



The Cancer Council Victoria

Victorian Cancer Registry

Arrangements for access to data and the recruitment of subjects for research

The following information defines the type of data that can be obtained from the Victorian Cancer Registry (VCR): criteria, conditions, and limitations for access, procedures to be followed when requesting data access and the fees for such access. The procedures as outlined have been put in place to protect as far as possible against potential breaches of privacy as well as ensuring the ethical integrity and scientific merit of proposals seeking access to VCR data. In considering the approval of access to the VCR, The Cancer Council Victoria's ethical review committees (Human Research Ethics Committee (CCV HREC) and Institutional Research Review Committee (CCV IRRC)) are mindful of the balance that they need to strike between the protection of VCR registrants' privacy and that of the public interest in the proposed research. If the value of the research is not deemed by either committee to adequately balance the need to breach privacy, access will be denied.

1.0 BACKGROUND

The Victorian Cancer Act 1958 (as amended in 1997) limits access to data held by the VCR "for the purposes of medical research or the administration of cancer related public health programs" and requires that an ethics committee that has been established by The Cancer Council Victoria approves the use to which the data will be put and the proposed research methodology.

2.0 DATA ACCESS STATEMENTS

- 2.1 The CCV encourages the use of the VCR's accumulated data for appropriate research relevant to any aspects of cancer control.
- 2.2 The VCR will only facilitate access to its data for projects that meet appropriate standards of scientific merit or public health importance as determined by the Director VCR or his/her nominee.
- 2.3 The VCR will adhere strictly to The Cancer Act (Victoria) and the Health Records Act (Victoria) when considering requests to release data.
- 2.4 The VCR will only release identifiable or re-identifiable case records or recruit research subjects with the approval of the CCV HREC.
- 2.5 In considering requests for access to VCR data the CCV HREC and CCV IRRC must also comply with the *National Statement on Ethical Conduct in Human Research (2007)*.
- 2.6 In instances of a potential unfair burden being placed on VCR registrants, researchers at Victorian based medical research institutes will have priority access.
- 2.7 The VCR will release the least sensitive level of data that is practicable in order to fulfil the uses identified in the research proposal submitted with the data request.
- 2.8 In releasing aggregate data, the VCR will suppress all individual cells with counts less than 5, because of the potential risk of identifying an individual person.
- 2.9 The VCR generally releases data on a non exclusive basis.

3.0 APPLICATION REQUIREMENTS AND PROCESS

- 3.1 Applications should be addressed to the Director VCR who will conduct or arrange for review of the proposal's scientific merit, as appropriate, and provide a quotation for any costs associated with meeting the request.
- 3.2 Applicants should not make any submission related to the application to the CCV HREC or CCV IRRC until they are requested to do so by the Director VCR.
- 3.3 Similarly, researchers should not make any research grant application that proposes to have access to the VCR without first obtaining approval from the Director VCR and a quotation for the costs of VCR services in this regard (subject to gaining final approval).
- 3.4 Applications must meet the following criteria:
- To have articulated a worthwhile question or hypothesis,
 - To have described a study design appropriate to the question,
 - To have provided a feasible research plan,
 - To have provided calculations of statistical power required to address the question,
 - To have provided an analysis plan,
 - To have provided an information dissemination plan,
 - To have provided a data disposal plan,
 - To have addressed issues of ethics and confidentiality consistent with the *National Statement on Ethical Conduct in Human Research (2007)*, in particular the chapter on databanks,
 - To have demonstrated that the researchers have the expertise or access to appropriate supervision required to conduct the research, and
 - To have provided information about funding source(s) along with evidence that sufficient funds will be available to complete the research project.
- 3.5 The documentation required by the NHMRC for project grant proposals should usually meet all of the criteria listed in item 3.4, and a copy of such a grant proposal would be acceptable for submission to the Director VCR for assessment of scientific merit. *Occasionally, applications that fail to meet all of the criteria in 3.4 may still be supported by the Director VCR should the public interest in the question be deemed to outweigh the usual considerations of scientific merit.*
- 3.6 For proposals that are not likely to form the basis of a NHMRC grant proposal, the Victorian Cancer Registry Application for Data Access form must be used (APPENDIX 1).
- 3.7 Applications should also include detailed data requirements by completing the data specification form (APPENDIX 2).
- 3.8 When the review is completed, the Director VCR will inform the applicant of the review outcome, advise them of costs (if any) and whether ethical approval needs to be sought. All proposals needing ethical approval are to be submitted via the CCV Research Management Unit (RMU) on one of two forms in accordance with the CCV Human Research Ethics Procedures document available in hard copy from the RMU and also from the website (see section 3.9).
- 3.9 Applicants advised by the Director VCR to proceed to ethical review should complete the standard forms as above. Information about committee meeting dates, closing dates for submissions and how to obtain the standard forms is available at http://www.cancervic.org.au/about-our-research/research-ethics/submission_and_meeting_dates/.

- 3.10 The Director VCR will report all successful applications to the Chair of the appropriate ethics committee.

4.0 MEMORANDUM OF UNDERSTANDING

4.1 Apart from routine tabulations (see sections 5.1), all information transactions between researchers and the VCR shall have a formal Memorandum of Understanding (MOU) authorised by responsible officers at each institution (see sample in Appendix 3).

4.2 These agreements shall include the following:

- A detailed description of the data to be supplied,
- An agreement on levels of data privacy and security, including named individuals who will have access to the data,
- An agreement not to attempt to identify any individuals,
- An agreement not to share the data with third parties,
- The required form of acknowledgement of the VCR,
- An agreement on the fee to be paid to the VCR (if applicable),
- Security provisions for storage and access to the data provided,
- An agreed schedule and scope for reporting, printed publication and other means of dissemination, and
- An agreed schedule for data disposal.

5.0 DATA REQUEST CATEGORIES

Most requests for data fall into four categories. The first and most common is access to de-identified aggregate data which are already in the public domain. Such data requests do not need to comply with the requirements outlined in section 3.0 and do not require separate ethical approvals. *Public domain data are currently limited to breakdowns of numbers and rates by cancer site or site grouping, 5-year age group, sex and diagnosis year or diagnosis year groupings.* The other three categories are further defined in 5.1 to 5.3.

- 5.1 **Non-identifiable aggregate data:** these include requests for data stratified by non-identifiable data elements e.g. age group, sex, cancer site, diagnosis year(s) and other data elements not available in the public domain. Such data requests should be submitted in writing and may require approval by the CCV IRRC. To prevent the indirect identification of any VCR registrant, the VCR will suppress any data cell containing fewer than 5 cases.
- 5.2 **Files containing re-identifiable individual case record information:** these files would not contain name, address or date of birth information but may include data elements that either singly or collectively may identify an individual e.g. country of birth, postcode and age group. Such data requests require approval by the CCV HREC.
- 5.3 **Files containing individually identified case record information:** these files would include personal identifiers along with cancer descriptors. Requests in this category may include: (1) record linkage requests (other than the exclusions identified in section 6.1.1) which require VCR individual case records to be linked to individual records included in occupational and/or research cohorts or (2) requests for the VCR to release confidential registrant information to researchers for studies requiring the collection of additional information through contact with registrants. Such data requests require approval by the CCV HREC. Further information about this category of data request can be found in section 6.0.

6.0 DATA REQUESTS THAT REQUIRE THE USE OF PERSONAL IDENTIFIERS

The CCV HREC has made the following determinations with respect to requests for data that require the release of individual case records (sections 5.2 and 5.3).

6.1 Applications for record linkage

6.1.1 The following instances do not require the applicant to make a full submission to the CCV HREC. The Director VCR will instead, report annually to the CCV HREC on projects such as the following:

- When the linkage is performed under statute (e.g. linkage to prescribed registers such as the BreastScreen database)

OR

- When the research proposal does not require the VCR to identify the cancer status of named individuals. In this instance the VCR would perform record linkage and return a set of tables broken down by age, sex and certain categories of exposure status identified by the researchers prior to linkage

OR

- When individual consent has been obtained from the study participants for continuing review of cancer incidence status.

6.2 Applications for VCR to collect additional data at the level of the individual

The approval of the CCV HREC is required for proposals in which additional data about treatment to particular registrants is sought without seeking the consent of the registrant concerned as, for example, in the quality assurance surveys VCR undertakes in collaboration with the Victorian Cooperative Oncology Group (VCOG).

6.3 Applications for the identification and recruitment of research subjects

6.3.1 The VCR has established standard procedures for the recruitment of VCR registrants to research projects. Researchers are not permitted to attempt to recruit a VCR registrant without the VCR first obtaining the registrant's consent (see Appendix 4).

6.3.1 The VCR does not have appropriate facilities for communicating with other than English speaking registrants. The VCR has no information about registrants' preferred language and has limited information about country of birth.

6.3.2 For studies of culturally and linguistically diverse groups, the VCR will identify relevant hospitals and other health care providers that have a relationship with, and the resources to communicate effectively with, registrants from these backgrounds. *It is the responsibility of researchers to approach providers directly in order to gain access to these patients.*

6.3.3 The VCR is not able to recruit minors. Furthermore, the VCR has no information on next of kin to assist in the identification of appropriate adult contacts. For research involving minors, the appropriate hospitals or health care providers need to be approached directly by the researchers.

7.0 FEES

Most requests generate some cost to the VCR. The VCR does not receive any funding to perform non-routine ad hoc data analysis. These costs, therefore, have to be recovered from the applicant. Fees will vary in accordance with the size and complexity of the request and quotations will be provided to researchers on application.

Professor Graham G Giles
Director, Victorian Cancer Registry

Revised: June 2008

APPENDIX 1: Victorian Cancer Registry Application for Data Access Form

APPENDIX 2: Data Specification Form

APPENDIX 3: Example MOU

APPENDIX 4: Procedures for recruitment of research subjects

APPENDIX 5: Sample registrants approach letter

APPENDIX 6: Sample VCR consent form

APPENDIX 7: Sample doctor approach letter

For Office Use Only

Registration No.

Date Received:

VICTORIAN CANCER REGISTRY

APPLICATION FOR DATA ACCESS

PROJECT TITLE:							
LEAD INVESTIGATOR:							
Title	Firstname	Surname					
Department							
Institution							
Address							
City/Suburb				State	Postcode		
Telephone		Fax		Email			

OTHER INVESTIGATORS				
	Title	Given Name	Surname	Institution
A				
B				
C				

CONTACT PERSON FOR THIS APPLICATION				If Lead Investigator	tick here	<input type="checkbox"/>
Title	Given Name	Surname	Role in this study			
Institution						
Address						
City/Suburb			State	Postcode		
Telephone		Fax		Email		

ADMINISTERING INSTITUTION:	
INSTITUTION(S) WHERE WORK WILL BE CARRIED OUT:	
Institution	Department

For Office Use Only

Registration No.

Date Received:

TIMELINES:

Estimated Start Date:	Estimated Completion Date:
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BACKGROUND & RESEARCH PLAN (maximum 6 A4 pages)

AIMS & HYPOTHESIS

Describe the specific aims of the project, including a clear statement of the hypothesis to be tested.

BACKGROUND

Describe the significance of the project, the objectives of the research on the project including scientific aspects and any other relevant material

RESEARCH PLAN

Methods and techniques to be used – Outline the research plan in detail, including as appropriate, a detailed description of the experimental design techniques to be used and methods of statistical analysis.

Clearly identify the expected outcomes of the research project.

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Registration No.

Date Received:

HUMAN RESEARCH ETHICS COMMITTEE APPROVALS

In accordance with the Cancer Act 1958 Section 61 (1A) all requests for information collected under the Act must receive approval from The Cancer Council's Human Research Ethics Committee. Applications to the Council's HREC should not be submitted without obtaining approval first from the Victorian Cancer Registry.

<p>Please provide a brief statement of the ethical issues that arise from the project and an explanation of how these issues will be addressed</p>

<p>Has this project been approved by the Human Research Ethics Committee of the institution where the research will be carried out?</p>	<p>Y / N</p>
<p>If 'Yes', please attach a copy of the approval letter. If 'No', please indicate the status of any application.</p>	

Certification by Principal Investigators

In signing this page, you certify that all details given in this application are correct and you agree to carry out the project according to the conditions as determined by The Cancer Council Victoria with respect to data supplied.

Name of Lead Investigator <i>(please print)</i>	Signature

Certification by Head of Department

<p><i>I certify that the project is appropriate to the general facilities in my Department and that I am prepared to have the project carried out in my Department.</i></p> <p>NAME (Block Letters)</p> <p>DEPARTMENT:.....</p> <p>SIGNATUREDate:.....</p>
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Please return this form to:

*The Director
Victorian Cancer Registry
The Cancer Council Victoria
1 Rathdowne Street, Carlton Vic 3053*

VICTORIAN CANCER REGISTRY DATA SPECIFICATION FORM

DATA REQUESTED

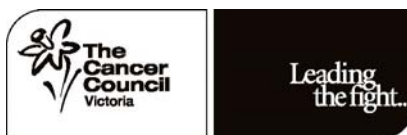
Who will have access to data?

Please list any individuals who will have access other than the Principal and Associate Investigators already named.

Data specification for: (insert name of study)

File Specification; please tick data elements required in your file from VCR.

Field Name	Tick	Comments
Patient Demographics		
Firstname	<input type="checkbox"/>	
Second name	<input type="checkbox"/>	
Surname	<input type="checkbox"/>	
Sex	<input type="checkbox"/>	
Country of Birth	<input type="checkbox"/>	
Aboriginality	<input type="checkbox"/>	
Date of Birth	<input type="checkbox"/>	
Date of Death	<input type="checkbox"/>	
Current address	<input type="checkbox"/>	
Tumour Demographics		
Age at diagnosis	<input type="checkbox"/>	
5 year age group	<input type="checkbox"/>	
ICS region	<input type="checkbox"/>	
LGA/SLA	<input type="checkbox"/>	
Statistical Division	<input type="checkbox"/>	
Tumour Specifics		
Primary Site (ICDO-3)	<input type="checkbox"/>	
Primary Site (ICD-10)	<input type="checkbox"/>	
Morphology (ICDO-3)	<input type="checkbox"/>	
Behaviour	<input type="checkbox"/>	
Grade	<input type="checkbox"/>	
Laterality	<input type="checkbox"/>	
Date of diagnosis	<input type="checkbox"/>	
Year of diagnosis	<input type="checkbox"/>	
Basis of diagnosis	<input type="checkbox"/>	
Size	<input type="checkbox"/>	Breast cancer only
Melanoma level	<input type="checkbox"/>	
Melanoma thickness	<input type="checkbox"/>	
Nodes sampled	<input type="checkbox"/>	
Nodes positive	<input type="checkbox"/>	Breast cancer only



Memorandum of understanding

Between

The Victorian Cancer Registry (VCR), The Cancer Council Victoria & (insert institution name)

The data transfer covered by this memorandum is restricted to the project entitled:
(insert project title)

The principal investigator for the project is:
(principal investigator name and institution)

The other investigators who are permitted access to the data are:
(other investigator names)

Approval of the project protocol has been obtained from the following HREC(s):

The data items that will be provided are listed in the attached schedule.

The investigators agree that:

- 1 The project completion date will be *(insert date)* when, if not renewed, this MOU will expire
- 2 The data will only be used for the purpose specified in the approved application.
- 3 The data will not be copied and will not be released to any third party.
- 4 The privacy of the individuals' records included in the data file will be respected. No attempt will be made to re-identify any record. No tables will be published with cell counts less than 5.
- 5 The data protection measures described in the approved application will be adhered to.
- 6 Any changes in the project plan, particularly with respect to the items reported in the approved application, will be notified immediately, and a new application including the changes will be submitted.
- 7 The data will be destroyed, or disposed of, as described in the approved application. The Research Management Unit, The Cancer Council Victoria, will be notified when this takes place.
- 8 A final project report, including adherence to confidentiality measures, will be submitted to The Research Management Unit, The Cancer Council Victoria, within a year of finishing the project.
- 9 An acknowledgement of the VCR will be included in any resulting publications (including reports and student theses) and copies will be presented to the VCR.

Ms Woody Macpherson
Research Management Unit
The Cancer Council Victoria

on behalf of
(Institution Name)

(signature)

(signature)

Date: ____/____/____

Date: ____/____/____

Studies Requiring Contact with Victorian Cancer Registry Registrants

Researchers conducting projects that involve contacting Victorian Cancer Registry (VCR) registrants need to be sensitive to the physical and emotional difficulties this group may be experiencing as a result of their cancer diagnosis and treatment. It may also be disturbing for some registrants to learn that their cancer diagnosis is known to individuals other than those responsible for their clinical care, most however do welcome the opportunity to have their data used for cancer research.

In addition to the requirements already outlined in the VCR's arrangements for access to data, researchers requesting disclosure of registrant contact details need to consider the following:

1. the VCR will not contact the same registrant on behalf of multiple researchers within a short time frame, in particular in the first year after diagnosis.
2. No registrant contact is usually permitted in the first six weeks following diagnosis. This is to give the treating clinician(s) time to inform the registrant of their diagnosis, possible treatments.
3. The minimum requirements for the VCR to obtain permission to release registrant's contact details to researchers are:
 - An approach letter to the registrant's treating clinician to determine any factors that would make individual registrants unsuitable for direct approach e.g. unable to speak English, not aware of their cancer diagnosis, complicating co-morbidity e.g. Alzheimer's disease.
 - Approach letter to registrants to include: (a) a copy of the VCR information brochure and b) a plain language statement about the study.
4. The content of the 'clinician approach' and 'registrant approach' letters must be approved by the VCR Director. Sample letters are attached.
5. During recruitment, any problems that arise with individual clinicians or registrants, for example hostile refusals, must be promptly reported to the VCR Director.
6. Researchers who require continued vital status updates need to identify this feature at the time of application
7. The VCR will prepare 6 monthly progress reports for researchers that summarise adverse events, if any, which occurred during recruitment.

[on registry letterhead]

Dear <<Title>> <<Surname>>

RE: <<insert study name>>

I am writing to you because the Victorian Cancer Registry has been notified that you have had a recent diagnosis of cancer. The Cancer Registry operates under the authority of the Cancer Act (1958) and receives information about all people who have cancer diagnosed in Victoria. I have enclosed a leaflet describing the Cancer Registry and how it operates. One of its purposes is to assist research into the causes and prevention of cancer, but it can only release information about you to researchers with your permission.

I would like to ask if you would be interested in joining a Victorian research project about <<insert brief description about study>>

If you agree to be contacted by the researchers I will give them your name, address and telephone number. If you do not agree your contact details will not be released and you will not be contacted again about this study.

If you do authorise me to give your contact details to the researchers they will contact you by mail, at which point you can decide whether or not to participate in the study. Participating in the study will involve completing one survey only.


Please complete the enclosed "Victorian Cancer Registry Consent to Pass on Contact Details" form to show **whether or not you agree to the Cancer Registry passing on your contact details**. Please return it to the Cancer Registry in the pre-paid envelope supplied.

For you to be eligible for this study, the VCR must receive consent to release your contact details before [Insert date]. Therefore, if you are interested in being contacted by the researchers about participating in this study, **please return the enclosed consent form as soon as possible**, to ensure that you can be involved.

If you would like to speak to someone at the Cancer Registry about this request, you can call Helen Farrugia on 03 9635 5318. If we have not heard from you in a couple of weeks, we will write again. If you have any concerns or complaints about the research you can contact Ms Woody Macpherson from The Cancer Council Human Research Ethics Committee on 03 9635 5100.

Thank you for considering this request.

Yours sincerely



Professor Graham Giles
Director, Victorian Cancer Registry

VICTORIAN CANCER REGISTRY

CONSENT TO PASS ON CONTACT DETAILS

Name: <Surname>, <Firstname>
 Address: <Address>
 <Suburb> <Postcode>

Project Title: *(insert)*

Principal Investigators: *(insert)*

If you sign this form and tick box **A**, the Victorian Cancer Registry will pass on your contact details (name, address, telephone number) to the researchers of the Patient Experiences Survey
 The researchers will then write to you to obtain your written consent to participate in the Study. You are **not** consenting to participate in the Study by signing this consent form.

If you sign this form and tick box **B**, the Victoria Cancer Registry will not pass on your contact details to the researchers of *(insert study name)*.

This project has been approved by The Cancer Council Victoria's Ethics Committee, so that it meets ethical standards, and ensures the confidentiality of participants.

If you have any concerns or complaints about this project, these should be directed to:
 The Chair of The Cancer Council Victoria's Human Research Ethics Committee who can be contacted via Ms Woody Macpherson, Head, Research Management Unit, The Cancer Council Victoria, 1 Rathdowne St Carlton 3053, telephone (03) 9635 5100.

If the person to whom this request applies cannot receive it, please indicate and return the form to us.
(Please tick the appropriate box print your name in the space provided and sign below)

A I _____ agree to have my contact details passed on to the researchers of the *(insert study name)*

B I _____ do not agree to have my contact details passed on to the researchers of the *(insert study name)*

Signed :..... **Date**:/...../.....

Correct name and contact details: Name: _____ Address: _____ Suburb: _____ Postcode: _____ Telephone number: _____ Preferred hours/ days for telephone contact: _____
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Please use the reply paid envelope to return completed form to:

Data Manager: <Study Name>

Victorian Cancer Registry, 1 Rathdowne Street, Carlton 3053

THANK YOU FOR YOUR CO-OPERATION

«Date»

«Title» «Initial» «doc_sname»
«doc_addr1»
«doc_addr2»
«doc_addr3»

Dear «Title» «doc_sname»

<Study Name>

The Victorian Cancer Registry, operated by The Cancer Council Victoria, has recently been advised that your patients(s) listed below, has/have been diagnosed with <cancer site> cancer. The notification of cancer to The Cancer Council Victoria is mandatory under the Cancer Act (information brochure attached).

I am writing to inform you that the Cancer Registry will contact the person(s) listed below in four weeks time to invite them to participate in the <Study Name>. This study is being conducted by <Insert who the study is being conducted by> and is funded by <Name of Funding Institution>

The study has been approved by The Cancer Council Victoria Human Research Ethics Committee. This committee, using the authority vested in it by the Cancer Act, has approved the Victorian Cancer Registry approaching people registered with a diagnosis of <cancer site> cancer to invite them to participate in this study. In this way, only the names of consenting individuals will be passed on to the researchers.

The study is described in the attached information sheet. Briefly, the study involves <insert brief statement of the purpose of the study>

All personal information collected will be kept secure and confidential in accordance with the NHMRC Guidelines for Epidemiological Research.

If you are aware of any reason why it might not be appropriate to approach any person listed to participate in this study, I would be grateful if you would contact this office within four weeks of receiving this letter. Also, if you are aware of any changes of address for this person(s), your advice in this respect would also be appreciated.

No information will be disclosed by the Registry to the <Study name> research team for this research without the consent of the persons concerned.

If you would like further information regarding the Victorian Cancer Registry, please call Ms Helen Farrugia on (03) 9635 5154. If you have any concerns or complaints about the conduct of the study, please contact Ms. Woody Macpherson from The Cancer Council Victoria Human Research Ethics Committee on (03) 9635 5100.

Thank you for your help.

Yours sincerely,



Professor Graham Giles
Director, Victorian Cancer Registry