



**Sydney South West Area Health Service  
Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital**

***Standard Operating Procedures***

## STANDARD OPERATING PROCEDURES

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**Reference Number:** SOP 001                      **Date:** April 2010  
**Subject:** HREC function  
**Purpose:** To describe the function of the HREC

**OVERALL FUNCTION**

1. The primary objective of the HREC is to protect the mental and physical welfare, rights, dignity and safety of participants in research, to facilitate ethical research through efficient and effective review processes, to promote ethical standards of human research and to review research in accordance with the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (National Statement)*.

**Scope of Responsibilities**

1. The functions of the HREC are:
  - i) To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
  - ii) To provide ethical oversight, monitoring and advice for research projects involving humans.
  - iii) To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
2. Research projects involving humans will be reviewed by the HREC where the research is to be undertaken at Concord Repatriation General Hospital, or (in the case of multi-centre research) where the research is to be conducted at more than one NSW Public Health Organisation (PHO)
3. Research projects may include, but are not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, access to health information, as well as epidemiological, social, and psychological investigations.
4. The HREC will assess projects submitted to it for review in accordance with the *National Statement* (and any other legal requirements) in order to determine their ethical acceptability.
5. The HREC may review projects involving quality assurance when required. In determining whether or not quality assurance proposals require review, the HREC will refer to the NHMRC document '*When does quality assurance in health care require independent ethical review?*' and the '*Health Records and Information Privacy Act 2002: Statutory Guidelines on Management of Health Services*'.

The HREC will review human research proposals for external institutions/organisations as specified in the Terms of Reference. In such circumstances, an agreement shall exist between the Health Service and the external institution/organisation that defines the role of the HREC in providing ethical approval and ethical monitoring of the research and the role of the external institution/organisation in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and shall also specify that the institution/organisation (not the Health Service) is responsible for liabilities arising from the conduct of the research.

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**Reference Number:** SOP 002                      **Date:** April 2010  
**Subject:** Membership composition  
**Purpose:** To describe the membership composition of the HREC

1. The composition of the HREC shall be in accordance with the *National Statement*. Minimum membership shall be seven members, being men and women, comprising:
  - Chairperson
  - At least two lay people, one man and one woman, who are not currently involved in medical, scientific, legal or academic work and who have no affiliation with the hospital.
  - At least one person who performs a pastoral care role in the community
  - At least one lawyer who is not engaged to advise the institution
  - At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend
  - At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, nurse)
2. To ensure the membership will equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.
3. Where required, the HREC may seek advice and assistance from appropriate experts to assist with the review of a project. However, the HREC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.
4. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the HREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members.

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**Reference Number:** SOP 003                      **Date:** April 2010  
**Subject:** Appointment of Members  
**Purpose:** To describe the procedure for the appointment of members to the HREC

1. Members are appointed as individuals rather than in a representative capacity. However, committee membership shall always include a representative from Nursing and a representative from the Clinical Trials Pharmacy.
2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. The minister of religion is nominated by the retiring or former member in this category, or by the Concord Repatriation General Hospital Pastoral Care service, or by other means as deemed appropriate. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the Concord Hospital Human Research Ethics Committee website.
3. A selection committee, consisting of the Chairperson, Executive Officer and any other interested HREC member shall interview the prospective applicant, consult with the Human Research Ethics Committee members and make a recommendation to the Chief Executive. Prospective members may be invited to attend a meeting of the HREC as an observer.
4. Members are appointed by the Chief Executive in consultation with the HREC and will receive a formal notice of appointment.
5. The Chairperson and Deputy Chairperson will be appointed by the Chief Executive. In the absence of the Chairperson, the Deputy Chairperson will perform the role and duties of the Chairperson.
6. The letter of appointment shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, and the conditions of their appointment.
7. A new member will be required to sign a confidentiality undertaking (see Attachment A) upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.
8. Upon appointment, members shall be provided with the following documentation:
  - HREC Terms of Reference;
  - HREC Standard Operating Procedures;
  - up-to-date list of members' names and contact information including that of the Executive Officer;
  - NHMRC National Statement on Ethical Conduct in Human Research 2007;
  - any other relevant information about the HREC's processes, procedures and protocols.
9. Members are appointed for a period of three years, renewable. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive. Membership is reviewed every third calendar year, regardless of the fraction of the term already

served by each member. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.

10. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
11. New members are expected to attend NSW Health and NHMRC education and training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the Health Service, where possible.
12. Members shall not be remunerated. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.
13. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.
14. Membership will lapse if a member fails to attend three consecutive meetings of the HREC without reasonable excuse/apology, unless exceptional circumstances exist. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy, which may arise.
15. Membership will lapse if a member fails, without reasonable excuse or without notifying the Chairperson, to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson will notify the member in writing of such lapse of membership. Steps shall be taken to fill the vacancy.
16. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will be expected to be available between meetings to participate in Executive meetings where required.
17. A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

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**Reference Number:** SOP 004                      **Date:** April 2010  
**Subject:** Orientation of new members  
**Purpose:** To describe the procedure for the orientation of new members

1. New HREC members must be provided with adequate orientation.
2. Orientation may involve all or some of the following:
  - Introduction to other HREC members prior to the HREC meeting.
  - Informal meeting with Chair and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures.
  - An opportunity to sit in on HREC meetings before their appointment takes effect.
  - 'Partnering' with another HREC member in the same category.
  - Priority given to participate in training sessions.
3. New HREC members will be provided with the following written information:
  - A list of the members' names and their roles on the HREC.
  - A copy of the *NH&MRC National Statement on Ethical Conduct in Human Research 2007*.
  - The HREC's Terms of Reference.
  - Calendar of meeting dates
  - Statutory Guidelines under HRIPA:
    - Statutory Guidelines on Research
    - Statutory Guidelines on the Management of Health Services

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**Reference Number:** SOP 005                      **Date:** April 2010  
**Subject:** Training and Education of HREC members  
**Purpose:** To promote ongoing education and training opportunities for all members of the HREC.

Every member of the HREC should aim to attend at least one training session every three years.

Training courses provided by NSW Health (Health Ethics branch) or the NH&MRC (National Health & Medical Research Council) are examples of suitable educational forums.

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**Reference Number:** SOP 006                      **Date:** April 2010  
**Subject:** Submission procedure for new applications  
**Purpose:** To describe the procedure for the submission of new applications

1. All applications for ethical review must be submitted to the Executive Officer of the HREC, by close of business on the relevant closing date. The closing date for receipt of new applications onto the next HREC agenda shall be readily available to prospective applicants.
2. The closing dates for applications should normally be no later than 14 days prior to each HREC meeting.
3. Applications must be submitted in the appropriate format as determined by the HREC, and shall include all documentation as required by the HREC. The procedures for application to the HREC and the application format shall be readily available to applicants.
4. Guidelines shall be issued by the HREC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the Human Research Ethics Committee is necessary.
5. A fee will be charged for HREC review of commercially-sponsored clinical trials, in line with NSW Health Document Number PD2008\_030 "*HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research*". The fee policy shall be made available to applicants prior to submission of an application to the HREC.

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**Reference Number:** SOP 007                      **Date:** April 2010  
**Subject:** Processing of applications for review  
**Purpose:** To describe the procedure for the processing of new applications

1. Applications will be checked for their completeness by the Executive Officer prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant.
2. The Executive Officer will determine whether or not the application has been submitted to the Shared Scientific Assessment Scheme for review.
3. Where the application has been submitted to the Shared Scientific Assessment Scheme, the scientific review of the Shared Scientific Assessment Committee will replace the HREC's own scientific review mechanism in accordance with the '*Shared Scientific Assessment Scheme Manual, version November 2004*'.
4. Once a completed application has been accepted for ethical review, the Executive Officer shall assign a unique project identification number to the project. The project will be added to the HREC's register of received and reviewed applications.
5. The Executive Officer will acknowledge acceptance of the application for ethical review by issuing an acknowledgement letter to the principal investigator within 7 days of receipt of the application. The acknowledgement letter shall include the date of the meeting at which the application will be reviewed, as well as the unique project identification number given by the HREC to the project.
6. The application will be included on the agenda for the next available HREC meeting, provided it is received by the relevant closing date and is complete. If a substantial number of applications are received a number of applications may need to be deferred to the following HREC meeting. If this occurs, priority will be given to those applications that were received first and/or urgent applications at the discretion of the Chairperson.

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**Reference Number:** SOP 008                      **Date:** April 2010  
**Subject:** Preparation of agenda  
**Purpose:** To describe the process and format of agenda for an HREC meeting

1. The Executive Officer will prepare an agenda for each HREC meeting.
2. All completed applications and relevant documents received by the Executive Officer will be included on the agenda for HREC consideration at its next available meeting.
3. The meeting agenda and associated documents will be prepared by the Executive Officer and circulated to all HREC members at least 7 days prior to the next meeting.
4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chairperson. Under no circumstances shall new applications for research be tabled at the meeting.
5. Agenda items will include at least the following items:
  - i) apologies;
  - ii) minutes of the previous meeting;
  - iii) business arising from the previous minutes;
  - iv) conflicts of interest;
  - v) new applications;
  - vi) amendments to approved protocols;
  - vii) correspondence;
  - viii) other business;
  - ix) close and next meeting.
6. The agenda and all documentation shall remain confidential.

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**Reference Number:** SOP 009                      **Date:** April 2010  
**Subject:** Conduct of meetings  
**Purpose:** To describe the format of meetings of the HREC

1. The HREC shall meet on a regular basis, which will normally be at monthly intervals. Meeting dates and agenda closing dates shall be publicly available.
2. Members may attend HREC meetings in person or via teleconference or video link.
3. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 7). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.
4. Meetings will be scheduled for an allocated time. If the business has not been completed within the allocated time, then the HREC may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting should be held within 5 working days.
5. The HREC meeting will be conducted in private, to ensure confidentiality and open discussion. Members will be advised of the meeting room details in the meeting agenda.
6. Notwithstanding paragraph 5, the HREC may agree to the presence of visitors or observers to a meeting. Such visitors (eg expert reviewers) will be asked to sign a Confidentiality Agreement, unless they are a named researcher on the proposal under consideration.  
There will be no direct communication between the HREC and the sponsor of a research proposal. Such communication shall be via the researcher. However, communication between a sponsor and the Executive Officer in relation to regulatory requirements and other procedural matters is permitted, in order to facilitate the timely review of research.
7. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Executive Officer or Chairperson. These should normally be received at least 3 working days prior to the meeting so that copies may be made available in advance to members. The minutes should record the submission of written comments.
8. A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum shall exist when a representative of each of the following categories is present:
  - Chairperson
  - At least two lay people, one man and one woman, who are not currently involved in medical, scientific, legal or academic work and who have no affiliation with the hospital.
  - At least one person who performs a pastoral care role in the community
  - At least one lawyer who is not engaged to advise the institution
  - At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend
  - At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, nurse)

In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of the following

categories: Chairperson/Deputy Chairperson, lay person, researcher familiar with the types of proposals that are normally reviewed by the HREC.

9. If the meeting does not achieve quorum, the Chairperson shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the HREC must be ratified by at least one representative from those membership categories not present.
10. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC, should declare such interest. This will be dealt with in accordance with SOP 025.

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**Reference Number:** SOP 010                      **Date:** April 2010  
**Subject:** Consideration of applications for ethical review by the HREC  
**Purpose:** To describe the process of the HREC's consideration of applications for ethical assessment

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date.
2. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance.
3. The HREC will deal with multi-centre research applications in accordance with SOP 021.
4. The HREC will ethically assess each application in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research 2007*. The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment. The HREC will review research in accordance with the *Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes*.
5. The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.
6. Where research involves the participation of persons unfamiliar with the English language, the HREC will ensure that the researcher has put in place arrangements for an interpreter to be present during the discussion on the project, unless alternative arrangements are available (and approved by the HREC).
7. The HREC, after consideration of an application at a meeting will make one of the following decisions:
  - It will approve the project as being ethically acceptable, with or without conditions.
  - It will defer making a decision on the project until the clarification of information or the provision of further information to the HREC.
  - It will request modification of the project.
  - It will reject the project.
8. The HREC will endeavour to reach a decision concerning the ethical acceptability of a project 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 project, provided that the majority includes at least one layperson. Any significant minority view shall be noted in the minutes.
9. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.
10. For projects where the HREC has requested clarification, the provision of further information, or modification of the project, the HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:
  - chairperson alone; or

- chairperson, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application; or
- a sub-committee of the HREC. In such circumstances, the HREC shall be informed at the next available meeting, of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.

11. Exceptionally, the HREC may decide that the information should be considered at a further meeting of the HREC.

12. The HREC may conduct expedited review of projects in accordance with SOP012.

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**Reference Number:** SOP 011                      **Date:** April 2010  
**Subject:** Preparation of minutes  
**Purpose:** To describe the process and format for minutes of a meeting of the HREC.

1. The HREC Executive Officer will prepare and maintain minutes of all meetings of the HREC.
2. The format of the minutes will include at least the following items:
  - i) apologies;
  - ii) attendance;
  - iii) minutes of the previous meeting;
  - iv) business arising from the previous minutes;
  - v) conflicts of interest;
  - vi) new applications;
  - vii) amendments to approved projects
  - viii) correspondence;
  - ix) other business;
  - x) close and next meeting.
3. The minutes should include the recording of decisions taken by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.
4. In relation to the review of new applications or amendments, the minutes shall record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.
5. In recording a decision made by the HREC, any significant minority view will be noted in the minutes.
6. To encourage free and open discussion and to emphasis 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 recorded.
7. Declarations of conflicts of interest by any member of the HREC and the absence of the member concerned during the HREC consideration of the relevant application will be minuted (refer to SOP025 regarding a member's declaration of a conflict of interest).
8. The minutes will be produced as soon as practicable following the relevant meeting and should be checked by either the Chairperson and/or the Deputy Chairperson, for accuracy.
9. 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.
10. The original copy of each meeting's minutes will be retained in a confidential 'Minutes' file.
11. The minutes of each Committee meeting shall be forwarded to the Chief Executive.

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**Reference Number:** SOP 012                      **Date:** April 2010  
**Subject:** Expedited review  
**Purpose:** To describe the procedure for the expedited review of research by the HREC.

1. The HREC may establish and convene an Expedited Ethical Review Panel (EERP) which meets monthly to discuss:
  - amended proposals
  - expedited proposals (minimal risk). eg: Quality Control projects; Medical Records research
  - authorised prescriber and Special Access Scheme (SAS) applications
  - advertisements
  - annual reports and on-going approvals
  - final reports
  - grievances
  - review of policies and practices of CRGH Research Office with regard to Ethics.

Membership of the EERP shall be open to anyone on the HREC who wishes to attend. The minimum membership shall be the Chairperson of the HREC, Deputy Chairperson and at least one clinician. The Executive Officer, or their delegate, will attend to take minutes, and to assist in providing corporate memory and advice.

The Chairperson and the Executive Officer, acting as an Executive may consider minor items of business that are considered to be of minimal risk to participants, between scheduled meetings.

2. The proceedings of the EERP are ratified by the full HREC at its meeting of the following month.
3. Research with the potential for physical or psychological harm should generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.
4. Where the Chairperson considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full HREC and cannot be dealt with by expedited review.

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**Reference Number:** SOP 013                      **Date:** April 2010  
**Subject:** Notification of decisions of the HREC for new applications  
**Purpose:** To describe the procedure for the notification of decisions of the HREC concerning the review of new applications.

1. The HREC will report in writing to the principal investigator, advising whether the application has received ethical approval (including any conditions of approval), within 10 working days of the meeting, unless otherwise notified.
  2. If the HREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification will refer to the NHMRC *National Statement on Ethical Conduct in Human Research 2007* or other relevant pieces of legislation.
  3. If the requested information is not received from the applicant within 3 months, the project will be dismissed and the applicant will be required to re-submit the project at a later date.
  4. The HREC shall endeavour to openly communicate 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 by inviting the applicant to attend the relevant HREC meeting.  
In addition, the Chair of the HREC, the Chair of the Scientific Sub-committee, the Executive Officer, the Clinical Trials Pharmacist and other institutional members of the HREC are available to speak with researchers about applications and matters arising from review of research proposals. This is arranged via consultation with the Executive Officer.
  5. The HREC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:
    - title of project;
    - name of the principal investigator(s);
    - unique HREC project identification number;
    - the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc;
    - date of HREC meeting at which the project was first considered;
    - date of HREC approval;
    - duration of HREC approval; and
    - conditions of HREC approval, if any.
- A standard response will be issued, in the format set out in Attachment B. Research projects may not commence until written notification that confirms this has been received.
6. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant pieces of legislation. A standard response will be issued, in the format set out in Attachment C.

7. The status of the project shall be updated on the HREC's register of received and reviewed applications.

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**Reference Number:** SOP 014                      **Date:** April 2010  
**Subject:** Submission of amendments and extensions to approved projects  
**Purpose:** To describe the procedure for the submission and HREC review of requests for amendments and extensions to approved protocols.

1. Proposed changes to approved research projects, changes to the conduct of the research, or requests for extensions to the length of HREC approval, are required to be reported by the principal investigator to the HREC for review.
2. Requests shall outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must include a summary of the proposed changes, and contain revised version numbers and dates.
3. Expedited review of requests for minor amendments and extensions may be undertaken by the EERP or by the HREC Executive between scheduled meetings at the discretion of the Chairperson and in accordance with SOP 012, on the condition that it be ratified at the next HREC meeting. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the HREC will review the decision at its next available meeting.
4. All other requests for amendments shall be reviewed by the HREC at its next available meeting, provided the request has been received by the Executive Officer by the agenda closing date.
5. The HREC will report in writing to the principal investigator, advising of the ethical approval of the proposed amendment and/or request for extension, within 10 working days of the meeting at which the request was considered.
6. A standard response will be issued, in the format set out in Attachment D.
7. If the HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the National Statement or relevant pieces of legislation.
8. All reviewed and approved requests for amendments and extensions to a protocol shall be recorded, and the status of the project shall be updated on the HREC's register of received and reviewed applications.

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**Reference Number:** SOP 015                      **Date:** April 2010  
**Subject:** Handling of adverse events  
**Purpose:** To describe the procedure for the reporting and handling of adverse events.

1. The HREC shall require, as a condition of approval of each project, that researchers report serious or unexpected adverse events to the HREC in a timely manner. This includes Serious Adverse Events (SAEs) that have occurred at other institutions participating in studies using the study drug or device.
2. Notifications of adverse events must be submitted in the appropriate format as determined by the, and shall include all documentation as required by the HREC. This documentation shall include as a minimum:
  - Advice from the principal investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device, if adequate information is available to make this assessment.
  - Advice from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the Patient Information Sheet/Consent Form.
  - Advice as to whether the event has been notified to the Independent Safety and Data Monitoring Board (if one exists).

For CRGH patients, SAEs shall be reported immediately as a detailed narrative report.

For non-CRGH patients, the Ethics Committee shall accept quarterly SUSAR Summaries (Suspected Unexpected Serious Adverse Reaction) in lieu of narrative reports. SUSARs shall be in a format approved by the HREC and shall be accompanied by an opinion from the Hospital Investigator regarding trends, seriousness and whether changes are needed to the protocol or other study documents.

3. For all adverse event reporting, if information is available as to the total number of participants enrolled in the study, the Investigator shall make this information available to the HREC.
4. The procedures and format for notification of adverse events to the HREC shall be readily available to investigators.
5. Adverse events may be reviewed by an Executive or the EERP of the HREC, which shall determine the appropriate course of action. This may include:
  - notation on file of the occurrence;
  - increased monitoring of the project;
  - request for an amendment to the protocol and/or Patient Information Sheet/Consent Form;
  - suspension of ethical approval; or
  - termination of ethical approval.

Any such adverse events shall be reported to the HREC at the next available meeting.

6. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:
  - Referral to the scientific/technical subcommittee;
  - Immediate request for additional information;
  - Immediate suspension of ethical approval;
  - Immediate termination of ethical approval.
7. The HREC shall provide notice to the investigator that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 016                      **Date:** April 2010  
**Subject:** Monitoring of approved research projects  
**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 and discuss 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 principal investigator submitting an annual report.
2. The HREC shall require the following information in the annual report:
  - progress to date or outcome in the case of completed research;
  - maintenance and security of records;
  - compliance with the approved protocol; and
  - compliance with any conditions of approval.
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;
  - interview, with their prior consent, of research participants.
4. The HREC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:
  - 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 trial, or which may indicate the need for amendments to the trial protocol.
5. The HREC shall require, as a condition of approval of each project, that investigators inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion.
6. 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 HREC may withdraw approval. In such circumstances, the HREC shall inform the principal investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.
7. 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.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 017                      **Date:** April 2010  
**Subject:** HREC requirements for research projects involving investigational devices.  
**Purpose:** To describe the requirements of the HREC for research involving investigational devices.

1. Where there is a possible risk to the safety of the researcher and/or the participant, the HREC may require certification of an investigational device by the relevant biomedical authority.
2. In the case of an implantable medical device, the sponsor, on behalf of the manufacturer of the investigational device is responsible for the following:
  - Ensuring that each investigational device is individually identified with a tracking number.
  - Ensuring that each device is supplied to the trial site with a registration card which includes the device's individual tracking number for completion by the clinician with details of the trial participant into which it is implanted.
  - Collecting the completed card from the clinician following implantation of the investigational device.
  - Maintaining a register of the investigational device, including:
    - (i) The clinical trial's protocol number and title
    - (ii) The individual tracking numbers
    - (iii) The trial identity of the participant into whom each device is implanted, ie the participant's study number
    - (iv) The date of device implantation
    - (v) Details of any suspected unexpected serious adverse events experienced by the participant
  - Reporting all serious adverse events to the Therapeutic Goods Administration (TGA).
3. In the case of an implantable medical device, the Principal Investigator at each study site is responsible for maintaining a register of the devices implanted at his/her site and recording details of the device into each study participant's medical record.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 018                      **Date:** April 2010  
**Subject:** Complaints about the conduct of a research project  
**Purpose:** To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the HREC.

1. The HREC shall nominate the Executive Officer as the person to whom complaints from research participants, researchers, or other interested persons about the conduct of approved research projects, may be made in the first instance. The name and/or position and contact details of the Executive Officer must be included in the Patient Information Sheet and/or Consent Form for each project.
2. Any concern or complaint about the conduct of a project should be directed to the attention of the HREC Executive Officer, who shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the HREC will instigate an investigation of the complaint and make a recommendation on the appropriate course of action. The investigation will take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstance exist. If the complaint is substantiated, action may include the requirement for amendments to the project, including increased monitoring by the HREC; suspension of the project; termination of the project; or other action to resolve the complaint.
3. Where the complaint concerns a serious matter within the jurisdiction of the Health Care Complaints Commission, the Chief Executive shall consider referral of the complaint to that body in accordance with NSW Health's *'Guideline on the Management of a Complaint or Concern about a Clinician, November 2001'*.
4. The complainant shall be informed in writing, or otherwise, of the outcome of the Chairperson's investigation.
5. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so.
6. The Chairperson of the HREC will provide the Chief Executive or his/her nominee with all relevant information about the complaint/concern, including:
  - the complaint;
  - material reviewed in the Chairperson's investigation;
  - the results of the Chairperson's investigation; and
  - any other relevant documentation.
7. The Chief Executive will determine whether there is to be a further investigation of the complaint. Where there is no further investigation, the Chief Executive will inform the complainant and the Chairperson of this.
8. If the Chief Executive determines there is to be a further investigation, then he/she will establish a panel to consider the complaint.
9. The panel will include, at least, the following members:
  - the Chief Executive or his/her nominee as convenor of the panel;

- two nominees of the Chief Executive (not members of the HREC); and
  - the HREC Executive Officer.
10. The panel will afford the HREC and complainant the opportunity to make submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with an opportunity to make submissions.
11. The panel may access any documents relating to the project. The panel may interview other parties, and seek internal and external expert advice, as it sees fit.
12. The Chief Executive will notify the complainant and the Chairperson of the outcome of the investigation, and the investigator if an allegation against them. The outcomes may include:
- The complaint/concern is dismissed.
  - The Chief Executive directs appropriate action to be taken to resolve the complaint.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 019                      **Date:** April 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.

1. Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing in writing the grounds of the concern or complaint. Complaints may also be made to the Chief Executive.
2. The Chairperson may at his/her discretion inform the Chief Executive as soon as possible of any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her.
3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
4. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so.
5. The Chairperson of the HREC will provide the Chief Executive with all relevant information about the complaint/concern, including:
  - the complaint;
  - material reviewed in the Chairperson's investigation;
  - the results of the Chairperson's investigation; and
  - any other relevant documentation.
6. The Chief Executive will determine whether there is to be a further investigation of the complaint.
7. If the Chief Executive determines there is to be a further investigation, then he/she will establish a panel to consider the complaint/concern. Where there is to be no further investigation, the Chief Executive will inform the application and the Chairperson of this.
8. The panel will include, at least, the following members:
  - The Chief Executive or his/her nominee as Convenor of the panel.
  - Two nominees of the Chief Executive (not members of the HREC).
9. The panel will afford the HREC and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advice. In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the NHMRC *National Statement on Research Ethical Conduct in Human Research 2007*, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.
11. The Chief Executive will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:

- The complaint/concern is dismissed.
- The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.

12. The panel may also make recommendations about the operation of the HREC including such actions as:

- Review Terms of Reference and Standard Operating Procedures;
- Review committee membership;
- Take other such action as appropriate.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 020                      **Date:** April 2010  
**Subject:** Complaints concerning the HREC's rejection of an application  
**Purpose:** To describe the procedure for receiving and handling complaints from investigators about the HREC's rejection of an application.

1. A person with a concern or complaint about the HREC's rejection of their application should detail the grounds of the concern or complaint in writing and bring it to the attention of the Chairperson of the HREC. Complaints may also be made to the Chief Executive.
2. The Chairperson may at his/her discretion bring to the attention of the Chief Executive as soon as possible any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her.
3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
4. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee, or request the Chairperson to do so.
5. The Chairperson of the HREC will provide the Chief Executive with all relevant information about the complaint, including:
  - the complaint;
  - material reviewed in the Chairperson's investigation;
  - the results of the Chairperson's investigation; and
  - any other relevant documentation.
6. The Chief Executive will determine whether there is to be a further investigation of the complaint.
7. If the Chief Executive determines there is a case to be investigated, then he/she will establish a panel to consider the complaint.
8. The panel will include, at least, the following members:
  - The Chief Executive or his/her nominee as convenor of the panel
  - Two nominees of the Chief Executive (not members of the HREC)
  - An expert/s in the discipline of research of the project under consideration
9. The panel will afford the HREC and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the project. The panel may interview other parties, and seek any other internal and/or external expert advice.
11. The Chief Executive will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:
  - The complaint/concern is dismissed.

- The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.
12. Should the HREC be requested to review its decision, then the outcome of this review by the HREC will be final.
  13. The panel or Chief Executive cannot substitute its approval for the approval of the HREC.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 021                      **Date:** April 2010  
**Subject:** Handling of multi-centre research  
**Purpose:** To describe the procedure for the handling by the HREC of multi-centre research, including applications submitted to the NSW Health Shared Scientific Assessment Scheme.

1. To facilitate the review of multi-centre research the HREC may:
  - communicate with any other HREC;
  - accept a scientific/technical and/or ethical assessment of the research by another HREC;
  - share its scientific/technical and/or ethical assessment of the research with another HREC.
  
2. The HREC will comply with the NSW Model for Single Ethical and Scientific Review of Multi Centre Research (PD2007\_072).

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 022                      **Date:** April 2010  
**Subject:** Record keeping  
**Purpose:** To describe the procedure for the preparation and maintenance of records of the HREC's activities.

1. The Executive Officer will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.
2. The Executive Officer will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:
  - unique project identification number;
  - the principal investigator(s);
  - the name of the responsible institution or organisation;
  - title of the project;
  - ethical approval or non-approval with date;
  - approval or non-approval of any changes to the project;
  - the terms and conditions, if any, of approval of the project;
  - whether approval was by expedited review; and
  - action taken by the HREC to monitor the conduct of the research.

The paper file shall 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.

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 Health Records and Information Privacy Act 2002 (HRIPA) and the *State Records Act 1998*.
4. To ensure confidentiality, all documents provided to HREC members, which are no longer required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the Executive Officer for disposal.
5. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 5 years after the date of publication or completion of the research or termination of the study. For clinical research, 15 years shall apply. Retention periods shall comply with NSW Health '*Information Bulletin 2004/20 General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17)*'.
6. A register of all the applications received and reviewed shall be maintained in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research 2007*.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 023                      **Date:** April 2010  
**Subject:** Special Access Scheme applications  
**Purpose:** To describe the procedure for the review and approval of access to unapproved therapeutic goods via the Special Access Scheme

HREC responsibilities in relation to the Special Access Scheme (SAS)\* are primarily concerned with the granting of approvals under section 19(1)(a) of the Therapeutic Goods Act by 'external delegates'. In accordance with Regulation 47A(6)(b) of the Act, all special access scheme applications approved by an external delegate must be approved by an HREC.

There is currently no external delegate at Concord Repatriation General Hospital.

*\*Refer to the Therapeutic Goods Administration Access to Unapproved Therapeutic Goods via the Special Access Scheme, October 2004.*

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 024                      **Date:** April 2010  
**Subject:** Authorised Prescriber applications  
**Purpose:** To describe the procedure for the review and approval of access to unapproved therapeutic goods via Authorised Prescribers.

1. The HREC may establish an Executive of members, consisting of the Chairperson, the Executive Officer and one other member (usually the Clinical Trial Pharmacist) to consider authorised prescriber applications. The HREC may also seek advice from its scientific/technical sub-committee or drug subcommittee, when considering the issues outlined in Point 3.
2. All decisions made by the Executive shall be tabled for ratification at the next HREC meeting.
3. When considering a proposal by a medical practitioner to become an Authorised Prescriber, the HREC shall undertake an assessment of the following, in accordance with the *Therapeutic Goods Act 1989* and associated regulations\*:
  - the safety of the product in relation to its proposed use;
  - the suitability of the medical practitioner; and
  - information to be given to the patient about the product and the informed consent form.
4. If endorsed, the HREC shall provide a letter of endorsement to the applicant in the format suggested by the Therapeutic Goods Administration [Note: Refer to Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004]. The HREC may impose any conditions on the endorsement such as:
  - a requirement that regular reports be provided to the HREC containing such information as the number of patients for whom the unapproved product has been prescribed;
  - requirements for reporting of any adverse events.
5. The HREC shall review its endorsement of the Authorised Prescriber if it becomes aware of:
  - inappropriate use of the product by the Authorised Prescriber;
  - a concern about the safety of the product;
  - failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or
  - failure of the Authorised Prescriber to comply with State/Territory legislation
6. The HREC may withdraw its endorsement of the Authorised Prescriber if it is satisfied that the welfare and/or rights of patients are not or will not be protected. The HREC shall advise the medical practitioner and the Chief Executive of its concerns in the first instance. The Chief Executive and the Chairperson of the HREC shall jointly determine whether to contact the Therapeutic Goods Administration.

\*Refer to the Therapeutic Goods Administration *Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004*.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 025                      **Date:** April 2010  
**Subject:** Handling of conflicts of interest  
**Purpose:** To describe the procedure for the handling of conflicts of interest of HREC members.

1. A HREC member shall, as soon as practicable during the HREC meeting, inform the Chairperson if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.
2. If a HREC member is present at a meeting at which a project is considered in which they have a conflict of duality of interest, the member will be asked to withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The member will not participate in discussions.

If the Chairperson has a potential conflict of interest as described above, the Deputy Chairperson will take over the conduct of the meeting for the proposal in question.

3. All declarations of conflict of interest will be minuted.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 026                      **Date:** April 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 Chief Executive, following confirmation.
2. The HREC shall provide an annual report to the Chief Executive at the end of each calendar year on its progress, including:
  - membership/membership changes;
  - number of meetings;
  - number of projects reviewed, approved and rejected;
  - monitoring procedures for ethical aspects of research in progress and any problems encountered by the HREC in undertaking its monitoring role;
  - description of any complaints received and their outcome;
  - description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval; 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 in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).
5. 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 Health Service website.

**SSWAHS Human Research Ethics Committee (HREC)  
Concord Repatriation General Hospital (CRGH)  
Standard Operating Procedures**

**Reference Number:** SOP 027                      **Date:** April 2010  
**Subject:** Review of Standard Operating Procedures and Terms of Reference  
**Purpose:** To describe the procedure for the approval of amendments to the HREC Standard Operating Procedures and Terms of Reference.

1. The Standard Operating Procedures and Terms of Reference shall be reviewed every three years and amended as necessary.
2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedure below:

For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive for review and approval if appropriate.

For those proposals made by the Chief Executive:

- The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.
3. Standard operating procedures, terms of reference, membership of the Ethics Committee and Ethics Committee submission documents will be maintained on the Research Office website and reviewed for currency at least every six months.

# Attachment A

## Responsibilities of Members of the Human Research Ethics Committee (HREC) Concord Repatriation General Hospital

The following policy is consistent with the *National Statement on Ethical Conduct in Human Research 2007*. It is important that all members of the HREC are familiar with the requirements of this document.

### Confidentiality

*Members of the HREC have a responsibility to :-*

- treat the matters discussed at meetings confidentially;
- exercise care with the storage and disposal of meeting papers; and
- return the agenda papers to the Executive Officer of the HREC at the end of a meeting.

### Conflict of Interest

If, at any time, a HREC member finds that he or she has a potential conflict of interest, the member should make the Chair aware of this. In general, a person who is involved in research that is to be discussed by the HREC will be asked to leave the room. He or she may respond to any questions posed by the HREC upon returning to the room. If any member is unsure whether they have a conflict of interest or not, he or she should bring it to the attention of the Chair. If the Chair is unsure, it will be brought to the attention of the HREC for its consideration and decision.

If, at any time, the Chair finds he or she has a potential conflict of interest, the Chair should make the Committee aware of this, vacate the chair in favour of the Deputy Chair during the discussion and leave the room.

### Preparation for Meeting

Members of the HREC are requested to :-

- prepare for the meeting appropriately, and, if asked to review a research project, be prepared to comment on all aspects of the research and give the HREC an opinion as to whether it should be approved and under what conditions.
- submit any agenda items or reports in reasonable time for inclusion in the pre-circulated meeting papers;
- inform the Secretariat if they are unable to attend, or will be arriving late; and
- if asked to give an opinion for the meeting but are unable to attend, pass on that opinion before the meeting or within a reasonable time period after the meeting.

S:\Policy Documents\Responsibilities of HREC members 2010.doc S:\Policy Documents\Responsibilities of HREC members 2010.doc

**During the Meeting**

Members of the HREC should :-

- address all matters through the Chair;
- remember that all members should be able to hear any discussion;
- leave the room when taking telephone calls;
- endeavour to stay until the end of the meeting, unless special arrangements have been made with the Chair.

**Declaration**

I declare that I have not been subject to any criminal conviction or disciplinary action, which may prejudice my standing as a HREC member.

I will keep confidential all matters discussed at HREC meetings.

I will inform the Chair of any conflicts of interest.

Signed: ..... Date: .....2010

Name: .....

# Attachment B

## Standard Letter for HREC Approval of New Application



CONCORD  
REPATRIATION GENERAL  
HOSPITAL

date

Dear ,

Re: **10/CRGH/xx** **CH62/6/2010- xxxx**  
[insert study title]

Thank you for submitting the above [multi-centre] project for single ethical and scientific review. This project was first considered by the Sydney South West Area Health Service Human Research Ethics Committee – CRGH Zone at its meeting held on xxxxx. This Human Research Ethics Committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

**Studies for which a waiver of consent was granted:** The Ethics Committee granted a waiver of the usual requirement for the consent of the individual to the use of their health information in a research project, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW).

I am pleased to advise that the Committee has granted ethical approval of this research project. The documents reviewed and approved include:

**National Ethics Application Form (NEAF)** – locked code AB/xxx/x

<b>Protocol Identification Number:</b>	Version:	Date: <b>xxx 2010</b>
<b>Investigator's Brochure</b>	Version:	Date: <b>xxx 2010</b>
<b>Amendment</b>	Version:	Date: <b>xxx 2010</b>
<b>[Master] Participant Information Sheet</b>	Version:	Date: <b>xxx 2010</b>
<b>[Master] Participant Consent Form</b>	Version:	Date: <b>xxx 2010</b>

**Other:** (e.g. Advertisement)

The HREC has provided ethical and scientific approval for the following sites:

1. xx
2. xx
3. xx
4. xx

Please note the following conditions of approval:

1. [insert any special conditions of approval imposed by the HREC eg: All liabilities arising from the conduct of the research at the Strathfield Breast Centre will be the sole responsibility of the Strathfield Breast Centre]
2. You will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project, (including Serious Adverse Events).
3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review in the specified format.
4. You will notify the HREC and other participating sites (if multi-centre), giving reasons, if the project is discontinued at a site before the expected date of completion.
5. You will provide an annual report to the HREC, and at completion of the study in the specified format.
6. **For drug or device trials:** You agree that you will not commence the trial named above until the Clinical Trial Notification (CTN) form has been lodged with the Therapeutic Goods Administration (TGA). **Add for trials being conducted at Concord ONLY - N/A if multi-centre:** A copy of the TGA acknowledgment must be submitted to the CRGH Clinical Trials Pharmacist for inclusion on file.
7. You will adhere to the study protocol at all times, **add for indemnified trials only:** as failure to do so will invalidate the Indemnity agreement.
8. **For trials of implantable devices:** This study involves the implantation of an investigational device. It is a requirement of ethics approval that all participants are included in a device tracking register and that arrangements are made for monitoring all participants for the lifetime of the device. Any device incidents must be reported to the Therapeutic Goods Administration and to the Committee.
9. **For drug or device trials (if this information not already provided):** It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.
10. **For drug/device trials or interventions:** Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study. **Also add for trials being conducted at Concord ONLY – N/A if multi-centre:** If you (or your co-investigators) are undertaking this research on behalf of the University of Sydney or as part of a conjoint appointment to the University, you must inform the University of Sydney Risk Management Office, so that appropriate indemnification can be arranged.

HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the Concord Hospital Research Office by xx/xx/2011.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - Ms Virginia Turner on (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: [www.sswahs.nsw.gov.au/concord/ethics](http://www.sswahs.nsw.gov.au/concord/ethics) .

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

**Add for multi-site trials only:** Please forward a copy of this letter to all site investigators for submission to the relevant Research Governance Officer

We wish you every success in your research.

**Please quote the above file number in all correspondence.**

Yours sincerely,

**Dr Garry Pearce**  
**Chairman**  
**SSWAHS Human Research Ethics Committee – CRGH**

cc: Lucy Nigro, Clinical Trials Pharmacist, CRGH. [\[remove if not a drug trial\]](#)

**Please complete and return a copy of this page to the Concord Hospital Research Office as acknowledgment of your acceptance of the Conditions of Ethical Approval.**

\_\_\_\_\_  
**Printed Name**  
Chief Investigator

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

# Attachment C

## Standard Response Letter for HREC Rejection of New Application

[On letterhead]

date

Professor XXX  
Department of  
CONCORD RGH

Dear [insert name of principal investigator]

**Re: CH62/6/2010-xx**  
**HREC/10/CRGH/xx**  
xx

- National Ethics Application Form
- Research Protocol Version xx
- Participant Information Sheet xx
- Participant Consent Form Version xx

Thank you for submitting the above new research proposal which was considered by the Scientific Sub-committee at its meeting of xx 2010 and by the Sydney South West AHS Human Research Ethics Committee – CRGH zone at its meeting of xx 2010.

The HREC has decided not to approve your project for the following reasons:

1. [List each reason separately. Each reason must refer to the relevant paragraph/s of the *National Statement*, relevant legislation or other applicable guidelines].

Should you wish to discuss the HREC's review of your project, please contact Virginia Turner, Executive Officer of HREC on 02 9767 5622.

Yours sincerely,

Virginia Turner  
**Executive Officer**  
**SSWAHS Human Research Ethics Committee – CRGH**

# Attachment D

## Standard Letter for HREC Approval of Amendment

[On letterhead]

date

Professor XXX  
Department of  
CONCORD RGH

Dear [insert name of principal investigator]

**Re: CH62/6/**  
[Study title to be inserted].

- ✎ **Amendment 3 dated xxxx 2006**
- ✎ **Revised Protocol No. xxxx dated xxxx 2006.**
- ✎ **Revised Patient Information Sheet and Consent Form Version 9 dated xxxx 2006.**

Thank you for submitting the above documents which were approved by the Concord Hospital Drug Committee at its meeting of xxxxx 2007 and by the Expedited Ethical Review Panel of the Concord Hospital Human Research Ethics Committee at its meeting of xxxxx 2007.

***Please quote the above Concord Hospital File No. in all correspondence.***

Yours sincerely,

**Virginia Turner**  
*Executive Officer*  
**SSWAHS Human Research Ethics Committee – CRGH**