research students or academic staff at least twice yearly;
   - opportunities to attend lectures or seminars held by HREC members tailored to provide advice in relation to human research ethics in specific research environments and research methodologies.