

**Australia and New Zealand Society of Cardiothoracic Surgeons (ANZSCTS) Database Program**

**Request for Data or Analysis of Data**

**Please send completed forms to: anzscts.sphpm@monash.edu**

**Please ensure that ALL persons involved in the Research Project have read and understood this document.**

**Introduction**

The ANZSCTS Database project was established in 1999 with the purpose of undertaking quality assurance and benchmarking of national cardiac surgical performance in Australia. The information collected is also valuable in addressing research questions related to cardiac surgery.

**ANZSCTS Research Program**

The ANZSCTS Research Program is directed by Professor Christopher Reid, Custodian of ANZSCTS Database and research program. Activities are financially supported through a NHMRC Senior Research Fellowship and NHMRC Program Grant awarded to Professor Reid. The Research Program focuses on three broad themes of research pertaining to (a) Risk Prediction; (b) Intra-operative Procedural Factors; and (c) Improvement of Clinical Outcomes following Cardiac Surgery. To facilitate this work, the ANZSCTS Database has established links to a number of registries including the Australian Institute of Health and Welfare’s National Death Index.

**ANZSCTS Research Governance**

ANZSCTS Research Program activities are governed by the ANZSCTS Research Committee (ANZSCTS-RC), chaired by Professor Julian Smith. ANZSCTS-RC members include (minimum of) the Chair, the Research Program Director, two nominees from the ANZSCTS Steering Committee and a nominee from the Centre of Cardiovascular Research and Education in Therapeutics (CCRET).

**Policies for Participation in ANZSCTS Research Initiatives**

The ANZSCTS-RC encourages participation in research activities from surgeons and stakeholders; priority will be given to researchers affiliated with sites that currently contribute to the Database.

1. Data requests should be submitted in the form of a research proposal and must have clearly stated aims/objectives, methods, an analysis plan and a comprehensive background and rationale. This document needs to be completed in its entirety before submission to the ANZSCTS-RC for review.
2. Human Research and Ethics Committee (HREC) approval from the Principal Investigator’s institution must be sought for all projects. Research activities will not be approved by the ANZSCTS-RC without evidence from an NHMRC registered HREC.
3. Data analysis requests must be approval by the ANZSCTS-RC prior to commencement of analysis.
4. Secondary or further research arising from the original request must be submitted separately for approval.
5. Access to the data is subject to the ANZSCTS Database Research Specific Access Guidelines outlined on page 5 of this document.
6. Only the Program Manager and staff who report directly to the Program Manager have access to the Database and data extracts.
7. Under no circumstances will individual Units or Patient identifiers be made available to third parties. The exception may be linkage studies.
8. Requests that meet the ANZSCTS Research Specific Guidelines 1-5 will be charged a fee. See ‘Fees for Provision of Data’ on page 6 for an explanation of fees.
9. All requests for data must take appropriate timelines into account as these requests will need to be scheduled along with routine tasks of the ANZSCTS Database Program. The Committee cannot guarantee analyses will be completed to meet timelines if insufficient time has been given.
10. It is under the discretion of CCRET to prioritise the order of data requests upon approval by the ANZSCTS-RC. Direct requests/enquiries to the statistician regarding outstanding requests should be avoided, unless in response to a specific query from the statistician.
11. The Principal Investigator will be asked to submit a Progress Report every 6 months.
12. Investigators are encouraged to complete their research in a timely manner. Data analysis 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 analysis, and manuscripts should be submitted within one year following completion of analysis.
13. Investigators affiliated 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.
14. Any material or manuscripts to be published using data from ANZSCTS Database must be submitted to the ANZSCTS-RC for review.

**Data Request Application Dates**

The ANZSCTS-RC meets four times per year to review and discuss research proposals. All proposals are to be submitted on the application form and sent to **anzscts.sphpm@monash.edu** by the **last Friday in January, April, July, or October,** for review at the subsequent meeting.

Incomplete applications will be returned to the researcher for re-submission. Late applications will be reviewed at the following quarterly meeting.

**Student Participation in Research**

The ANZSCTS-RC encourages student participation in research activities. Student authorship will be carefully considered in light of candidature submission requirements.

**Maintaining ANZSCTS Database Data Security**

Under no circumstances will the ANZSCTS Database Program give third parties the entire dataset. In order to maintain ANZSCTS Database data security and integrity, all data analyses will be conducted and/or supervised by the CCRET. All data will remain under the custodianship of the CCRET.

**Human Research and Ethics Committee (HREC) approval**

Human Research and Ethics Committee (HREC) approval from the Principal Investigator’s institution must be sought for all projects. Research projects may be provisionally approved by the ANZSCTS RC pending HREC approval, however final approval to begin the research activities will not be granted without evidence from an NHMRC registered HREC. If HREC approval has already been obtained for the research project, please submit the HREC certificate with the application.

**Authorship Criteria**

As a guide, authorship should be based on the following criteria, outlined by the ICMJE:

* Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
* Drafting the work or revising it critically for important intellectual content;
* Final approval of the version to be published;
* Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

As stated by the ICMJE, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The ANZSCTS Database expends significant time, effort and other resources in collecting, cleaning and preparing the data for research. Because the national dataset comes from multiple centres, the investigators connected to the ANZSCTS Database are also exclusively positioned to take responsibility for the quality and accuracy of the data. For these reasons, consistent with the ICMJE criteria, it is expected that any manuscript arising from the ANZSCTS Database research dataset include a minimum of two authors from the ANZSCTS Database-RC and/or CCRET.

All persons who make substantial contributions to the manuscript should be offered authorship. The actual contributor/s to be named should depend on the input to the particular data exercise and should conform to the *Australian Code for the Responsible Conduct of Research.*

Authorship should be discussed openly among investigators. In the event of disagreement either on the list or order of authors, a meeting will be held with all authors to discuss. Persistent disagreements concerning authorships may be raised to the ANZSCTS Database-RC to offer arbitration.

**Abstract Submission and Manuscript Preparation**

It is expected that research proposals be progressed into manuscripts within one year following completion of analysis. The Data Custodian for the ANZSCTS Database will be listed as the Author for Correspondence on manuscript submissions. Prior to submission, all manuscripts must be reviewed by all authors and all members of the ANZSCTS-RC. Failure to do so may result in a retraction of all submitted manuscripts until all authors and members have been given the opportunity to review and comment.

**Acknowledgment Guidelines**

All publications AND presentations arising from ANZSCTS data must include in the ‘Acknowledgement’ section the following:

*The ANZSCTS National Cardiac Surgery Database Program is funded by the Department of Health (Victoria), the Clinical Excellence Commission (NSW), Queensland Health (QLD), and funding from individual Units. ANZSCTS Database Research activities are supported through a National Health and Medical Research Council Senior Research Fellowship and Program Grant awarded to C.M. Reid. The Database thanks all of the investigators, data managers, and institutions that participate in the Program.*

**ANZSCTS National Steering Committee Members**

The ANZSCTS National Steering Committee (SC) is the governing body for the ANZSCTS database and provides strategic decision-making activities, as well as overseeing the successful delivery of the ANZSCTS Database project.

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| --- | --- | --- |
| Mr. Gilbert ShardeyChair/ANZSCTS Surgeon/ASCRIL | Prof. Chris ReidData Custodian/Epidemiologist | Prof. Julian SmithANZSCTS Surgeon/RC Chair |
| Mr. Andrew NewcombANZSCTS Surgeon | Mr. Andrew CochraneANZSCTS Surgeon | Mr. Gregory RiceANZSCTS Surgeon |
| A/Prof. Jurgen Passage ANZSCTS Surgeon | Prof. Paul Bannon ANZSCTS Surgeon | Mr. Hugh WolfendenANZSCTS Surgeon |
| Mr. Deepak MehrotraANZSCTS Surgeon | Dr. Christopher ColeANZSCTS Surgeon | Dr. Sumit YadavANZSCTS Surgeon |
| Prof. Rob BakerPerfusionist | Dr. Robert CostaANZSCTS Surgeon | Mr. Ashutosh HardikarANZSCTS Surgeon |
| A/Prof. Rochelle WynneData Manager | Mr. Tom HunterData Manager | Ms. Gemma RicketsonManager, VCCN |
| Ms. Dervla O’ReganProject Lead, VCCN | Prof. Danny LiewEpidemiologist/CCRET  | Mrs. Angela BrennanCCRET |
| Dr. Lavinia TranProgram Manager, ANZSCTS Db | Dr. Jenni Williams-SpenceProgram Manager, ANZSCTS Db |  |

**ANZSCTS Database Research Committee (ANZSCTS-RC)**

The RC reviews all requests for data access and use for research purposes.

|  |  |  |
| --- | --- | --- |
| Prof. Julian SmithChair/ANZSCTS Surgeon  | Prof. Chris ReidData Custodian/Epidemiologist | Mr. Gilbert ShardeyChair/ANZSCTS Surgeon/ASCRIL |
| Mr. Andrew NewcombANZSCTS Surgeon | Prof. Rob BakerPerfusionist | Prof. Alistair RoyseANZSCTS Surgeon |
| Prof. Brian BuxtonANZSCTS Surgeon | Mr. Bruce DavisANZSCTS Surgeon | Mr. Cheng-Hon YapANZSCTS Surgeon |
| Mrs. Angela BrennanCCRET | Dr. Lavinia TranProgram Manager, ANZSCTS Db | Dr. Jenni Williams-SpenceProgram Manager, ANZSCTS Db |

**Access to Data**

Once approval to access the data is provided, researchers will have access to the data via the following methods:

* **Safe Haven**

The Centre of Cardiovascular Research and Education in Therapeutics (CCRET) utilises a Safe Haven system for investigators to remotely and securely access and analyse data from ANZSCTS Database. The Safe Haven enables investigators to download their research outputs from the server but the data file remains locked.

There are costs associated with access to Safe Haven. Investigators are encouraged to obtain a quote of their workstation fees from the ANZSCTS Database Program Manager early in the application process**.**

* **Attending CCRET**

Researchers may choose to attend the CCRET office to access data during office hours. A laptop will be provided with the researcher’s data and statistical packages to view and analyse the data. The CCRET office is located at 553 St Kilda Road, Melbourne.

* Researchers may receive a 10% random sample of data in order to aid the writing and checking of syntaxes. This will enable early detection and correction of errors, and streamline the data process.
* Statistical support may be offered depending on the project. Investigators must submit a robust statistical plan before access to data is permitted.

Data is only to be used for the research purposes it was intended and approved. If researchers wish to use the data for subsequent research projects, an additional request must be submitted to the ANZSCTS RC.

**ANZSCTS Database Research Specific Access Guidelines**

No requests by third parties for direct access to individual records will be approved under any circumstances as this contravenes privacy legislation and ethics approvals for the ANZSCTS Database Program granted by Monash University and participating hospitals.

1. Summary data may be provided by ANZSCTS Database staff, without approval from the ANZSCTS Steering Committee. Investigators are required to submit the proforma entitled ‘Hospital and Summary Data Requests’, for review by the ANZSTCS Database-RC. A caveat and conditions of use statement will be provided with the data.
2. Requests for aggregate data must be made to the Program Manager, for review and approval by the ANZSCTS-RC. Only de-identified data will be provided. A caveat and conditions of use statement will be provided with the data.
3. Researchers may request the CCRET to undertake specific analyses of data. In all cases, the researchers would subsequently be provided with resulting aggregate data only. A formal written request should be made to the ANZSCTS-RC for approval. A caveat and conditions of use statement will be provided with the data.
4. If a researcher requires linkage of other datasets to ANZSCTS data, the linkage must be performed within the CCRET or at either an Accredited Integrating Authority, or a Population Health Research Network Australian Data Linkage Unit. A formal written request should be made to the Program Manager, for review and approval by the ANZSCTS-RC.
5. If a researcher requires data from a particular hospital or hospitals, a specific ethics application approval from that hospital(s) will be required before data is made available. This ethics approval should be made jointly with the ANZSCTS Database Program.
6. If a hospital makes a specific request for its own performance data, beyond that available on the Hospital Data Report, this will be provided by the ANZSCTS Database Program. Such provision of data does not require Committee approval but the ANZSCTS-RC will require hospitals to submit the ‘Hospital and Summary Data Requests’ proforma. All requests for this category data should be made in writing to the Project Manager.

**Fees for Provision of Data as a Report**

The ANZSCTS-RC and the CCRET encourages research collaboration with Investigators. Research collaboration will not incur a fee.

Non-collaborative research will incur a fee for the provision of data as outlined below:

1. Requests and access to data from ANZSCTS Database are subject to strict access guidelines outlined above.
2. All data summaries and analyses (Categories 1-5) provided by the CCRET, may incur a fee to cover the costs for staff to undertake this work.
3. The charge per hour of work (or part thereof) is $150 (ex GST). The minimum number of hours charged is two. Thus, a data analysis/report requiring two and a half hours of staff time will be charged $450 (ex GST).
4. The fee of $150 (ex GST) per hour (or part thereof) is for basic tabulations and data extractions only. When detailed analysis of data is required (e.g. statistical comparisons, statistical modelling, etc.), a higher rate will be charged (available upon application).
5. CCRET will provide a cost estimate within 2 weeks of receipt of the request. Those requesting data must agree to these costs (in writing) before any data request will be met.

**SECTION A – APPLICANT DETAILS & CONTACT INFORMATION**

**PRINCIPAL INVESTIGATOR/PROJECT SUPERVISOR:**

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| --- | --- |
| **Title and Name** |  |
| **Appointment** |  |
| **ANZSCTS member** | Yes [ ]  No [ ]  |
| **Department** |  |
| **Institution** |  |
| **Mailing Address** |  |
| **Email** |  |
| **Contact Phone No.** |  |
| **Brief description of the role of this researcher for this project** |  |
| **Brief summary of relevant experience for this project** |  |
| ***Please attach CV (2 page max)*** |

**ASSOCIATE INVESTIGATOR / STUDENT:**

|  |  |
| --- | --- |
| **Title and Name** |  |
| **Appointment** |  |
| **ANZSCTS member** | Yes [ ]  No [ ]  |
| **Department** |  |
| **Institution** |  |
| **Mailing Address** |  |
| **Email** |  |
| **Contact Phone No.** |  |
| **Brief description of the role of this researcher for this project** |  |
| **Brief summary of relevant experience for this project** |  |
| ***Please attach CV (2 page max)*** |

Copy and paste tables for each additional investigator. ALL investigators must be listed. Any changes to investigators must be submitted in writing to the CCRET.

**SECTION B – DATA REQUEST**

1. **DATA CATEGORY REQUIRED (refer to page 6).**

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1. **PROJECT TITLE:**

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1. **WHAT IS YOUR RESEARCH QUESTION / PROPOSAL ?**

**(1 page minimum excluding references)** *N.B Only applications that provide sufficient information will be reviewed by the Research Committee.*

* 1. **Background information and preliminary data**

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* 1. **Objectives and hypotheses**

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* 1. **Summary (novelty and value adding to current knowledge)**

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* 1. **Methodology (detailed research and analysis plan)**

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* 1. **Project timeline**

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* 1. **References**

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1. **DATA REQUESTED**
	1. **Research cohort**

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* 1. **Time period**

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* 1. **List of hospitals**

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1. **WHAT STATISTICAL ANALYSES ARE REQUIRED FOR THIS PROPOSAL?**

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1. **HAS HUMAN RESEARCH ETHICS COMMITTEE (HREC) APPROVAL BEEN OBTAINED?**

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| Yes [ ]  | Date of approval \_\_\_\_/\_\_\_/\_\_\_\_\_\_ to \_\_\_/\_\_\_/\_\_\_\_\_\_\_ Please submit the certificate of HREC approval with your application. |
|  |  |
| No [ ]  | If HREC approval has not been obtained, please provide reason.

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| N.B – Projects with HREC approval will strengthen your application to the ANZSCTS Research Committee.  |

**SECTION C – UTILISATION OF DATA**

**How will you utilise this data?** Check all that apply and describe in detail.

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| --- | --- |
| **[ ]  Publications** | Details: |
| **[ ]  Oral Presentation** | Local:  | International:  |
| **[ ]  Quality Assurance**  | Details:  |
| **[ ]  Student Project** | Details:  |

**SECTION D: CHECKLIST**

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| [ ]  | All investigators are listed in section A |
| [ ]  | All CVs are attached to request |
| [ ]  | HREC approval evidence attached |

**PRINCIPAL INVESTIGATOR:**

|  |
| --- |
| **NAME:**  |
| **SIGNATURE:** | **DATE** |

**Please email completed proforma to ANZSCTS Database Program:** **anzscts.sphpm@monash.edu**

**For any queries relating to ANZSCTS Database Research, please contact the Research Program Manager for the ANZSCTS Database:**

**Dr Lavinia Tran**Tel: +61 3 9903 0528

Email: Lavinia.Tran@monash.edu

CCRET, School of Public Health and Preventive Medicine

Monash University

553 St Kilda Road

Melbourne Victoria 3004

**SECTION E – *ANZSCTS-RC use only.***

1. **Project outcome**

[ ]  Approved [ ]  Reject [ ]  Pending

 Review date:

Comments:

 Date:

1. **Data Release:**

 Prepared by:

 Date File Used:

 File Name:

 File Type:

 File Location:

 Actioned and Released by:

 Date: