Human Research Ethics Policy – RGU 03

Version 5

Approved by the Board – Cancer Council Victoria on 6 February 2017

1. **Purpose**
   The purpose of this policy is to ensure that the human research ethics obligations are clearly defined and the necessary ethical review processes for human research are clearly articulated, implemented, monitored and reviewed.

2. **Scope and Application**
   This policy applies to all CCV and external researchers engaging in research at CCV involving humans; and all CCV and external researchers engaging in research approved by the CCV HREC or IRRC.

3. **Policy Statement**
   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 institutions (section 5.1). It can be viewed at:

   https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf

   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 (e.g. privacy and consent) and helps determine which review process is required.

3.1 Risk assessment criteria

There are three levels of risk

a) Negligible risk: which involves inconvenience only i.e. there is no foreseeable 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 foreseeable 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 i.e. it may involve distress, injury, illness, pain, psychological disturbance, devaluation of personal worth or social disadvantage.

3.2 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:
    a. is negligible risk research; and
    b. involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

    Research exempt from ethical review must meet the requirements of the *National Statement* and be ethically acceptable.

b) Low and negligible risk projects (that do not meet the requirements of point (a) above) 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* (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review)*:*

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

    Chapter 3.5: Human genetics,

    Chapter 4.1: Women who are pregnant and the human fetus,

    Chapter4.4: 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.*

3.3 Consent and Privacy

a) 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. Included in this information should be information on how privacy and confidentiality will be protected.
b) Guidelines on the general requirements for consent are provided in Chapter 2.2 of the *National Code.*
c) Qualifying or waiving conditions for consent can be approved according to Chapter 2.3 of the *National Statement*. Only an HREC can grant a 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.
d) In undertaking ethical review of research proposals, which privacy legislation may apply to the research must also be considered, i.e. Commonwealth or state/territory legislation, keeping in mind that in some cases more than one Act will apply. It must then be decided whether a research proposal conforms to the relevant privacy principles, and where necessary, apply the Guidelines under Section 95 or Section 95A of the Privacy Act 1988.

3.4 Human Research Ethics Review Committees

There are two ethical review bodies for human research at CCV.

The Cancer Council Victoria's **Human Research Ethics Committee (HREC)** is constituted in accordance with the *National Statement* and reviews greater than low risk research proposals.

The members are appointed by the Board of CCV and 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

The *HREC Terms of Reference* provide further details about the constitution, role and responsibilities of the HREC.

The Institutional Research Review Committee (IRRC) is delegated to approve research that is negligible or low risk, as outlined in Section 5.1.20 of the *National Statement.* The *IRRC Terms of Reference* provide further details about the constitution, role and responsibilities of the IRRC. The IRRC is also tasked with overseeing the scientific peer preview of internal research projects that are $25,000 or greater in value, as detailed in clause 3.5 below.

3.5 Scientific Peer Review - IRRC

A Research Peer Review process was established to provide an avenue for assessing internal research projects (> $25,000 in value) to ensure their scientific quality. The research proposals would fall within the broad strategic directions already approved by the Cancer Council.

The Internal Research Review Committee receives details of proposed projects and arranges independent external peer review of them, prior to approving their commencement.

In order to comply with this policy, researchers need to adhere to the Institutional Research Review Committee procedures - IRRC Peer Review Procedures.

It is the responsibility of the relevant Unit Head to submit research proposals from their Unit for peer review.

3.6 Reporting

1. Exempt projects: Are reported to the next IRRC meeting for ratification of their exempt from ethical review status.
2. Low risk and negligible 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.

4. 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 IRRC reports to the HREC.

The HREC reports to the Cancer Council Board

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

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

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

5. Compliance

In order to comply with this policy, researchers need to adhere to the Cancer Council Victoria Human Research Ethics Procedures, the *National Statement on Ethical Conduct in Human Research (2007)*, *The Australian Code for Responsible Conduct of Research* and the *Privacy Act 1988*.

6. **Policy Owner**

All queries in relation to this policy should be directed to the Research Governance Unit Manager.

7. **Scheduled Review Date**

This policy is to be reviewed within two years from date of approval.

8. **Definitions**

HREC: Human Research Ethics Committee
IRRC: Institutional Research Review Committee

9. **Related Documents**

9.1 External Publications

Australian Privacy Principles

Guidelines Under Section 95 of the Privacy Act 1988 (s95 guidelines)

Guidelines approved under Section 95A of the Privacy Act 1988 (s95A guidelines)

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

Privacy Act 1988 (Cth)

Victorian Health Privacy Principles

Victorian Information Privacy Principles

9.2 Internal Policies

CCV Discip*linary Procedure for Research Mi*sconduct

CCV Human Research Ethics Committee (HREC) Terms of Reference

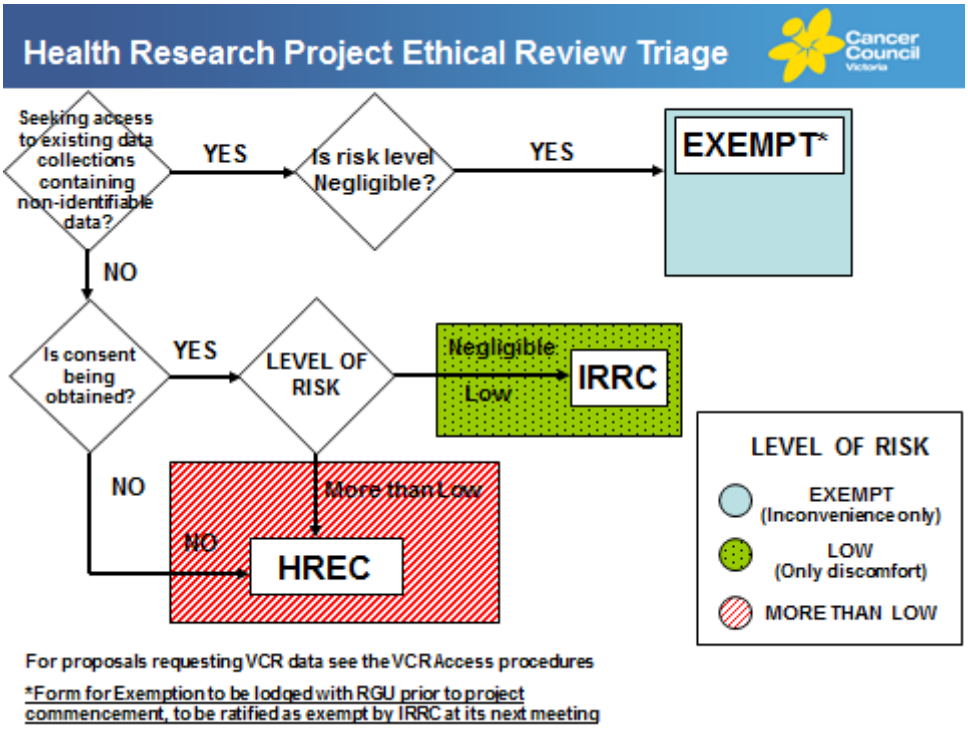
CCV Human Research Ethics Procedure

CCV Institutional Research Review Committee (IRRC) Terms of Reference

Research Code of Practice (RMU 02)

Responsible Conduct of Research Policy (RGU 01)

Victorian Cancer Registry Data Access Policy



Version Control

Version #	Board approval date	Author	Details
5	6/2/17	Cathy Schapper	Review of policy