Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Ref Numbers	Title	Page
1.0	**Overview**	2
1.1	**Eastern Health Research Application Fee**	5
1.2	**Clinical Trial Research Agreements**	6
1.3	**Indemnity documents**	7
1.4	**Insurance documents**	8
1.5	**Clinical Trial Notification form**	9
1.6	**Principal investigators who are not Eastern Health employees**	10
1.7	**Protocol and application forms**	11
1.8	**Participant Information and Consent Forms**	13
1.9	**Advertisements and flyers**	14
1.10	**Tracking of implantable devices**	15
1,11	**Post authorisation monitoring & document submission**	16
1.12	**Administrative support**	17
	Eastern Health Approval Page	18

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.0**	**Date** May 2015
Title	**Overview**	
Purpose	To describe the administrative steps for governance review and authorisation of a research project	

1. Research governance encompasses a broad range of regulations, principles and standards in order to:
    a. safeguard research participants
    b. protect researchers
    c. minimise risk for the health service
    d. monitor practice and performance
    e. promote good practice

    Governance review includes checks to ensure that the research:
    - has approval by an accredited or certified Human Research Ethics Committee (HREC)
    - meets requirements stipulated by relevant Australian and Victorian legislation, national guidelines and standards
    - meets financial and sign off requirements
    - meets insurance and indemnity requirements
    - has an appropriate written agreement in place if initiated externally

2. Research governance review applies to all research being conducted at Eastern Health. Research governance review will be undertaken prior to research being authorised to be conducted at Eastern Health and on a continual basis until the research is completed.

3. Ethically approved multi-centre research applications do not undergo duplicated scientific or ethical review by the Eastern Health HREC. Rather, Eastern Health will accept the review and approval obtained from a certified or accredited HREC in accordance with any relevant Memorandum of Understanding or other formal arrangement. Research governance review can be undertaken prior to multi-centre research being authorised to be conducted at Eastern Health.

4. All documents are date stamped as they are submitted

    a. except for Clinical Trial Notification form, Clinical Trial Research Agreements and Indemnity documents, where only the cover letter should be date stamped

5. All documents are checked against *New Project Submission Checklist* and *Research Governance Checklist for all Principal Investigators*.

6. The *Research Governance Checklist for all Principal Investigators* is a checklist devised and maintained by the Coordinating Office for Human Research Ethics. The checklist can be downloaded by researchers from the Consultative Council for Human Research Ethics website: http://www.health.vic.gov.au/clinicaltrials/site-specific.htm

7. A *New Project Submission Checklist* is a department checklist developed for use by personnel in the Eastern Health Office of Research and Ethics. Checklist is available to personnel in the Office of Research and Ethics on the department share drive: N:\02-03&current\Ethics - Eastern Health\Agendas\Checklists

8. Research governance review will commence if essential documents have been submitted. Essential documents include application fee, Protocol and the Clinical Trial Research Agreement, including a budget.

9. One copy of all documents is required and may include all or some of the documents from the list below.

   Both paper copy and electronic files required for:

   a. Site Specific Assessment (SSA) Form
   b. Ionising Radiation Use - Eastern Health site (Section 4 of Victorian Specific Module)
   c. Medical Physicist's report - Eastern Health site
   d. Protocol
   e. Insurance documents
   f. Final approval letter from the reviewing Human Research Ethics Committee (HREC)

   Paper copy only required for: (electronic files not essential)

   g. Confidentiality agreements
   h. Clinical Trial Notification form
   i. Clinical Trial Research Agreements
   j. Indemnity documents
   k. Application Fee and Compliant Tax Invoice

   Only electronic files required for: (paper copy not essential)

   l. National Ethics Application Form (NEAF)
   m. Victorian Specific Module (VSM)
   n. Investigator Drug Brochure
   o. Product Information
   p. Master approved Participant Information and Consent Forms
   q. Eastern Health specific Participant Information and Consent Forms
   r. Questionnaires
   s. Advertisements
   t. Curriculum vitae
   u. Other HREC approved documents

   Documents should be checked against the HREC final approval letter to ensure all documents received are the correct approved versions.

10. Some documents require detailed review. These should be reviewed in accordance with Standard Operating Procedures.

11. All new projects are registered into Australian Research Ethics Database (AuRED).

12. Electronic files of documents are submitted via email or through other means supported by the Office of Research and Ethics (e.g. USB) by the research applicant. Electronic files are saved in appropriate folders and named by local reference numbers.

13. A written response is issued to research applicants detailing any outstanding documents or changes required. A letter template for governance requirements is available.

14. Any outstanding documents and requested, changes are checked to ensure they are satisfactory. Further changes are requested if necessary.

15. If all issues are addressed and all documents are satisfactory, Eastern Health authorisation will be recommended.

16. Eastern Health signatory for research authorisation will sign the Clinical Trial Notification form, Clinical Trial Research Agreements and Indemnity Forms.

17. Eastern Health signatory for research authorisation is the Executive Director – Medical Services & Research or delegate. A delegate must not be involved in the research nor has other conflicts of interest in relation to the research.

18. One original fully executed Clinical Trial Research Agreement and Indemnity Form is retained in the research ethics file. Documents are also scanned and saved for electronic record keeping.

19. A letter of authorisation is issued for the project to commence at Eastern Health. A letter template for final authorisation is available.

20. Projects that are reviewed by the Eastern Health HREC may have only one letter issued combining written HREC approval and Eastern Health authorisation.

21. Authorisation documents and other regulatory documents are sent to the research applicant.

22. The research project authorisation status is updated in the Australian Ethics Database (AuRED).

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.1**	**Date** May 2015
Title	**Eastern Health Research Application Fee**	
Purpose	To describe the steps for processing research application fee	

1. Check research application fee has been submitted according to current Eastern Health fee schedule which is available from the Eastern Health HREC Handbook.

2. Check a Compliant Tax Invoice has been completed and submitted. A Compliant Tax Invoice template is available for download on the research ethics web-page: http://www.easternhealth.org.au/research-ethics/research-ethics/quick-links-to-forms-and-templates

3. Check payment and details are correct. Make one copy of payment for the file and send original payment to Cashier for processing. A receipt will be sent to the contact person named on the Compliant Tax Invoice from the Cashier. A copy of the receipt will be sent to the Office of Research and Ethics for filing.

4. If payment has not been submitted or if details are incorrect, a request for payment or a request for revised payment will be made in writing.

5. Final authorisation of the research project cannot be granted if payment is outstanding.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.2**	**Date** May 2015
Title	**Clinical Trial Research Agreements**	
Purpose	To describe the steps for review of Clinical Trial Research Agreements	

1. A Clinical Trial Research Agreement must be in place between Eastern Health and the Sponsor, if the research is initiated or sponsored by an external entity, such as a collaborative group, a commercial company or any other external entity.

2. The Clinical Trial Research Agreement must adhere to the appropriate template provided by Medicines Australia, Medical Technology Association of Australia, or the Victorian Managed Insurance Authority (VMIA), using the most current version. Templates can be accessed via links from the research ethics web-page: http://www.easternhealth.org.au/research-ethics/research-ethics/quick-links-to-forms-and-templates

3. Details such as project title, entities, addresses, protocol details must be correctly entered.

4. Special Conditions, if any, must have been approved by Health Departments of NSW, QLD, SA and Vic.

5. The payment schedule must include the correct payee details and Eastern Health department fees as agreed between the Eastern Health departments, the researcher and the Sponsor.

6. Arrangement on intellectual property rights and publication practices are included in the approved Clinical Trial Research Agreement templates. Any deviation from the standard arrangement will require review and approval by Eastern Health senior personnel as appropriate, such as the Director of Research, Executive Director of Medical Services and Research and/or the Chief Counsel.

7. Clinical Trial Research Agreements (at least 2 originals) must be signed by the researcher and the Sponsor, prior to submission.

8. The Clinical Trial Research Agreement, where an approved template is not available or not appropriate, must be reviewed by the Office of Research and Ethics and the Eastern Health (EH) Legal Counsel prior to acceptance.

9. The research applicant will be advised of any problems with the document and any request for changes in writing.

10. The Eastern Health signatory for Clinical Trial Research Agreements is the Executive Director - Medical Services and Research, or delegate. A delegate must not be involved in the research nor has other conflicts of interest in relation to the research.

11. Clinical Trial Research Agreements will only be signed by the Eastern Health signatory on the recommendation of the Office of Research and Ethics, after all research project queries have been addressed fully and all requirements (if any) from the Legal Counsel have been met.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.3**	**Date** May 2015
Title	**Indemnity documents**	
Purpose	To describe the steps for review of indemnity documents	

1. An indemnity must be provided if a research project is commercially sponsored.

2. The indemnity must adhere to the Medicines Australia Form of Indemnity for Clinical Trials. The template is available via a link from the research ethics web-page: http://www.easternhealth.org.au/research-ethics/research-ethics/quick-links-to-forms-and-templates

3. Details of the provider of indemnity (the Sponsor), the indemnified party (Eastern Health), principal researcher, protocol name and protocol number must be correctly entered.

4. Provider of the indemnity must be an Australian entity and must not be an agent of an overseas company.

5. Indemnity provision must comply with the requirements stipulated by the Victorian Managed Insurance Authority (VMIA) in its published guidelines.

6. Indemnity forms (at least 2 originals) must be signed by the Sponsor, prior to submission.

7. The research applicant will be advised of any problems with the document and any request for changes in writing.

8. The Eastern Health signatory for Indemnity documents is the Executive Director - Medical Services and Research or delegate. A delegate must not be involved in the research nor has other conflicts of interest in relation to the research.

9. Indemnity documents will only be signed by the Eastern Health signatory on the recommendation of the Office of Research and Ethics, after any appropriate review and after all research project queries have been addressed fully.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.4**	**Date** May 2015
Title	**Insurance documents**	
Purpose	To describe the steps for review of insurance documents	

1. Evidence of current insurance in the form of a certificate of currency must be provided by the Sponsor if a research project is commercially sponsored.

2. The Certificate of Currency must detail the type of insurance – Public and Product Liability – or equivalent such as General Liability or Clinical Trials Insurance.

3. The full and legal name of the Australian entity acting as sponsor must be stated as the insured. (The full and legal name of the Australian Sponsor should be identical in all regulatory documents ie Clinical Trial Research Agreements, indemnity and insurance documents.)

4. The Certificate of Currency must be provided by an Australian insurer.

5. Insurance coverage must be provided for a minimum of A$10 million for any one occurrence and in the annual aggregate.

6. Any excess, deductible, or self insured retention amount must not be greater than A$25,000 for each and every claim or series of claims arising out of one original cause. The amount of deductible should be stated on the Certificate of Currency, even if it is nil.

7. The Certificate of Currency must be provided on the underwriter's or insurer's letterhead, not on the broker's letterhead.

8. Details of the study name and protocol number must be correct, if included in the document.

9. Period of insurance must be detailed and must be current.

10. Insurance provision must comply with the requirements stipulated by the Victorian Managed Insurance Authority (VMIA) in its published guidelines and any relevant communication from the VMIA.

11. Insurance requirement may vary depending on the risk profile of the research. Advice should be sought from the Chief Counsel if unsure.

12. Research applicant will be advised of any problems with the document and any request for changes in writing.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.5**	**Date** May 2015
Title	**Clinical Trial Notification form**	
Purpose	To describe the steps for reviewing Clinical Trial Notification form	

1. A Clinical Trial Notification (CTN) form is required to be submitted for a research project conducted under the Clinical Trial Notification (CTN) Scheme.

2. This is required when the research project involves the use of any medicine or device not entered in the Australian Register of Therapeutic Goods, or the use of a marketed medicine or device beyond the conditions of its marketing approval.

3. Details of requirement are provided by the Therapeutic Goods Administration (TGA) on its web-site: http://www.tga.gov.au/industry/clinical-trials.htm

4. Ensure all details are complete and correct on the CTN form. These include protocol name and number, drug and device details, Sponsor details, Eastern Health principal investigator's details, Eastern Health site details and the reviewing Human Research Ethics Committee (HREC) details.

5. If details are incorrect and are minor, changes can be made manually by crossing out incorrect information with one line, adding the correct information, and initialling and dating beside the changes made on the form.

6. If details are incorrect and are extensive, a written request should be made to the research applicant or Sponsor to submit a revised CTN form.

7. The CTN form should be signed by the reviewing Human Research Ethics Committee (HREC) and the Eastern Health Principal Investigator before submission for Eastern Health sign off.

8. Once the CTN form is satisfactory, provided all other project submission is satisfactory and all project queries have been addressed, the CTN form will be signed by the Executive Director - Medical Services & Research, or delegate on behalf of Eastern Health. A delegate must not be involved in the research nor has other conflicts of interest in relation to the research.

9. The Sponsor will sign the CTN form last and is responsible for forwarding the completed CTN form with payment to the TGA.

10. If the Sponsor is Eastern Health (such as when a research protocol is initiated by an EH investigator, and not by an external entity) the CTN form will be signed by Eastern Health and returned to the applicant for forwarding to the TGA with payment.

11. A research project cannot commence until a written acknowledgement is received from the TGA. A copy of the TGA acknowledgement should be forwarded to the Office of Research and Ethics at Eastern Health.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.6**	**Date** May 2015
Title	**Principal investigators who are not Eastern Health employees**	
Purpose	To describe the steps to ensure that: • non Eastern Health principal investigators have appropriate indemnity and insurance cover; • there is adequate monitoring of study conduct by Eastern Health employees involved in the research	

1. On occasions a principal researcher may not be an employee of Eastern Health. The principal researcher may be employed by an external organisation such as another health service; or is no longer in paid employment but with expertise of value to the research.

2. Depending on the nature of the research, and the nature of access to Eastern Health patients and records, the external researcher may be requested to provide a letter of information from the external organisation, stating that:

    a. the researcher is a current employee;
    b. the nature of that employment ie full time, part time;
    c. what their role is, such as psychologist, medical practitioner, etc;
    d. the external organisation is aware of their role in the research;
    e. appropriate insurance and indemnity is in place for the researcher in relation to the research at Eastern Health.

3. External researchers who request access to Eastern Health patients and/or records must sign a Confidentiality Agreement, unless there is an approved Clinical Trial Research Agreement in place, where adequate confidentiality clauses are included. A template of a Confidentiality Agreement is available on the web-site: http://www.easternhealth.org.au/research/ethics/attachments.aspx

4. An Eastern Health employee must be named and must provide written sign off to take responsibility for study conduct at Eastern Health. An appropriate Eastern Health employee may be the relevant clinical director, program director or their delegate.

5. If the external researcher is a clinician:

    a. evidence of appropriate current registration with the Australian Health Professionals Registration Authority must be provided; (there should be no restrictions on their practice);
    b. the appropriate Eastern Health professional chief should be informed that they are entering Eastern Health service;
    c. additional checks on their credentials may be required if clinician is a medical practitioner.

6. Following receipt of relevant information, ensure consistency with VMIA advice.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.7**	**Date** May 2015
Title	**Protocol and application forms**	
Purpose	To describe the steps for reviewing a research protocol and application forms	

7. Review and identify from the Protocol and application forms study characteristics such as

    a. any drug or device intervention
    b. study phase
    c. procedures
    d. number of participants
    e. number of records required
    f. duration of intervention and follow up
    g. hospital sites
    h. study personnel

8. Review and make note of relevant details in *New Project Submission Checklist.* Checklist is available to personnel in the Office of Research and Ethics on the department share drive: N:\02-03&current\Ethics - Eastern Health\Agendas\Checklists

9. Information identified from the Protocol and application forms will be used to determine what other documents are required to be submitted and reviewed.

10. Review and identify from the Protocol and application forms any relevant information which may impact on regulatory or legislative compliance, such as:

    a. the use of radiation
    b. the use of personal and health information
    c. waiver of consent
    d. involvement of participants unable to give consent

11. Review and make note of relevant details in *New Project Submission Checklist*.

12. Information identified from the Protocol and application forms will be used to determine if any legislation or regulation applies to the research. Research applicant will be advised to ensure legislative and regulatory compliance.

13. Review and identify from the Protocol and application forms all Eastern Health departments which will be involved or impacted by the research. Check that all departments have provided sign off to confirm their awareness and support of the research.

    The following departments are commonly involved or impacted by research

    a. Pharmacy
    b. Health Information Services
    c. Radiology
    d. Pathology

14. However other departments may be impacted, such as Cardiology, Day Procedure Ward, Endoscopy, Outpatients, and other general wards. A sign off must be submitted in writing for all departments involved.

15. If the research involves more than one Eastern Health site, sign off must be obtained from the departments at each site as appropriate.

16. Head of department must provide a sign off to confirm their support of the research. Researcher who is also the Head of Department should not sign off to approve their own project.

17. Sign off must be provided by the person who has line management responsibility for the researcher.

18. Financial and budget requirements from departments are checked against the payment section of the Clinical Trial Research Agreement, as per SOP 1.2, point 5.

19. Eastern Health Executive Director – Medical Services & Research will give consideration as to whether any new device or procedure needs to be notified to the "New Prosthesis and Procedures Committee".

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.8**	**Date** May 2015
Title	**Participant Information and Consent Forms**	
Purpose	To describe the steps for review of Participant Information and Consent Forms	

1. A master Participant Information and Consent Form (PICF) that is approved by the reviewing Human Research Ethics Committee (HREC) should be provided.

2. Check master PICF version number and date correspond to what is listed in the HREC final approval letter.

3. An Eastern Health specific PICF should be provided.

4. Check the Eastern Health specific PICF against the master PICF approved by the reviewing HREC.

5. Eastern Health specific PICF should include Eastern Health specific details including

    a. logo
    b. hospital site
    c. contact details for researcher and coordinator
    d. contact details for complaint - this is in addition to the reviewing HREC's contact details
    e. other relevant site specific information (see point 8 below)

    (In the footer)

    f. the version number and date of the Eastern Health specific PICF
    g. the version number and date of the master approved PICF

6. Eastern Health specific PICF should be identical to the master PICF approved by the reviewing HREC, except for items listed in 5.

7. Where there is more than one PICF for the research project, the same requirements will apply to all PICF.

8. Other relevant site specific information may vary depending on the research.

    An example is the recommended wording for radiation procedures, as advised by a Medical Physicist for inclusion in the Eastern Health specific PICF. The Eastern Health specific PICF should be checked against the medical physicist's report to ensure any recommended wording has been included.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.9**	**Date** May 2015
Title	**Advertisements and flyers**	
Purpose	To describe the steps for review of documents such as advertisements and flyers	

1. A master advertisement or flyer that is approved by the reviewing Human Research Ethics Committee (HREC) should be provided.

2. Check master advertisement or flyer name, version number and date correspond to what is listed in the HREC final approval letter.

3. An Eastern Health specific advertisement or flyer should be provided, if applicable.

4. Check the Eastern Health specific advertisement or flyer against the master advertisement or flyer approved by the reviewing HREC.

5. Eastern Health specific advertisement or flyer should include Eastern Health specific details including

    a. logo
    b. hospital site
    c. contact details for research team
    d. other relevant site specific information
    e. the version number and date of the advertisement or flyer

6. Eastern Health specific advertisement or flyer should be identical to the master advertisement or flyer approved by the reviewing HREC, except for items listed in 5.

7. Where there are other documents which need to be Eastern Health specific, the same requirements will apply.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.10**	**Date** May 2015
Title	**Tracking of Implantable Device**	
Purpose	To describe the process for ensuring a system is in place for tracking implantable devices (in a device trial)	

1. For research that involves implantable devices, details of a proposed mechanism for tracking these devices must be provided by the researcher or the sponsor.

2. Any tracking mechanism must meet any minimum standards or requirements stipulated by the Therapeutic Goods Administration (TGA). Confirmation and details should be provided by the researcher or the sponsor.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.11**	**Date** May 2015
Title	**Post authorisation monitoring & document submission**	
Purpose	To describe the process of continuing monitoring and documents review post authorisation of the research project	

1. Throughout the life of the research project, changes may occur. Any new or amended documents must be submitted to Eastern Health for authorisation. Detailed instructions are provided in the HREC Handbook at http://www.easternhealth.org.au/research-ethics/research-ethics

2. Eastern Health authorisation of new or amended documents will be granted after approval from the reviewing Human Research Ethics Committee (HREC); and after satisfactory governance review, in accordance with SOP 1.6.

3. Revised Participant Information and Consent Forms (PICF) for Eastern Health should be submitted with the approved revised Master PICF. Mark up and clean versions of the revised documents are required. Revised PICF are reviewed in accordance with SOP 1.7.

4. Advertisements are reviewed in accordance with SOP 1.8.

5. Some documents are submitted directly to Eastern Health, such as addendum or amended Clinical Trial Research Agreements (CTRA) and updated insurance certificates.

6. Addendum or amended CTRA are reviewed in accordance with SOP 1.2.

7. Updated Insurance Certificates are reviewed in accordance with SOP 1.4.

8. Monitoring of authorised research will continue until project completion, early cessation or site closure.

9. Monitoring includes the requirement to submit notifications of local serious adverse event (SAE) reports, local protocol deviation reports and local progress reports. These are processed by administrative staff, in accordance with reporting requirements stipulated by the Victorian Managed Insurance Authority and the National Health and Medical Research Council guidelines.

10. Notifications that may require review or action within Eastern Health are forwarded to senior personnel including the Director of Research and University Relations and/or the Executive Director of Medical Services and Research.

11. Final report is required on study completion, early cessation or site closure. Results and publications should be submitted. These are used to generate internal reports and closure of study file.

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

Reference Number	**1.12**	**Date** May 2015
Title	**Administrative support**	
Purpose	To describe the administrative support for governance review.	

1. Administrative personnel in the Office of Research and Ethics provide research governance review for research undertaken at Eastern Health, including single site and multi-centre research.

2. Administrative personnel provide support to researchers in submitting research governance applications.

3. Detailed instructions for the submission of research applications for governance review are provided in the HREC Handbook: http://www.easternhealth.org.au/research-ethics/research-ethics

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

5. Application documents are date stamped on receipt to monitor response times; and to provide information in case of queries from researchers. Key dates of communication are recorded in tracking sheets, the Australian Ethics Database (AuRED) and the respective research files.

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

    a. process application fees;
    b. 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 *Research Governance Checklist for all Principal Investigators*.

10 *New Project Submission Checklist* is a department checklist for use by administrative personnel only. Checklist is available on the department share drive.

11 *Research Governance Checklist for all Principal Investigators* is a checklist devised and maintained by the Coordinating Office for Human Research Ethics. The checklist can be downloaded by researchers from the Consultative Council for Human Research Ethics website: http://www.health.vic.gov.au/clinicaltrials/site-specific.htm

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

Office of Research and Ethics
Research Governance
Standard Operating Procedures (SOP)

(1)

Signature: _____ Date: _____

Name: Prof David Taylor

Position: Director of Research & University Relations

Eastern Health Approval

(2)

Signature: _____ Date: _____

Name: Adj Clin A/Prof Colin Feekery

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