Statement of assessment of ethical considerations regarding the use of WebAIRS for quality assurance

Project Title

The project title is the WebBased Anaesthetic Incident Recording and Reporting System (WebAIRS) from the Australian and New Zealand Tripartite Anaesthetic Data Committee (ANZTADC).

Project Description

ANZTADC is funded and supported by the Australian and New Zealand College of Anaesthetists (ANZCA), the Australian Society of Anaesthetists (ASA) and the New Zealand Society of Anaesthetists (NZSA). ANZTADC has developed the WebAIRS software which facilitates the collection and analysis of non-identifiable data relating to incidents and near misses that relate to anaesthesia. This data will then be used to monitor these and similar incidents and devise strategies at a national level for preventing similar incidents in the future. These strategies will be published in the newsletters and bulletins of the parent organisations and articles will be submitted to "peer reviewed" journals. There will be online access to a knowledge base which describes how to avoid certain incidents. These publications will use summarised results and steps will be taken to avoid surrogate identification of the registered sites, the staff involved or the patients involved.

Existing hospital incident recording and management systems will co-exist with the WebAIRS system and will not be affected by the project. Likewise the open disclosure policy of the hospital will not be affected or circumvented.

All the data collected will be de-identified to a non-identifiable form before the data is entered into the system. 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. Secure methods will be used to transit and store the data. The data will be stored securely as an enduring resource of non-identifiable incident data to allow future improvements in patient safety thus forming a epidemiological record of anaesthetic incident data for future generations.

Grounds for asserting compliance with ethical consideration and appropriate oversight.

The primary purpose for which the data is collected and used is for Quality Assurance at the local institution where the patient is treated. A de-identified subset of this data is forwarded to WebAIRS to be held and analysed nationally. The use of the de-identified data for the secondary purpose of Quality Assurance complies with the Australian Privacy Principles and with the National Medical Health and Research Council (NHMRC) recommendations regarding the ethical use of Quality Assurance (QA) data. Once the data has been de-identified in this manner it is no longer personal data and therefore not subject to the privacy act if it continues to be used for quality assurance purposes. The Australian Privacy principles recognise the need for data to be collected in the interests of patient safety and ANZTADC fulfils the requirements for improvements in patient safety.

Regarding ethical consideration the National Health and Medical Research Council has referenced three sources for guidance **(1,2,3)** The first of these has been rescinded**(1)** but it is still referred to in the latest advice published in the document titled ***"Ethical Considerations in Quality Assurance and Evaluation Activities"*** released In March 2014**(3)**. This document explains the ethical considerations when undertaking quality assurance activities. This document in turn takes into account the new Australian Privacy Principles which were also released in March 2014**(4)**. One of the purposes of these documents**(1-4)** was to clarify the position regarding quality assurance activities with regard to the privacy act and with regard to the need for ethical review.

On page 2 of *"Ethical Considerations in Quality Assurance and Evaluation Activities"* **(3)** it states *"In some circumstances, attempts to clearly separate QA from research are unhelpful. Moreover, QA, evaluation and research exist on a continuum of activity, and work that begins as one form of activity can evolve into another over time. Importantly, QA and evaluation commonly involve minimal risk, burden or inconvenience to participants, and, while some level of oversight is necessary, Human Research Ethics Committee (HREC) review processes are often not the optimal pathway for review of these activities. What really matters is that:*

> *Participants in QA/evaluation are afforded appropriate protections and respect.*
> *QA and/or evaluation is undertaken to generate outcomes that are used to assess and/or improve service provision.*
> *Those who undertake QA and/or evaluation adhere to relevant ethical principles and state, territory and Commonwealth legislation.*
> *Organisations provide guidance and oversight to ensure activities are conducted ethically including a pathway to address concerns.*

This advice is designed to assist organisations in deciding the appropriate level of oversight for QA and evaluation. Organisations should consider this guidance when developing policies/advice on QA activities, particularly as related to the triggers for ethical review listed below."

The document [3] continues with this section

"Appropriate Oversight of Quality Assurance and Evaluation

Irrespective of whether an activity is QA, evaluation or research, the activity must be conducted in a way that is ethical. This should include consideration of whether the people involved will be exposed to any harm as a result of the activity. Those conducting the activity need to consider a range of issues including consent, privacy, relevant legislation, national/professional standards and whether ethical review is required.

In many situations, oversight of the activity is required, but ethical review is not necessary. *These include situations where:*

1. The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols;

2. The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;

. The data being collected and analysed is not linked to individuals; and

. None of the triggers for consideration of ethical review (listed below at point (e)) are present.

Organisations should develop policies on QA/evaluation which provide guidance for oversight of QA or evaluation activities. It is recommended that such policies address the following issues:

Appropriate Oversight Checklist

Item	WebAIRS
The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols	**Yes**
The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;	**Yes**
The data being collected and analysed is not linked to individuals;	**It is Not linked**
and None of the triggers for consideration of ethical review (listed below at point (e)) are present.	**No triggers present** (See Checklist below)

Collection and use of data for QA/evaluation: Checklist

Risks and burdens to participants	WebAIRS
Physical risks	**None**
Psychological, spiritual and social harm or distress (e.g. stigmatisation or discrimination) and may involve people associated with participants	**The data is de-identified to the point where reidentification is a neglible risk. Therefore mitigating these risks to a neglible level.**
Consideration should be given as to whether the proposed QA/evaluation activity poses any risks for participants beyond those routinely experienced in the environment where QA/ evaluation is being conducted.	**No additional risks beyond those routinely routinely experienced in the environment where QA/ evaluation is being conducted.**
Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, e.g. persistent phone calls, additional hospital visits or lengthy questionnaires.	**No additional patient contact and therefore no burdens.**
Guidance to assist in ensuring that consent from participants, where required, is adequate.	**The data has been collected and de-identified within the primary purpose of routine care and internal quality assurance purposes. Consent is routinely obtained on admission to hospital. Once the data is de-identified for the primary purpose of quality assurance within the institution, it is no longer personal data and therefore additonal consent is not required.**
Guidance on the provision of information to participants including related to the use of an opt-out approach. The opt-out approach is a method used in the recruitment of participants into an activity where information is provided to the potential participant regarding the activity and their involvement and where their participation is presumed unless they take action to decline to participate.	**Most hospitals have an option on the hospital admission form with regard to using their data for quality assurance purposes. Therefore the hospital must comply with the consent option when selecting the data for internal quality assurance processes. Once it has been de-identified as part of the internal QA process it is no longer personal data.**

Privacy and data security

Item	WebAIRS
Advice on the management of data (i.e. how it is	**The responsibility for the identified data**

collected, stored, used and destroyed).	**(patient medical records) lies with the hospital.** **WebAIRS data is no longer personal data but it is stored securely and transferred securely. It is also protected by Qualified Privilege from the Dept of Health. The data is used for quality assurance purposes. As it is not personal data there is no requirement to destroy the data. This data will be stored securely as an enduring resource of non-identifiable incident data to allow future improvements in patient safety thus forming a epidemiological record of anaesthetic incident data for future generations.**
Advice on who is able to access data.	**The WebAIRS data is accessed by the treating practitioner, registered quality and safety personnel employed by the hospital, WebAIRS analysers and WebAIRS adminsitrators. There are strict controls on who has access to the data which includes using secure login credentials. All these registered users only have access to the de-identified data which is therefore not personal data.**
Advice on confidentiality.	**Not applicable to de-identified data however WebAIRS still has strict access to the system by a login process and also the data is protected by Qualified Privilege.**
Relevant legislative requirements including: Privacy Act 1988. State and territory privacy acts. Any other relevant Commonwealth, state, or territory legislation or guidance.	**The WebAIRS system is compliant.**
Relevant national/professional standards:	**The WebAIRS system is compliant.**
Organisations should provide a listing of relevant documents.	**No documents are accessed by WebAIRS.**

Triggers for consideration of ethical review checklist

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Item	WebAIRS
Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.	**Not Applicable** - As the participants, providers and organisations are not identifiable.
Secondary use of data - using data or analysis from QA or evaluation activities for another purpose.	**The data will not be used for any other purpose.**
Gathering information about the participant beyond that which is collected routinely.	**All the information will be data that is routinely collected.**
Information may include biospecimens or additional investigations.	**The information does not include these items.**
Testing of non-standard (innovative) protocols or equipment	**The project does not include testing of non-standard (innovative) protocols or equipment.**
Comparison of cohorts.	**The project does not include comparison of**

	cohorts.
Randomisation or the use of control groups or placebos.	**The project does not involve** "Randomisation or the use of control groups or placebos".
Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity.	**The analysis does not involve the "**Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity."

Where ethical review by an HREC is not required, organisations should consider providing a statement which affirms that an alternative approach to ethical review was considered to be appropriate for the specific QA/evaluation activity if this is required for publication purposes.

The Relevance of the Australian Privacy Principles (March 2014)[4] to the collection of data by WebAIRS

When a person is admitted to a health care institution, under normal circumstances that person gives consent to the use of their *Health Information*[4] for the primary purpose of provision of health care. This extends to the collection of data at that institution for the purpose of maintaining quality standards and other forms of benchmarking. It also extends to the use of the data for billing purposes and to comply with standards imposed by state and federal legal requirements. Written consent is obtained for each of these purposes.

WebAIRS collects de-identified data at a national level for quality and safety purposes, which is derived from the *Health Information* collected for the primary purpose of providing health care.

The following Australian Privacy Principles (APPs) are relevant to the collection of information by WebAIRS.

> *"B.53 Personal information is de-identified 'if the information is no longer about an identifiable individual or an individual who is reasonably identifiable' (s 6(1)). De-identified information is not 'personal information' (see paragraphs B.79–B.90)."* **(4)**

> *"6.73 Personal information is de-identified 'if the information is no longer about an identifiable individual or an individual who is reasonably identifiable' (s 6(1))."* **(4)**

WebAIRS data complies with both of these principles.

Regarding the de-identification process prior to the collection of the data by WebAIRS, the anaesthetist or quality assurance staff at the institution that accessed personal data are subject to the Privacy Act 1988[5] and Australian Privacy Regulation 2013[6]. However the initial de-identification is permitted because at this point of the process the data is still being used for the primary purpose of quality assurance within the institution. After the data is de-identified then it is no longer personal health data and no longer subject to the same privacy restrictions.

Secondly de-identification is permitted under the privacy legislation as a primary purpose in its own right. These APPs support this statement.

> " 6.22 Examples of where an individual may reasonably expect their personal information to be used or disclosed for a secondary purpose include where:

- the secondary purpose is a normal internal business practice, such as as auditing, business planning, billing or de-identifying the personal information." **(4)**

6.25 Examples of where a secondary purpose is related to the primary purpose of collection include:

- an APP entity uses personal information for the purpose of de-identifying the information. " **(4)**

6.28 states that *"The use of sensitive information for the purpose of de-identifying the information will also be directly related to the primary purpose of collection."* **(4)**

Thirdly there are other permitted health situations that might be applied but it is not neccessary to argue the alternative cases as WebAIRS has a strong argument that use of the data is permitted under the APPs ; B53, 6.73, 6.22, 6.25 and 6.28.

The ANZTADC incident recording and reporting project

It is affirmed that an alternative approach to ethical review was considered to be appropriate for this Quality Assurance activity. It is confirmed that there will be appropriate oversight of the activity as described in this document.

On Behalf of _____(enter site name)

Name _____ Position ___ _____

Signature _____ Date _____

References

1. When does quality assurance in health care require independent ethical review? NHMRC 2003, http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e46.pdf

2. Australasian Evaluation Society Incorporated Guidelines for the Ethical Conduct of Evaluations, August 2010, http://www.aes.asn.au/images/stories/files/About/Documents%20-%20ongoing/AES%20Guidlines10.pdf

3. ETHICAL CONSIDERATIONS IN QUALITY ASSURANCE AND EVALUATION ACTIVITIES National Health and Medical Research Council | Published: March 2014. http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf Accessed 17/6/14.

4. Australian Privacy Principles guidelines version 1 March_2014 APP_guidelines_complete_version_1_March_2014.pdf http://www.oaic.gov.au/privacy/applying-privacy-law/app-guidelines/ Accessed 23/3/14.

5. Privacy fact sheet 17 Australian Privacy Principles http://www.oaic.gov.au/images/documents/privacy/privacy-resources/privacy-fact-sheets/privacy-fact-sheet-17-australian-privacy-principles_2.pdf Accessed 22/3/14.

6. Privacy Act 1988 http://www.comlaw.gov.au/Details/C2014C00076/Download Accessed 23/3/14.