The Cancer Council Victoria
Human Research Ethics Procedures

(This document accompanies the Human Research Ethics Policy – RMU 03)

1. Background

Ethical Review of Human Research

The *National Statement on Ethical Conduct in Human Research* (the National Statement) was developed jointly by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee in March 2007. It defines the responsibilities of researchers (Section 5.2.5-5.2.12), review body members (section 5.2.2-5.2.4) and institutions (section 5.1). It can be viewed at:

http://www.cancervic.org.au/research-ethics

At the Cancer Council Victoria there are two ethical review bodies responsible for the ethical review of research projects involving human participation.

They are:

The Human Research Ethics Committee (HREC); and
The Institutional Research Review Committee (IRRC)

The Triage diagram (attached to the Human Research Ethics Policy) is designed to assist researchers in identifying the ethical review process and body that their project needs to be submitted to. Researchers are entitled to submit exempt projects to the IRRC and low risk projects to the HREC should they wish to do so.

Our research ethical review bodies have the following overall roles in order to protect the welfare and the rights of participants involved in research conducted by Units within the Cancer Council and from external researchers proposing to use data from the Victorian Cancer Registry and other databases held by the Cancer Council.

(i) to review, in accordance with the *National Statement*, in a timely and efficient manner, the ethics of research project proposals, and to provide approval (or otherwise) for the project to proceed.

(ii) to monitor the progress of all research projects approved, at least annually,

(iii) to take action, if necessary, when notified of serious or unexpected adverse effects on participants or unforseen events that might affect continued ethical acceptability of the project.

(iv) to consider and approve proposed changes to project protocols.

The HREC and IRRC meetings and processes are supported by the Research Management Unit.

Advice on the interpretation of the *National Statement*, the Cancer Council Victoria's *Human Research Ethics Policy* and the application of these procedures is available from the the Research Management Unit (the Unit Head and/or the Ethics Officer).

2.1 Committee membership, role and meetings

2.1.1 The Institution Research Review Committee (IRRC)

Membership of the IRRC is defined in the Human Research Ethics Policy document. This Committee has two roles in relation to research – the assessment of the scientific merit of research proposals, (refer policy RMU 04) and the ethical review of low risk research.

The **role** of IRRC in relation to ethical consideration of projects is to:

a) Receive proposals a) which involve no more than low risk to participants. Low risk research is where the only foreseeable risk is that of discomfort; b) for which consent will be obtained and there is not more than low risk to participants involved; and c) which don't fall within the categories listed in 2.1.2 below.

b) If IRRC considers that any proposal involves greater than low risk it will refer them to the Human Research Ethics Committee.

c) Consider and approve amendments to project protocols.

d) Monitor the progress of approved projects.

IRRC **meetings** will be scheduled monthly (except January) and internal research units will be advised of the meeting dates in advance by posting on the intranet under "Research". Proposals must be submitted to the Research Management Unit no later than two weeks prior to each meeting date. In urgent and exceptional circumstances *ad hoc* meetings could be called at the discretion of the Chair.

Proposals are to be prepared and submitted on the Ethics submission form. The guide to completing the submission form should be consulted for assistance.

2.1.2 The Human Research Ethics Committee (HREC)

Membership of the HREC is defined in the Human Research Ethics Policy document.

The term of office for each member will be reviewed at least every 3 years. Each member will receive formal notice of appointment and assurance that The Cancer Council Victoria will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as a committee member.

Committee members will abide by The Cancer Council Victoria's Code of Conduct for Committee Members.

The **role** of the HREC in relation to ethical consideration of projects is to:

- Receive proposals involving greater than low risk to participants, (where the risk is greater than discomfort), and projects covered by the Chapters listed in Section 5.1.6 (b) of the *National Statement* and other sections as follows*:*

  Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations

  Chapter 3.5: Human genetics

  Chapter 3.6: Human stem cells

  Chapter 4.1: Women who are pregnant and the human foetus

  Chapter 4.2: Children and young people

  Chapter 4.4: People highly dependent on medical care who may be unable to give consent

  Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness

  Chapter 4.7: Aboriginal and Torres Strait Islander Peoples, and some categories of research falling under *Chapter 4.6: People who may be involved in illegal activities*

  Section 2.3.5: Waiver of Consent

  Section 2.3.4: Research involving active concealment or planned deception or that aims to expose illegal activities

- Consider and approve amendments to project protocols
- Monitor the progress of approved projects

Meetings: The HREC shall meet 5 times each year.

The closing date for submissions to the HREC is approximately 4 weeks prior to the meeting. Closing dates and meeting dates are available on The Cancer Council's Internet and Intranet.

Proposals are to be prepared and submitted on the Ethics submission form HREC. The guide to completing the submission form should be consulted for assistance.

3 Committee operation – Review Body member responsibilities

The primary responsibility of each review body member is to decide, independently, whether, in their opinion, the conduct of each research proposal submitted complies with the *National Statement*.

To fulfill this responsibility, each member of a review body should:

(a) become familiar with this National Statement, and consult other guidelines relevant to the review of specific research proposals;

(b) prepare for and attend scheduled meetings of the review body or, if unavailable, provide written comment for tabling at the meeting and

(c) attend continuing education or training programs in research ethics at least every three years.

Members of review bodies should disclose any actual or potential **conflict of interest**, including any financial or other interest or affiliation, that bears on any research coming before the review body and will excuse themselves from the Committee's deliberations about any proposal where it is agreed that the conflict of interest requires such absence.

Decisions about whether a research proposal meets the requirements of the *National Statement* must be informed by an exchange of opinions from each of those who constitute the minimum membership. This exchange should, ideally, take place at a meeting with all those members present.

Where a review body member is not available to make comment on projects to be considered or has a conflict of interest, comment from an appropriately qualified person with relevant competencies shall be sought.

Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered. In the event that it is not possible to have the views of the member or an alternate, the members at that meeting may agree to continue and have their decisions ratified at the next meeting.

4 Committee Working Procedures

4.1 The review body shall endeavour to reach decisions by general agreement. This need not involve unanimity.

4.2 **Confidentiality** of protocols and proceedings: documents are submitted to the review bodies for the sole purpose of consideration and, if thought fit, approval. Generally speaking review bodies should consider this as confidential material. Committee members should take care to prevent it being disclosed outside of the committee except for example for obtaining an opinion from an expert.

4.3 The principle investigator will be invited to make themselves or their nominee available at the time of the review body meeting in order to respond to questions raised.

4.4 **Agenda** papers, including the previous minutes, all projects received and other relevant material will be distributed no less than two (2) weeks prior to the scheduled meeting date for the HREC and not less than one (1) week prior to the scheduled meeting for the IRRC.

4.5 **Minutes** will reflect the deliberations of the Committee, including, as appropriate, project approval, suggested amendments, clarification and reasons for project rejection.

4.6 Researchers will be informed of the outcome of the deliberations of the Committee within 2 weeks of the meeting.

4.7 In order to ensure projects are not delayed, responses to suggested amendments or requests for clarification may be delegated to the chairperson or a sub-committee for consideration and approval on behalf of the Committee.

4.8 The Research Management Unit shall provide **secretariat support** for the HREC and IRRC and will keep a record of decisions made and shall retain on file a copy of each research protocol and submission for ethical review, including any information sheets, consent forms or relevant correspondence in the form in which they are approved. Each project will be allocated a reference code number. All project submissions will be kept secure and confidential by the Research Management Unit and will be accessible only to those involved with the day to day administration of the HREC and IRRC.

4.9 **Expedited review** In special circumstances when projects require urgent consideration of ethical review between scheduled meetings a system of expedited review may be conducted as follows: The HREC or IRRC Chair (whichever appropriate) will determine if a case deserves consideration between meetings and that if the proposal is very straightforward and similar to other approved studies the Chair may approve it on behalf of the Committee. In most cases the Chair and one other committee member should decide. The option of subsequently referring it to the whole Committee is also available**.** Decisions made pursuant to this section must be ratified at the next meeting of the Committee.

5 Assistance to other researchers and organisations

5.1 The HREC and IRRC shall, from time to time, consider receipt of applications for ethical review from researchers without affiliation to an institution or organisation with an HREC. In the event of such applications, researchers will be required to provide a statement indicating legal responsibility for the conduct of the research. The researcher will also be required to agree to accept the decisions and monitoring processes of the Cancer Council's review bodies until completion of the project.

5.2 The HREC and IRRC shall, from time to time, consider receipt of applications for ethical review from researchers from institutions or organisations without an HREC *(eg BreastScreen Victoria, Victorian Cervical Cytology Registry)*. On such occasions, the researchers will be required to provide a statement of agreement with their institution or organisation indicating who will carry legal responsibility of the conduct of the research. The researcher and the institution or organisation will also be required to agree to accept the decisions and monitoring processes of the Cancer Council's review bodies until completion of the project.

6 Victorian Cancer Registry (VCR) data

Full details of the process for access to data or participants from the VCR are available in the VCR Procedures document "Victorian Cancer Registry – Arrangements for access to data and the recruitment of subjects for research".

7 Monitoring/Reporting Procedures

The level of risk involved in the research determines the process of reporting and monitoring.

7.1 Negligible risk projects

Researchers will obtain approval from their Unit Head for negligible risk projects prior to their commencement. Approval should be sought using the ethical approval of negligible risk projects form. The signed form should be forwarded to the Research Management Unit for registration and reporting purposes. Projects will be reported to the next IRRC meeting, for ratification of their exempt from ethical review status.

7.2 Low risk and greater than low risk projects

Annual reports will be sought by the Research Management Unit for each project including details of project progress, outcome of completed research, maintenance and security of records, protocol compliance, complaints received and action taken, adverse or unexpected side effects on participants, any other difficulties encountered, protocol amendments, discontinuation.

These reports will be considered by the review body that approved the project.

Researchers will report immediately in relation to adverse events or unexpected outcomes and projects that are suspended or discontinued

The review body may withdraw ethical approval and recommend discontinuation of a project in the event that the research is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected. In such an event, the review body will inform the researcher(s) and the institution(s) or organisation(s) of ethical withdrawal and its recommendation for discontinuation, suspension or other necessary steps to be taken.

7.3 Committee Reporting

The HREC will report as follows

After each meeting the HREC will report to the Board on projects approved

The HREC will report annually to the Board. This report will include a summary of HREC activities including:

- Membership
- Number of meetings
- Confirmation of participation by required categories of members
- Number of protocols presented, number approved, number rejected
- Monitoring procedures and problems encountered
- Complaints procedures and number of complaints handled
- A summary (numbers and types of projects) reported to it as considered by the IRRC

The IRRC will report as follows

After each meeting the IRRC will report to the HREC on projects approved
The IRRC will report annually to the HREC. This report will include a summary of IRRC activities including:

- Membership
- number of meetings
- confirmation of participation by required categories of members
- number of protocols presented, number approved, number rejected
- monitoring procedures and problems encountered
- complaints procedures and number of complaints handled
- the number and type of negligible risk projects reported to it that were deemed exempt from ethical review

7.4 Organisation Reporting

The Cancer Council Victoria will report

- Annually to the NHMRC Australian Health Ethics Committee, in the format and timeline requested
- Annually to Victorian Health Services Commissioner, in the format and timeline requested

8. Complaints Procedures

The Head, Research Management Unit will be nominated to receive complaints from research participants, researchers, or other interested persons in the first instance. Complaints will be referred to the HREC or IRRC Chair. The chairperson may consult the Committee in an attempt to resolve a complaint. Where a complaint cannot be resolved by the chairperson and the Committee, the matter will be referred to the Director, The Cancer Council Victoria. If the complaint is not able to be resolved by the Director the complaint will be referred to the Health Services Commissioner (to be confirmed) or a professional mediator agreed by both parties.

9 Review

The Head, Research Management Unit, will review these procedures every 12 months and any changes will be approved by the IRRC and HREC as appropriate.

Version 5 – March 2008: Approved by HREC (11 March 2008), Approved by IRRC (5 March 2008)
Version 6 – July 2010: QA process removed

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