



ANZSCTS Database Program – Supporting Information for Research Project Ethics Applications

All ANZSCTS Database research projects must secure independent low-risk ethics approval before access to the data will be granted. Previous researchers have indicated that some ethics committees do not have a good understanding of clinical quality registries and therefore request additional information following review, or do not approve applications to use the data held by the ANZSCTS Database for research. The following information may assist you in preparation of your application to better inform ethics committees about the processes of the Database. You are welcome to use the text as is, or customise it as you require.

The ANZSCTS Cardiac Surgery Database is a clinical quality registry that collects data on the treatment and outcomes of patients undergoing cardiothoracic surgery across contributing sites in Australia and New Zealand. The Database is hosted by Monash University in Melbourne, Victoria, and data is managed and stored according to the highest industry standards. The primary function of the Database is a quality assurance program consisting of quarterly peer review of key performance indicators for each hospital. The secondary purpose of the Database is for use as a research dataset for projects furthering knowledge in the cardiothoracic surgery domain.

The Database uses an opt-off consent model, whereby patients eligible for inclusion are provided with an information sheet outlining the purpose of the Database, the nature of the data collected, how that data will be used, and how they can have their identifying information removed, should they not wish to participate. The patient information sheet expressly states that the information collected may be used for further research.

The ANZSCTS Database has its primary ethics approval through the Alfred Health HREC, with reciprocal approval via the Monash University HREC. The approvals permit the disclosure of de-identified data to third parties for the purpose of research, provided those projects have independent individual ethics approval. De-identified data does not include any identifiable patient information (names, UR or Medicare numbers, addresses, phone numbers) or hospital or surgeon level identifiers.

De-identified data can be accessed by one of two methods. The first is through physical attendance at the Database office, where a secure laptop with a copy of the dataset can be used to conduct analyses. The laptop has the internet, USB ports, and SD card slots disabled, preventing the user from being able to transfer or copy the dataset. The second is through a secure online environment, known as Safe Haven, that allows researchers to perform analyses remotely without the ability to copy, move, or export the data out of the secure platform. Researchers are not supplied with a full copy of the dataset for use outside of these environments under any circumstances. These procedures significantly limit the potential risk for re-identification of the data.

In the case where the research project involves data linkage and therefore requires patient identifiers, the Database has ethics approval to supply this information to Accredited Integrating Authorities or Population Health Research Network Australian Data Linkage Units. Identifiable data will not be released to any other researchers or organisations under any circumstances.

All researchers requiring access to ANZSCTS Database data must submit an application to the ANZSCTS Database dedicated Research Committee, which comprises academics, cardiac surgeons, and statistical experts. The Database Research Committee assess each application based on scientific and clinical merit, originality, and feasibility. Only projects deemed appropriate and likely to contribute to knowledge regarding cardiothoracic surgery are approved. All approved projects require independent ethics approval before access to the data is granted. Based on the ethics approvals held by the Database, the de-identified and existing nature of the data, and the limited data access methods for researchers, we believe a low-risk ethics approval is appropriate for this purpose.

If you require any further information for your ethics application, or have any questions about the above information, please contact the ANZSCTS Database Program Manager:

Dr Jenni Williams-Spence

Phone: 03 9903 0229

Email: jenni.williams-spence@monash.edu