TAVI Research and Publications Committee

ACOR
Australasian Cardiac Outcomes Registry Ltd

Process for the Data Access Requests

1. All requests must be made in writing to the TAVI Research and Publications Committee (RPC) and include the following headings:

   - Project Title
   - Principle Investigator/co – investigators
   - Proposed research plan
     - Background
     - Specific Aims and Objectives
     - Methods and Statistical Analysis Plan
     - Source of funding
     - Proposed publication/presentation plan
   - Template to be in the form of an extended abstract
   - **DO NOT EXCEED 4 PAGES (included references and tables)**

2. The following **criteria** must be adhered to:

   - 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 investigators institution
   - The requirement for risk – adjusted outcome analysis
   - 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 ACOR
   - 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

3. The following support **documentation** needs to accompany your submission to the TAVI RPC:

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

All research requests must comply with the Acknowledgment and Authorship guidelines outlined in the ACOR Data Access, Submission, Review & Retrieval Policy.

TAVI DATA REQUEST FORM

Australasian Cardiac Outcomes Registry Ltd

- All data requests must adhere to the ACOR Publications Policy and User Agreement 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 clearly.

Please return your application via email to:

ACOR Project Officer
Email: info@acor.net.au
Phone: 02 9226 7994

SECTION 1: APPLICANT DETAILS				
All correspondence regarding this application should be directed to:				
Title		**Name**		
Institution				
Postal Address				
Phone		**Mobile**		
Email				

PROJECT LEAD, PRINCIPAL INVESTIGATOR OR SUPERVISOR:		☐ SAME AS CONTACT PERSON ABOVE	
Title		**Name**	
Institution			
Postal Address			
Phone		**Mobile**	
Email			

I currently submit data to the ACOR TAVI Registry YES ☐ NO ☐

LIST ALL OTHER RESEARCHERS NAMED ON THIS PROJECT:		
ADDITIONAL RESEARCHERS:		

REQUESTING PARTY		
Organisation:		
	☐ Research/Academic Institution	☐ Government Department
	☐ Registry	☐ Treating Physician / Clinical Interest
	☐ Industry (please specify)	
	☐ Other (please specify)	

SECTION 2: PURPOSE OF THE DATA REQUEST			
☐ Academic Research	☐ Clinical Investigation	☐ Planning	☐ Commercial / Business
☐ Other (please specify)			

SECTION 3: TYPE OF DATA REQUEST		
☐ Raw Data (please specify)	☐ ACOR Summary Data (ACOR run analysis)	☐ Data Linkage
☐ Other (please specify)		

SECTION 4: WOULD YOU CONSIDER COLLABORATING WITH ANOTHER SIMILAR RESEARCH REQUESTEE?		
☐ Yes	☐ No	

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 incl. aims, methods and 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 be completed manuscript will be submitted, Details of conferences/forums where data will be discussed) ○ References Refer to Sections 5&6 of the ACOR Data Access Policy for more information	
SHORT TITLE OF PROJECT:	
PROJECT HYPOTHESIS:	

1. Scientific rationale: Please provide detail (attach additional pages as required).

2. Specify the data fields you are requesting from ACOR. Please review the ACOR Data Dictionary and include all data fields required. Attach additional pages as required.

3. Describe the projects resources. Please provide information about how the project will be resourced at your institution (including funding details). Please also indicated what additional support from ACOR is required. Attach additional pages as required.

4. Provide the projects timeframe. Include study end point (attach additional pages as required).

5. Target Audience / Proposed Output: Include details of conferences/forums data will be discussed.

6. References:

SECTION 5: ETHICS APPROVAL

Any research that extends beyond the approved ACOR 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 ethics 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 HRECs 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 ACOR Data Access Policy and the ACOR Publications Policy. I agree to all the terms outlined in both documents. I agree to undertake all ACOR related activities in accordance with the current protocol and provisions of the reviewing human research ethics committee (HREC) in keeping with the Therapeutic Goods Administration's Guidelines for Good Clinical Practice and all relevant State, Territory 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 ACOR 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 ACOR, whether in the form of data, reports, 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**	

Once the proposal has been approved, the TAVI RPC will provide the specified information to the researcher on receipt of a signed User Agreement undertaking to:

a) Use the information only for research purpose stated in their application

b) Store the information in a secure manner and only for an agreed time period related to the purpose of the research

c) Not provide the information to any other person other than an associate researcher nominated in the application;

d) Not link the information with any other data set; and

e) Not seek to identify individual patients by any process, including by attempting linkage with another data set