HUMAN RESEARCH ETHICS POLICY

POLICY NUMBER
RMU 03

Approved by the Cancer Council Board on 18 October 2007

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HUMAN RESEARCH ETHICS POLICY

1.0 Policy Number - RMU 03

2.0 Policy

In Australia, any individual or organisation conducting research involving humans is required to consider the ethical aspects of their research.

The Cancer Council Victoria conducts research into many aspects of cancer and has a Human Research Ethics Committee (HREC) which oversees the ethical aspects of this research.

The *National Statement on Ethical Conduct in Human Research* (hereafter referred to as 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 insitutions (section 5.1). It can be viewed at:

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

Research proposals (and amendments to approved proposals) are reviewed to ensure ethical standards are met and that the confidentiality of participants' information is protected.

The progress of approved research proposals is also monitored via annual progress reports from the researchers.

The *National Statement* allows institutions to choose to establish levels of ethical review other than by the full HREC, depending on the level of risk involved in participating. For ethical review at The Cancer Council Victoria, the attached triage diagram describes these levels of risk and other ethical considerations (eg privacy and consent) and helps determine which review process is required.

2.1 Risk assessment criteria

There are three levels of risk

a) Negligible risk: which involves inconvenience only ie there is no forseeable risk of harm or discomfort. This may include filling in a form, participating in a street survey or giving up time to participate

b) Low risk: where the only forseeable risk is discomfort. This may include participation in activities such as the measurement of blood pressure or the anxiety induced by an interview

c) More than a low level of risk: where for example participation involves more than discomfort and the potential for harm ie it may involve distress, injury, illness, pain, psychological disturbance, devaluation of personal worth or social disadvantage.

2.2 Process of review

a) Negligible risk projects are exempt from ethical review provided the conditions in Section 5.1.22 of the *National Statement* are met

b) Low risk projects are reviewed by the Institution Research Review Committee (IRRC)

c) Higher risk projects are reviewed by the Human Research Ethics Committee (HREC), as are projects covered by the Chapters listed in Section 5.1.6 (b) of the *National Statement*

2.3 Privacy and consent

In addition to the level of risk involved, the appropriate level of ethical review is also determined by the type of personal information or health information involved and the requirement for consent.

The guiding principle in relation to consent is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

Waiver of consent can be approved according to Chapter 2.3 of the *National Statement*. Only an HREC can grant waiver of consent for research using personal information in medical research, or personal health information. The IRRC may grant waiver of consent for other research.

2.4 Review bodies - membership

2.4.1 Human Research Ethics Committee

The Cancer Council Victoria's Human Research Ethics Committee (HREC) is constituted in accordance with the *National Statement*.

The members are appointed by the Executive Committee (The Board) of The Cancer Council Victoria. The categories of appointment include:

- a chairperson
- two lay people, one man and one woman
- two researchers, with knowledge of research regularly considered by the HREC (an epidemiologist and a behavioural scientist)
- one medical, clinical or para-medical professional
- one minister of religion
- one lawyer

2.4.2 Institutional Research Review Committee (IRRC)

Membership of the IRRC is as follows

- a Chairperson appointed by the Chief Executive Officer, who is respected in the field of cancer research who has no major conflict of interest and the expertise to consider research in epidemiology, behavioural science, clinical and health services research.
- a maximum of 4 members of Cancer Council staff who have expertise in behavioural science, health services and epidemiological research, as well as experience and training in research ethics.

2.5 Reporting

1. Negligible risk projects: Are reported to the next IRRC meeting for ratification of their exempt from ethical review status.
2. Low risk projects: The IRRC will report to each HREC meeting and annually, on projects approved.

3. Higher risk projects: The HREC reports after each meeting and annually to the Board of the Cancer Council.
4. The Cancer Council Victoria reports annually to the Australian Health Ethics Committee of the NHMRC and annually to the Victorian Health Services Commissioner.

3.0 References

3.1 External Publications

National Statement on Ethical Conduct in Human Research (2007)

NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

The Australian Code for the Responsible Conduct of Research

National Privacy Principles (Cth)

Information Privacy Principles (Cth)

Victorian Health Privacy Principles

Victorian Information Privacy Principles

3.2 Internal Policies

Research Peer Review Policy (RMU 04)

Research Code of Practice (RMU 01)

Victorian Cancer Registry Data Access Policy

4.0 Responsibilities

It is the responsibility of the Research Unit Heads to inform their staff of ethical review requirements and processes and to ensure that research proposals from their unit are submitted to the appropriate review process for evaluation.

The Institutional Research Review Committee reports to the Human Research Ethics Committee.

The HREC reports to the Cancer Council Board

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

Advice on the interpretation of the *National Statement* and the application of this policy and associated procedures is available from the the Research Management Unit (the Head and/or the Ethics Officer)

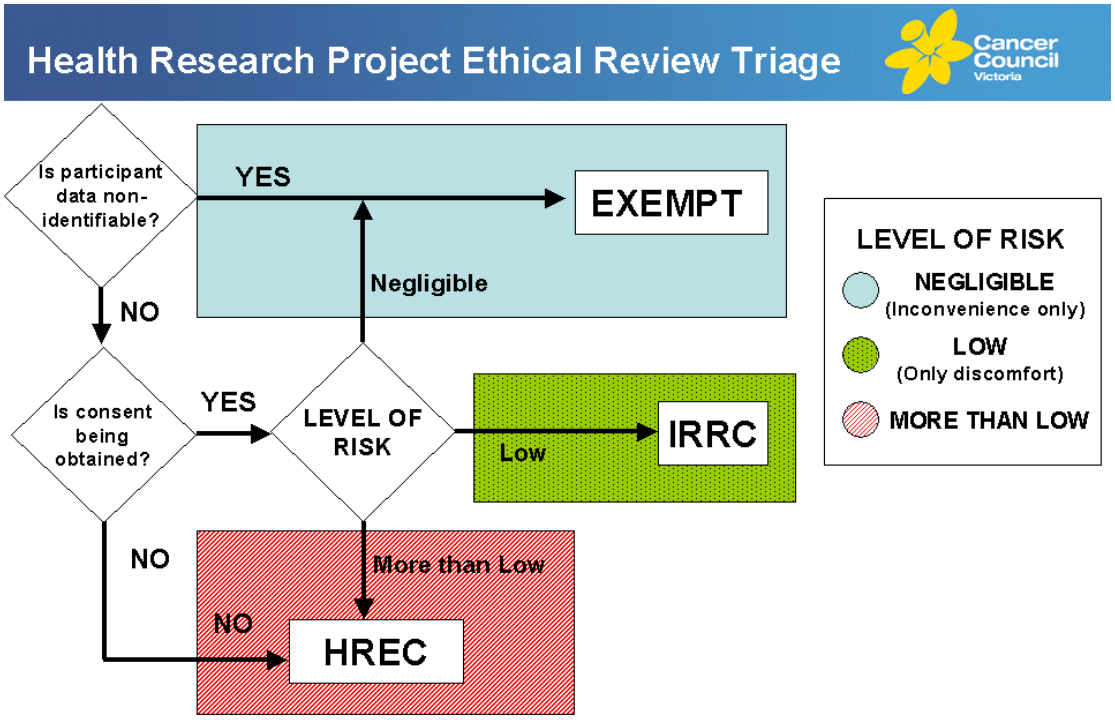
Promotion of the existence and requirements of this policy is carried out by the Research Management Unit.

5.0 Compliance

In order to comply with this policy, researchers need to adhere to the Human Research Ethics Procedures.

6.0 Review

This policy will be reviewed annually thereafter, by the Head Research Management Unit. Amendments are approved by the IRRC, HREC and Board as appropriate.



For proposals requesting VCR data see the VCR Access procedures

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