# Information to assist with ANZTADC low risk ethics applications

These paragraphs may cut and pasted into your local low and negligible ethics application form. If there is any other information that your require then please contact ANZTADC (details at the end of the document).

# Title

The Web based Anaesthetic Incident Reporting System from the Australian and New Zealand Tripartite Anaesthetic Data Committee.

# Description

The project's aim is to collect nonidentifiable data relating to incidents and near misses that occur during anaesthesia. The project will not replace or interfere with existing hospital incident recording and management systems but merely forward a nonidentifiable subset of the data to a national database. Likewise the open disclosure policy of the hospital will not be affected or circumvented by this project. The national database will monitor these and similar incidents and then work out strategies at a national level for preventing such incidents in the future. It is therefore a system with the potential to bring about substantial improvements in public safety during anaesthesia.

The Australian and New Zealand Tripartite Anaesthetic Data Committee (ANZTADC) is supported and funded by the Australian and New Zealand College of Anaesthetists(ANZCA), the Australian Society of Anaesthetists(ASA) and the New Zealand Society of Anaesthetists(NZSA.

The ultimate aim is to improve patient quality and safety during anaesthesia. In order to prevent similar incidents from occurring in the future the following communication methods will be employed. Alerts will be sent electronically, newsletters and bulletins will be produced and publications will be submitted to peer reviewed journals. There will be online access to a knowledge base which describes how to avoid certain incidents. Individual patient data will not be used in these publications and only summarised results will be published.

All the data collected will be deidentified to a nonidentifiable state before the data is entered into the system. Personal data or sensitive data will not be stored. This will be checked by a data officer before analysis and if necessary cleansed by deleting any data that may have the potential for identification including data that might allow surrogate identification. Secure methods will be used to transit and store the data.

# Frequently asked questions

## Ethical considerations

* + The National Health and Medical Research Council guidelines advise that Ethics approval is not always required for quality assurance activities. However they do recommend following the same principles that ethics committees consider when dealing with patient data. ANZTADC can supply documentation to assist with ethics approval if your ethics committee requires a review.
	+ Privacy legislation – ANZTADC complies with the Australian Privacy Principles that were released in March 2014 and can supply documentation to support this statement if required by your organisation.

## Surrogate identification

Steps will be taken to prevent surrogate identification.

* Ages will be grouped into ranges to prevent identification using individual age and rare conditions.
* Location of the incident will not be stored to prevent matching using location and rare condition.
* Metrics of the patient such as BMI will be grouped to prevent matching using BMI and rare condition.
* Other specific items will also be grouped.
* The results published will either contain multiple grouped cases or the data will be further de-identified to protect the identity of patients and anaesthetists.

## Cost

WebAIRS is included as a member service of ANZTADC and consequently there is no cost for members of ANZCA, the ASA or the NZSA. As webAIRS provides a tool to complete part of the practice evaluation category for ANZCA CPD taking part in the program may reduce the time taken the comply with this aspect of CPD which in turn is required for medical registration in Australia. Therefore taking part in the program may help to reduce hospital costs.

## Anonymity

* The system is completely anonymous by default. However if the user wishes to send an email with some information to their department quality and safety officer they can do so. The latter feature is completely optional.
* The user may optionally send an email to themselves with the incident ID number. This will allow that user to log back in and view the results of the analysis.
* The user may optionally send that ID number to their local quality and safety officer so that the incident can be reviewed by the anaesthetic department.
* The user may optionally send an email with CPD credits to themselves.

## Confidentiality of the data

* The proposed quality assurance activity would be conducted by the anaesthetist who observed the incident and who normally has access to the patient records at the local site. The persons at ANZTADC who have access would only view none identifiable data (that is would not view patient records) and would have agreed to confidentiality agreements in the form of a memorandum of agreement. In addition as the activity has approved for Qualified Privilege by the Department of Health and Ageing all those with access to the data are bound to confidentiality by Australian Federal Law.
* The data is deidentified so individual cases cannot be distinguished from other cases in the registry. The data is further cleansed and any surrogate identifiers removed before being analysed. The data stored is therefore not personal data as defined by the Australian Privacy Principles 2014.
* The identity of the person who submitted the case is not recorded within the registry.
* The name of the hospital may optionally be stored as an encrypted key and therefore nonidentifiable using the database alone. The encrypted key would also be required which is not stored in the database itself.
* The data is held in a secure server, data is transferred encrypted and authentication is required when logging into the server.

## Retrieval of data by the participating hospital

* + There are technical difficulties in having an anonymous system but still being able to extract data for one hospital or one anaesthetist. At present every incident is allocated a randomly generated incident number. An individual can optionally send this number by email to themselves and/or their local administrator. The person accessing the data would first have to log in (first security step) then enter a valid incident number (second security step). This principle has been extended to generate an encrypted anonymous name for each hospital and by this means it would be possible to extract the data for this location. Individual hospitals can opt to use the system or not as they choose. If an individual anaesthetist opts to send the incident ID to their local QA officer then it will be able to be retrieved by that person but if not then it won’t be able to be retrieved in this way. Individual anaesthetists will therefore be able to opt in or not as per the current anonymous or not option when they enter each separate incident.

## Analysis of the incidents

* + - The Alerts and Analysis Sub Committee (Volunteer Anaesthetists) of the Australian and New Zealand Tripartite Anaesthetic Data Committee (ANZTADC). ANZTADC has started analysing the incidents.
	+ Results from this data have been used in presentations at the national scientific meetings of ANZCA, the ASA and NZSA since May 2011.
	+ Reports will be sent to fellows of ANZCA via the bulletin, members of the ASA and NZSA by Newsletter. They will also be permanently shown in the member area of the ANZTADC website. Analysis on individual cases will not be published in case there is ‘surrogate identification’. Periodically methods for improvement in quality and safety as well as suggestions for methods to avoid certain incidents will be promulgated.

## CPD Credits

* + The system is approved in the Practice Evaluation Category of the new ANZCA CPD program at 2 credits per hour. If you enter the time taken to collect the information the system will add the time taken to enter the information and then calculate the credits for you. You can then either print out a certificate or have confirmation emailed to you. No permanent record of your activity is stored on the system. An alternative would be to record the activity in your diary.

## Risks and Burdens

* There are no significant additional risks or burdens to patients or to staff. The patients will have no requirements in regard to the ANZTADC project. The system will streamline the additional work for healthcare workers and it will award CPD credits in the audit category. In the latter regard it will enable health workers to gain credits in an otherwise difficult category for CPD credits. However, if the healthcare worker chooses to opt out then this is their choice and there will be no repercussion. The HealthCare providers and Institutions will benefit from the increased quality and safety in anaesthesia at their sites and it will be ensured that existing systems are not compromised and attempts will be made to improve the local hospital system if requested.

## Overlap with research

The activity does not involve a deviation from routine clinical care.

It does not involve randomisation.

It does not seek information beyond that involved in routine clinical care.

## Border implications

It does not infringe any rights, privacy or professional reputation of carers, health providers or institutions. This is further protected because the data collected will not include identifying data relating to health professionals or institutions.

## Feedback

* If you have any other questions of if your ethics committee requires any other information please contact ANZTADC at anztadc@anzca.edu.au