Human Research Ethics Committee (HREC)
Scientific and Ethical Review
Standard Operating Procedures (SOP)

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**1.0**	**Date** January 2015
Title	**Overview**	
Purpose	To provide an overview of the process involved in the scientific and ethical review of research	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.1.6 - 5.1.8; 5.1.10 – 5.1.21 5.1.24	

1. Depending on the risk level of the research, scientific and ethical review of the research may be undertaken by the:

    a. Full Human Research Ethics Committee (HREC);
    b. HREC Sub-Committee; or
    c. HREC Chair.

2. Risk level of research is assessed according to the National Statement's criteria:

    Negligible risk research is:

    > "*where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk*."

    Low risk research is:

    > "*where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk*."

3. Research involving the following categories of participant groups must be reviewed by the full HREC:

    - Women who are pregnant and the human foetus;
    - People highly dependent on medical care who may be unable to give consent;
    - People with a cognitive impairment, an intellectual disability, or a mental illness;
    - People who may be involved in illegal activities;
    - Aboriginal and Torres Strait Islander peoples.

4. The following types of research must be reviewed by the full HREC:

    - interventions and therapies, including clinical and non-clinical trials, and innovations;
    - human genetics;

- human stem cells.

5. Inter-jurisdictional and multi-centre research falling within the category of observational studies and registries will be reviewed by the full HREC.

6. Administrative personnel use the criteria from #2, #3, #4 and #5 above to allocate projects for appropriate level of scientific and ethical review. The HREC Chair or delegate verifies and confirms projects are appropriately allocated using the same criteria.

7. Negligible and low risk research projects are reviewed by the HREC Sub-Committee, the HREC Chair or delegate.

8. Allocation of projects for the HREC Sub-Committee, HREC Chair or delegate takes into account the need to provide a timely response to researchers; and the workloads of the Chair and the Sub-Committee at the time. See SOP 2.1.

9. Research that is assessed to be "*more than* low risk" will be reviewed by the full HREC, in addition to research listed in #3, #4 and #5 above. See SOP 2.2.

10. Procedures for managing conflicts of interests in relation to scientific and ethical review are detailed in SOP 2.6.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.1**	**Date** January 2015
Title	**Negligible & Low Risk Research**	
Purpose	To describe the process of the review of new research applications by the HREC Chair or HREC Sub-Committee	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.1.7; 5.1.8; 5.1.18 – 5.1.21	

1. The HREC Chair, delegate or the HREC Sub-Committee provides review of research projects that are of negligible or low risk on behalf of the full HREC.

2. The HREC Chair, delegate or HREC Sub-Committee may deem that some projects require escalation to the full HREC for review. In that case, researchers will be notified of the decision and any additional documents required to be submitted.

3. Ethical Review of multi-centred research projects are to be reviewed by the Eastern Health HREC and not in an alternative expedited review process.

4. Chair out-of-session review takes place as required, usually weekly. HREC Sub-Committee review takes place fortnightly on scheduled meeting dates or as appropriate according to workload. Deadlines for submissions do not apply to the Sub-Committee meetings or the Chair out-of-session reviews.

5. Applications should be submitted using the appropriate application forms, such as the *Low Risk and Negligible Risk Research Application Form*. These are available from the research ethics web-page.

6. Sub-Committee members are reminded that meetings are subject to confidentiality whether commercial or otherwise.

7. The HREC Chair, delegate or HREC Sub-Committee members review project applications and provide comments and queries in writing on the *Low Risk Application Checklist*. An outcome of the review should be listed accordingly such as;
    a. Approval without changes;
    b. Approval subject to changes; and
    c. Non-approval or request for resubmission following amendments.

8. Deliberations are recorded in the HREC Chair minutes, and the HREC Sub-Committee *meeting minutes;* incorporated into the full Ethics Committee agenda. All Minutes are tabled at the full Committee meetings for endorsement and noting.

9. A written response is sent to the research applicant, noting any queries and comments. Instructions on how to provide a response are included in the written correspondence. An official email template is used.

10. Researchers are required to provide a written response to queries or comments. These will be verified by administrative personnel when appropriate. Non-approved applications should be returned to the Chair, delegate or Sub-Committee for further review.

11. If administrative personnel are uncertain whether researchers have addressed queries satisfactorily, additional advice would be sought from the HREC Chair or delegate or Sub-committee Chair.

12. When all queries and changes are addressed, a written approval letter will be issued, along with any conditions of approval. An approval letter template is used.

13. The approval letter will be signed by a member of the administrative team within the Office of Research and Ethics, on behalf of the Human Research Ethics Committee (HREC).

14. Australian Research Ethics Database (AuRED) will be updated with details and status of the research project.

15. Monitoring of approved research; on-going correspondences; and submissions from an approved research project will be processed in accordance with SOP 3.1.

16. Procedures for managing conflicts of interests in relation to scientific and ethical review are detailed in SOP 2.6.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.2**	**Date** January 2015
Title	**Research that is *more than* low risk**	
Purpose	To describe the process of the review of new research applications by the full Human Research Ethics Committee (HREC)	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.1.6 (a)(b); 5.1.24	

1. The full Human Research Ethics Committee (HREC) provides review of research projects that:

    a. are considered to constitute *more than* low risk, as defined by the National Statement.

    b. involve the following categories of the following participant groups:

    - Women who are pregnant and the human foetus;
    - People highly dependent on medical care who may be unable to give consent;
    - People with a cognitive impairment, an intellectual disability, or a mental illness;
    - People who may be involved in illegal activities;
    - Aboriginal and Torres Strait Islander peoples.

    c. involve the following types of research:

    - Research that involves interventions and therapies, including clinical and non-clinical trials, and innovations;
    - Research that involves human genetics;
    - Research that involves human stem cells;
    - Inter-jurisdictional, multi-centre research falling within the category of observation studies and registries.

2. Applications should be submitted using the appropriate application forms namely:
    - The National Ethics Application Forms (NEAF),
    - relevant Victorian Specific Module (VSM), and
    - Site Specific Application (SSA) form

    which are available from the Eastern Health Research Ethics web-page.

3. Full HREC meetings take place monthly, according to pre-scheduled meeting dates. Meeting dates and submission deadlines are advertised on the Research Ethics web-page.

4. The HREC Chair and/or delegate will allocate appropriate HREC members as primary reviewers for each new research application to provide a detailed scientific and ethical review.

5. The primary reviewers will usually consist of a researcher and a non-institutional member preferable a lay member. Additional expertise may be sought to determine scientific and ethical merit of applications. This will be determined by the HREC Chair with input from administrative personnel.

6. Where there is no conflict of interest, all HREC members are expected to be familiar with all items on the meeting agenda, in order to take part in ethical discussion.

7. Pharmacy members do not usually receive specific allocation of projects, rather they review all Investigator Drug Brochures and other drug information; and provide written or verbal feedback to the HREC. They also consider legislative framework related to the use of unapproved therapeutic goods.

8. HREC Members who cannot be present at the scheduled meeting should notify administrative personnel as soon as possible in writing, eg an email.

9. HREC Members should provide written comments where possible. On occasion when allocated primary reviewers send a late apology and have not provided comments, the Chair will be notified as soon as possible and an alternative reviewer allocated.

10. During HREC meetings, primary reviewers present their allocated projects to the HREC and advise the HREC of their queries and comments.

11. Scientific and ethical discussion follows involving all members of the HREC.

12. Deliberation is by general agreement and usually includes one of the following:
    a. approval without changes;
    b. approval subject to changes; or
    c. non-approval.

13. Ethical review and decisions should be made with reference to the National Statement on Ethical Conduct in Human Research (2007). Decisions are recorded in the meeting minutes; and should be linked to the relevant parts in the National Statement.

14. Researchers are not routinely invited or required to attend HREC meetings to present their research applications. See SOP 2.4.

15. Final approval of research is processed in accordance with SOP 4.1.

16. Procedures for managing conflicts of interests in relation to scientific and ethical review are detailed in SOP 2.6.

17. Monitoring of approved research, on-going correspondences and submissions for an approved research project will be processed in accordance with SOP 3.1.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.3**	**Date** January 2015
Title	**HREC members' expertise - Expert reviewers pool**	
Purpose	To describe the process of maintaining HREC members' expertise and the expert reviewers pool	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.1.28(a)(b); 5.1.34 – 5.1.36	

1. Scientific review of research relies on the availability of appropriately qualified and experienced HREC members.

2. HREC members are recruited through various means of advertisement throughout the Eastern Health community. Advertisements may be placed in both local and national newspapers.

3. Individuals may also be identified and approached directly for their knowledge, qualities and experience; and may be invited to apply for HREC membership.

4. Informal enquiries regarding HREC membership are made to the Manager of the Office of Research and Ethics or delegate.

5. Prospective HREC members are invited to submit a written application enclosing their resume/Curriculum Vitae.

6. Prospective HREC members are invited for an interview with HREC Chair and/or Director of Research and/or Executive Director Medical Services & Research. A current HREC member, who is in the same membership category, may also attend the interview. The Manager of the Office of Research and Ethics or delegate may also be in attendance.

7. In consultation with the Executive Director Medical Services and Research HREC members will be appointed for a term of three years and be eligible for re-appointment for a second term. No member may serve two successive terms, except with the express approval for the Executive Director Medical Services and Research.

8. After obtaining appropriate references, and police check for external members, HREC members will be formally appointed. A formal notice of appointment is provided, including information on appropriate indemnity and insurance; and terms of appointment. An appointment letter template is used.

9. Members are made aware that documents from a research application may be of a confidential nature, whether commercial or otherwise. Members should only discuss the research application with members of the HREC in the course of providing the scientific and ethical review; and must not divulge any confidential information to unauthorised persons. At the commencement of each year members will be required to sign a Privacy and Confidentiality agreement as part of the Member Undertaking.

10. A new HREC member is provided with written information and guidance to carry out the responsibilities associated in their new role. Mentoring is provided by the HREC Chair and a current member of the HREC in the same membership category. A new HREC member induction folder contains details of documents that are provided to new members; and is kept in the Office of Research and Ethics. The Office of Research and Ethics will provide ongoing induction and training to all members.

11. During their terms of office, HREC members are provided with opportunities to attend internal and external education relevant to their role. A training and attendance record is maintained for all HREC members.

12. There may be occasions when HREC members do not possess sufficient expertise in an area under consideration. There may also be occasions when a higher than expected number of research applications are under review, resulting in an increase in HREC workload. Available HREC members may not be able to complete scientific and ethical reviews of all projects in time. Additional qualified and experienced reviewers may be drawn from an *Expert Reviewers' Pool*.

13. An *Expert Reviewers' Pool* is a collection of personnel who have experience in clinical practice, research or other related speciality. They are personnel with qualifications in medicine, pharmacology, toxicology, statistics or other relevant disciplines.

14. Expert reviewers are identified and invited to join the *Expert Reviewers' Pool* for their clinical, research and other professional expertise.

15. An expert reviewer is to be made aware that documents from a research application may be of a confidential nature, whether commercial or otherwise. An expert reviewer must only discuss the research application with members of the HREC in the course of providing the scientific and ethical review; and must not divulge any confidential information to an unauthorised person.

16. An expert reviewer receives induction by attending at least one HREC meeting and by acting as the primary scientific reviewer for an allocated research project, with support from other HREC members and the HREC Chair, as required.

17. From time to time, an inducted expert reviewer may be asked to provide scientific review of a research application; and provide written comments on the scientific merits of the research, risks and benefits of the research, and any recommendations.

18. Each time an inducted expert reviewer is asked to provide a scientific review, he/she will be prompted to declare any conflict of interests in relation to the research application being reviewed; and will be reminded of his/her duty to maintain confidentiality. An Expert Reviewer Undertaking form is used.

19. An expert reviewer has the option to attend the HREC meeting to present relevant comments; or provide written comments to the HREC Chair to present on their behalf.

20. Expert reviewers' comments will form the basis of the scientific review of the research project.

21. Procedures in managing conflicts of interests in relation to scientific and ethical review are detailed in SOP 2.6.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.4**	**Date** January 2015
Title	**HREC meeting with researchers**	
Purpose	To describe the process of HREC inviting researchers to attend a meeting; a researcher requesting to attend a HREC meeting; or HREC holding face to face meetings with researchers where written and telephone communication fail to resolve issues	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.2.13 – 5.2.15; 5.2.18	

1. Researchers are not routinely invited or required to attend HREC meetings to present their research applications.

2. Routine attendance of researchers at HREC meetings may impact on researchers' workloads and increase the duration of HREC meetings.

3. A researcher, whose research application has not been approved, may receive an invitation from the HREC to attend a forthcoming meeting to address queries and discuss main issues. Invitation is usually in writing and a specified time will be allocated. Researchers' needs are accommodated, where possible.

4. The HREC Chair, and/or other HREC delegates may arrange to meet with researchers face to face out-of-session in order to resolve misunderstanding; or to address issues where written or telephone communication has been inadequate. Out-of-session meetings may be initiated by the HREC or researchers. Administrative personnel may be in attendance.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.5**	**Date** January 2015
Title	**Observers at HREC meetings**	
Purpose	To describe the process of accommodating observers at HREC meetings	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Section 5.1.37(r)	

1. The HREC welcomes the attendance of observers at their meetings.

2. Observers are people who have an interest in HREC process; but are not HREC members or researchers whose applications are being reviewed.

3. The HREC may invite individuals to attend as observers.

4. Individuals may contact the HREC to request attendance as observers.

5. Observers are informed of the confidential nature of meeting discussion; and must sign to confirm that they will not divulge any confidential information. A template memorandum is available for use.

6. Individuals who request attendance as observers and are not Eastern Health employees may be subject to further security checks prior to attendance.

7. Observers' attendance at HREC meetings is recorded in the HREC meeting minutes.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.6**	**Date** January 2015
Title	**Managing conflicts of interests in relation to ethical review**	
Purpose	To describe the process of managing conflicts of interests in relation to ethical review	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Section 5.4.5	

1. HREC members must declare any perceived, potential and actual conflicts of interests, in relation to ethical review on becoming members of the HREC. Conflicts of interests may be discussed with the HREC Chair, the Director of Research, or administrative personnel. A written declaration should be signed by all HREC members and expert reviewers on induction and annually.

2. During full HREC meetings, any members who have any involvement in a research application must remove themselves from the ethical review, discussion and deliberation of the research. HREC members with a conflict of interest should notify the HREC Chair at the start of the meeting and leave the meeting room when their relevant research is discussed.

3. Declaration of conflict of interests and HREC members removing themselves from the meeting should be recorded formally in the full HREC meeting minutes.

4. During Sub-Committee and Chair out-of-session meetings, Sub-Committee members and the HREC Chair must not review or approve submissions related to their own projects.

5. Administrative personnel should be aware of such documents being presented and must provide them to alternative members of the Sub-Committee for review.

6. Declaration of conflicts of interests should be recorded in the HREC Sub-Committee and the HREC Chair meeting minutes.

7. Expert reviewers (from the Expert Reviewers' Pool) must declare any conflicts of interest, in relation to the research applications they have been asked to provide scientific and ethical review. Expert reviewers must confirm that no conflicts of interests prevent them from conducting the scientific and ethical review.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**2.7**	**Date** January 2015
Title	**HREC Fees**	
Purpose	To describe the process of setting fees	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Section 5.1.26 & 5.1.37(s)	

1. Eastern Health utilises a fee schedule for Eastern Health HREC to undertake ethical and scientific review of research projects submitted.

2. The payment of fees will not compromise the integrity of the process of ethical review or monitoring of approved research.

3. The fee schedule will take into account the following attributes of the application:

    a. Commercial sponsorship and/or external funding
    b. Eastern Health affiliations
    c. External or internally initiated research

4. Furthermore fees can be charged on an activity basis, for example:

    a. Addition of sub-studies
    b. Protocol amendments
    c. Investigator Brochure changes

5. Fee schedules are reviewed annually and approved by the Executive Director Medical Services and Research.

6. The compliant tax invoice is uploaded onto the Eastern Health Research Ethics web-site and provides the fee schedule payable.

7. All research applications are subject to the payment of application fees as described on the compliant tax invoice, whether applications are submitted for review by the Eastern Health HREC or as submitted under the National Mutual Acceptance.

8. Requests for fee waivers cannot be made at the time of application as fees must be paid on application. Any requests must be made in advance of application and will be considered prior to application submission.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.1**	**Date** January 2015
Title	**Monitoring of approved research – Annual progress reports and final reports**	
Purpose	To describe the process of monitoring approved research and subsequent review of documents after ethical approval	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 3.3.19 – 3.3.22; 5.5.1 – 5.5.5; 5.2.23	

1. Projects that have received ethical approval will require on-going monitoring until project completion.

2. Researchers must submit annual progress reports or more frequently if it is a condition of approval. A progress report template is provided on the research ethics web-site.

3. For single-site ethical review (Eastern Health) approved projects

    a) Progress reports are required annually on the completion of the calendar year (December 31). The return date to the Office for Research and Ethics will be the end of the second week in February.

    b) Signature of Principal Investigator is not required[1] if the report is sent from his/her identifiable[2] (i.e. staff) email account.

    c) Reports are required for all projects that are continuing in the next year as well as those that were completed or abandoned this year. As stated on the HREC approval letter *'continuing approval is subject to the timely submission of a satisfactory progress report.'*

[1] Alternatively a signed PDF copy can be emailed. Hard copies are not required.

[2] Identifiable email address is one by which a standard of verification has taken place to ensure the email belongs to an employee of an organisation. For this purpose it cannot be gmail, live, hotmail or any other generic email address.

4. Researchers are advised that all approved research is subject to random inspection by the HREC. Inspection may include the research site, research data and consent documentation. A written report will be generated after inspection.

5. Researchers must submit documents according to instructions provided on the Research Ethics web-site.

6. Web-site instructions are reviewed and updated regularly by administrative personnel in the Office of Research and Ethics.

7. Documents are date stamped on receipt (if not sent electronically) and are initially screened by administrative personnel; to process application fees (if required); and to identify any governance issues in accordance with SOP 1.0 to 1.12.

8. What is included in reporting?
    a. Progress to date (or outcome in case of completed research)
    b. Maintenance and security of records
    c. Compliance with the approved proposal
    d. Compliance with any conditions of approval
    e. Is the research project to be discontinued and why?

9. Reports that advise that the conduct of the research project has conformed in all respects to the approved protocol will be administratively reviewed by a member of the Administrative team.
    Any reports requiring further action will be allocated to the Chair, delegate or Sub-Committee for further review and action.

Conforming:	
Allocation to:	Administrative Officer as delegated by HREC
Review responsibility:	Report to HREC of receipt and recording the report
Exceptions	
Allocation to:	HREC Chair or HREC delegate(s)
Review responsibility:	Notify HREC of the need for approval and recommend approval/non approval with reasons.
Inform:	Coordinating Principal Investigator, Principal Investigator, sponsor, trial coordinator and Research Governance Officers (RGOs) at study sites.

10. HREC Sub-Committees /Director of Research have the delegated authority to review documents. HREC Sub-Committee review takes place fortnightly, according to pre-scheduled meeting dates. Sub-Committee members are provided with documents for review at the meeting. Members review documents during the meeting and discuss with other members as required. Access to current study files is available in hard copy file and electronically to facilitate review of documents.

11. Administrative personnel will record HREC Chair, delegate and Sub-Committee deliberations in the Chair out-of-session minutes, and the Sub-Committee meeting minutes; which are incorporated into the full HREC Agenda.

12. Administrative personnel will issue a written response advising researchers of HREC's comments, noting and approval of documents. A Chair/Sub-Committee letter template is used.

13. Letters are signed by administrative personnel, on behalf of the HREC Chair and HREC Sub-Committee.

14. Office of Research and Ethics database will be updated, as required.

15. For procedures in managing conflicts of interests in relation to ethical review, see SOP 2.6.

16. Dates of Sub-Committee and Chair meetings are not advertised. This is because submission deadlines do not apply to these meetings.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.2**	**Date** January 2015
Title	**Monitoring of approved research – Adverse event reporting and handling**	
Purpose	To describe the procedures for the reporting and handling of Serious Adverse Events (SAE) and other adverse events.	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 3.3.19 – 3.3.22; 5.5.1 – 5.5.5; 5.2.23	

1. Projects that have received ethical approval will require on-going monitoring until project completion.[1]

2. Researchers must submit reports of local Serious Adverse Events (SAE); and summaries of safety reports and notifications from other sites if research is multi-centred. Templates for safety notification and reporting local SAE; and detailed submission instructions are provided on the Research Ethics web-site.

3. Individual local site event reports or reports from multiple sites may be forwarded through the Coordinating Principal Investigator to the reviewing HREC.

4. Periodic and Non-periodic safety reporting are expeditiously reviewed via allocation to HREC Chair or delegate(s) of HREC. HREC to be advised if further action is required.

5. The investigator/researcher must capture and report Adverse Events including Serious Adverse Events, which occur at their site to the sponsor in accordance with the study protocol.

6. The investigator/researcher must report all SAEs to the sponsor immediately (within 24 hours) in accordance with the study protocol and GCP guidelines as adopted by the TGA.

7. When investigator/researcher submits Adverse Events to institutions they should provide their own opinion in regards to potential impact on ethical acceptability and need for action.

8. The Eastern Health HREC has an obligation to ensure that any changes in the benefit/risk balance of a study are compatible with continued ethical approval.

[1] *NHMRC Australian Health Ethics Committee (AHEC) Position Statement - Monitoring and reporting of safety for clinical trials involving therapeutic products. (May 2009)*

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.3**	**Date** January 2015
Title	**Post-approval submissions**	
Purpose	Subsequent review of documents after ethical approval	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 3.3.19 – 3.3.22; 5.5.1 – 5.5.5; 5.2.23	

1. Documents that may be submitted post approval of research include protocol amendments, investigators' drug brochures, safety reports, progress reports, notifications, protocol deviations, advertisements and general correspondences.

2. Researchers must submit documents according to instructions provided on the research ethics web-site: http://www.easternhealth.org.au/research/ethics/submissions.aspx

3. Web-site instructions are reviewed and updated regularly by administrative personnel in the Office of Research and Ethics.

4. Documents are date stamped on receipt and are initially screened by administrative personnel to ensure documents are sufficient for HREC review; to process application fees; and to identify any governance issues in accordance with SOP 1.0 to 1.12.

5. The HREC Sub-Committee has the delegated authority to review documents. HREC Sub-Committee review takes place once monthly, according to pre-scheduled meeting dates. Sub-Committee members are provided with documents for review at the meeting. Members review documents during the meeting and discuss with other members as required. Access to current study files is available in hard copy file and electronically to facilitate review of documents.

6. The HREC Chair or delegate provides additional out-of-session review of documents. Chair out-of-session review takes place as required, usually weekly.

7. Documents that have just missed a monthly Sub-Committee meeting will be provided to the Chair for out-of-session review, to avoid an extended delay waiting for another scheduled meeting, usually in the following month.

8. Documents that require HREC approval (rather than routine noting) may also be presented for Chair out-of-session review, to ensure a timely response to researchers. Examples are advertisements, flyers, protocol amendments and changes to Participant Information and Consent Forms. Allocation to either Sub-Committee or Chair review takes into account workloads of the Chair and the Sub-Committee members at the time.

9. Documents that require HREC noting are usually presented for Sub-Committee review, as researchers are less likely to be waiting for a determination. Examples are safety notifications, progress reports, protocol deviations, other notifications and general correspondences.

10. HREC Chair, delegate and the Sub-Committee may refer matters to the full HREC for review, if required.

11. Administrative personnel will record HREC Chair, delegate and Sub-Committee deliberations in the Chair meeting minutes, and the Sub-Committee meeting minutes; which are incorporated into the full HREC agenda.

12. Administrative personnel will issue a written response advising researchers of HREC's comments, noting and approval of documents. A Chair/Sub-Committee letter template is used.

13. Letters are signed by administrative personnel, on behalf of the HREC Chair and HREC Sub-Committee.

14. Office of Research and Ethics database will be updated, as required.

15. For procedures in managing conflicts of interests in relation to ethical review, see SOP 2.6.

16. Dates of Sub-Committee and Chair meetings are not advertised. This is because submission deadlines do not apply to these meetings.

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Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.4**	**Date** January 2015
Title	**Suspension, cessation and completion of research**	
Purpose	To describe the process when research is suspended, ceased or completed	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.5.6 – 5.5.10	

1. During the course of monitoring approved research, the HREC may become aware of safety concerns or other matters which:

    a. may impact on the continuing ethical acceptability of a research project; and
    b. may compromise the welfare of participants.

2. The HREC must seek information to establish whether ethical approval for the research should be withdrawn; and whether the research should be immediately suspended or ceased.

3. Where the HREC finds reason to suspend research it will contact the investigator as soon as practicable. An investigator cannot continue with the research if ethical approval has been suspended and must comply with any special conditions imposed by the HREC.

4. Where the ethical approval for a research is withdrawn, the researcher must notify research participants; and make arrangement to ensure participants' needs are met.

5. In case of withdrawal of ethical approval the HREC will notify the Executive Director Medical Services and Research.

6. Official communication to participants should be reviewed and approved by the HREC prior to use. (Exception may apply where communication is urgent; the HREC must be notified of urgent communication afterwards, as soon as possible.)

7. Communication is usually reviewed by the HREC Chair, or delegate in the first instance. Communication can be further escalated to the Sub-Committee or the full HREC as directed by the HREC Chair, or delegate.

8. The research may only resume:

    a. if it can be subsequently established that continuance will not compromise the welfare of participants;
    b. if the research is modified to provide sufficient protection to participants; and if the modified research is reviewed and approved by the HREC.

9. A final progress report must be submitted on study completion, early cessation or site closure. Results and publications are presented to the HREC Sub-Committee for review and noting.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.5**	**Date** January 2015
Title	**Handling of complaints**	
Purpose	To describe the process of handling research related complaints	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.6.1 – 5.6.7	

1. Complaints may be made by a variety of people, including research participants, their relatives, research personnel, and personnel from departments impacted by the research.

2. Complaints may involve a number of possible issues, including the conduct of the research, research personnel themselves, the conduct of the Human Research Ethics Committee or the administrative process.

3. Complaints received from participants are directed to the HREC Chair in the first instance, via the Office of Research and Ethics. Research participants are provided with information on how to make a complaint in the Participant Information and Consent Forms.

4. Contact details for complaints are 'The HREC Chair, phone: 03 9895 3398, email: ethics@easternhealth.org.au '

5. All complaints are processed promptly and sensitively. Details of the complaint and complainant's contact details are recorded by administrative personnel in the Office of Research and Ethics.

6. The HREC Chair investigates the complaint, with the assistance of administrative personnel. The research team will be involved in the resolution of the complaint, as appropriate.

7. Depending on the nature of the complaint, the HREC Chair may seek advice from senior personnel at Eastern Health, such as the Director of Research, Executive Director Medical Services & Research, Department heads or line managers.

8. The HREC Chair may refer the complaint to the full HREC or the HREC Sub-Committee, as appropriate.

9. Complaints directed at the administrative process or administrative personnel may be directed to the HREC Chair, the Manager of the Office of Research and Ethics, the Director of Research or/and the Executive Director Medical Services and Research, as appropriate.

10. Complaints directed at the HREC's conduct should be referred directly to a senior person who is independent of the HREC, eg the Executive Director Medical Services & Research.

11. Eastern Health's complaint resolution process will be followed in the case of an unresolved complaint.

12. Electronic records of all complaints, investigations and resolutions are kept on the network drive in the Office of Research and Ethics.

13. When dealing with allegations of research misconduct involving United States Public Health Service (USPHS) supported research, in addition to the Eastern Health policies and procedures responding to allegations of research misconduct, Eastern Health will comply with the obligations of United States Office of Research Integrity Assurance Program for research-related activities for Foreign Institutions.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.6**	**Date** January 2015
Title	**Maintenance of records**	
Purpose	To describe the process of record keeping and storage	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Sections 5.2.23 – 5.2.27, 5.3.3 & 5.5.1 – 5.5.5	

1. Low risk research application documents and correspondences are stored electronically on the Office of Research and Ethics network drive, and named according to ethics reference numbers. No paper copy is kept.

2. However where research documents include an executed research agreement with original signatures, the hard copy agreement should be kept in a research ethics folder.

3. For each new Research Ethics application that is *more than* low risk, a research ethics folder is created. All Research Ethics application documents, correspondences and documents submitted throughout the duration of the research are filed in the research ethics folder. Ethics reference numbers should be clearly visible on the folder.

4. Other documents such as HREC reviewers' comments sheets or checklists may also be filed in the research ethics folder in the appropriate section.

5. All research ethics folders are maintained and stored securely in the Office of Research and Ethics for the duration of the research.

6. Application documents and correspondences are also increasingly stored electronically on the Office of Research and Ethics network drive for easy access. Electronic files are named according to ethics reference numbers.

7. Administrative personnel in the Office of Research and Ethics are the only people who have routine access to research ethics files. HREC Chair or delegates may access files through administrative personnel. Access to research ethics files is not usually granted to researchers. Rarely restricted access is granted to researchers, if there is a specific need, under the supervision of personnel in the Office of Research and Ethics. Other requirements to access files include internal auditing and accreditation and will be accommodated as required.

8. After research project closure or completion, research ethics paper records will be archived according to Public Record Office Victoria requirements.

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Section	**3.7**	**Date** January 2015
Title	**Data Requests**	
Purpose	Process for dealing with Data requests to Decision Support Systems	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Waiver of Consent Sections 2.3.5 – 2.3.8	

1. Wherever approval for data requests have been granted by the HREC it is imperative that researchers:
    a. provide supporting evidence of HREC approval (HREC approval letter).
    b. details as to the specific nature of the data requests.

2. Any request for data that is received by Decision Support Systems (DSS) or Hospital Information Systems (HIS) shall be referred to the Office for Research and Ethics for authorisation.

3. The Office for Research and Ethics will confirm:

    a. HREC approval for data request
    b. Currency of protocol application and ensure all annual reports have been submitted. Protocols approvals lapse if annual reports are not received.
    c. The applicant making the data request is listed on the protocol otherwise a change of personnel form will also be required.

4. Office for Research and Ethics will review the original application (or approval documents) and will provide DSS/HIS exact data requests as per HREC approval. Any data request outside this approval will require a further amendment to the protocol and subsequent HREC approval.

5. A template has been devised to deal with DSS/HIS requests

Human Research Ethics Committee (HREC)

Scientific and Ethical Review

Standard Operating Procedures (SOP)

Number	**4.1**	**Date**
Title	**Administrative Support**	
Purpose	To describe the administrative process of scientific and ethical review	
Reference	National Statement on Ethical Conduct in Human Research (2007) – Section 5.1.26, 5.1.37	

1. Administrative personnel in the Office of Research and Ethics (ORE) provide support to the Human Research Ethics Committee (HREC) in conducting scientific and ethical review.

2. Personnel provide support during full HREC meetings, Sub-Committee meetings and Chair out-of-session reviews.

3. Administrative personnel provide support to researchers in submitting research applications.

4. Detailed instructions for the submission of research applications for scientific and ethical review are provided on the research ethics web-site.

5. Web-site instructions are reviewed and updated regularly by administrative personnel.

6. Scheduled dates for the full HREC meetings and associated submission deadlines are made available in advance on the research ethics web-site.

7. Research applications are date stamped on receipt by administrative personnel. Date stamps are used to monitor response times and to provide information in case of queries from researchers. Key dates of communication are recorded in tracking sheets and the respective research files.

8. Administrative personnel carry out initial screening of research applications to:

    a. ensure documents are sufficient for scientific and ethical review;
    b. process application fees;
    c. identify any research governance issues in accordance with SOP 1.0 – 1.12; for example,
    - what impact the research has on Eastern Health resources;
    - whether research is compliant with legislation, guidelines and regulations.

9 Screening is done using the *New Project Submission Checklist* and/or the *Low Risk Application Checklist*.

10 *New Project Submission Checklist* and *Low Risk Application Checklist* are Office of Research and Ethics checklists for use by administrative personnel. Checklists are available on the Office of Research and Ethics share drive.

11 Process for the preparation, printing and distribution of agenda papers are detailed in a separate document in the Office of Research and Ethics network drive, available to administrative personnel.

14. Reviewer's checklist for scientific review of new applications is available if required by new HREC scientific members.

15. Reviewer's checklist for new Participant Information and Consent Forms (PICF) is provided to primary reviewers of each new research application, to ensure PICF contains all relevant information according to recommended templates for PICF.

16. PICF templates and writing guidelines are available on the research ethics web-page for researchers.

17. HREC members are provided with electronic files of research applications via a secure web-page approximately 2 weeks before each scheduled meeting. Log on requires a password which is changed monthly.

18. HREC members are provided with hard copy agenda papers one week before date of the scheduled meeting.

19. Hard copy agenda papers are delivered to internal Eastern Health HREC members by administrative personnel. Non Eastern Health HREC members receive their hard copy agenda papers by courier delivery.

20. Scientific Protocols and Investigator Drug Brochures, due to their bulky size, are not usually included in the hard copy Agenda papers. A hard copy of these documents is provided to the primary scientific reviewer of the research project and the HREC Chair. However all HREC members can access electronic files of the scientific Protocols and Investigator Drug Brochures.

21. HREC members will be provided with relevant guidelines or legislations as required to assist them in the review of specific projects.

22. During the HREC meeting administrative personnel take detailed notes of HREC discussion and deliberation.

23. Reviewers' checklists and additional written comments are collected from HREC members at the end of the meeting.

24. Meeting minutes are drafted from notes taken during the meeting and from reviewers' checklists. Minutes should make reference to relevant parts of the National Statement on Ethical Conduct in Human Research (2007). Draft minutes are sent to the HREC Chair or delegate for verification.

25. Once the HREC Chair confirms that meeting minutes are accurate, administrative personnel will issue correspondences to researchers.

26. Correspondences will incorporate comments and decisions from the HREC meeting, as recorded in the minutes, and should include reference to the National Statement on Ethical Conduct in Human Research (2007). In addition any unresolved governance issues; requests as a result of legal review, if applicable, will be added to correspondence. Instructions to researchers on how to respond to queries and address requests for changes are included in the correspondence. Letter templates for *approval*, *approval subject to changes*, and *non-approval* are available.

27. Researchers' response to queries and requested changes are checked by administrative personnel. If there is uncertainty whether all issues have been addressed adequately, advice should be sought from the HREC Chair, or delegate.

28. When all queries and changes have been addressed satisfactorily, a written final approval letter will be issued, along with any conditions of approval. A final approval letter template is used. Final approval letter will be signed by administrative personnel of the Office of Research and Ethics, on behalf of the Human Research Ethics Committee (HREC).

29. A letter of HREC composition at the time of the meeting will be issued with the approval letter. A HREC composition letter template is used.

30. Regulatory documents such as Clinical Trial Research Agreements and Indemnity forms will be reviewed in accordance with SOP 1.2 and 1.3 and signed by the Eastern Health signatory for research authorisation. The Eastern Health signatory for research authorisation is the Executive Director Medical Services & Research and Medical Services, or delegate. A delegate must not be involved in the research nor has any conflict of interest.

31. One fully signed original of the regulatory documents will be retained by Eastern Health. Other originals are returned to the research applicant.

32. The Australian Research Ethics Database (AuRED) will be updated with details and status of the research project.

33. Minutes of the meeting will be presented to the full HREC in the following month for noting. Final minutes will be signed by the HREC Chair and administrative personnel. Signed minutes are scanned and stored electronically in the Office of Research and Ethics network drive. Only administrative personnel have routine access to electronic and paper records of the Minutes.

34. Towards the end of each calendar year administrative personnel will arrange the following year's meeting dates for the full HREC and the Sub-Committee. Full HREC meeting dates will be advertised on the web-site in advance.

35. Catering and room bookings are also organised in advance for the forthcoming year.

(1)

Signature: _____ Date: 29/1/2016

Name: Prof David Taylor

Position: Director of Research & University Relations

Eastern Health Approval

(2)

Signature: _____ Date: 29/1/16.

Name: Adj Clin A/Prof Colin Feekery

Position: Executive Director – Medical Services & Research
& Chief Medical Officer