VCOR
VICTORIAN CARDIAC OUTCOMES REGISTRY

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Data Access Policy

Version 4.1.1

11th July 2023

MONASH University

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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.
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4.0	20-NOV-2019	Updated sections 2.2, 4, 6, 7 and Appendix 1. Approved by the DRP Committee 03-Dec-2019
4.1	8th FEB-2021	Review and updated section 7.0 Approved by the DRP Committee 15-Feb-2022
4.1.1	11th JULY-2023	Updated section 7 & 9.1

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, procedures for data request applications and associate costs (as 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 are gathered using predetermined procedures and standardised definitions and includes collecting patients' identifying information, presenting and treatment details and related clinical outcomes. Data are collected at baseline and 30 days from discharge. Data is captured electronically in an online data entry system.

Data are 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. Feedback 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.

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 analysis or data are 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 to 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 DRP approval and further 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 Service Guidelines for Provision of Data or Analyses' statement (section 7 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 require approval by the VCOR DRP. Under exceptional circumstances, when data are required earlier, the VCOR Project Manager may request an 'out of session' approval by the VCOR DRP electronically to consider specific data requests.

10. Investigators are encouraged to complete their research in a timely manner. Data analyses should be completed within 12 months of commencement of the project. If the project exceeds 12 months duration, the topic of research will no longer be reserved for exclusive use by the investigators. Presentation and publication of outcomes is expected following analyses, and manuscripts should be submitted within one year following completion of analyses.

11. Investigators (primary) with projects that have exceeded 24 months in duration will not have new projects considered unless sufficient progress in the existing projects has been demonstrated. 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)
    553 St Kilda Road
    MELBOURNE VIC 3004
    AUSTRALIA

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. Following VCOR approval, the requester/s must submit an ethics application 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. Following VCOR approval, the requester/s must submit an ethics application and provide evidence of approval of the same prior to the release of any analyses or output/s. A caveat and conditions of use statement will be provided with the analyses 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

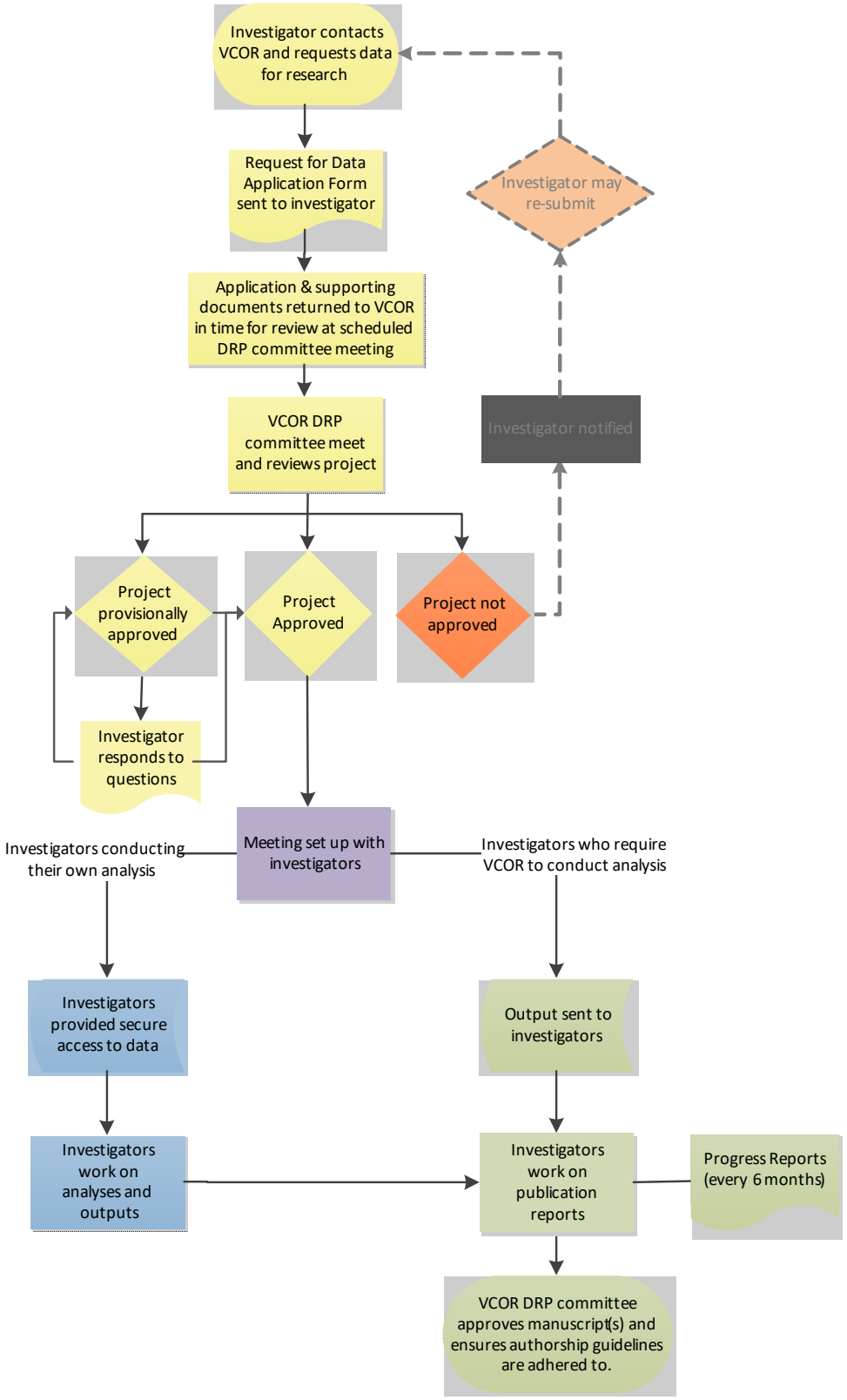
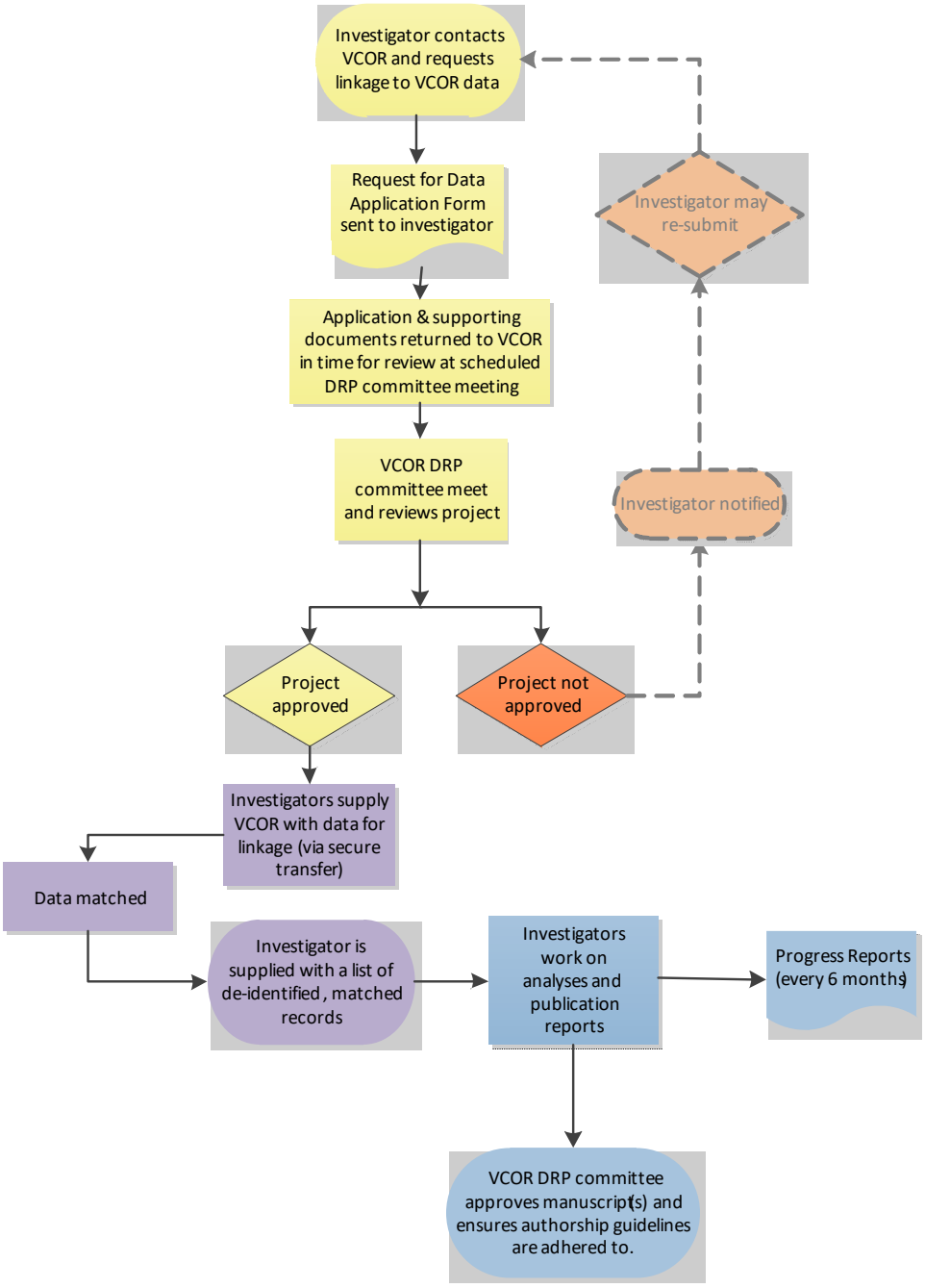


Figure 2. Flow Chart for VCOR Data Linkage Requests



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/statistician
- Proposed research plan

This detailed project description should be in the form of an extended abstract and is not to exceed six (6) 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 will be submitted to;
- 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:

- Application for Release of Data Form (see appendix 1)
- Study Proposal

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 or analyses undertaken by VCOR (on behalf of approved applicants) will incur a fee.

- VCOR Data Management fees are applicable to all projects And will be discussed with researchers. Project fees may be reduced or waived under special consideration by the VCOR Program Manager and/or the DRP. Costs will be calculated on a recovery basis and will be based on the estimated time and effort involved in undertaking the work.

- For provision of analyses, per project fees will apply however these may be reduced or waived under special consideration by the VCOR Program Manager and/or DRP. Costs will be calculated on a recovery basis and will be based on the estimated time and effort involved in undertaking the work.

  External researchers using extracted data will utilise the VCOR Secure eResearch Platform (SeRP) to remotely and securely access and analyse data. Within the SeRP environment, researchers can access a range of statistical software including Stata, SPSS, and R.

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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.

Once a project is completed and published the data and folders will remain in the VCOR SeRP environment for the required . After this the folders will be transferred to a long-term storage facility indefinitely.
Folders from the long-term facility can be reactivated at anytime by submitting a written request to VCOR.

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.

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

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. It's imperative that applicants refer to the VCOR Data Access Policy for details about appropriate use of VCOR DATA AND for the current data access fees.
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 the Application for Research form, a cover letter and relevant supporting documentation.
Please type your answers or print clearly. Completed applications are to be submitted a minimum of four weeks prior to the Data Access, Reports and Publications Committee (DRP) meeting date. Meeting Dates are published on the VCOR Website - http://vcor.org.au/Data-Access

Please return your application to the address below:

VCOR Project Manager
C/- Department of Epidemiology & Preventative Medicine
Monash University
553 St Kilda Road
Melbourne Vic 3004

Email: vcor@monash.edu
Ph: +61 3 9903 0334

Fees may apply - refer to the VCOR Data Access Policy v4 Section 7 for the current data access fees

Section 1: Applicant Details

All correspondence regarding this application should be directed to:							
Title:	☐ Ms	☐ Mrs	☐ Miss	☐ Mr	☐ Dr	☐ A/Prof	☐ Prof
Name:							
Affiliation:							
Address:							
Email Address:				Phone Number:			

Project Lead, Principal Investigator or Supervisor				☐ Same as Contact Person Above			
Title:	☐ Ms	☐ Mrs	☐ Miss	☐ Mr	☐ Dr	☐ A/Prof	☐ Prof
Name:							
Affiliation:							
Address:							
Email Address:				Phone Number:			

List All other Researchers named on this project:		
Additional Researchers:		

Requesting Party		
Organisation:		
	☐ Hospital	☐ Government Department
	☐ Academic Institution	☐ Physician / Clinical Interest
	☐ Registry	☐ Other (please specify):

SECTION 2: PURPOSE OF THE DATA REQUEST

☐ *ACADEMIC RESEARCH*	☐ *CLINICAL INVESTIGATION*	☐ *PLANNING OR QA*	☐ *COMMERCIAL / BUSINESS*
☐ *OTHER (PLEASE SPECIFY):*			

SECTION 3: TYPE OF DATA REQUEST

☐ *DATA EXTRACT (INVESTIGATORS RUN ANALYSES)*	☐ *VCOR SUMMARY DATA (VCOR RUN ANALYSIS)*	☐ *DATA LINKAGE (DISCUSS WITH VCOR PRIOR)*
☐ *OTHER (PLEASE SPECIFY):*		

SECTION 4: TYPE OF DATA REQUEST

PROJECT PLAN (ATTACH A STUDY PROTOCOL)

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

PLEASE LIMIT YOUR PLAN TO 6 PAGES INCLUDING REFERENCES AND TABLES.

PROJECT PLAN MUST INCLUDE:

BACKGROUND
PROJECT OBJECTIVES & SPECIFIC AIMS
METHODS & DATA ANALYSIS PLAN
(INCLUDE PERSON RESPONSIBLE FOR DATA ANALYSIS)
HOW POTENTIAL RESULTS WILL BE DISPLAYED (SHOW EXAMPLES)
PROPOSED OUTPUT FROM THE PROJECT (E.G. INTENDED JOURNALS FOR MANUSCRIPT PUBLICATIONS, DETAILS OF CONFERENCES/FORUMS WHERE DATA WILL BE DISCUSSED; ETC.).
REFERENCES

REFER TO SECTIONS 5 & 6 OF THE VCOR DATA ACCESS POLICY FOR MORE INFORMATION ABOUT WHAT TO INCLUDE IN YOUR APPLICATION

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 if any 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 be approved by a relevant Human Research Ethics Committee and/or Independent Review Board prior to any Data/analyses being released.

Following DRP review and should approval be granted, VCOR will issue a letter that can be used in HREC applications

List all HRECs from which you will be seeking approval for the ethical conduct of this research:

Note: Prior to VCOR releasing any data, analyses or linkage, the certificate of HREC approval must be provided. HREC applications should NOT be submitted until such time as your request to VCOR has been approved. The letter of approval from VCOR should be included with your HREC submission.

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:**	