

VICTORIAN CARDIAC OUTCOMES REGISTRY

Data Access Policy

Version 2.0

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Document Version Control

Version	Date	Reason/Comments/Approvals
1.0	12-FEB-2014	Initial Version Release. Approved by the VCOR Steering Committee on 11-MAR-2014.
1.1	20-OCT-2014	Review of the data access review process expressed in Figures 1 & 2. Approved by the VCOR Data Access, Reports & Publications Committee on 21-10-2014
2.0	1-DEC-2016	Updated sections 2.1 & 2.2, 4 and 9.1. Approved by the VCOR Steering Committee on 7-FEB-2017.

1. Preface

The following policy defines how data can be obtained from the Victorian Cardiac Outcomes Registry (VCOR). This policy includes the criteria and conditions for provision of aggregate data or provision of an analysis of aggregate data and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable.

Data collected and collated by VCOR is guided by strict protocols and procedures to protect against potential breaches of privacy as well as to ensure appropriate ethical integrity and scientific merit of proposals using VCOR data. VCOR data is housed centrally within Monash University and as such, provision of data to VCOR is subject to strict data management guidelines. The study project is approved by participating hospitals' and Monash University Human Research Ethics Committees. In particular, specific measures have been put in place to maintain the confidentiality of personal identifying information.

Access to data is subject to the approval of the Data Access, Research and Publications Committee (DRP) and/or VCOR Steering Committee (in some cases standing approval exists). When considering the approval of access to VCOR data, the VCOR DRP seeks to balance the importance of privacy protection and the significant public health interest from the proposed research.

This document separates and specifically addresses 1) requests for access to aggregate registry data; and 2) requests for specific research-related activities (e.g. data analyses, statistical modelling and/or data linkage requests).

2. Project Information

2.1 Purpose of VCOR

The purpose of the VCOR is to improve the safety and quality of health care provided to patients with cardiovascular disease. Key clinical information from individual healthcare encounters is collected to allow for risk-adjustment of outcomes to facilitate benchmarking of performance and quality improvement in the delivery of health care services. VCOR monitors the safety and quality of care given to patients with cardiovascular disease undergoing specific cardiac procedures or with specific cardiac conditions. Selected risk-adjusted outcomes are reported back to stakeholders. This has been achieved by undertaking a Victoria-wide clinical quality registry: a proven mechanism for data analysis, reporting and benchmarking quality in the provision of health services.

2.2 Project Overview

Monash University in conjunction with the Cardiac Clinical Network and funding from the Victorian Department of Health and Human Services have developed and maintain a secure, online data collection tool and data storage mechanism for analysis and reporting. The success of relevant treatments and procedures performed on patients presenting in Victorian hospitals with cardiovascular symptoms is assessed and reported. This is achieved by capturing data about patient demographics; symptoms; clinical presentation and diagnosis; treatments they receive and related clinical outcomes.

VCOR is designed to collect a minimised, standard set of information from all patients undergoing specific cardiac procedures or treatments at participating hospital sites. The data is gathered using predetermined procedures and standardised definitions and includes collecting patients' identifying information, presenting and treatment details and related clinical outcomes. Data is collected at baseline (time of

presentation for procedure), 30 days and potentially 12 months, with the additional potential for ongoing annual follow up in the future. Data is captured electronically in an online data entry system.

Data is stored securely within Monash University servers and retained indefinitely. The project conforms to national operating principles for clinical quality registries (CQRs) as set out by the Australian Commission on Safety and Quality in Health Care (ACSQHC). As such, the governance of the registry is in keeping with these principles. All project matters are governed by the VCOR Steering Committee (SC) by way of liaison with two subcommittees: The Clinical Quality Committee (CQC); and the Data Access, Research & Publications Committee (DRP). Monash University's Centre of Cardiovascular Research and Education in Therapeutics (CCRET) will act as the coordinating data management centre, answering to the Steering Committee. A Clinical Director has been appointed as the Chair of all three committees and site liaison.

Monash University, eSolutions, under the guidance of CCRET is responsible for developing and maintaining the data entry system. CCRET is responsible for performing data quality controls, and reports for providing structured feedback to participating sites. Feed-back is provided quarterly to each participating hospital. Emphasis is on performance relative to other hospitals and performance over continuous reporting periods. An annual report is published yearly.

All hospital data remains the property of that institution. All collective registry data and data management systems operate under the custodianship of Monash University.

3. Confidentiality of VCOR data

Data held by VCOR is confidential. In general, requests for access to data will require approval from the VCOR DRP.

Sharing VCOR data with relevant public, clinical and academic communities is an objective of the Registry and VCOR will facilitate the use of aggregate data for appropriate research to further the scientific understanding of cardiovascular disease and/or related outcomes. As such, the following information has been provided to Registry participants and must be adhered to by all parties engaging in VCOR activities and/or utilising VCOR data:

*“We will produce general reports on cardiac outcomes for public, government, clinical and academic audiences. We anticipate that these publications will help to inform the community about common trends and/or gaps that may exist in service provision. **No publication or report will ever contain any identifying information about you.**”*

Researchers may use unidentified, group data for future research projects. Any further research undertaken using VCOR data will require approval by a Human Research Ethics Committee. Please be aware that by consenting to having your information stored in the Registry, you agree that the information collected may be used for further research relating to the standard of care provided to patients undergoing cardiovascular treatments and interventions in Victoria.

Any information obtained for the purpose of this registry that can identify you will be treated as confidential and stored securely. Identifying information is protected by privacy legislation and would only be disclosed with your permission, or in compliance with the law. All data will be safeguarded by State and Commonwealth privacy laws. We will ensure that our security measures conform to national standards to prevent unauthorised access. Access will be limited to approved Registry staff. Any future access to registry data by other organisations or researchers will be approved by a Human Research Ethics Committee and will be bound to the same State and Commonwealth legislations.”

From: VCOR Patient Information Sheet

4. Access to data from VCOR

Interested parties may present requests for a data extract or an analysis of data for the purposes of academic research, clinical review, planning or scientific investigation. These requests will be reviewed by the DRP. The formal process is outlined below.

All requests must seek approval from the VCOR Project Manager and/or DRP prior to any data being released or analysis being undertaken. In all instances where group aggregate data is requested, ethics committee approval will be required. NHMRC guidelines, approved under Section 95A of the Privacy Act 1988 and the Privacy Amendment (Enhancing Privacy Protection) Act 2012, allow VCOR to request applicant investigators to submit a proposal to a Human Research Ethics Committee (HREC) even if it has received written notification of ethics committee approval from the investigators’ institution. It is therefore the preference of VCOR that applications for release of aggregate data are submitted and reviewed by a HREC who has already approved data collection of the core VCOR dataset. Please contact the VCOR Project Manager for more information about investigators involved in VCOR and relevant HREC committees to approach.

Secondary or further research arising from the original approved request must be submitted separately for HREC approval.

All requests must be on the official form and have clearly stated aims/objectives, methods and be accompanied by a background, rationale and in the case of requests for aggregate data have a clear analysis plan. This document needs to be completed in its entirety before submitting to the VCOR DRP for review.

All requests are subject to the guidelines and policies in this document.

The principal investigator will be asked to provide an update as to the progress of the project every 6 months. Any material or manuscripts to be published using VCOR data must be submitted to the VCOR DRP for review.

A site remains the owner of the data they contribute and they have access to this data via the online system. Only the VCOR Project Manager and Project team who report directly to the Data Custodian will have direct access to the entire cohort of raw data.

VCOR encourages the use of aggregate, de-identified data for appropriate research relevant to any aspects of treatment/prevention of cardiovascular disease and/or related clinical outcomes but holds the rights to reject or revoke access if the terms of this data access policy are exploited.

VCOR encourages collaborative ventures. The VCOR Data Custodian and DRP envisage that VCOR data will be of use to a large number of organisations, investigators and policy writers.

To ensure that the data and any limitations in scope or quality of the data provided has been properly understood by the user, pre-publication drafts of any derivative works must be submitted to the VCOR DRP for review and potential advice on data interpretation. VCOR must be acknowledged in the appropriate way in all publications and presentations (see below).

This document should be read in conjunction with the *VCOR Publications Policy*.

4.1 Data Access Statements

All requests for data or analyses of data are subject to the following:

1. Access to the data is subject to the Specific Access Guidelines outlined in section 4.2 of this document.
2. Provision of data will depend on the available resources at the time of request. It is under the discretion of the Data Custodian, VCOR Project Manager and VCOR DRP to prioritise the order of data requests, upon approval.
3. The use of data for research purposes must receive approval from the VCOR DRP. Research related requests will require specific ethics committee approval.
4. Any material or manuscript to be published using VCOR data must contain appropriate acknowledgements of VCOR. Preferred wording for the acknowledgement will be provided with the data. See *VCOR Publications Policy* for more information.
5. Any material or manuscript to be published using VCOR data must be submitted to the VCOR DRP for approval prior to submission for publication. VCOR reserves the right to dissociate itself from conclusions drawn from the data if it deems necessary.
6. In usual circumstances data that can identify patients will not be made available to third parties. All recipients of data from the VCOR registry must agree not to use that data, alone or in conjunction

with any other information, to attempt to identify patients. The exception would be approved linkage studies.

7. Only submitted (validated) case data will be released or be included in any summary reports about VCOR.
8. Only requests that meet Specific Access Guidelines Categories 1 and 5 will be provided free of charge, unless a large number of such requests are made (refer to section 4.2 of this document). This will be reviewed periodically. The provision of data or analyses for all other requests (Specific Access Guidelines Categories 2-4) may be subject to a fee-for-service. See the 'Fees for Provision of Data' statement (section 6 of this document) for an explanation of the fees.
9. All third party requests for access to VCOR data must take appropriate timelines into account as these requests will need to be scheduled along with routine VCOR tasks and meetings. As a general rule, requests for data under Specific Access Guidelines Categories 1 and 5 will take 2-4 weeks to complete, once approved. All other requests must first be made to the VCOR Project Manager, who will then table such request at the next VCOR DRP meeting. VCOR DRP meetings will be held at least four times per year and data cannot be extracted until approval is given by the VCOR DRP. Under exceptional circumstances, when data is required earlier, the VCOR Project Manager may request an 'out of session' approval by the VCOR DRP electronically to consider specific data requests.
10. All data requests must be formally lodged, using the Application for Release of Data Form downloadable from the VCOR website and found at the end of this document, via:

Email:	vcor@monash.edu
Mail:	The Project Manager VCOR Monash University (SPHPM) The Alfred Hospital Commercial Road MELBOURNE VIC 3004 AUSTRALIA
Fax:	1800 022 730

4.2 VCOR Specific Access Guidelines

- Category 1.** Where basic summary data only is requested, this information can be provided by VCOR staff. Such provision of data does not require DRP approval but VCOR will require a formal request in writing and will keep a record of such requests. The VCOR Steering Committee will be provided with a summary of such requests on a biannual basis. A caveat and conditions of use statement will be provided with the data.
- Category 2.** All requests for aggregate de-identified data must be in made in writing to the VCOR Project Manager who will submit the data request to the next VCOR DRP meeting. A decision on whether to provide the data will be made by the VCOR DRP following advice from the Project Manager. The requester/s must submit the relevant ethics applications required and provide evidence of approval of the same prior to the release of data. At no stage will data that could identify hospitals, individual clinicians and/or patients be provided. A caveat and conditions of use statement will be provided with the data. See figure 1 – Flow Chart for Requests
- Category 3.** Researchers may request VCOR undertake specific ad hoc data analyses. A formal written request should be made to VCOR for approval from the VCOR DRP. A decision on whether to undertake the analysis work will be made by the VCOR DRP following advice from the Project Manager. The requester/s must submit the relevant ethics applications required and provide evidence of approval of the same prior to the release of analysis output/s. A caveat and conditions of use statement will be provided with the analysis output/s. See figure 1 – Flow Chart for Requests
- Category 4.** If a third party researcher or student requires individual data for linkage, this cannot be provided directly. However, it may be possible for the third party to provide their data to VCOR for linkage purposes and for VCOR to provide de-identified data or aggregate data summaries based on the linked data. Individual record data (patients, clinicians, specific sites) will not be made available to a third party in any circumstance. All such linkage projects will require ethics committee approval. A formal written request should be made to VCOR for approval from the VCOR DRP. This also applies to the comparison of external data sets with data maintained by VCOR. See figure 2 – Flow Chart for Linkages
- Category 5.** If a hospital or its representative makes a specific request for its own performance data, beyond that available on Hospital Data Report and/or on-line downloadable reports, VCOR will provide such reports. No data that could specifically identify a patient will be provided. All requests for this category of data should be made in writing to the VCOR Project Manager and is bound by the timelines and processes listed in this document. Whilst such data requests do not require committee approval, the Project Manager will notify the Steering Committee and VCOR DRP of these requests.

Figure 1. Flow Chart for VCOR Data Requests

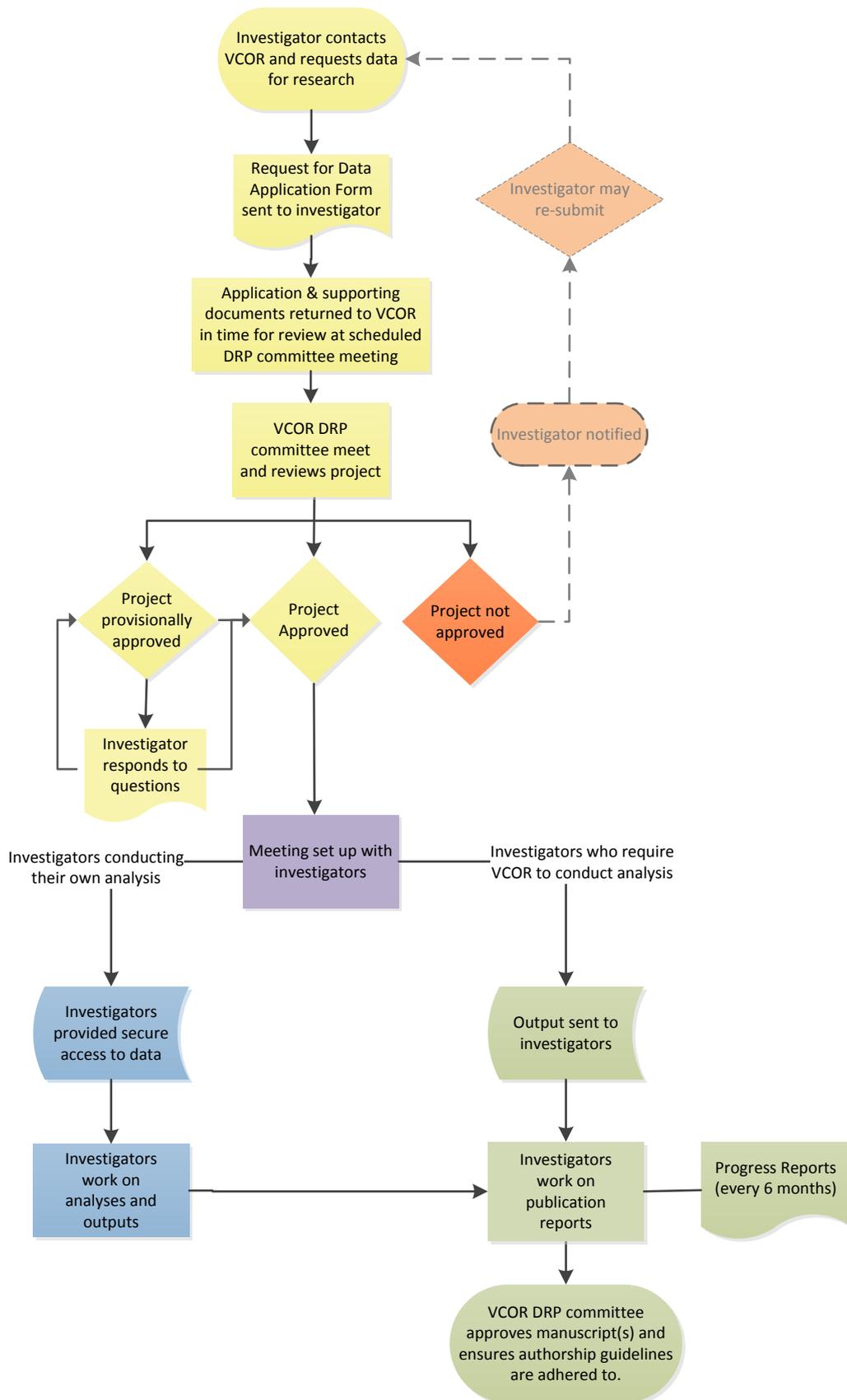
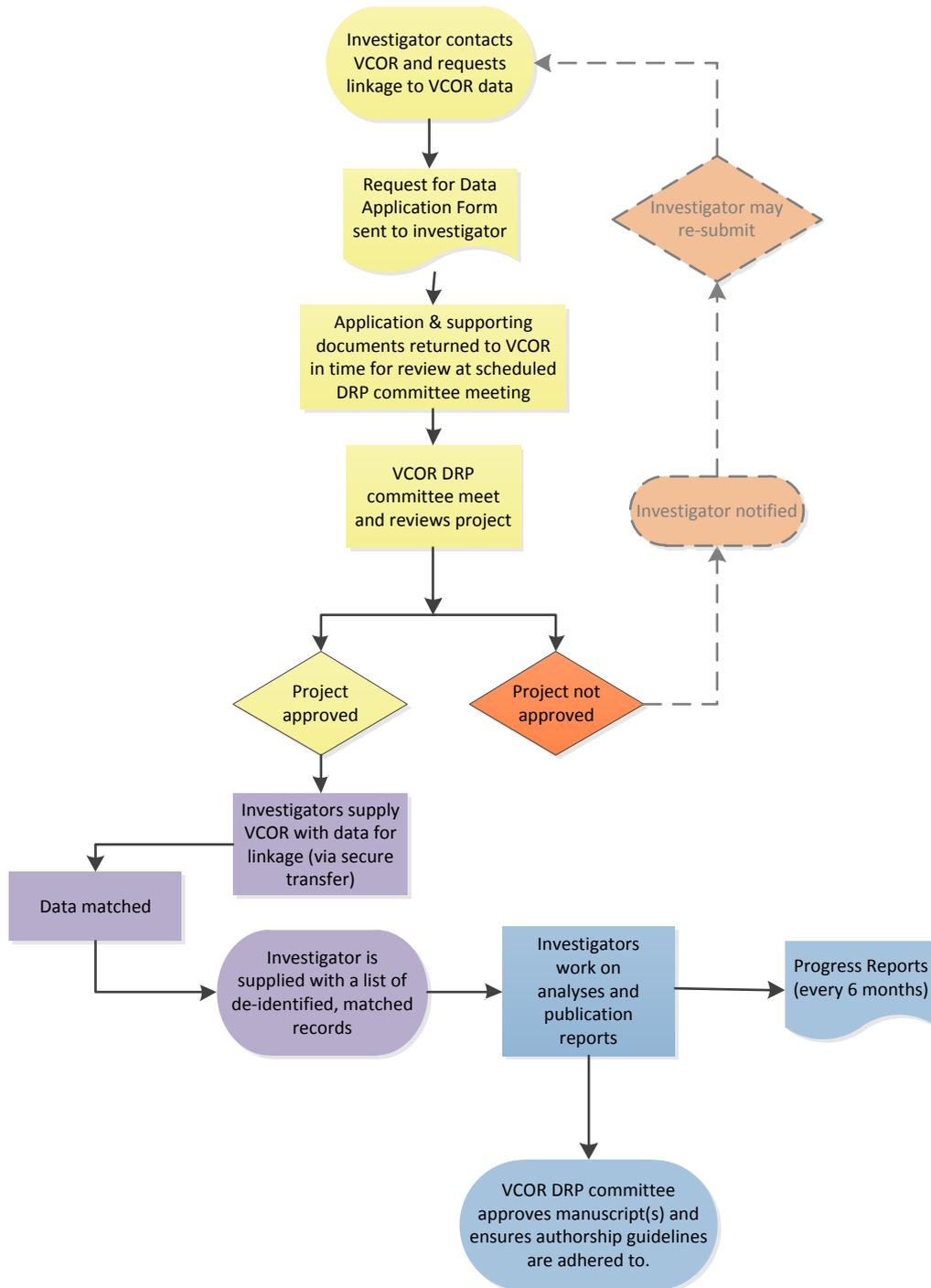


Figure 2. Flow Chart for VCOR Data Linkage Requests



5. Process for Requests for Data Access

All requests must be made in writing and include the following information:

- Project title
- Principle investigator/co-investigators
- Proposed research plan

This detailed project description should be in the form of an extended abstract and is not to exceed four (4) pages, including references and tables. The plan should include the following information: Background, specific aims and objectives, methods and detailed statistical analysis plan, source of funding and proposed publication/presentation plan. It should also address the following:

- The degree of analytical and statistical support that the investigators anticipate will be necessary from VCOR;
- The exact nature of the dataset to be developed and used in the analysis;
- The format of the dataset to be used in the analysis, including medium and software requirements;
- The resources available for the project at the Investigator's institution;
- Include a table illustrating how potential results will be displayed;
- Details of the NHMRC approved HREC to which the project has been submitted to or that the Investigator intends to submit to, attaching copies of letters of approvals and conditions, where appropriate;
- The timeframe for completion of the project;
- An outline of the support required from VCOR;
- Which scientific journal(s) the completed manuscript(s) are likely to be submitted and/or information about any conferences or seminars that the Investigator(s) intend to submit the project.

All research requests must comply with the Acknowledgement and Authorship guidelines outlined in the *VCOR Publications Policy*.

6. Documents Required to Support Requests for Data Access

Where relevant, once ethics approval has been granted from your institution or body, please provide an electronic copy and an original hard copy of the submission with a covering letter to the Chair of the Management Committee via the VCOR Project Manager (vcor@monash.edu).

Once the project has been discussed with the VCOR Project Manager, please complete the Application for Release of Data form (more information available from <http://www.vcor.org.au/Data-Access>).

The documents that need to be included in your submission to the VCOR DRP are:

- Covering Letter
- Application for Release of Data Form (see appendix 1)
- Ethics approval (or evidence of application) from institution or recognised body (NHMRC registered HREC)
- Signed Confidentiality Form

This document should be read in conjunction with the *VCOR Publications Policy* which provides more information on this topic.

6.1 Review of Requests

The requests will be reviewed for scientific merit and potential to contribute to the primary or secondary research goals of the VCOR project. In addition, the amount of resources necessary to fulfil the request, and intended use of requested information will be taken into consideration. The VCOR DRP will seek to avoid duplication of research efforts and/or publications.

7. VCOR Fees for Service Guidelines for Provision of Data or Analyses

Provision of data extracts and/or analyses may incur a fee. Following review, the VCOR DRP will provide recommendations as to whether fees will be applicable and the overall cost negotiated on a case by case basis. The overall cost will be calculated on a cost recovery basis and will be based on the time & effort involved in undertaking the work. The requestor will be advised in writing and will need to agree in order for the work to proceed.

8. Student Participation in Research

VCOR encourages student participation in research activities particularly for those students enrolled in advanced degrees (Hons, Masters, PhD, Advanced Surgical Trainee). Student authorship will be carefully considered in light of candidature submission requirements.

9. VCOR Data Security

Data security and storage remains the responsibility of the Data Custodian and data management centre at Monash University. In order to maintain data security and integrity, all data analyses will be conducted and/or supervised by the VCOR Project Manager or staff at the delegated Data Management Centre. All data will remain under the custodianship of the VCOR Custodian. See *VCOR Data Security Policy* for more information.

9.1 Data storage and data sharing

No identifiable **or potentially re-identifiable** research data and/or health information should ever be sent via email or fax or transported on a portable disk or disk drive.

9.1.1 Secure File Transfer Protocol (SFTP)

Any transfer of electronic registry data that contains **potentially re-identifiable** information will follow a Secure File Transfer Protocol (SFTP). SFTP is a secure network protocol that provides file access, file transfer and file management functionalities by way of a secure online file sharing portal. Files will be manually uploaded, and will only appear for a limited period before access is removed and the file is

archived. Recipients will be granted a username and password to access the SFTP website and will be notified via email when files are available for download.

9.1.2 *Secure Unified Research Environment (SURE)*

Data for use in approved research of group aggregate de-identified may be accessed via the Secure Unified Research Environment (SURE).

SURE, the Secure Unified Research Environment, is a high-powered computing environment developed to help make best use of our national knowledge base. It is helping to bring researchers together from across Australia and the world to collaborate on large-scale projects tackling major health and social issues such as population ageing, diabetes and mental health. It has been purpose-built as Australia's only remote-access data research laboratory for analysing routinely collected data, allowing researchers to log in remotely and securely analyse data from sources such as hospitals, general practice and cancer registries. SURE was established with funding from the Australian Government National Collaborative Research Infrastructure Strategy (NCRIS) as part of the Population Health Research Network (PHRN). The PHRN is a collaboration that was set up in 2009 to further develop Australia's data linkage capabilities.

Monash University, through CCRET has established a contract with SURE. The benefit of using SURE is that the data is not able to be downloaded and is accessible only via the secure research environment. There are costs involved in accessing SURE which will be passed onto researchers. Information related to SURE related costs will be provided as needed.

Appendix 1: Example Application for Release of Data Form

Please contact vcor@monash.edu for an electronic copy of this form for completion.

DATA ACCESS STATEMENT	
<p>THE VICTORIAN CARDIAC OUTCOMES REGISTRY (VCOR) ENCOURAGES USE OF ITS DATA FOR A VARIETY OF PURPOSES SUCH AS QUALITY IMPROVEMENT PROJECTS, RESEARCH AND CLINICAL PLANNING. PLEASE REFER TO THE VCOR DATA ACCESS POLICY FOR DETAILS ABOUT APPROPRIATE USE OF VCOR DATA. ALL DATA REQUESTS MUST ADHERE TO THE CAVEAT AND CONDITIONS OF USE PROVIDED UPON APPROVAL OF EACH REQUEST FOR RELEASE OF DATA. ALL REQUESTS MUST BE ACCOMPANIED BY THIS COMPLETED FORM, A COVER LETTER AND RELEVANT SUPPORTING DOCUMENTATION. PLEASE TYPE YOUR ANSWERS OR PRINT CLEARLY. PLEASE RETURN YOUR APPLICATION TO THE ADDRESS BELOW:</p>	
<p>VCOR PROJECT MANAGER C/- DEPARTMENT OF EPIDEMIOLOGY & PREVENTATIVE MEDICINE MONASH UNIVERSITY THE ALFRED HOSPITAL COMMERCIAL ROAD MELBOURNE VIC 3004</p>	<p>EMAIL: vcor@monash.edu PH: +61 3 9903 0302 FAX: 1800 022 730</p>
SECTION 1: APPLICANT DETAILS	
ALL CORRESPONDENCE REGARDING THIS APPLICATION SHOULD BE DIRECTED TO:	
TITLE:	<input type="checkbox"/> Ms <input type="checkbox"/> Mrs <input type="checkbox"/> Miss <input type="checkbox"/> Mr <input type="checkbox"/> DR <input type="checkbox"/> A/PROF <input type="checkbox"/> PROF
NAME:	
AFFILIATION:	
ADDRESS:	
EMAIL ADDRESS:	PHONE NUMBER:
PROJECT LEAD, PRINCIPAL INVESTIGATOR OR SUPERVISOR <input type="checkbox"/> SAME AS CONTACT PERSON ABOVE	
TITLE:	<input type="checkbox"/> Ms <input type="checkbox"/> Mrs <input type="checkbox"/> Miss <input type="checkbox"/> Mr <input type="checkbox"/> DR <input type="checkbox"/> A/PROF <input type="checkbox"/> PROF
NAME:	
AFFILIATION:	
ADDRESS:	
EMAIL ADDRESS:	PHONE NUMBER:
LIST ALL OTHER RESEARCHERS NAMED ON THIS PROJECT:	
ADDITIONAL RESEARCHERS:	
REQUESTING PARTY	
ORGANISATION:	<input type="checkbox"/> RESEARCH/ACADEMIC INSTITUTION <input type="checkbox"/> GOVERNMENT DEPARTMENT <input type="checkbox"/> REGISTRY <input type="checkbox"/> TREATING PHYSICIAN / CLINICAL INTEREST <input type="checkbox"/> INDUSTRY (PLEASE SPECIFY): <input type="checkbox"/> OTHER (PLEASE SPECIFY):

SECTION 2: PURPOSE OF THE DATA REQUEST

- | | | | |
|---|--|--|---|
| <input type="checkbox"/> ACADEMIC RESEARCH | <input type="checkbox"/> CLINICAL INVESTIGATION | <input type="checkbox"/> PLANNING | <input type="checkbox"/> COMMERCIAL / BUSINESS |
| <input type="checkbox"/> OTHER (PLEASE SPECIFY): | | | |

SECTION 3: TYPE OF DATA REQUEST

- | | | |
|---|---|--|
| <input type="checkbox"/> RAW DATA (INVESTIGATORS RUN ANALYSIS) | <input type="checkbox"/> VCOR SUMMARY DATA (VCOR RUN ANALYSIS) | <input type="checkbox"/> DATA LINKAGE |
| <input type="checkbox"/> OTHER (PLEASE SPECIFY): | | |

SECTION 4: TYPE OF DATA REQUEST

PROJECT PLAN

IN ADDITION TO THIS FORM, PLEASE INCLUDE A DETAILED DESCRIPTION OF YOUR PROJECT.

PLEASE LIMIT YOUR PLAN TO 4 PAGES INCLUDING REFERENCES AND TABLES.

PROJECT PLAN MUST INCLUDE:

BACKGROUND

PROJECT OBJECTIVES & SPECIFIC AIMS

METHODS & DATA ANALYSIS PLAN

PERSON RESPONSIBLE FOR DATA ANALYSIS

HOW POTENTIAL RESULTS WILL BE DISPLAYED (SHOW EXAMPLES)

PROPOSED OUTPUT FROM THE PROJECT (E.G. SCIENTIFIC JOURNAL/S TO WHICH THE COMPLETED MANUSCRIPT WILL BE SUBMITTED, DETAILS OF CONFERENCES/FORUMS WHERE DATA WILL BE DISCUSSED).

REFERENCES

REFER TO SECTIONS 5 & 6 OF THE VCOR DATA ACCESS POLICY FOR MORE INFORMATION.

SHORT TITLE OF PROJECT:

1. WHAT DATA FIELDS ARE YOU REQUESTING FROM VCOR? PLEASE REVIEW THE VCOR DATA DICTIONARY AND INCLUDE ALL DATA FIELDS REQUIRED. ATTACH ADDITIONAL PAGES AS REQUIRED.

2. HOW WILL THE PROJECT BE RESOURCED? PLEASE PROVIDE INFORMATION ABOUT HOW THE PROJECT WILL BE RESOURCED AT YOUR INSTITUTION (INCLUDE FUNDING DETAILS). PLEASE ALSO INDICATE WHAT ADDITIONAL SUPPORT FROM VCOR IS REQUIRED. ATTACH ADDITIONAL PAGES AS REQUIRED.

3. PLEASE INDICATE HOW LONG YOU EXPECT THE PROJECT TO CONTINUE? ATTACH ADDITIONAL PAGES AS REQUIRED.

SECTION 5: ETHICAL APPROVAL

ANY RESEARCH THAT EXTENDS BEYOND THE APPROVED VCOR PROJECT SCOPE MUST FIRST BE APPROVED BY A RELEVANT HUMAN RESEARCH ETHICS COMMITTEE AND/OR INDEPENDENT REVIEW BOARD PRIOR TO REQUEST FOR RELEASE OF DATA.

HAVE YOU RECEIVED FULL ETHICAL APPROVAL FOR THIS PROJECT?

PLEASE ATTACH HREC APPROVAL CERTIFICATES.

Yes

No

PENDING

LIST ALL HRECS THAT HAVE APPROVED OR ARE CURRENTLY CONSIDERING THE ETHICAL CONDUCT OF THIS RESEARCH:

IF NO HREC APPROVAL HAS BEEN LODGED, PLEASE EXPLAIN WHY:

SECTION 6: DECLARATION

PLEASE READ AND SIGN THE FOLLOWING DECLARATION BEFORE SUBMITTING YOUR APPLICATION:

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE VCOR DATA ACCESS POLICY AND THE VCOR PUBLICATIONS POLICY. I AGREE TO ALL THE TERMS OUTLINED IN BOTH DOCUMENTS. I AGREE TO UNDERTAKE ALL VCOR RELATED ACTIVITIES IN ACCORDANCE WITH THE CURRENT PROTOCOL AND PROVISIONS OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) KEEPING WITH THE THERAPEUTIC GOODS ADMINISTRATION'S GUIDELINES FOR GOOD CLINICAL PRACTICE AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.

I AGREE TO ADHERE TO ALL THE STIPULATIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN THE VCOR CAVEAT AND CONDITIONS OF USE THAT WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY OR DATA ANALYSIS.

I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY VCOR, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

APPLICANT SIGNATURE:

DATE:

**LEAD INVESTIGATOR/
SUPERVISOR SIGNATURE:**

DATE: