

GUIDELINES FOR APPLICANTS

PUBLIC HEALTH RESEARCH PROJECTS 2007-08

DEPARTMENT OF HUMAN SERVICES
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INTRODUCTION

The mission of the Department of Human Services is to enhance and protect the health and wellbeing of all Victorians, emphasising vulnerable groups and those most in need.

Public Health is a Branch of the Department of Human Services (DHS) Rural and Regional Health and Aged Care Services (RRHACS) Division.

The Public Health Branch has major responsibilities for maintaining and improving the health and wellbeing of all Victorians. Our broad vision is to promote better health and wellbeing for all, respond to major threats to public health including epidemics and disasters and, wherever possible, prevent ill-health and disability. To meet these challenges our work must be based on sound science, good management and effective partnerships.

The Public Health Branch is committed to a broad view of health complemented by effective action, based on informed decision-making through a solid foundation of research, policy and legislation. Six priorities for action provide a solid framework for our work:

- Protecting the health of all Victorians
- Reducing the toll of chronic diseases, conditions and injuries
- Addressing health inequalities
- Addressing the factors that sustain health and wellbeing
- Addressing health impacts of climate change and environmental sustainability
- Enhancing organisational development and continuous improvement.

The Program Coordination Unit within the Public Health Branch focuses on developing the capacity and increasing the effectiveness of the Branch to achieve its identified strategic directions through the provision of a strong evidence base for action, planning and service delivery and improved engagement with the public health community. Particular attention is paid to safety and ethical principles in the utilisation of new technologies and research involving humans, maintenance of an up-to-date legislative framework and optimal responsiveness to critical public health needs.

The Research and Biotechnology Section within the Program Coordination Unit oversees the development and implementation of strategies and policy matters associated with health and medical research. This function includes provision of funding for a broad range of public health research projects in State priority areas, support for the ethical review of research involving humans and management of health-related policy issues concerning biotechnology.

This link <http://www.dhs.vic.gov.au/rrhacs/branches.htm> describes the DHS Rural & Regional Health & Aged Care Services Division and its branches, units and sections.

POLICY CONTEXT

The 'Public Health Research Policy Statement – *New Knowledge for Improved Health*', October 2005 provides a framework that will guide future public health research decisions and actions in line with the Public Health Branch strategic directions. The goal of the research program is '*the advancement of scientific knowledge and the utilisation of knowledge to improve health and health equity*'. The four categories of research funding include:

- Research capacity and capability – scholarships/fellowships/research related event funding;
- Public health research grants – a mix of short or longer-term research projects;
- Urgent funding – commissioned research to investigate an urgent public health issue; and
- Partnership funding – collaborative funding provided to leverage national/international funds to Victoria.

The level of funding available for each category may fluctuate from year to year. A copy of the Policy Statement is available at: <http://www.health.vic.gov.au/researchprograms/>

PUBLIC HEALTH RESEARCH GRANT OBJECTIVES

In 2007-08 Public Health research project funding will be available for research questions that address the project briefs available on the research program web site: www.health.vic.gov.au/researchprograms.

Project funding is provided to support research that has a public health/population focus and that has the potential to have a significant impact on current public health policy and practice. Applications must include evidence of support from key partners or other sources of funding that will be necessary for the conduct of the research and a dissemination strategy for potential users of the research. The development and maintenance of workforce capacity within the Victorian public health research sector is a secondary outcome of project funding.

APPLICATION and ASSESSMENT PROCESS

The application process will be conducted as follows:

1. A request for applications will be advertised in local print media, emailed via research-related networks, and will appear on the DHS public health research program website: <http://www.health.vic.gov.au/researchprograms>
2. Applicants are strongly encouraged to attend an information session related to their topic. Further information is provided within the research project brief and on the research program website above.
3. Applications will be due on 18 January 2008. Applications will be reviewed by a panel consisting of senior internal experts and interstate peer reviewers.

Applicants will be asked to provide a detailed submission on the *Application Form, Public Health Projects 2007-08* and include all supporting documentation. The *Application Form* is the prime source of information used for assessment of projects. The application must contain all the information necessary without the need for further written or oral explanation. All details in the application must be current at the time of application. It is not possible to amend an application once it has been submitted. If significant changes do occur, to either the project team or the content of the application, applicants must notify DHS immediately to avoid ongoing assessment of a potentially ineligible application. Applicants may withdraw their application at any time.

Applications will be assessed by panels consisting of senior internal experts and interstate peer reviewers. Panels will examine the strategic relevance, quality and methodological rigour of the applications. Panels will assess and rank the applications in accordance with the criteria listed below.

When the research topic is about the health of Indigenous Australians, or when Indigenous Australians form a significant participant group, additional assessment by an appropriately qualified Indigenous person will be sought. Consideration will be given to cultural appropriateness and respect for cultural sensitivities. These applications must be developed in accordance with the NHMRC *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, 5 June 2003.

Proposals must be within budget limits, however value for money rather than price will be considered paramount. All project assessments will be in confidence and the identity of assessors remains confidential. Final project funding will be subject to the negotiation of modifications to the project which may result from the assessment process.

DHS reserves the right, without further consultation, to remove applications from assessment that do not fit within the advertised priority areas, do not meet the eligibility criteria or are incomplete or provide misleading material.

In making their final recommendations, the DHS Panel will consider applications against the assessment criteria, DHS program priorities and available budget.

The Principal Chief Investigator and/or the nominated contact person from the administering institution will be notified of the outcome of their application as early as possible.

ELIGIBILITY

Project funding is available to Victorian researchers working in the relevant health field. The project must be undertaken in Victoria and is dependent on the continuing employment of the nominated Chief Investigators and Associate Investigators as detailed in the application. At least one Chief Investigator must be an employee of the Administering Institution.

Project funding will be provided through a DHS Research Project Agreement (RPA) with an eligible Australian organisation for the purpose of enabling an individual researcher or a group of researchers to undertake public health research in a Victorian university, health agency or other recognised research institution. The authorised representative of the Administering Institution will be required to sign the RPA. When the Administering Institution does not employ the Principal Chief Investigator, he/she will also be required to sign the RPA.

The Administering Institution is responsible for administration of the funding in accordance with the terms and conditions outlined in the RPA, must accept financial responsibility for the grant, and is responsible for providing basic infrastructure support to those involved in the research project.

ASSESSMENT CRITERIA

The Assessment Criteria are described below:

Policy and Strategic Relevance (30%)

- ⇒ Demonstrated understanding of the key issues and tasks specified in the Project Brief
- ⇒ The potential of the project to generate new knowledge
- ⇒ Relationship and relevance to existing research gaps in evidence
- ⇒ The potential for reducing the burden of disease and improving health outcomes
- ⇒ The applicability of the research to government policies and or practice settings

Quality & Innovation (30%)

- ⇒ Feasibility of the research design, timelines and outcome measures
- ⇒ Rigor of the methodology
- ⇒ Appropriateness of the budget
- ⇒ Project management and governance arrangements that demonstrate appropriate organisational, financial and management ability and resources

Collaboration (30%)

- ⇒ Demonstrated partnerships between experts in the fields of research, health policy and practice
- ⇒ Dissemination of the research findings to DHS and Government
- ⇒ Dissemination of research findings through demonstrated linkage with the public health sector and relevant primary, secondary and tertiary health systems

Track Record of the Research Team (10%)

- ⇒ Dissemination of previous research to policy and/or practice settings
- ⇒ Publication record (relevant publications in the last 5 years of Chief Investigators)
- ⇒ Relevant grant fund history over the last 5 years
- ⇒ National and international presentations.

FUNDING & TIMEFRAME

Decisions about the number of projects to be funded and the level of individual project funding to be allocated will be based on the assessed quality of applications and in accordance with available budget.

As a guide to the complexity and scale of the research, expected project budgets should be in the range of \$20,000 to a maximum of \$100,000 (exclusive of GST) for a 6 to 12 month project, except where stipulated otherwise.

A limited number of longer-term projects with related budgets may be considered.

Funding is limited and DHS may not necessarily fund to a level that allows for full cost recovery. Applications should clearly identify other funding sources and the amount of funds being requested of DHS and any relevant IP ownership issues/arrangements arising out of such co-funding. Potential applicants should read the relevant RPA for full details of the DHS funding terms and conditions.

Budgets must include details of all materials that will be required to conduct the proposed research, additional funding will not be provided. Project budgets will be subject to critical review.

Funds must only be used for the purposes approved as set out in the Application Form, or negotiated upon the approval of the project for funding, and in accordance with the terms and conditions included in the DHS RPA.

Project funding will not be paid to the Administering Institution if the DHS RPA is not signed. Further, if ethics approvals are not obtained within six months of the commencement date set out in the RPA, the project funding must be repaid to DHS.

FEEDBACK TO APPLICANTS

Feedback to unsuccessful applicants may be provided on request. Applicants may contact the Senior Project Officer, Research and Biotechnology by telephone on (03) 9096 0351.

GENERAL CONDITIONS

1.1 Legal Status

Applicants must provide proof of their legal status. A legal agreement can only be entered into by DHS with an organisation or individual with legal status established under:

- Associations Incorporation Act
- Co-operatives Act
- Corporations Law
- Health Services Act
- An Individual Act of Parliament
- Natural Person (a person at least 18 years of age, with a mental capacity to understand the agreement, not under any order or bankrupt), or
- Trustee Act.

DHS prefers to deal with organisations that have an Australian Business Number (ABN).

Consortia and Coalitions

There are three legal and management options available to consortia in making an application. Each of these types of arrangements is acceptable to DHS:

- incorporate as a single body, DHS enters into the RPA with the new legal entity
- non incorporated consortium – all individual members sign the RPA in their own right, or
- each member authorises (in writing) the lead agency to sign the RPA on their behalf.

DHS recognises that partnership arrangements may form within the research sector with the objective of promoting collaboration. Where the applicant is a consortium, the submission must indicate which parts of the project each entity comprising the consortium is proposing to undertake. The application must also detail how the individual agencies would relate to each other to ensure the completion of the project and how ownership by the Administering Institution of the project intellectual property and all necessary licences to the State are to be achieved. Funding provided by DHS must be used within Victoria.

1.2 Ethics Clearance and Approvals

Research funded by DHS must comply with the National Statement on Ethical Conduct in Human Research (2007) which can be found at:

<http://nhmrc.gov.au/publications/synopses/e72syn.htm>

and established guidelines including the Joint NHMRC/AVCC Statement and Guidelines on Research Practice which can be found at:

<http://www.nhmrc.gov.au/funding/policy/researchprac.htm>

The project must not commence until all relevant approvals, ethical and/or biosafety, have been received from the appropriate ethics committee.

It is the responsibility of the applicant to ensure that a copy of the project application is referred to the relevant Human Research Ethics Committee or other approval body. It is also the responsibility of the applicant to ensure that the completed form is forwarded to the Administering Institution's Research Office who will hold a copy of the form.

The Administering Institution's Contact Officer or the Principal Chief Investigator must provide a copy of the approval documentation to DHS when the relevant Ethics Committee has granted ethics clearances. Provisional approvals are not acceptable. All institutional approvals must be obtained (and copies provided to DHS) within 6 months of the Commencement Date as defined in the RPA. If the institutional approvals are not obtained, the RPA may be terminated. It is the responsibility of the Administering Institution to ensure that this is done on time.

DHS reserves the right to request all information relating to decisions regarding ethical issues arising from an application and the institutional response to the application.

Note

DHS will only support human research that is conducted in accordance with the current requirements of the *National Statement*. See Appendix I for more detail.

1.3 Privacy of Individuals

Documents containing personal, health and sensitive information are to be handled and protected in accordance with the provisions of the Victorian *Information Privacy Act 2000*, the *Health Records Act 2001* and the Commonwealth *Privacy Act 1988* ("Acts") as applicable. These Acts set the standards for the collection, storage, use and disclosure of, and access to, personal information. Personal, sensitive and health information is disclosed only with the permission of the individual to whom it relates, or where the Acts allow. Further information is available in Appendix II and at the following web addresses:

www.nhmrc.gov.au/publications/synopses/e43syn.htm

www.health.vic.gov.au/hsc

www.privacy.vic.gov.au

1.4 Intellectual Property

Ownership of and access to intellectual property resulting from funded research projects will be determined in accordance with the purposes for which the particular research project is being funded. For the majority of public health research projects the prime objective is to maximise access and use of intellectual property generated from the research. In this situation, the intellectual property created from the research will be owned and managed by the Administering Institution, with the Administering Institution granting to the State of Victoria a non-exclusive, irrevocable, world-wide, royalty free licence to use, reproduce, publish, communicate, adapt and exploit all such intellectual property. A standard Research Project Agreement – version 1 has been created for this type of research. Agreements for situations where the research may produce commercialisable outcomes will be developed on a case-by-case basis. The State will retain ownership of intellectual property for some public health research projects when it is considered that this position will optimise the benefit of the intellectual property for the people of Victoria.

If the Administering Institution wishes students to contribute to the research undertaken for the submitted project, full details of their status (e.g. PhD) involvement and supervision must be included in the Application Form and Ethics Committee approval obtained. DHS is supportive of the involvement of students in research projects provided their involvement does not compromise DHS' or the State's intellectual property or other rights.

1.5 Moral Rights and Licences from Third Parties

It is the responsibility of the Administering Institution to obtain and provide all licences and consents from any relevant project partners, employees, contractors or other individuals, students or other third parties which are necessary for the uninhibited and unencumbered use

by DHS of any project, background or third party intellectual property involved in or resulting from the carrying out of the project.

1.6 False & Misleading Information

If an application is incomplete or contains information that DHS considers to be misleading, it will be excluded from any further consideration for funding.

If DHS believes that omissions or inclusion of misleading information are intentional, DHS will refer the matter to the relevant authorities or solicitors for the consideration of appropriate legal action. The Government of Victoria is committed to protecting its revenue, expenditure and property from any attempt, either by members of the public, contractors, sub-contractors, agents, intermediaries or its own employees to gain financial or other benefits by deceit.

Examples of false or misleading information in an application include, but are not restricted to:

- Providing fictitious track records; or
- Falsifying claims in publications records (such as describing a paper as accepted for publication when it has only been submitted).

1.7 Conflict of Interest

Applicants must declare to DHS any matter or issue which is, may be perceived to be, or may lead to, a conflict of interest regarding their application or participation in the project described. Where applicable, applicants must also describe a strategy designed to avoid any conflict of interest.

If applicants are currently receiving funding from another source for the project topic, applications must clearly demonstrate how the outcomes of this DHS funding will add value to the existing project and how any conflict as to any potentially competing IP rights/ownership will be resolved.

1.8 Ownership of Information

Ownership of Applications - All applications and any accompanying documents become the property of DHS.

Ownership of all information, reports or data provided by DHS to applicants resides in the State of Victoria. The applicant shall not, without written approval of the Secretary to DHS or the relevant Minister, use the information or reports other than in the development of the application or the undertaking of the project. This information, in whatever form provided by DHS or converted by the service provider, must be returned or (at DHS' option) destroyed in a secure fashion following advice of the outcome of the application process or at the completion of the project.

1.9 Disclosure

Presumption of Full Disclosure

The Victorian Government has a strong presumption in favour of disclosing agreements and in determining whether any clauses should be confidential, specific Freedom of Information (FOI) principles from the *Freedom of Information Act* (Vic) 1982 (including a public interest test) will apply. The Government cannot pre-empt the workings of the FOI Act or constrain the Auditor General's powers to secure and publish documents as appropriate.

Disclosure of Application and RPA Details

Subject to this clause and the RPA, all documents provided by the applicant will be held in confidence so far as the law permits. Notwithstanding any copyright or other intellectual property right that may subsist in any documents, by making a submission the service provider licenses DHS to reproduce the whole or any portion of the submission documents for the purposes of evaluation.

In making its application, the applicant accepts DHS may publish (on the internet or otherwise) the name of the successful applicant/s and administering organisation, the project title and

description and the value of the successful RPA(s), together with the provisions of the RPA generally.

Non-Disclosure of RPA Provisions

Non-disclosure of RPA provisions must be justified under the principles for exemption within section 34(1) of the *Freedom of Information Act 1982*, providing that information acquired by an agency or a Minister from a business, commercial or financial undertaking is exempt under the Act if the information relates to trade secrets or other matters of a business, commercial or financial nature and the disclosure would be likely to expose the undertaking unreasonably to disadvantage. DHS will consider these arguments in the evaluation and negotiations with the applicants.

1.10 Right to Negotiate

DHS reserves the right to negotiate the project proposal with short-listed applicants after the close of submissions. DHS may communicate with researchers to refine proposals as required.

1.11 Presentations / Interview

Short-listed applicants may be asked to attend an interview and make a presentation on their project submission.

1.12 Reservations

DHS may withdraw from the advertised process described in this document for any reason, prior to signing any agreement with any applicant for the project funding described in this document.

1.13 Lobbying

Applicants are reminded that they should not attempt to exert influence on the outcome of the assessment process by lobbying, directly or indirectly, DHS staff or Members of Parliament. DHS may reject an application if an applicant has attempted to exert influence on the outcome of the assessment process through lobbying. DHS will not consider consultation with DHS by applicants regarding the development of their project application, or the project application process, as lobbying to exert influence on the outcome of assessment.

ADMINISTRATION

1.14 Research Project Agreement (RPA)

All funding is offered in accordance with the DHS RPA between DHS and the Administering Institution and the Principal Chief Investigator (when relevant). The Principal Chief Investigator also represents the Chief Investigators and Associate Investigators. By submitting an application in response to this document, applicants will be deemed to be indicating their willingness to accept the conditions and schedules included in the RPA.

The RPA will include specific information on key performance measures and targets. A project may not commence prior to the signing of the RPA and schedules and all required ethics clearances and approvals having been obtained. If the RPA is not signed, project funding will not be provided to the Administering Institution. If the ethics clearances and approvals are not obtained within 6 months from the commencement date (as defined in the RPA) and DHS has already provided the project funding to the Administering Institution, the Administering Institution must repay the project funding to DHS.

1.15 Indemnity and Insurance

When the Administering Institution is a university, insurance policies held with UniMutual, which is not authorised under the *Insurance Act 1973*, will generally be acceptable, but DHS must be notified in advance and prior written confirmation obtained.

1.16 Financial Management – Payments

Payments will commence once the RPA has been signed with payment made to the Administering Institution. Funding must not be used until Ethics (Institutional) Approvals for the project have been received and must be returned immediately if these are not received in time and the RPA is terminated.

Successful applicants must have the capacity to accept electronic funds transfer as a facility for payments. Successful applicants may be required to authorise DHS to issue a Recipient Created Tax Invoice (RCTI) in respect of any part of the project funding.

1.17 Submission of Applications

Signed Applications are to be submitted in hard copy on the forms provided. Incorrect or incomplete forms will not be accepted. Entries in the form must be typewritten in black in 10 point Verdana or Arial, or 12 point Times New Roman.

The original Application Forms and ten hard copies (all unbound/unstapled) must be provided.

In addition, electronic copies of forms must be submitted to Kay.Munro@dhs.vic.gov.au (forms are available at www.health.vic.gov.au/researchprograms).

The closing date for Applications is 18 January 2008.

Applications must be marked CONFIDENTIAL and addressed to:

Manager, Research and Biotechnology
Program Coordination Unit
Public Health Branch
Department of Human Services
Level 14/50 Lonsdale Street
MELBOURNE 3000

Hand delivered or couriered applications must reach the mailroom in the basement of 50 Lonsdale Street by the due date (access is via the underground car-park ramp off Little Lonsdale Street).

Late applications will not be accepted.

1.18 Contacting DHS

Enquiries about the public health research funding round process should be directed to Lee Barclay on (03) 9096 0351 (Lee.Barclay@dhs.vic.gov.au) or Kay Munro on (03) 9096 5190 (Kay.Munro@dhs.vic.gov.au).

Additional information specific to the research topics is available from the contact person named in the individual project briefs.

APPENDIX I - ETHICS CLEARANCE & APPROVAL

Research funded by DHS must comply with the National Statement on Ethical Conduct in Human Research (2007) which can be found at: <http://nhmrc.gov.au/publications/synopses/e72syn.htm> and established guidelines including the Joint NHMRC/AVCC Statement and Guidelines on Research Practice which can be found at: <http://www.nhmrc.gov.au/funding/policy/researchprac.htm>. There may be other guidelines and/or legislation that apply to particular types of research (e.g. human stem cell research). If in doubt, ensure that you seek up to date advice from your Institutional Human Research Ethics Committee (HREC).

Summary information about approvals that may be required is provided below. For further information, please contact your Institution's HREC or the DHS HREC Committee Executive Officer, on telephone 9096 5239, or visit the DHS web site at www.health.vic.gov.au/ethics.

Research Involving Humans

The *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) states that research is 'widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers.' (National Statement, page 7). Activities that require consideration and approval by an HREC may include:

participation in surveys, interviews or focus groups, observations, access to individuals' information (irrespective of whether it is identifiable or not), research involving any human tissue, no matter what the source, and research in which there is any intervention (physical or psychological).

Institutions may establish different procedures for the ethical consideration of human research proposals, depending on the degree of risk involved.

It should be noted that HREC clearance is required prior to the initiation of activities requiring any form of human participation.

All projects involving the administration of drugs, chemical agents or vaccines need to be considered by the relevant HREC to assess the appropriateness of their use and other relevant Committees. Clearance by the HREC is not only required for projects involving the use of imported substances, but also for projects involving the experimental use of locally produced therapeutic substances.

In the case of multi-centre research, researchers should determine whether separate approval must be obtained from the HREC of each institution involved or whether there are mutual acceptance agreements between the HRECs involved.

Where appropriate, DHS funds may also be subject to clearance from the Therapeutics Division, Commonwealth Department of Health.

Health Research Involving Indigenous Australians

Research that includes Indigenous Australians as the study population (or involves a significant number of Indigenous Australians) must be based on the NHMRC *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, 5 June 2003, available at: <http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>

The Collection of Personal and Health Information

Please note that due to the guidelines issued pursuant to the *Privacy Act 1988 (Cth)* (Sections 95 and 95A) and the *Health Records Act 2001 (Vic)*, activities such as research (including epidemiological research) and the compilation or analysis of statistics that collection use or disclosure of personal, sensitive or health information without consent must be reviewed by a Human Research Ethics Committee. Guidelines regarding protocols to be adopted by organisations, issued under the *Information Privacy Act 2000 (Vic)*, also state that this is desirable. Note that other privacy legislation may also apply. See Section 1.5 *Privacy of Individuals* and Appendix II for specific information.

Biosafety Committee

Clearance for projects that involve use of radioactive substances, ionising radiation, recombinant DNA, potent teratogens or carcinogens may need to be obtained from the appropriate Institutional Biosafety Committee and where human research is involved, from the relevant HREC.

An explanation of how the project application meets these guidelines must be included in the ethics section of the application form.

Animal Research

Research involving animals must conform to the provisions of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* and the general principles encapsulated in Section 1 of the Code. The Code is available on the NHMRC website at:

<http://www.nhmrc.gov.au/publications/synopses/ea16syn.htm>

Genetic Manipulation

Applicants proposing research involving organisms being genetically manipulated, such that they fall under the current Gene Technology Technical Advisory Committee (GTTAC) guidelines, must seek approval from their Institutional Biosafety Committee (or equivalent).

It should be noted that prior approval from GTTAC is required for applications that fall under Category A of the Small Scale Guidelines. GTTAC guidelines are available from the:

- Research Office of the Administering Institution; or
- Office of the Gene Technology Regulator (OGTR) site on the Internet at: <http://www.ogtr.gov.au>

Use of Carcinogenic or Highly Toxic Chemicals

Applicants proposing research involving the use and disposal of potent carcinogenic or other highly toxic chemicals are referred to the *NHMRC Guidelines for Laboratory Personnel Working with Carcinogenic or Highly Toxic Chemicals* catalogue code DP12, copies of which can be obtained from the Publications Officer of the NHMRC: Telephone (02) 6289 9520.

DHS Human Research Ethics Committee

Information about applying to the DHS Human Research Ethics Committee (HREC), using the Common Application Form (CAF), which is accepted and used by a large number of Victorian sites listed on the DHS website, and the criteria to help decide whether referral to the DHS HREC is required for your project can be found at: www.health.vic.gov.au/ethics. Alternatively, you can contact the DHS HREC Executive Officer on telephone 9096 5239.

APPENDIX II – PRIVACY OF INDIVIDUALS

Summary information about the following State and Commonwealth privacy legislation, which may impact upon research is described below. – *Information Privacy Act 2000*; *Health Records Act 2001*; and the *Privacy Act 1988* (Commonwealth).

Copies of the relevant legislation, policy documents and guidelines can be downloaded from the web sites listed below. This information does not constitute legal advice and is only a summary (and therefore, does not provide detailed information regarding all of the relevant laws). If in doubt about their legal obligations, researchers should seek their own advice, or contact the responsible Commissioner.

Health Records Act: Victorian Health Services Commissioner (1800 136 066);

Information Privacy Act: Victorian Privacy Commissioner (1300 666 444);

Privacy Act: Federal Privacy Commissioner (1300 363 992).

VICTORIAN LAW

(a) Health information – where the collection, use or disclosure is by an organisation in Victoria

The *Health Records Act 2001* (Victoria) (“HRA”) applies to all health information (see definitions in section 3 of the HRA) handled by the Victorian public sector and private sector. There are eleven Health Privacy Principles (“HPPs”). HPP 1 and 2 govern the collection, use and disclosure of health information, including for the purposes of research. The Victorian Health Services Commissioner, who may issue or approve Guidelines in relation to the HPPs, administers the HRA. The Guidelines in relation to research can be obtained from the Health Services Commissioner’s website: www.health.vic.gov.au/hsc. Any researcher who considers that the HPPs might apply to their research should read these guidelines.

It is important to note that the HRA applies generally to private sector organisations when they handle health information in Victoria. Unlike the Commonwealth Privacy Act (see below), it does not contain any exemptions for “small businesses”.

(b) Other personal information - where the collection, use or disclosure is by the Victorian public sector or a contracted service provider to the public sector

The *Information Privacy Act 2000* (Victoria) (“IPA”) sets out ten Information Privacy Principles (“IPPs”) that regulate the responsible collection and handling of personal information, which includes “sensitive information” but excludes health information (see definitions in section 3 and schedule 1 of the IPA), by organisations in the Victorian public sector, including universities set up by state legislation. The IPPs also apply to agencies that provide services under contract to the Victorian Government (note that by signing the RPA, the Administering Institution will be regarded as one of those agencies). IPPs 1, 2 and 10 deal with the collection, use and disclosure of this information for the purposes of research. There are no separate guidelines regarding research issued in relation to the IPA, although the Guidelines for Developing a Code of Practice provide considerations regarding protocols for the collection and use of personal information for research that organizations should adopt. The Victorian Privacy Commissioner administers this Act and all of the guidelines that the Commissioner has published can be located at: www.privacy.vic.gov.au

Although the IPPs are very similar to the National Privacy Principles of the Commonwealth legislation (see below), there are some minor points of difference and the numbering of the principles is also different.

(c) Other laws

Other more specific laws may apply to particular categories of research. For instance, section 60 of the *Cancer Act 1958* regulates the disclosure of information from registries established under that Act.

COMMONWEALTH LAW

(a) Personal information held by the Commonwealth public sector

The *Privacy Act 1988* (Commonwealth) ("PA") applies to the Commonwealth public sector and has implications for medical research using information held by a Commonwealth agency. The PA sets out eleven Information Privacy Principles ("IPPs") and these treat all categories of personal information (including sensitive information and health information) in the same way. Section 95 of the PA permits the National Health and Medical Research Council ("NHMRC") to issue guidelines, such that medical research carried out in accordance with the guidelines will not be in breach of the IPPs.

Any researcher wishing to obtain information from a Commonwealth agency should read the Guidelines Under Section 95 of the PA, issued by the NHMRC (see www.nhmrc.gov.au/publications/synopses/e43syn.htm)

(b) Personal information – where the collection, use or disclosure is by a "private sector organisation"

In 2000, the PA was amended to incorporate the Privacy Amendment (Private Sector) Act 2000 (Commonwealth), which extends the scope of the PA to include information held by organisations in the private sector. This amendment sets out ten National Privacy Principles ("NPPs") (which are now included as schedule 3 of the PA), but these apply only to businesses and bodies that fall within the definition of "organisation" as set out in the PA. Therefore, the NPPs will apply only in certain circumstances. Furthermore, the NPPs distinguish sensitive information and health information from other types of personal information. Section 95A of the PA permits the NHMRC to issue guidelines that form part of the compliance requirements under the NPPs and any researcher who considers that the NPPs might apply to their research should read the Guidelines approved under Section 95A of the PA, issued by the NHMRC (see www.nhmrc.gov.au/publications/synopses/e43syn.htm).