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Human Research Ethics Committee (HREC)

Standard Operating Procedures (SOP)

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Number	**2.0**	**Date** November 2011
Title	**Scientific and Ethical Review** - Overview	
Purpose	To provide an overview of the process involved in the scientific and ethical review of research	
Reference	National Statement Sections – Sections 5.1.7; 5.1.8; 5.1.16(a)(b); 5.1.18 – 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:

    a. the full Human Research Ethics Committee (HREC);
    b. the Ethics Sub-Committee; or
    c. the Ethics 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:

    Research that involves:

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

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

6. Negligible and low risk research projects are reviewed by the Ethics Sub-Committee or the Ethics Chair.

7. Allocation of projects for the Ethics Sub-Committee or Ethics Chair review 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.

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

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

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Number	**2.1**	**Date** November 2011
Title	**Scientific and Ethical Review** Negligible & Low Risk Research	
Purpose	To describe the process of the review of new research applications by the Ethics Chair or Ethics Sub-Committee	
Reference	National Statement – Sections 5.1.7; 5.1.8; 5.1.18 – 5.1.21	

1. The Ethics Chair or the Ethics Sub-Committee provides out-of-session review of research projects that are of negligible or low risk on behalf of the full Ethics Committee.

2. Projects that otherwise fit the low risk or negligible risk criteria may require escalation to the full Ethics Committee for review. For example, observational and registry studies involving more than one jurisdiction may warrant review and consideration by the full Ethics Committee.

3. Chair out of session review takes place as required, usually weekly. Ethics Sub-Committee review takes place monthly on scheduled meeting dates. Deadlines for submissions do not apply to the Sub-Committee meetings or the Chair out of session reviews.

4. Applications should be submitted using the appropriate application forms. The *Low Risk and Negligible Risk Research Application Form*, the National Ethics Application Form (NEAF) and the Common Application Forms (CAF) are available from the research ethics web-page: http://www.easternhealth.org.au/research/ethics/lowriskquprojects.aspx

5. The Ethics Chair or Ethics Sub-Committee members review project applications and provide comments and queries in writing on the *Low Risk Application Checklist*. These queries are discussed with administrative personnel who are in attendance.

6. Ethics Chair and Ethics Sub-Committee deliberations are recorded in the Ethics Chair minutes, and the Ethics Sub-Committee meeting minutes; as attachments to the full Ethics Committee minutes. All Minutes are tabled at the full Committee meetings for endorsement and noting.

7. 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.

8. Researchers are required to provide a written response to queries or comments. These will be verified by administrative personnel.

9. If administrative personnel are uncertain whether researchers have addressed queries satisfactorily, additional advice would be sought from the Ethics Chair.

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

11. Approval letter will be signed by a member of the administrative team, usually the Manager, Office of Research and Ethics, on behalf of the Human Research Ethics Committee (HREC).

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

13. Monitoring of approved research; on-going correspondences; and submissions from an approved research project will be processed in accordance with SOP 2.7.
14. Procedures for managing conflicts of interests in relation to scientific and ethical review are detailed in SOP 2.6.

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Number	**2.2**	**Date** November 2011
Title	**Scientific and Ethical Review** - 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 – Sections 5.1.16 (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 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.

2. Applications should be submitted using the appropriate application forms. The National Ethics Application Forms (NEAF) and the Common Application Forms (CAF) are available from the research ethics web-page:
http://www.easternhealth.org.au/research/ethics/applicationguidelines.aspx

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:
http://www.easternhealth.org.au/research/ethics/newprojects.aspx

4. The Ethics Chair will allocate 2 HREC members as primary reviewers for each new research application to provide a detailed scientific and ethical review.

5. The 2 primary reviewers will consist of a scientific member and a community (lay) member. More than 2 reviewers may be allocated to a research application if the application requires additional expert review. This will be determined by the Ethics Chair with input from administrative personnel.

6. 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 Investigators 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. Legal and pastoral care members do not usually receive specific allocation of projects; rather they are expected to provide a general review of all projects according to their respective expertise.

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

10. 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.

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

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

13. 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.

14. 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.

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

16. Final approval of research is processed in accordance with SOP 2.9.

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

18. Monitoring of approved research, on-going correspondences and submissions from an approved research project will be processed in accordance with SOP 2.7.

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Number	**2.3**	**Date** November 2011
Title	**Scientific and Ethical Review** - HREC members' expertise - Expert reviewers pool	
Purpose	To describe the process of maintaining HREC members' expertise and the expert reviewers pool	
Reference	National Statement – 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 general advertisement. 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.

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

6. Prospective HREC members are invited for an interview with the Ethics Chair, Director of Research and 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 will be in attendance.

7. After obtaining appropriate references, and police checking (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.

8. 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 Ethics 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.

9. 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.

10. 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*.

11. 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.

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

13. 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.

14. 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 Ethics Chair, as required.

15. 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.

16. 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.

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

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

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

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Number	**2.4**	**Date** November 2011
Title	**Scientific and Ethical Review** - 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 – 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 Ethics 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.

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Number	**2.5**	**Date** November 2011
Title	**Scientific and Ethical Review** - Observers at HREC meetings	
Purpose	To describe the process of accommodating observers at HREC meetings	
Reference	National Statement – 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. A record of observers' attendance at HREC meetings is kept in the Office of Research and Ethics.

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Number	**2.6**	**Date** November 2011
Title	**Scientific and Ethical Review** - 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 – 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 should be discussed with the Ethics Chair, the Director of Research or the Manager. A written declaration should be signed by all HREC members and expert reviewers.

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 Ethics 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 Ethics 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 Ethics Sub-Committee and the Ethics Chair meeting minutes.

7. Expert reviewers (from the Expert Reviewers' Pool) must be requested to 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.

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Number	**2.7**	**Date** November 2011
Title	**Scientific and Ethical Review** - Monitoring of approved research - Submissions from approved research projects	
Purpose	To describe the process of monitoring approved research and subsequent review of documents after ethical approval	
Reference	National Statement – 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: http://www.easternhealth.org.au/research/ethics/approvedongoing.aspx

3. 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-page: http://www.easternhealth.org.au/research/ethics/approvedongoing.aspx

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. 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.

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

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

8. 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.

9. The Ethics Sub-Committee provides review of documents. Ethics 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.

10. The Ethics Chair provides additional out of session review of documents. Chair out of session review takes place as required, usually weekly.

11. 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.

12. 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.

13. 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.

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

15. Administrative personnel will record Ethics Chair and Sub-Committee deliberations in the Chair meeting minutes, and the Sub-Committee meeting minutes; which are attachments of the full Ethics Committee minutes.

16. 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.

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

18. Department database will be updated, as required.

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

20. 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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Number	**2.8**	**Date** November 2011
Title	**Scientific and Ethical Review** - suspension, cessation and completion of research	
Purpose	To describe the process when research is suspended, ceased or completed	
Reference	National Statement – 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 ethical approval for a research is withdrawn, the researcher must notify research participants; and make arrangement to ensure participants' needs are met.

4. 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.)

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

6. 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.

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

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Number	**2.9**	**Date** November 2011
Title	**Scientific and Ethical Review** - Handling of complaints	
Purpose	To describe the process of handling research related complaints	
Reference	National Statement – 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 Ethics 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 Ethics 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 Ethics 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 Ethics 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 Ethics Chair may refer complaint to the full HREC or the Sub-Committee, as appropriate.

9. Complaints directed at the administrative process or administrative personnel may be directed to the Ethics Chair, the Manager of the Office of Research and Ethics, the Director of Research or/and the Executive Director – Medical Services & 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 case of unresolved complaint resolution.

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

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Number	**2.10**	**Date** November 2011
Title	**Scientific and Ethical Review** - Maintenance of records	
Purpose	To describe the process of record keeping and storage	
Reference	National Statement – Sections 5.6.1 – 5.6.7	

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

    a. However where research documents include an executed research agreement with original signatures, all research documents should be kept in a research ethics folder.
    b. An executed research agreement with original signatures must be kept as a paper copy in the research ethics folder.

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

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

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

5. Application documents and correspondences are also increasingly stored electronically on the department network drive for easy access. Electronic files are named according to ethics reference numbers.

6. 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. Restricted access is granted to researchers, if necessary, 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.

7. After research project closure or completion, research ethics paper records will be archived off-site. General research files are kept for 5-7 years and clinical trials records are kept for 15 years prior to confidential destruction. Addition storage time applies to research involving children and human genetics.

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Number	**2.11**	**Date** November 2011
Title	**Scientific and Ethical Review** - Administrative process	
Purpose	To describe the administrative process of scientific and ethical review	
Reference	National Statement – Section 5.1.26	

1. Administrative personnel in the Office of Research and Ethics 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:
http://www.easternhealth.org.au/research/ethics/ethicsresearch.aspx

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:
http://www.easternhealth.org.au/research/ethics/newprojects.aspx

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; 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 the *Low Risk Application Checklist*.

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

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

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

14. 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.

15. PICF templates and writing guidelines are available on the research ethics web-page for researchers: http://www.easternhealth.org.au/research/ethics/attachments.aspx#participant%20info%20and

16. HREC members are provided with electronic files of research applications via a secure web-page: http://www.easternhealth.org.au/ethics/index.asp approximately 2 weeks before each scheduled meeting. Log on requires a password which is changed monthly.

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

18. 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.

19. 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 Ethics Chair. However all HREC members can access electronic files of the scientific Protocols and Investigator Drug Brochures.

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

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

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

23. 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 Ethics Chair or delegate for verification.

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

25. 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.

26. 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 Ethics Chair.

27. 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 the administrative personnel, usually the Manager, Office of Research and Ethics, on behalf of the Human Research Ethics Committee (HREC).

28. 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.

29. Regulatory documents such as Clinical Trial Research Agreements and Indemnity forms will be 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 or has any conflict of interest.)

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

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

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

33. 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.

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

easternhealth
GREAT HEALTH AND WELLBEING

Standard Operating Procedures 2.0 to 2.11

(Scientific and Ethical Review)

(1)

Signature: B Kent Date: 21/11/2011

Name: Prof Bridie Kent

Position: Ethics Chair

(2)

Signature: _____ Date: 21/11/2011

Name: Prof David Taylor

Position: Director of Research & University Relations

Eastern Health Approval

(3)

Signature: _____ Date: 21/11/11

Name: A/Prof Colin Feekery

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