

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

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Definitions and Abbreviations	
AHEC	Australian Health Ethics Committee
DTS	Drug Trial Subcommittee (a scientific subcommittee of the HREC)
DUC	Drug Usage Committee (internal committee)
EDMS	Executive Director of Medical Services
HREC	Human Research Ethics Committee
MCRI	Murdoch Childrens Research Institute
National Statement	NHMRC National Statement on Ethical Conduct in Human Research (2007)
NHMRC	National Health & Medical Research Council
P/GIS	Parent/Guardian Information Statement
PI	Principal Investigator
RCH	The Royal Children's Hospital Melbourne
REG	Research Ethics & Governance (also 'Ethics Office')
RGO	Research Governance Officer
SOP	Standard Operating Procedure
TGA	Therapeutic Goods Administration
ToR	Terms of Reference
VMIA	Victorian Managed Insurance Authority (RCH Insurers)

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	001	Date created	February 2010
Subject	Submission procedure for new applications		
Purpose	To describe the procedure for the submission of new applications		

1. Human Research conducted on the RCH Campus is defined by 3 categories (levels of risk) which determine the process for submission & review:
 - a. CATEGORIES
 1. **Low & Negligible Risk Research**
 2. **Drug/Device Research** (research using an unapproved drug/device, or an approved drug/device in an unapproved indication, age group or dosage)
 3. **Standard Human Research** (which is greater than low risk but does not involve a drug or device)
 - b. LEVEL OF RISK
 1. **Negligible Risk Research** (inconvenience)
 2. **Low Risk Research** (burden)
 3. **Greater than Low Risk Research** (harm, or risk of harm)
2. Investigators are required to complete the [Risk Assessment Checklist](#) to categorise their research into one of the above 3 categories and risk levels prior to submission. The different categories determine which application form must be completed and what form the ethical review will take. (See the [REG website](#) for more information)
3. Research falling into category (1) is reviewed by the HREC Chairman. As such may be submitted on any date (no applicable deadline) (see [SOP 003: Low & Negligible Risk Research](#) for more information).
4. Research falling into category (2) undergoes a scientific review by the Drug/Device Trial Subcommittee (DTS) before being reviewed by the HREC. As such it must be submitted by the researchers to the REG by the closing date for the DTS (see [SOP 005: Preparation of DTS Agenda](#)) for more information on the review of drug & device research). The relevant closing dates for receipt of applications are readily available to prospective applicants on the [REG website](#).
5. Research falling into category (3) undergoes a scientific review by an expert reviewer (if determined as required following review by REG) before being reviewed by the HREC. As such it must be submitted to REG by the closing date (see [SOP 004: Scientific review of Human Research](#) for more information).
6. Applications must be submitted by researchers in the appropriate format and must include all required documentation. The procedures for application and the application format is on the [REG website](#).
7. Guidelines to assist applicants in the preparation of their applications, including guidance on how to determine the appropriate application process (forms) is available on the [REG website](#).

8. A fee will be charged for research and governance applications as outlined in the fee policy on the [REG website](#).

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Reference Number	002	Date created	February 2010
Subject	Processing of applications for review		
Purpose	To describe the procedure for the processing of new applications		

1. Once received by REG the research application is entered into REG database of applications. A unique project identification number is given to the project. This unique identifier is emailed to the PI (and study contact) and should be used by the researchers in all correspondence to the REG regarding that research project.
2. Applications will be checked for their completeness by REG prior to commencing the review process. Any missing documents will be requested from the researchers by REG. Incomplete applications will be held back from scientific & ethical review until they are complete. A full list of required documentation & signatures is listed on the REG website
3. REG will acknowledge acceptance of the application for scientific & ethical review by email to the PI and or nominated contact person within 5 working days of receipt of the application.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	003	Date created	February 2010
Subject	Low & Negligible Risk Research (Expedited Review)		
Purpose	To describe the procedure for the review & approval of low and negligible risk research		

1. As defined by the [RCH Risk Assessment Checklist](#) (in compliance with the National Statement) the term 'low risk research' describes research in which "*the only foreseeable risk is one of discomfort*" and 'negligible risk research' in which "*there is no foreseeable harm or discomfort; and any foreseeable risk is not more than inconvenience*"
2. Researchers conducting Low and Negligible Risk Research are required to complete a short application form as per instructions on the [REG website](#).
3. The application will be reviewed in accordance with the National Statement on Ethical Conduct in Human Research.
4. The application will be reviewed by the HREC Chair, REG Director or delegate within 5 working days of receipt of the application. Any queries, clarification or comments will be emailed to the PI (and study contact by REG).
5. Once all necessary queries, clarification or comments have been responded to satisfactorily the HREC Chair or delegate will provide approval for the project.
6. The HREC Chair & REG Director reserves the right to escalate any project to the full HREC as they deem necessary.
7. REG will email the PI (and study contact) with an approval letter.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	004	Date created	February 2010
Subject	Scientific review of Standard Human Research (non-drug/device)		
Purpose	To describe the procedure for the scientific review of non-Drug/Device research which is greater than low risk		

1. Human Research which is greater than low risk as defined by [RCH Risk Assessment Checklist](#) (in compliance with the National Statement) and does not involve a drug or device is reviewed as per this SOP.
2. In the first instance, a scientific review is undertaken by way of a peer review. On receipt of the application, REG (in consultation with the HREC Chair) will identify whether the peer review provided is considered sufficient. If so, the project will proceed to HREC for review. If not, the following process will be followed.
3. REG retains a list of Expert Reviewers including their area of expertise.
4. As required, an application is sent out for review by an Expert Reviewer who has the appropriate expertise and experience to conduct a scientific review of the particular discipline(s) and procedures involved. If the research spans more than one discipline or if a single reviewer cannot be found with all necessary expertise then the application may be assigned to more than one reviewer (this is at the discretion of REG).
5. Applications are sent out for review within 3 working days of receipt by REG. The Expert Reviewer is given 2 weeks to review the research application.
6. Conflicts of Interest of the Expert Reviewer(s) are dealt with in accordance with [SOP 026: Conflicts of Interest](#).
7. The Expert Reviewer(s) will scientifically assess each application using a [Reviewer Proforma](#) supplied by REG in accordance with the National Statement.
8. The Expert Reviewer(s) will formulate a list of queries, comments and clarifications and must categorise the project as follows:
 - a. The project is scientifically sound. Response to queries is not required before ethical review (any queries raised can be answered post ethical review). The project may proceed directly to ethical review by the HREC.
 - b. The project requires some work. Response to queries and updated documentation is required before ethical review. Responses from researchers required prior to ethical review by the HREC.
 - c. The project requires a lot of work. Response to queries is required and additional scientific review required following submission of responses.

9. The PI (and study contact) will be notified of the review outcome by REG within 3 working days of the receipt of the Expert Review. The letter will contain instructions for the submission of the project for ethical review including:
 - a. Queries, comments or clarifications required
 - b. Numbers and types of documents required for submission
 - c. Closing date for the next HREC agenda
 - d. Information that the researchers may contact REG to discuss the comments, request clarification or to seek advice with regard to the submission of their response documents.
10. The correspondence to the PI articulates the reasons for this decision and outlines the information that is required. Where possible, requests for additional information, clarification and/or amendment refer to the NHMRC National Statement on Ethical Conduct in Human Research (2007) (National Statement) or relevant pieces of legislation.
11. REG retains on file a copy of the Expert Reviewer(s) comments and a copy of the correspondence to the researchers and the REG database is updated accordingly.
12. The responses and updated documents (once received by the REG) will undergo an ethical review by the full HREC. See [SOP 015: HREC Review of research applications](#).

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	005	Date created	February 2010
Subject	Preparation of Drug Trial Subcommittee (DTS) Agenda		
Purpose	To describe the process and format of agenda for an DTS meeting		

1. As per the [RCH Risk Assessment Checklist](#) research which involves the following is reviewed by the Drug/Device Trials Subcommittee (DTS):
 - a. use of an investigational product (drug, device, complementary medicine, biotechnology etc) as a reference in a clinical trial e.g. use of an unapproved product;
 - b. use of an approved product for an unapproved indication, age group or dose; or
 - c. use of an approved product to gain further information about an approved use (i.e. pharmacokinetic or pharmacodynamic research, evaluation or comparison of drugs or devices)
2. The DTS Secretariat is responsible for preparing an agenda for each DTS meeting.
3. All completed applications and relevant documents received by the DTS Secretariat by the relevant DTS closing date are included on the agenda for DTS consideration at its next meeting. Meeting dates and deadlines are available on the [REG website](#).
4. The meeting agenda and associated documents are prepared by the DTS Secretariat and circulated to all DTS members at least 10 days prior to the DTS meeting.
5. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the DTS Chair or REG Director.
6. Agenda items will include at least the following items:
 - a. Apologies
 - b. Confirmation of minutes from the previous DTS meeting
 - c. Conflicts of interest
 - d. Business arising
 - e. New trials submitted for review
 - f. Projects outstanding (to return to DTS)
 - g. Project amendments
 - h. Project correspondence
 - i. Reports of adverse events
 - j. General business
7. The agenda and all documentation shall remain confidential.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	006	Date created	February 2010
Subject	Conduct of DTS Meetings		
Purpose	To describe the format of meetings of the DTS		

1. The DTS meets on a regular basis, which is normally at monthly intervals and generally 1-2 weeks prior to the RCH HREC. Meeting dates and agenda closing dates are available on the [REG website](#).
2. Members attend DTS meetings in person or may nominate a proxy if necessary.
3. The DTS Chair may cancel a scheduled meeting if a quorum cannot be achieved (refer to point 8). Should this occur, the DTS will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.
4. Meetings are scheduled for an allocated time. If the business has not been completed within the allocated time, then DTS may either continue the meeting until all agenda items have been considered or schedule an additional meeting.
5. The DTS 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 point 5, DTS may agree to the presence of visitors or observers to a meeting.
7. Members who are unable to attend a meeting are required to contribute prior to the meeting through written submissions to the REG Director, DTS Secretariat or DTS Chair. Written comments must be received prior to the meeting so that they may be discussed at the meeting by the members present. The minutes record the submission of written comments. If the comments cannot be submitted prior to the meeting then their inclusion in the minutes and/or letter to researchers is at the discretion of the DTS Chair.
8. A quorum shall consist of two (2) members, including one (1) clinician plus one (1) pharmacist/clinical pharmacology representative.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	007	Date created	February 2010
Subject	Scientific review of Drug/Device research		
Purpose	To describe the process of scientific assessment of research applications by the DTS.		

1. It is the role of the DTS to advise the HREC on matters relating to scientific, medico-legal (and in some case ethical) issues associated with clinical drug or device trials conducted on the RCH campus.
2. The research application is reviewed by all members of the DTS present at the meeting or providing written comments in lieu of attendance; except for those with a conflict of interest, who will leave the room and not participate in the adjudication.
3. The DTS will scientifically assess each application in accordance with the NHMRC National Statement, the TGA Note for Guidance on Good Clinical Practice and appropriate regulatory requirements and guidelines pertaining to the conduct of clinical trials in Victoria and Australia.
4. The DTS may decide to refer the application to an external expert reviewer(s) if necessary.
5. The DTS, after consideration of an application at a meeting will make one of the following recommendations about the project:
 - a. **Scientifically sound:** Responses to any queries raised by DTS are not required before ethical review. The project will be considered at the next HREC meeting and queries, comments or clarifications from the DTS (where applicable) will be sent to the researcher after the HREC meeting, in addition to the queries arising from the HREC meeting (where applicable).
 - b. **Scientifically sound with conditions/clarification:** Response to DTS queries and updated documentation is required before ethical review. Responses from researchers required prior to ethical review by the HREC.
 - c. **Not scientifically sound:** Response to DTS queries is required and full DTS review is required following submission of responses.
6. The DTS will endeavour to reach a decision concerning the scientific 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 the members who examined the project.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	008	Date created	February 2010
Subject	Preparation of DTS minutes		
Purpose	To describe the process and format for minutes of a meeting of the DTS & notification of outcome to researchers		

1. The DTS Secretariat is responsible for preparing and maintaining minutes of all meetings of the DTS.
2. The minutes include the recording of decisions taken by the DTS as well as a summary of relevant discussion. This includes reference to views expressed by absent members.
3. In relation to the review of new applications or amendments, the minutes record a summary of the main scientific issues considered, including any requests for additional information, clarification or amendment of the project.
4. In recording a decision made by the DTS, any vote including numbers for and against (and numbers of members abstaining from voting where applicable) will be noted in the minutes.
5. To encourage free and open discussion and to emphasise the collegiate character of the DTS, particular views are not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.
6. Declarations of conflicts of interest by any member of the DTS and the absence of the member concerned during the DTS consideration of the relevant application are minuted (refer to [SOP 026: Conflicts of Interest](#)).
7. The minutes are finalised within 3 working days following the relevant meeting including review by the REG Director and DTS Chair, for accuracy.
8. The minutes are circulated to all members of the DTS after the minutes have been finalised and are included as an agenda item for the next meeting. All members are given the opportunity to seek amendments to the minutes prior to their ratification. The minutes are formally approved at the subsequent DTS meeting.

9. A copy of each meeting's minutes are retained in a confidential 'DTS Minutes' file.
10. The PI (and study contact) will be notified of the review outcome by REG within 5 working days of the meeting, unless otherwise notified. The letter will contain instructions for the submission of the project for ethical review including:
 - a. Queries, comments or clarifications required
 - b. Numbers and types of documents required for submission
 - c. Closing date for the next HREC agenda
 - d. Information that the researchers may contact the REG to discuss the comments, request clarification or to seek advice with regard to the submission of their response documents.

In the case that the project is *Fast-tracked* (see [SOP 007: Scientific review of Drug/Device research](#) point 5a) the PI will be notified that the project has proceeded directly to HREC and they will be notified of any scientific and ethical queries following the HREC meeting.

11. The correspondence to the PI clearly articulates the reasons for this decision and outlines the information that is required. Where possible, requests for additional information, clarification and/or amendment refer to the National Statement or relevant pieces of legislation.
12. The REG retains on file a copy of the correspondence to the researchers and the REG database is updated accordingly.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	009	Date created	February 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 of 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 NHMRC National Statement on Ethical Conduct in Human Research (2007) (National Statement) and Victorian Health Policy Directives

Scope of Responsibilities

2. The functions of the HREC are:
 - a. To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
 - b. To provide ethical oversight, monitoring and advice for research projects involving humans.
 - c. To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
3. The Terms of Reference for the RCH HREC can be found on the [REG website](#).
4. This operating procedure does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve an expedited review of the project, provided that such other HREC is accredited for review of paediatric research or in the case of multi-centre research, an accredited lead HREC accredited for review of paediatric research (see [SOP 028: Research which is exempt from HREC Review](#) for more information).
5. 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.
6. The HREC will assess projects submitted to it for review in accordance with the National Statement and any relevant guidelines and legislation in order to determine their ethical acceptability.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	010	Date created	February 2010
Subject	HREC Membership		
Purpose	To describe the membership composition of the HREC		

1. The composition of the HREC is in accordance with the NHMRC National Statement.
2. Minimum membership comprises of eight members, men and women as follows:
 - a. a Chair (and a Deputy Chair);
 - b. at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work;
 - c. at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - d. at least one member who performs a pastoral care role in the community;
 - e. at least one member who is a Lawyer;
 - f. at least two members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC.
3. To ensure the membership equips 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.
4. Where required, the HREC may seek advice and assistance from appropriate Expert Reviewers to assist with the review of a project. An up-to-date list of Expert Reviewers is kept by REG. However, the HREC must be satisfied that such experts have no conflicts of interest, or have declared any 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) is required to provide an undertaking of confidentiality and is not entitled to vote on any matter.
5. 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, where possible.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	011	Date created	February 2010
Subject	Appointment of HREC members		
Purpose	To describe the procedures for the appointment of members to the HREC		

1. Members are appointed as individuals rather than in a representative capacity.
2. Prospective members of the HREC are recruited by direct approach, nomination or by advertisement. Prospective members are 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 REG website.
3. A selection committee, consisting of the Chair, REG Director and at least one other HREC member review the prospective applicant's Curriculum Vitae, and may consult with the HREC members in order to make a recommendation to the RCH Board. Prospective members are invited to attend a meeting of the HREC as an observer before the recommendation is made.
4. Members are nominated for appointment by the HREC Chair in consultation with the selection committee. Members are reference checked, police checked and finally appointed by the RCH Board. New members receive a formal notice of appointment.
5. The Chair and Deputy Chair are nominated for appointment by the Executive Director of Medical Services and appointed by the RCH Board. In the absence of the Chair, the Deputy Chair performs the role and duties of the Chair.
6. The letter of appointment includes:
 - a) the date of appointment
 - b) length of tenure
 - c) 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
 - d) conditions of their appointment including:
 - i. Familiarising themselves with National Statement & other guidelines as provided
 - ii. Preparing for & attending scheduled meetings; or if unavailable, providing comments
 - iii. Attend continuing education or training in research ethics at least every 3 years
 - iv. An assurance of confidentiality on undertaking their appointment (all matters of which they become aware during the course of their work on the HREC will be kept confidential)
 - v. Declaration of any conflicts of interest, which exist at the time or may arise during their tenure on the HREC. These may be made to the REG Director or at an HREC meeting if the COI relates to a specific research project.

7. Upon appointment, members are provided with the following documentation:
 - a) National Statement on Ethical Conduct in Human Research (2007)
 - b) HREC Terms of Reference
 - c) HREC Standard Operating Procedures
 - d) List of members' names and contact information for the REG team
 - e) Any other relevant information including web links to HREC processes, state & national guidelines and legislation.
8. Members are appointed for a period of three years and may serve consecutive terms at the discretion of the HREC Chair & RCH Board. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the RCH Board. Members are advised when his/her term has expired. Reappointment is by application to the HREC Chair who then makes a recommendation to the RCH Board.
9. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
10. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions are met by the RCH.
11. The HREC Chair holds a position within the REG and is remunerated accordingly. Members shall not be remunerated. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.
12. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy where necessary.
13. Membership lapses if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.
14. Members are expected to participate in relevant specialised working groups as required. The Chair and Deputy Chair will be expected to be available between meetings to participate in REG meetings where required.
15. A member may resign from the HREC at any time upon giving notice in writing to the HREC Chair or REG Director. Steps shall be taken to fill the vacancy of the former member where necessary.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	012	Date created	February 2010
Subject	Induction & Training of HREC members		
Purpose	To describe the procedure for the orientation of new of members to the HREC		

1. New HREC members are provided with adequate induction following their appointment as per [SOP 011: Appointment of HREC Members](#).
2. Induction involves some or all of the following:
 - a. Introduction to other HREC members prior to the HREC meeting.
 - b. Informal meeting with Chair and REG Director to explain their responsibilities as an HREC member, the HREC processes and procedures.
 - c. An opportunity to sit in on HREC meetings before their appointment takes effect.
 - d. 'Partnering' with another HREC member in the same category.
 - e. Priority given to participate in training sessions.
3. REG will organize a Professional Development (PD) sessions (30 minutes) for the HREC members within HREC meetings throughout the year. The PD will be on sections of the National Statement and/or other relevant legislation and guidelines. Members may suggest topics for PD. Members are expected to attend the session as part of attending the meeting.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	013	Date created	February 2010
Subject	Preparation of HREC Agenda		
Purpose	To describe the process and format of agenda for an HREC meeting		

1. Research which poses greater than low risk as defined by the National Statement as research which poses "*a foreseeable risk of harm to the participant, even if unlikely*". All research which is greater than low risk is ethically reviewed by the HREC.
2. Low & Negligible Risk research is ethically reviewed by the HREC Chair but may be escalated to full HREC review at the discretion of the HREC Chair.
3. The HREC Secretariat is responsible for preparing an agenda for each HREC meeting.
4. All completed applications and relevant documents received by the HREC Secretariat by the relevant HREC closing date are included on the agenda for HREC consideration at its next meeting.
5. The meeting agenda and associated documents are prepared by the HREC Secretariat and circulated to all HREC members at least 10 days prior to the HREC meeting.
6. Documentation received after the closing date can be included on the agenda and/or tabled at the meeting at the discretion of the REG Director and HREC Chair.
7. Agenda items include at least the following items:
 - a. Apologies
 - b. HREC Minutes (from the previous meeting)
 - c. Subcommittee Minutes (DTS) (from the previous meeting)
 - d. Conflicts of Interest
 - e. Renewals & Amendments to approved protocols requiring HREC review
 - f. New Research Applications
 - g. Approval Notifications
 - h. Information & Relevant Literature
 - i. General Business/ Matters Arising
8. The agenda and all documentation are confidential.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	014	Date created	February 2010
Subject	Conduct of HREC Meetings		
Purpose	To describe the format of meetings of the HREC		

1. The HREC meets on a regular basis, 11 times per year at approximately monthly intervals. Meeting dates and agenda closing dates are available on the [REG website](#).
2. Members attend HREC meetings in person or via teleconference.
3. The Chair may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 8). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.
4. Meetings are scheduled for an allocated time. If the business is not completed within the allocated time, the HREC either continues the meeting until all agenda items have been considered or schedules an additional meeting. If an additional meeting is called for, then the meeting is held within 5 working days (where possible).
5. The HREC meeting is conducted in private, to ensure confidentiality and open discussion. Members are 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.
7. Members who are unable to attend a meeting contribute prior to the meeting through written submissions to the REG Director, HREC Secretariat or HREC Chair. Written comments must be received prior to the meeting so that they may be discussed at the meeting by the members present. The minutes record the submission of written comments. If the comments cannot be submitted prior to the meeting then their inclusion in the minutes and/or letter to researchers is at the discretion of the HREC Chair.
8. A quorum shall consist of the eight (8) members required to fulfil the minimum membership requirements as outlined in the National Statement (Sections 5.1.29-5.1.30). If the eight core members are not present the chairperson must be satisfied that these members have received all the relevant papers and have had the opportunity to contribute their views and that these have been received and considered before a final decision is made (as per Section 5.2.30 of the National Statement).

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	015	Date created	February 2010
Subject	HREC Review of research applications		
Purpose	To describe the process of the HREC's consideration of the applications for the ethical assessment		

1. The HREC considers research applications once the science of the application has been reviewed and passed by the relevant scientific assessment committee (DTS or TP-) (as per [SOP 004: Scientific review of Human Research \(Non Drug/Device\)](#) & [SOP 007: Scientific Review of Drug/Device Research](#)).
2. The application is reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance; except for those with a conflict of interest, who will leave the room and not participate in the adjudication.
3. The HREC ethically assesses each application in accordance with the NHMRC National Statement on Ethical Conduct in Human Research and other relevant guidelines and legislation. 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.
4. The HREC may also choose to refer the application to an external expert reviewer(s).
5. The HREC must consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.
6. The HREC, after consideration of an application at a meeting makes one of the following decisions:
 - a. To approve the project as being ethically acceptable, with or without conditions.
 - b. To provide provisional approval to the project with requested amendments, this may then be reviewed for final approval by the HREC Chair and/or HREC subcommittee.
 - c. To defer making a decision on the project until the clarification of information or the provision of further information to the HREC.
 - d. To not approve the project (at this time the researcher may choose to rewrite the protocol in order to make it ethical)
7. The HREC endeavours to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision is considered to be carried by a majority of the members who examined the project. The vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.
8. 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.
9. For projects where the HREC has requested clarification, the provision of further information, or amendment 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:

- i. Chair or Deputy Chair alone
- ii. Chair or Deputy Chair, 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
- iii. A sub-committee of the HREC.

In such circumstances, the HREC is informed at the next appropriate meeting, of the final decision taken on its behalf, when the approval will be ratified.

10. If the HREC decides that further information or responses from the investigator (as in Point 6, c & d above) should be considered at a further meeting of the HREC, the PI (and/or delegate) is invited to attend the HREC meeting in order to provide clarification and answer any further questions raised.
11. The HREC delegates the expedited ethical review of low and negligible risk research projects to the HREC Chair in accordance with [SOP 003: Low & Negligible Risk Research \(Expedited Review\)](#).

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	016	Date created	February 2010
Subject	Preparation of HREC minutes		
Purpose	To describe the process and format for minutes of a meeting of the HREC		

1. The HREC Secretariat is responsible for preparing and maintaining minutes of all HREC meetings.
2. The minutes 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.
3. In relation to the review of new applications or amendments, the minutes record a summary of the main ethical issues considered, including any requests for additional information, clarification or amendment of the project.
4. In recording a decision made by the HREC, any vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.
5. To encourage free and open discussion and to emphasize the collegiate character of the HREC, particular views are not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.
6. 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 are minuted (refer to [SOP 026: Conflicts of Interest](#)).
7. The minutes are finalised within 5 working days following the relevant meeting including review by the HREC Chair or delegate for accuracy.

8. The minutes are circulated to all members of the HREC once finalised and also as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their finalisation. The minutes will be formally approved and signed by the HREC Chair at the next HREC meeting.
9. The signed final copy of each meeting's minutes is retained in an electronic, secure and confidential 'HREC Minutes' file.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	017	Date created	February 2010
Subject	Notification of HREC decisions		
Purpose	To describe the procedure for notification of decisions of the HREC concerning the review of new applications		

1. The HREC Secretariat reports the HREC decision in writing to the PI (and study contact) within 5 working days of the meeting, unless otherwise notified.
2. If the HREC determines that further information, clarification or amendment is required for the consideration of a project, the correspondence to the PI clearly articulates the reasons for this determination and outlines the information that is required. Where possible, requests for additional information, clarification and/or amendment refer to the National Statement or relevant pieces of legislation.
3. If the requested information is not received from the applicant within 60 days of the letter being sent the project may be dismissed and the applicant may be required to re-submit the project at a later date.
4. The HREC endeavors to openly communicate with researchers to resolve outstanding requests for further information, clarification or amendment of projects relating to ethical issues. The HREC may nominate one (or more) of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.
5. REG notifies the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or amendment have been satisfactorily resolved. Notification of ethical approval is in writing, and contains the following information:
 - i. Title of project
 - ii. Name of the Principal Investigator
 - iii. Unique HREC project identification number
 - iv. The version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets and Consent Forms, Advertisements, Questionnaires etc.
 - v. Date of HREC approval.
 - vi. Conditions of HREC approval.
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. HREC member(s) or REG staff may be nominated to work with the researcher to assist in re-submission.
7. The status of the project is updated by the HREC Secretariat on the REG database.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	018	Date created	February 2010
Subject	Submission of Amendments and Renewals		
Purpose	To describe the procedures for the submission and HREC review of requests for amendment and renewal (extension) of HREC approval for approved protocols		

1. Proposed changes to approved research projects or conduct of the research (amendments) and requests for extensions to HREC approval (renewals) must be submitted by the PI (or study contact) to REG for review.
2. Requests must 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 have the changes highlighted and contain revised version numbers and dates.
3. Requests for amendments and renewals undergo a two tier review; 1) scientific & 2) ethical:

Scientific Review:

 - Firstly a scientific review is undertaken by an expert reviewer (or member of REG).
 - For minor amendments and renewals the expert reviewer(s) will be asked to provide scientific review and comment within 3 working days, for major amendments they will be given 10 working days.
 - REG collates the comments, queries and requests for clarification into a letter and reports in writing to the PI (or study contact) within 3 working days of the receipt of the scientific review. This letter contains instructions for submission for ethical review.
 - The PI (or study contact) is responsible for responding to these queries (updating documents where necessary) and submits the amendment or renewal to the REG for ethical review.
 - If no scientific queries are raised then the amendment or renewal proceeds straight to ethical review.

Ethical review:

 - An ethical review is conducted by the HREC Chair or delegate (within 3 working days) who is responsible for providing final sign off as per delegation from the RCH HREC.
 - REG reports in writing to the PI and/ or nominated contact person, advising of the ethical approval outcome of the proposed amendment and/or request for extension, within 3 working days of the ethical review.
 - If ethical comments, queries or requests for clarification are raised these are forwarded to the PI (or study contact) by REG. The PI (or study contact) is responsible for replying to these queries (updating documents where necessary) before final approval can be granted by the HREC Chair.
 - The HREC Chair reserves the right to escalate any amendment or renewal to the full HREC if it contains major ethical implications.
 - Renewals to HREC Approval which are more than 6 months expired require full HREC review.
4. If the HREC (or HREC Chair) determines that further information, clarification or amendment is required for the consideration of the request for amendment or extension, the

correspondence to the investigator clearly articulates the reasons for this determination and outlines the information that is required. Where possible, requests for additional information, clarification and/or amendment refer to the National Statement or relevant pieces of legislation.

5. Amendment and renewal requests approved by the HREC Chair are ratified by the HREC at a subsequent meeting. Researchers do not need to wait for the HREC ratification to occur before proceeding.
6. Where an urgent protocol amendment is required for safety reasons, the Chair may review and approve the request (with the help of an expert reviewer if necessary). In such circumstances, the amendment or renewal information is tabled at the next HREC meeting.
7. All reviewed and approved requests for amendments and extensions are recorded, and the status of the project is updated by REG on the REG database.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	019	Date created	February 2010
Subject	Safety Reporting		
Purpose	To describe the procedures for the reporting and handling of safety reports and other adverse events.		

1. The HREC shall require, as a condition of approval of each project, that researchers report Significant Safety Issues (SSI's, as defined by the TGA) and other Adverse Events to the REG according to the following procedure

Serious Adverse Events (Drug/Device trials):

- i. **Internal SSI's (occurring in RCH participants)** must be reported to the RCH HREC within 72 hours of occurrence (using the Safety Reporting form)
- ii. **External SSI's (occurring in participants at other sites)** must be reported in a prompt manner if the information impacts the continued ethical acceptability of the trial. This includes cases where the information requires, or indicates the need for, a change in the trial protocol or information statement, including changed monitoring (using the Safety Reporting form)
- iii. **Annual safety reports** must be reported without undue delay (using the Annual Safety Report Form). For Investigator Initiated Trials this can be submitted with the annual progress report. The report should be attached as an appendix. For Commercially Sponsored Trials, the Executive Summary of safety information produced for international regulators, such as a Development Safety Update Report (DSUR), may serve as the annual safety report sent to HRECs (a full DSUR is not required). The timing of the annual safety report may be aligned with the reporting cycles of global companies or aligned with the annual progress report sent to the HREC.

Other events (all research) (submitted in letter or e-mail format to the REG Director)

- iv. Any adverse event that occurs as part of a research which falls into one (or more) of the categories below must be submitted to the RCH HREC:
 1. Is a deviation from or violation of the protocol which affects patient safety
 2. May result in a claim against the hospital
 3. Is 'unexpected' and 'possibly' related to the procedures of the study
 4. Requires a change in the consent form
 5. Requires a change in the conduct of the study i.e. Protocol

2. Notifications of SSI's are submitted by the PI (or delegate) to REG on a completed Safety Report Form which includes:
 - i. Advice from the PI 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
 - ii. Advice from the PI as to whether, in his/her opinion, the adverse event necessitates an amendment to the protocol and/or the Patient Information Sheet/Consent Form.
 - iii. Advice from the PI regarding whether the event was expected or unexpected as per the protocol or for drug/device trials as per the safety profile of product.
 - iv. Advice from the PI as to whether the event has been notified to the Independent Safety and Data Monitoring Board (if one exists).

3. For studies where RCH HREC are the reviewing HREC, SSI's are reviewed by a member of the Drug Trials Subcommittee (DTS) as per delegation from the HREC. The SSI's are reported to the DTS at the next available meeting, and any relevant discussion recorded in the meeting minutes. SSI's are reported to the HREC via a copy of the DTS minutes. The DTS Chair (an attendee of the HREC) draws to the HREC attention any issues requiring discussion or consideration. The DTS (or delegate) are required to determine the appropriate course of action (as specified above). This may include:
 - i. No action, information on file of the occurrence
 - ii. Request for additional information or clarification from the investigator
 - iii. Request for an amendment to the Protocol and/or P/GIS & Consent Form
 - iv. Suspension of ethical approval and project halted (see [SOP 023: Suspension or Withdrawal of HREC Approval](#))
 - v. Increased monitoring of the project
 - vi. Reporting the event to the VMIA
 - vii. Referring the decision to the HREC (the HREC then decides on one of the above actions at the HREC meeting)

4. Where RCH is an accepting site, all SSI's and other adverse events are reviewed by the REG Director who determines the appropriate course of action. SSI's may be escalated to the HREC Chair or HREC for review at the discretion of the REG Director. The HREC or HREC Chair is then required to determine the appropriate course of action. This may include:
 - i. No action, information on file of the occurrence
 - ii. Request for additional information or clarification from the investigator
 - iii. Request for an amendment to the Protocol and/or P/GIS & Consent Form
 - iv. Suspension of ethical approval and project halted (project requires HREC review)
 - v. Increased monitoring of the project
 - vi. Reporting the event to the VMIA

5. Please also see [SOP 021: Complaints from Research Participants \(Management & Resolution\)](#).

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	020	Date created	February 2010
Subject	Monitoring of Approved Research		
Purpose	To describe the procedures for monitoring research projects approved by the HREC		

The HREC monitors approved projects to ensure compliance with the protocol and relevant legislation and guidelines as per HREC approval. The RCH HREC mechanisms for monitoring are as follows:

1. Annual Reports (including DSMB reports)

An annual report must be submitted to REG by the PI (or delegate) at the anniversary of the HREC approval (or renewal). The annual report is submitted on the RCH Annual Report Form.

The Annual Reports are reviewed by the REG Research Governance Officer (RGO) or delegate within 5 working days of receipt. The REG RGO corresponds with the PI (or delegate) with any queries, comments or clarification required. Once the Annual Report is complete and correct it is listed on the agenda for the next HREC meeting. The HREC may request to review the report and any queries, comments or clarifications raised are sent to the PI by REG within 5 working days. If no queries are raised the Annual Report is accepted and filed in the REG study file (the PI is not notified).

2. Final Reports

A final report must be submitted to REG by the PI (or delegate) at the completion of a research project or if the project is discontinued or abandoned. The final report is submitted on the RCH Final Report Form.

The final reports are reviewed by the REG Research Governance Officer (RGO) or delegate within 5 working days of receipt. The REG RGO corresponds with the PI (or delegate) with any queries, comments or clarification required. Once the final report is complete and correct it is listed on the agenda for the next HREC meeting. The HREC may request to review the report and any queries, comments or clarifications raised are sent to the PI by the REG within 5 working days following the meeting. If no queries are raised the Final Report is accepted and filed in the REG study file (the PI is not notified).

3. Serious Adverse Event (and other adverse event) reports

Please see [SOP 019: Adverse Event Reporting & Handling](#) for more information.

4. Monitoring & Auditing visits

The REG Research Governance Officer conducts on site monitoring and auditing. The purpose of the auditing program is to review how research is conducted, and to detect, correct and prevent potential and existing problems. The objectives of the auditing program are:

- i. to ensure research is conducted ethically, safely, legally and in compliance with the protocol, conditions of HREC approval and institutional policies & procedures.
- ii. to raise awareness of requirements and promote researchers' accountability.

- iii. to ensure that the conduct of research does not compromise the integrity of the results.

All ongoing human research projects with ethics approval granted by the RCH HREC are eligible to be audited, including clinical trials, observational studies, clinical audit activities and public health research projects.

Studies from all tiers of risk (negligible risk, low risk and greater-than-low risk) will be audited, however higher risk studies will be the focus of more audits than those considered to be lower risk.

Projects may be selected for auditing for a variety of reasons:

- Human Research Ethics Committee request
 - following approval of a new protocol;
 - as part of the approval process; or
 - due to the classification of risk.
- Random selection
- A complaint i.e. from a participant, parent, fellow researcher
- Annual report verification

Further details of the auditing process can be found on the [REG website](#)

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	021	Date created	February 2010
Subject	Complaints from Research Participants (Management & Resolution)		
Purpose	To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the HREC		

1. Role of the Principal Investigator (PI):

- PIs have a responsibility to ensure that their research protocol conforms to the national ethical guidelines and any relevant regulations and has full ethics approval from the relevant HREC.
- In doing so the information statements must state that:
 - the research participant can contact a member of the study team to obtain further information about a research project or to discuss any concerns or complaints about the project.
 - If the participant wishes to speak to an independent person regarding concerns and complaints about the research project then the Director of Ethics & Research may be contacted directly.
- If a member of the study team receives a complaint, the PI should be notified. The PI must act appropriately, impartially and in proportion to the complaint. In most cases, this person will be able to resolve the complaint by addressing the concerns of the complainant.
- The PI must also consider that they have a responsibility to determine whether to suspend/modify the research procedure should there be reasonable suggestion of harm to a participant(s) and must report these concerns to the HREC and may seek their assistance.
- PIs must inform the Director of Research Ethics & Governance (REG) of all relevant concerns and complaints received or ethical issues raised during the course of their research in a timely fashion. The HREC may impose a penalty on applicants for not reporting relevant concerns and complaints received from participants.

2. Role of the Director of Research Ethics & Governance (REG Director)

- Should the response not satisfy the complainant, the PI should advise the complainant of their right to contact the Director of REG who is responsible for receiving complaints relating to research activity at the institution.
- At any time the PI and/or Director of REG may request assistance from the Consumer Liaison Officer.
- The PI must ensure that privacy legislation is adhered to by asking the complainant to directly contact the Director of REG, or seeking written permission to refer a complaint to the complaints officer with any identifying information, as in some cases it could preclude a comprehensive investigation of a complaint.
- Complainants can contact the Director of REG to discuss the complaints procedure; however, in most cases only a formal written complaint can be investigated (Exclusion would be if physical disability prevents this and a written record will be taken by the investigator or complaints officer). The complaint and the identity of the complainant will be treated confidentially.
- The Director of REG must handle the complaint in a co-operative and sensitive way and in most cases will be able to resolve the matter.

- If the complaint cannot be resolved or if the Director of REG determines that further investigation is required (i.e. if the complaint relates to the ethical conduct of a research study) then the HREC Chair will be informed of the complaint.

3. Role of the HREC & HREC Chair

- Should the complaint not be resolved (or require further investigation as detailed above), the HREC Chair and Director of REG will conduct a preliminary investigation into the complaint and determine the appropriate course of action. If urgent action is deemed to be required, the Chairperson and/or Director of REG may take appropriate steps to ensure that the rights and welfare of participants are protected. Such action may include suspending the approval for a research project whilst an investigation is conducted.
- Following the initial review of a complaint, possible outcomes are that
 1. no further action is required; or
 2. there are sufficient grounds to investigate the complaint further.
- If a further investigation is warranted, a meeting may be required between the HREC Chairperson or full HREC and the researcher/s. The following procedures which are recommended in the National Statement, may occur:
 - Invite the PI to explain the situation to the committee and to demonstrate why the project should not be discontinued and ethical approval withdrawn.
 - Advise the PI that they may be accompanied by one or more colleagues including their line manager.
 - Reconsider the original research proposal and seek additional information from the PI in relation to the conduct of the study, or any other relevant factors, before making a final decision whether to revise or reconfirm the original decision to approve the project.
- Having considered the matter, the committee may:
 - Withdraw approval and stop the project; or
 - Require amendments to the original research proposal or to the conduct of the research; or
 - Allow the project to continue without amendment; and/or
 - Choose to inform the Researcher's line manager of their discussion and/or decision.
- The HREC should provide the PI and the complainant with an explanation of the outcome. In some cases (e.g. if approval is withdrawn) it may be necessary to notify the other research participants.
- In some circumstances, it is recommended that the complainant address the HREC or meet with members of the HREC, depending on whether the complainant would be comfortable in this situation and nature of the complaint, to discuss the concerns.

4. Role of the Executive Director of Medical Services & Clinical Governance (EDMS)

- Where a complaint cannot be resolved, the HREC must refer the matter to the EDMS. The EDMS will investigate the complaint and depending on the query raised, the matter will be referred to the appropriate RCH campus authority or resolved through communication via the Chairperson and HREC.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	022	Date created	February 2010
Subject	Complaints from Researchers (Management & Resolution)		
Purpose	To describe the procedure for handling concerns or complaints from researchers regarding the HREC review process.		

1. Any concern or complaint about the HREC review process is to be submitted to the Research Ethics & Governance (REG) Director. This is done in writing and must detail the grounds of the concern or complaint.
2. The REG Director will ask the secretariat of the relevant subcommittee of the HREC to prepare all the material relating to the project (If necessary) and the complaint will be considered by the HREC Chair.
3. If the complaint is in regard to an application which has not been approved by either Committee there are further opportunities to negotiate the details involved in the research which will assure compliance with ethical issues. If an application has had conditions placed upon it which the researcher feels adversely affects the quality of the project, the researcher may request that the HREC reconsider its decision. This may involve the researchers being asked to attend a meeting to discuss the project. The Committee may wish to co-opt expert advice at this stage.

If the outcome is still considered unsatisfactory, the Executive Director of Medical Services & Clinical Governance (EDMS) will be contacted and may review the procedures by which the HREC came to its decision.

4. The National Statement advises that if the matter is not thereby resolved to the satisfaction of the complainant, they may take further steps, including an appeal against the decision. These steps may include the following.
 - i. The HREC or the researcher may contact the Australian Health Ethics Committee (AHEC) for advice on interpreting NHMRC Guidelines in order to reach an appropriate decision or to help a complainant understand the reasons for the HREC decision.
 - ii. If the complainant(s) are still not satisfied, they may seek a meeting with the HREC Chair, and the REG Director for further clarification. The complainant(s) may be accompanied by one or more support persons, or, in the case of researchers, one or more colleagues. A record of any such meeting should be kept.
 - iii. The institution and the complainant(s) may agree on a person who can take the role of mediator, not necessarily a professional mediator, in an attempt to resolve the dispute. The institution should bear the costs of such mediation.
 - iv. The mediator should consider the complaint, the reason(s) for the committee's original decision (from the minutes of the relevant meeting), the advice, if any, provided by AHEC and the record of the meeting above. Having considered this material, the mediator should then meet with the parties, attempt to facilitate a resolution of outstanding issues and provide a report of the results of that meeting to the institution.

5. If the matter remains unresolved despite such steps being taken, the final decision rests with the relevant institution. In some circumstances it may be open to a complainant to seek judicial review.
6. The Committee will make every effort to resolve complaints promptly and within a reasonable timeframe as circumstances dictate.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	023	Date created	February 2010
Subject	Suspension or Withdrawal of HREC Approval		
Purpose	To describe the procedure for suspension or withdrawal of ethical approval by the HREC		

1. Where the HREC (or HREC Chair) finds reason to believe that continuance of a research project will compromise participants' welfare, or that a research project is not being or cannot be conducted in accordance with its ethical approval, it should immediately seek to establish whether ethical approval for the project should be suspended or withdrawn.
2. In such circumstances, Research Ethics & Governance (REG) /HREC must immediately notify the PI (and study contact) of the suspension of the HREC Approval.
3. An investigator cannot continue with the research if ethical approval has been suspended and must comply with any special conditions imposed by the HREC.
The research may not be resumed unless either:
 - The investigator subsequently establishes to the HREC that continuance will not compromise participants' welfare and/or is to be conducted in accordance with its ethical approval; or
 - The research is modified to provide sufficient protection for participants, the amendment is ethically reviewed, and the modified research is approved by the HREC.
4. The HREC, after consideration at a meeting, makes the final decision with regards to reinstatement or withdrawal of ethical approval. The PI (and study contact) is notified in writing of the HREC decision within 5 working days.
5. In the case of withdrawal of ethical approval the HREC will notify the RCH Executive.
6. REG will update the status of the project on the REG database.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	024	Date created	February 2010
Subject	Record keeping		
Purpose	To describe the procedure for the preparation and maintenance of records of the HREC activities		

1. Research Ethics & Governance (REG) prepares and maintains electronic records of the HREC activities, including agendas and minutes of all meetings of the HREC.
2. REG prepares and maintains a confidential electronic record for each application received and reviewed and records the following information:
 - Unique project identification number
 - Principal Investigator(s)
 - Title of the project
 - Ethical approval or non-approval with date
 - Approval or non-approval of any changes to the project
 - Terms and conditions, if any, of approval of the project
 - Whether approval was by expedited review
 - Action taken by the HREC to monitor the conduct of the research.
3. The file contains a copy of the application, including signatures (scanned or electronic), relevant correspondence (including that between the applicant and the HREC), all approved documents and other material used to inform potential research participants.
4. All relevant records of the HREC, including applications, membership, minutes and correspondence, will be kept as secure confidential electronic files in accordance with the requirements of the Health Records and Information Privacy Act 2002 (HRIPA).
5. To ensure confidentiality, any documents provided to HREC members, which are no longer required, are disposed of in a secure manner, such as shredding or placed in confidential bins. HREC, DTS Members & Expert reviewers who do not have access to secure disposal give their documents to REG for disposal.
6. Data pertaining to research projects is held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 7 years following the completion of the research or termination of the study. For clinical research, records will be retained for 15 years following the completion of the research or until the youngest participant turns 25 years of age, which ever date is the latter.
7. The database of all the applications received and reviewed is maintained in accordance with the NHMRC National Statement on Ethical Conduct in Human Research.

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	025	Date created	February 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 Chair (or delegate) will consider authorised prescriber applications. The HREC Chair may also seek advice from the Drug Usage Committee (DUC) or the New Technologies Committee (NTC).
2. When considering a proposal by a medical practitioner to become an Authorised Prescriber, the HREC Chair (or delegate) 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
 - information to be given to the patient about the product
3. Approval must be made in parallel with the Drug Usage Committee (drugs) or New Technologies Committee (devices or other technologies)
4. If endorsed, the HREC Chair shall provide a letter of HREC endorsement to the applicant in the format suggested by the Therapeutic Goods Administration. 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
 - requirements for information provision and consent from participants (or parent/guardians)
5. The HREC shall review its endorsement of the Authorised Prescriber if they become 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 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 RCH Executive of its concerns in the first instance. The RCH Executive and the HREC Chair shall jointly determine whether to contact the Therapeutic Goods Association.

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

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	026	Date created	February 2010
Subject	Conflicts of Interest		
Purpose	To describe the procedure for the disclosure and management of potential conflicts of interests in research.		

1. The following process outlines the procedure for the disclosure and management of potential conflicts of interests in research. In all cases members are not required to detail the conflict of interest if they choose not to, but must state they have one. Conflicts of interest which are not detailed will be assumed as 'actual' conflicts of interest (in lieu of an explanation otherwise).
2. The process for the disclosure and handling of potential conflicts of interest of HREC members is as follows:
 - a. HREC Members are asked to declare any conflicts of interest at the time of their appointment or as they arise during their appointment.
 - b. Conflicts of interest that do not relate to a specific research project must be notified to the Research Ethics & Governance (REG) Director by the member.
 - c. For conflicts of interest that relate specific research projects the HREC Chair calls for members to declare these at the beginning of the HREC meeting.
 - d. A HREC member must, as soon as practicable during the HREC meeting, inform the Chair if he/she has a potential conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.
 - e. If the member details the perceived conflict of interest then it is the responsibility of the HREC to determine if the declaration is an actual conflict of interest for the member. If so, the member will withdraw from the meeting until the HREC consideration of the relevant matter has been completed. The member is not permitted to adjudicate on the research.
 - f. Written reviews/comments from (absent) HREC members are to include a full disclosure of any potential conflict of interest, financial or otherwise, in a project or other related matter(s) under consideration by the HREC. The HREC will determine if the conflict of interest renders the review/comments unacceptable.
 - g. The existence of all conflicts of interest which are declared (and details where given) and the absence of member(s) during the consideration of relevant matters are minuted.
3. The same process (above) is followed at the Drug Trial Subcommittee meetings presided over by the DTS Chair (or their delegate).
4. Expert Reviewers who review projects make a full disclosure of any potential conflicts of interest, financial or otherwise, prior to reviewing a project. The process for handling the conflicts of interest of expert reviewers is as follows:
 - a. If the REG Director deems these to be actual conflicts of interest then the reviewer is not chosen to conduct the review and another reviewer is found.
 - b. If the REG Director determines that the conflict of interest is a perceived conflict but not an actual one then the reviewer conducts the review and records the

- perceived conflict of interest on the [Reviewer Proforma](#).
- c. If a review has already been submitted and a declared or known conflict of interest becomes apparent then the conflict of interest is documented. It is the responsibility of the REG Director and/or HREC Chair to determine if the conflict of interest renders the review unacceptable. If so, another reviewer is found.
5. The process for handling potential conflicts of interest from Institutions involved in Multicentre applications is as follows:
 - a. PI (including those from institutions external to RCH) is responsible for making a full disclosure of any potential conflicts of interest, financial or otherwise for their institution (in the [RCH Application Coversheet](#)) when submitting to the RCH HREC.
 - b. Strategies for addressing the perceived, actual or potential conflicts of interest are to be discussed, agreed and documented between the Institution and the RCH HREC. This may include but is not limited to the following:
 - i. Public disclosure of the Institutions financial or other interest in the research.
 - ii. Public disclosure of the Institution's financial interest in the commercial success of any therapeutic outcome or product resulting from the research.
 - iii. Independent monitoring of the research project.
 6. The process for handling potential conflicts of interest from researchers involved in research is as follows:
 - a. Researchers are required to make a full disclosure of any potential conflicts of interest, financial or otherwise, when submitting an application for RCH HREC approval (in the [RCH Application Coversheet](#)).
 - b. Strategies for addressing the perceived, actual or potential conflicts of interest are to be discussed, agreed and documented between the researcher and the RCH HREC. This may include, but is not limited to the following:
 - i. Public disclosure of the researcher's financial or other interest in the research.
 - ii. Public disclosure of the researcher's financial interest in the commercial success of any therapeutic outcome or product resulting from the research.
 - iii. Independent monitoring of the research project.
 - iv. Amendment of the researcher responsibilities as per the protocol.
 - v. Exclusion of the Researcher from participating in all or a portion of the research.



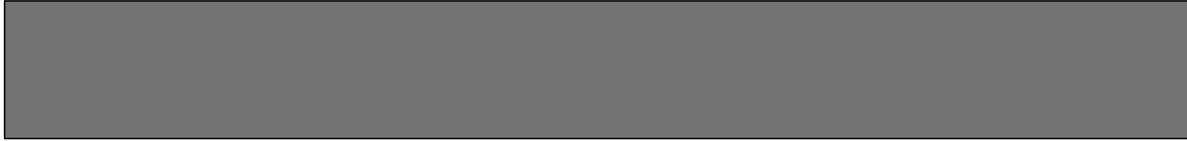
Reference Number	027	Date created	February 2010
Subject	HREC Reporting Requirements		
Purpose	To describe the procedure reporting requirements of the HREC		

1. Research Ethics & Governance (REG) shall notify the RCH Board of HREC membership changes as they occur. New members are to be approved by the Board prior to membership commencement.
2. The HREC shall provide an annual report to the Executive Director of Medical Services (EDMS) at the end of each calendar year on its progress, including:
 - number of meetings
 - number of projects reviewed, approved and rejected (provided monthly)
 - 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
 - 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 VIC Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act (VIC).
5. The HREC Terms of Reference & Standard Operating Procedures will be posted on the [REG website](#).



Reference Number	028	Date created	February 2010
Subject	Research which is exempt from RCH HREC review		
Purpose	To describe the procedures for determining which projects which are exempt from review		

1. A research project may be exempt from review if the research falls out of the RCH HREC jurisdiction (or simply does not require HREC review) such as:
 - a. The project has HREC approval from another site and involves only a service being provided by RCH/MCRI e.g. allergy testing, MRI scan.
 - b. The project is collaboration to share non-identifiable data collected from an approved research project (please note this is subject to the informed consent conditions, if applicable).
 - c. The project proposes to use RCH as a recruitment tool (i.e. through a currently established database, or posting flyers in the hospital) however the research is being conducted by a separate institution.
2. In these cases the PI must email (or mail) the Research Ethics & Governance (REG) Director providing an explanation on the project and why it falls into one of the above categories and include necessary documentation as follows:
 - a. Approval certificate from reviewing HREC
 - b. Protocol
 - c. Information letter or flyer to be used at RCH (if applicable)
 - d. Material Transfer or Collaboration Agreement (if applicable)
3. The PI will be notified via email from REG within 5 working days as to whether their application has been exempt from review or whether clarification is required. If the application is exempt from review, an Exemption Letter will be provided to the PI (or study contact) by the REG Director. The PI may then conduct their research without RCH HREC Approval.
4. REG will include the project on the Exempt from Review database.



Reference Number	029	Date created	February 2010
Subject	Review of Standard Operating procedures & Terms of Reference		
Purpose	To describe the procedures for the approval of amendments to the HREC Standard Operating Procedures and Terms of Reference.		

1. The RCH HREC Standard Operating Procedures and Terms of Reference shall be reviewed at least every two years and amended as necessary.
2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedure below:
 - a. For those proposals made by an HREC member:
 - i. The proposal must be in writing and approved by the Research Ethics & Governance (REG) Director (at the REG Director's discretion it may be circulated to all HREC members for their consideration)
 - ii. Where necessary, 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.
 - iii. The proposal shall be ratified if two thirds of the members agree to the amendment.
 - b. For those proposals made by the REG Director or Executive Director of Medical Services:
 - i. The Director or Executive Director will send the proposal to the HREC Chair and/or seek the views of any relevant stakeholders before the amendment is implemented (where necessary).

Human Research Ethics Committee (HREC) Standard Operating Procedures (SOP)

Reference Number	030	Date created	August 2012
Subject	Multi-site Research		
Purpose	To describe the procedures for the approval multi-site research via the single ethical review scheme		

1. The RCH HREC is accredited for the review of multi-site research by:
 - a. National Health & Medical Research Council (first accredited January 2011)
 - b. Department of Health (Victoria) (first accredited December 2011)
2. The RCH HREC participates in the Streamlined Ethical Review Process as both:
 - a. A primary reviewing HREC for multi-site research
 - b. An accepting site for multi-site research approved by another accredited HREC.
3. The RCH HREC follows the [Standard Operating Procedures](#) of the Clinical Trials Coordinating Center of the Victorian Department of Health and Human Services for the review and approval of multi-site research.