Research Policy

Scope: Eastern Health
Executive Sponsor: ED Medicine and Research
Policy Status: Revised
Last Review Date: 01-05-2011
Policy Number: 1862
Approving Body: EH Executive Committee
Policy Developed: 01-03-2009
Next Review Date: 01-05-2014

Purpose:

Set out the framework within which all research in Eastern Health is undertaken.

Details:

Scope:

Policy applies to:

(1) All persons employed by Eastern Health.

(2) Any person undertaking research involving Eastern Health patients, staff and other resources.

(3) All persons who are involved in collaborative research projects with Eastern Health.

Rationale:

Compliance with relevant Commonwealth and State legislations in relation to research.

Compliance with the requirements of relevant regulatory and professional bodies.

Compliance with existing Eastern Health policies. (See “Relevant Policies” further in the document.)

Definitions:

Clinical trial is any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationships between a medical intervention and health outcomes.

Conflicts of interest are situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's judgement in conducting or reporting research. A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might therefore, in actuality or appearance compromise the integrity of the research. Conflicts of interest also apply to HREC members who may use information obtained during the reviewing process for personal advancements.

Eastern Health comprises Angliss, Box Hill, Maroondah and Healesville and District Hospitals; Peter James Centre, Wantirna Health, Yarra Valley Community Health Service and Yarra Ranges Health.

Human Research Ethics Committee (HREC) is a NHMRC registered committee which undertakes to provide review and approval of research projects. Its composition and conduct is governed by guidelines in particular the *National*

Statement on Ethical Conduct in Human Research (2007). Its function is to protect the welfare and rights of participants involved in research by reviewing research proposals involving humans, monitoring the conduct of research and dealing with complaints that arise from research.

Intellectual Property includes patents, copyright, future copyright, know how and designs.

Low risk research describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

Negligible risk research The expression 'negligible risk research' describes research in which 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.

Research is an intellectual investigation aimed at discovering, interpreting and revising human knowledge. It is a broad concept and there is no simple, single way to define research for all disciplines.

Research Governance is a system of managing and governing research.

Research Misconduct includes fabrication, falsification, or plagiarism in proposing, performing or reviewing research or in reporting research results.

Policy/Guidelines

Ethical review and approval of research & Registration of audit

Eastern Health establishes and maintains a Human Research Ethics Committee (HREC) constituted in accordance with relevant NHMRC guidelines, in particular the National Statement on Ethical Conduct in Human Research (NHMRC, 2007).

All research projects must have written approval from the HREC - Eastern Health Research and Ethics Committee prior to commencement.

Exemptions from *full* ethical review apply to quality assurance activities (QA) and projects involving negligible risk, as determined by clear published criteria, as reflected in the National Statement (NHMRC, 2007).

Regardless of whether a project is considered Audit or Research, all new projects must be registered with the Office of Research and Ethics.

Research projects that are deemed to involve low risk or negligible risk to participants may be approved at alternative levels of review.

HREC Terms of Reference (link: http://www.easternhealth.org.au/research/ethics/generalinfo.aspx) are revised every 3 years or as necessary.

Research Governance

(1) Compliance with relevant legal, regulatory and insurer's requirements.

Research and ethical guidance is provided to researchers and sponsors through education and detailed information on **the Research and Ethics web-page** (http://www.easternhealth.org.au/research/ethics/ethicsresearch.aspx).

Early phase research projects are subject to review by external legal advisors in accordance with the **hospital insurer's guidelines** (http://www.vmia.vic.gov.au/Risk-Management/Clinical-trials.aspx).

Contract agreements and indemnity and insurance documents must be compliant with the hospital insurer's requirements and must be acceptable to the Eastern Health legal counsel prior to execution.

Therapeutic Goods Administration (TGA) must be notified of all research projects involving: a) unregistered therapeutic goods or b) marketed therapeutic goods being used outside of their marketing approval. **For more**

information. (http://www.tga.gov.au/industry/clinical-trials-forms-ctn.htm).

The radiation section (http://www.health.vic.gov.au/environment/radiation/index.htm) of the Department of Human Services must be notified prior to research commencement where projects involve the use of radiation outside of standard clinical care.

(2) Continuing ethical acceptability & Withdrawal of ethical approval

HREC projects are monitored from approval through to completion in accordance with established processes as described in the Standard Operating Procedures.

Where the HREC in its routine deliberations, or the chair and those members immediately contactable in urgent situations, considers that it is unethical to continue a research project, the HREC may suspend or withdraw ethical approval in order to ensure participants' welfare. (Note the chair, acting in urgent situations, must submit the case to the next HREC meeting for the formal deliberation and decision by the entire committee.)

Circumstances where withdrawal of ethics approval and discontinuance of research may be appropriate:

- substantial deviations from the research protocol have occurred;
- side-effects of unexpected type, severity, or frequency are encountered;
- some of the research participants have become disadvantaged as one treatment or procedure appears to be significantly better or worse than others being compared.

(3) Financial management

Eastern Health employees and researchers must demonstrate good stewardship and responsible management of the public resources used to conduct research.

Adequate human and material resources must be available to cover all the requirements involved in conducting the research.

Research projects must have all the relevant Eastern Health department approval prior to commencement including Pathology, Medical Imaging and Pharmacy, if relevant. Full cost recovery arrangements should be in place.

Research budgets need to be adequate in order to cover anticipated costs.

Research payments from sponsors must not be deposited directly into a personal account; a special purpose fund should be set up for this purpose.

It is not appropriate to bill Medicare for research related investigations.

(4) Data/record management and retention

Eastern Health must ensure that research material and data management and practices comply with relevant legislation, codes of conduct, regulations and guidelines.

Researchers and employees are bound by the relevant laws governing health records and the Eastern Health code of conduct in relation to privacy and confidentiality.

All research data/records are to be maintained securely in their electronic or written format.

In general, identifiable data/record must not be transferred outside of Eastern Health. Exemptions may apply in some circumstances if participants have given written informed consent and if the relevant law provides for a transfer or disclosure.

Research data/records are retained for specified periods according to the nature of the projects. A clinical trial's records should be retained for 15 years from project completion. Non-clinical trial records should be retained for a

period of 5 – 7 years. Data from research involving gene therapy must be retained permanently.

Records may be archived off-site. Details of archiving location and process of retrieving record must be available.

At the end of the retention period, data and records must be securely destroyed in accordance with the Public Records Act and Eastern Health policy.

(5) Researchers' responsibilities

Researchers must:

Foster and maintain intellectual honesty, integrity, and scholarly and scientific rigour.

Respect the rights of research participants

Adopt appropriate research methods for the enquiry.

Follow proper practices for safety and security.

Ensure publications accurately reflect research findings.

Comply with the requirements of the sponsors of research subject to those requirements not being in conflict with the law or with the policies and interests of Eastern Health.

Register clinical trial research with a publicly accessible registry to promote access to information. Further guidance is available in th*e Editorial - Clinical Trial Registration: a Statement from the International Committee of Medical Journal Editors* (2004).

Submit projects to the HREC for review and approval prior to commencement.

Immediately report serious adverse events, serious adverse drug reactions, serious unexpected suspected adverse reactions and serious adverse device events that occur in the course of the research to the HREC, the sponsor and other regulatory authorities, in accordance with the research protocols, research agreements, and relevant ethical and regulatory guidelines. Hospital insurers are notified via the Office of Research and Ethics in accordance with their guidelines.

Notify changes to safety measures, protocol amendments, and significant protocol deviations to the HREC.

Submit progress report to the HREC annually or more frequently if requested.

Submit a final report on completion of the research.

Keep clear and accurate records of research methods and data sources including approvals.

Maintain and retain primary records and research data in a retrievable format.

Comply with the privacy and confidentiality legislation.

Declare any conflicts of interests to the HREC and if applicable to potential participants.

Report any research misconduct promptly

Comply with any agreements reached between Eastern Health, the sponsor of the research and the investigator regarding any intellectual property rights arising from the trial.

(6) Eastern Health's responsibilities

Provide adequate resource to maintain the HREC, constituted in accordance with the National Statement (2007).

Seek assurance from researchers that they are adequately qualified to undertake the research.

Provide support and protection to researchers through education, HREC processes and governance structures.

Promote awareness of all guidelines and legislation relating to the conduct of research.

Provide a governance framework to ensure research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability.

Maintain mechanism and processes to ensure compliance with relevant legislation, codes, guidelines and best practice.

Deal promptly with any suspected or actual research misconduct by researchers.

Provide induction, formal training and continuing education for research staff including trainees, in areas of research methods, ethics, confidentiality, data storage, records retention, regulation, governance and Eastern Health research policy.

Comply with any agreements reached between Eastern Health, the sponsor of the research and the investigator regarding any intellectual property rights arising from the trial

(7) Supervisors and trainees' responsibilities

Supervisors will provide oversight for the conduct of the research from initial study design, ethics submission, data collection to final study completion.

Supervisors will provide training and feedback to students and trainees in a timely manner.

Supervisors should be listed as co-investigators. They have overall responsibility through out the duration of the research projects, including after student and trainee researchers have moved on from their placements.

Trainees and students must have a nominated supervisor who should have expertise in research and/or in the study area.

Trainees and students must seek guidance when required and undertake induction and training as soon as practicable.

(8) Participants

Respect must be shown for all human research participants, animals and the environment.

Information about research should be presented in a way that promotes understanding and enhances a participant's right to information and autonomy in accordance with the Charter of Human Rights and Responsibilities

Considerations should be given to the participant's age, educational attainment, impairment in hearing, sight, or speech and in their cognition, culture and language ability.

Consent procedures must be compliant with legislation and Eastern Health policy and the trial protocol. Potential participants must give informed consent prior to commencement of the research project.

Informed consent can be obtained in various forms including written, verbal or implied consent. These must be compliant with legislation and Eastern Health policy and the trial protocol.

Consent waiver may be granted if the risks and benefits have been considered and the project has received approval by the HREC in the knowledge that consent may not be required in all or any circumstances. Consent waiver is granted according to clear established guidelines, as reflected in the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007). Summaries of research projects that have been granted waivers of consent will be made

publicly accessible, such as in a research report or on an Eastern Health web-page, in order to maintain public confidence.

(9) Complaints process

Research participants must be made aware of how to raise concerns.

Research complaints must be forwarded to HREC Chair in the first instance through the Research and Ethics Office.

In the handling of complaints, the HREC Chair would seek the advice and support of senior Eastern Health personnel eg. leader of the research group, head of department or a senior administrator, if required.

In principle and where possible, complaints are dealt with locally. Eastern Health policies on complaints handling are applicable.

In circumstances where the complaint involves a member of the research group or the head of department, these may be dealt with by an alternative senior person who is not directly involved in the study.

A person who is the subject of an allegation must be treated fairly and must have the opportunity to respond to allegations in writing.

A person who makes an allegation must be treated fairly

Complaints policy and procedure are compliant with the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007) and other workplace agreements and the law.

Serious research misconduct may require investigation by an external body.

Proven misconduct may require disciplinary actions.

(10) Conflicts of Interest: Disclosure and management

HREC members must declare any conflicts of interests or potential conflicts of interest prior to appointment, at least annually and when their circumstances change.

Conflicts of interests must not influence decision making unfairly. Any perceived conflicts of interests must not be ignored.

Examples of potential conflicts of interests are consultancies, membership of committees, boards of directors, advisory groups, selection committees and financial delegations.

Researchers must declare any interests or conflicts of interests prior to undertaking their research. Declaration of conflicts of interests must be made at the start of the project and subsequently if circumstances change. Discreet disclosure may be applicable in some circumstances. Researchers must withdraw themselves from decision making that may be influenced by conflict of interests. Complete withdrawal from discussion may be appropriate eg. by leaving the meeting room.

Disclosure of conflicts of interests should be made as soon as they become apparent.

(11) Intellectual property rights, authorship and publication

Research results should be communicated responsibly.

A culture supporting knowledge creation, knowledge transfer and entrepreneurial endeavour is encouraged.

Eastern Health seeks to attract industry and government funding for research and knowledge transfer. Research

agreements must make clear the distribution of Intellectual Property rights which might either precede or arise from the trial.

Eastern Health encourages affiliations with other institutions including universities and research collaborative groups.

Clear written arrangements of the research data custodianship and publication guidelines are necessary prior to research commencement.

Eastern Health has ownership of all intellectual property created by its staff during their period of employment. This excludes moral rights and scholarly work. Circumstances may exist where employees should be assigned additional rights.

Intellectual property arising from collaborative research projects such as those with affiliated universities is subject to the terms and conditions of any formal agreements between Eastern Health and the University or the collaborative group in question.

Where there has been contribution from others to a research project, the rights associated with joint contribution need to be respected. Collaborators should discuss, define, agree and document decisions according to intellectual property principles.

Publication is encouraged as soon as possible after completion of a research project. It should not be delayed unnecessarily. Specific requirements may apply to collaborative and commercially sponsored research. These should be agreed in a clinical trial research agreement.

Collaborating researchers should agree on authorship of a publication prior to commencement of study.

Authorship should be based on substantial contributions such as conception and design of the project; analysis and interpretation of the data; drafting significant parts of the work or critically revising it. Further guidance is provided in the *Australian Code of the Responsible Conduct of Research* (NHMRC, 2007).

Persons should not be offered authorship solely by virtue of their positions eg. the Head of the Department, providing routine assistance or technical assistance only or providing published materials without other intellectual input

Authors who fulfil the criteria of authorship, including trainees, must be offered the opportunity to claim appropriate authorship (first, second etc) and can only be excluded with their written permission.

Authorship should not include those who do not meet the above authorship criteria.

(12) Collaborative Research Projects with external sponsors

Contractual agreement should be in place between Eastern Health and other establishments prior to the commencement of research project. The agreement should cover the following:

Financial management

Intellectual property

Authorship and publication

Secondment

Ethics approval

Ownership of equipment and data

Confidentiality

Copyright

Commercial returns

Responsibility for ethics and safety clearances

Reporting arrangements.

Management of research materials and data including after research completion.

(13) Research misconduct/ breaching of research standards

Research misconduct includes fabrication, falsification, plagiarism, deception in proposing, carrying out or reporting the results of research, misrepresentation to obtain funding, persistent negligence in failure to observe research codes and guidelines; and failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow ethically approved research proposals especially where there is an unreasonable risk or harm to participants. Research misconduct also includes a wilful concealment or facilitation of research misconduct by others.

Research misconduct does not include honest differences in judgement or honest errors that are minor or unintentional. However once identified any breaching of standards must be addressed promptly by the responsible officers of Eastern Health and research supervisors, as appropriate.

All alleged misconduct must be investigated and acted upon promptly. This may involve the following steps:

A discreet investigation locally

A formal inquiry

The imposition of a sanction or penalty

Actions to remedy the situation

Advice to expert groups and public statements.

Protocol/Procedure:

Guidance in the following topics are available (Hypertext to: http://www.easternhealth.org.au/research/ethics/ethicsresearch.aspx)**:**

- Research project submission guideline
- Ethical review and approval process
- Clinical trial agreement; indemnity and insurance requirements
- Progress monitoring and reporting requirement
- Safety notification and reporting
- Documentation
- Low risk and Negligible risk projects
- HREC meeting dates
- Submission of protocol amendments
- Projects that have been approved with a consent waiver should be made available to the public to maintain public confidence.
- Mutual recognition arrangements may be established with other HRECs.
- HREC Terms of Reference

Records of the following are maintained:

- HREC member recruitment
- HREC standard operating procedures

- HREC observers
- HREC meeting agendas and minutes

Related Policy:

- Complaints by Patients or Clients
- Privacy Policy
- Consent Policy – Adults and Children
- Retention and storage of medical records
- Use of Interpreters' services
- Translation of materials
- Confidentiality policy
- Radiation safety policy
- Staff complaints Policy
- Incident and Adverse Event Reporting Policy
- Conflicts of Interest and Gifts, Benefits & Hospitality Policy
- Ethical and Scientific Review of External Research Policy

References/Legislation:

(1) Relevant Guidelines and Codes:

The National Statement on Ethical Conduct in Human Research (NHMRC, 2007)

Australian Code for the Responsible Conduct of Research (NHMRC, 2007)

Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (NHMRC, 2003).

Guideline for Ethical Research in Indigenous Studies (AIATSIS, 2000).

Guidelines for Clinical Trials (VMIA, 2007)

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments (2000)

(2) Victorian State Laws:

Human Tissue Act 1985

Infertility Treatment Act 1995

Health Records Act 2001

Guardian & Administration Act 1986

Medical Treatment Act 1988

Freedom of Information Act 1982

Mental Health Act 1986

Radiation Safety Act 2005

Gene Technology Act 2001

Human Tissue Act 1982

Information Privacy Act 2000

Public Records Act 1973

Charter of Human Rights and Responsibilities Act 2006

(3) Commonwealth Laws:

National Health & Medical Research Council Act 1992

Therapeutic Goods Act 1989

Human Tissue Act 1983

Privacy Act 1988

Epidemiology Studies (Confidentiality) Act 1981

Gene Technology Act 2001

(4) Other reference document:

Editorial - Clinical Trial Registration: a Statement from the International Committee of Medical Journal Editors 2004.

Policy History:

Created in February 2009.
Revised in May 2011

Dissemination/Education Strategy:

Policy document to be available in OBJECTIFY for all internal staff

Policy document to be available on the research and ethics web-page for all staff who cannot access OBJECTIFY

Individual feedback to be provided to researchers in response to their research projects.

Compliance Measurement Strategy:

Determine researchers' knowledge base on reviewing of all new research proposals.

Assess compliance in the course of the HREC monitoring of on-going conduct of the research project.

Ascertain compliance by auditing of research documentation.

Interview of research participants and research personnel.

Policy Upload:

Research checklist 24May11.doc