**Department for Health and Wellbeing - Quality Assurance Projects**

Guidelines for DHW staff

**Aim**

This guide aims to assist DHW staff undertaking quality assurance (QA) activities by outlining the processes and determining when ethical review by the DHW Human Research Ethics Committee (HREC) is required. The need for such review is based on identifying any ethical risks that such activities may pose to participants. This guideline provides a checklist to assist in this task and instructions on how to proceed once a QA project is identified.

Quality improvement activities may also be referred to as continuous improvement (CI), quality improvement (QI), service improvement, an evaluation, an audit or gap analysis.

**Background information**

As per the *Ethical Considerations in Quality Assurance and Evaluation Activities* there can be uncertainty about what level of oversight QA and evaluation activities require and there can be confusion about whether an activity is research or evaluation or QA. This can be because QA and evaluation activities may include the use of methods or approaches also used in research such as surveys and observation.

Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity.

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.

Irrespective of whether an activity is QA, evaluation or research, the activity must be conducted in a way that is ethical.

**Quality Improvement Risk Checklist**

Use of the following checklist may assist DHW staff in identifying when a proposed QA activity entails ethical ‘risks’.

If responses to all of the above statements in the checklist are true, then no ethical risks have been identified with this project and no ethics review is required.

|  |  |
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| Risk Decision Checklist | Yes/No |
| The collection of information about participants is not beyond that which is collected routinely. Information may include additional investigations. |  |
| The data being collected and analysed is expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained. |  |
| The activity is being undertaken by a DHW staff member or a student on placement with DHW. |  |
| There is no risk or burden to participants beyond those routinely experienced in the environment where the activity is being conducted.*Risks include not only physical risks, but also psychological, spiritual and social harm or distress e.g. stigmatisation or discrimination) and may involve people associated with participants.**Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, e.g. persistent phone calls, additional hospital visits or lengthy questionnaires.* |  |
| The data being collected and analysed is not linked to individuals or has a process for de-identifying individuals*See National Statement Chapter 3, Element 4 ‘Identifiability of Information’ for more detail* |  |
| There is no secondary use of data. i.e., The data or analysis from this activity will not be used for another purpose. |  |
| Data will be stored for at least 7 years following the activity in accordance with the relevant State Records General Disposal Schedule |  |
| Data will be accessed by a DHW employee who would normally have access to this data through either their employment or in the case of a student, during the course of their placement with DHW. |  |
| The confidentiality of participants will be maintained in any publication arising from the activity. The identity of an individual will be maintained by not revealing details or characteristics which would have the potential to reveal the participant’s identity. |  |
| Data will not be obtained from other sources or organisations. Eg. Medicare, Health Insurance Company, another health service. |  |
| The activity does not involve 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 QI activity.Examples of minority/vulnerable groups include Aboriginal or Torres Strait Islander peoples, ethnic, religious or minority groups.  |  |
| The activity does not involve testing of a non-standard protocol or equipment. |  |
| The activity does not involve a comparison of cohorts. |  |
| The activity is seeking consent from participants to engage in interviews, focus groups or other procedures related to the activity, if applicable. |  |
| The activity is **not** supported by a competitive research grant. Ie. NHMRC Project Grant, ARC Grant etc. |  |
| The activity is **not** seeking to establish a registry/databank |  |

If the answer to each question is **yes**, then the project can be classified as quality assurance. The project team should seek relevant approvals from their line manager or higher, depending on the budget and scope of the project. No ethics review is required.

If the answer to any question is **no** and the project team is of the opinion that the project is quality assurance, the investigator should email the project details and rationale for why they think it is a QA project to health.humanresearchethicscommittee@sa.gov.au. The Executive Officer will liaise with the HREC Chair to review the proposal and advise the appropriate pathway for the project.