**CALVARY HEALTH CARE Bruce**

**HUMAN RESEARCH ETHICS COMMITTEE**

**QUALITY ASSURANCE/AUDIT AND ETHICAL REVIEW**

**Should an Application for Ethical Review be submitted to an HREC?**

Under the *National Statement on Ethical Conduct in Research Involving Humans*, any research project involving humans must be submitted to an HREC for ethical review. This checklist is intended for use with projects where there is some doubt as to whether the project involves research or audit/QA.

The NHMRC publications “*When does quality assurance in health care require independent ethical review?”* and “ Ethical consideration in Quality Assurance and Evaluation Activities” served as the basis for this checklist,

*To place a check in the relevant box in the following checklist, double click on the box and select the “checked” option.*

1. Does the proposal involve any significant alteration to the routine care or service provided to the individuals?

[ ]  Yes [ ]  No

If yes, provide details:

1. Does the proposal pose any risks for participants beyond those of their routine care, treatment or activity?

[ ]  Yes [ ]  No

If yes, provide details:

1. Does the proposal impose a burden on participants beyond that experienced in their routine care, treatment or activity?

[ ]  Yes [ ]  No

If yes, provide details:

1. Does the proposal seek to gather information beyond that collected in routine care or service?

[ ]  Yes [ ]  No

If yes, provide details:

1. Is the proposed activity to be conducted by a person who does not normally have access to the client’s health or other records for care or a directly related secondary purpose?

[ ]  Yes [ ]  No

If yes, provide details:

1. (a) Is the proposed activity covered by the National Privacy Principles (NPPs) of the Commonwealth *Privacy Act* 1988 (i.e. is a private sector organisation involved in the collection, use or disclosure of information)?

[ ]  Yes [ ]  No

(b) If yes, is the consent from participants *inadequate* or is the activity *inconsistent* with NPP 2.1(a)?

[ ]  Yes [ ]  No

If yes, provide details:

(c) You should note that the activity must be reviewed by an HREC if the activity involves the **collection** of health information (by an organisation in the private sector) under NPP 10.3(d)(iii) for the purposes of

*[ ]  Research* relevant to public health or public safety

*[ ]  Compilation or analysis of statistics* relevant to public health or public safety

*[ ]  Management, funding or monitoring* of a health service

or if the activity involves the **use** or **disclosure** of health information (by an organisation in the private sector) under NPP 2.1(d)(ii) for the purposes of

*[ ]  Research* relevant to public health or public safety

*[ ]  Compilation or analysis of statistics* relevant to public health or public safety

1. Does the proposal risk breaching the confidentiality of any individual’s personal information, beyond that experienced in the provision of routine care or service?

[ ]  Yes [ ]  No

If yes, provide details:

1. Does the proposal involve randomization or the use of a control group or placebo?

[ ]  Yes [ ]  No

If yes, provide details:

1. Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health providers or institutions?

[ ]  Yes [ ]  No

If yes, provide details:

1. Does the proposed activity to be conducted outside the premises of Calvary Health Care , Bruce

[ ]  Yes [ ]  No

1. Does the project only exercises that pose negligible risk, burden or inconvenience to participants?

[ ]  Yes [ ]  No

12 Does this proposed activity is component of an academic training (Honours, Masters or PhDs) or involve staff from external institutions

[ ]  Yes [ ]  No

13 Does the proposed activity envisage the secondary use of the data (using data or analysis from Quality improvement activity for another purpose)?

[ ]  Yes [ ]  No

14 Does the proposed activity involves the comparison of cohorts

[ ]  Yes [ ]  No

15) Does the proposed activity require the consent of participants in the activity?

[ ]  Yes [ ]  No

16) Does the proposed activity involves the targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of the data collected or analysed as a part of this activity

[ ]  Yes [ ]  No

17) Does the proposed activity in any way disregard the guidelines and research policy of the Calvary Health Care and Catholic Health Australia (Please refer to the ‘*Calvary Health Care guidelines for research practice’ and Code of Ethical Standards by Catholic Health Australia)*

[ ]  Yes [ ]  No

18) Will the proposed activity; upon completion, intends to be published in journals or other publishing avenues?

[ ]  Yes [ ]  No

19) Does this research needs access to identifiable data /information from Calvary health care Bruce

[ ]  Yes [ ]  No

***Signature of the applicant …………………………………***

***Date……………………………………………………..***

If all of the above questions can be answered “no”, then the proposal does not need consideration by an HREC. Please provide a brief summary of the project (Max 500 words) as well as the costs involved for the project below.

***Brief summary of the project …………………………..***

***Costs involved…………………………….***

*I herewith undertake that I shall provide the oversight required for the quality improvement activity mentioned above as per the policy and ensure the receipt of reports from time to time.*

***Signature of the Head of the Department……………………………….***

Provide a signed copy of this document to the Department manager’s office as well as HREC office. If any of the questions are answered “yes”, further advice should be obtained from the Executive Officer of the HREC about the need for an application.

Note that if you answered “yes” to question 6(a), but answered “no” to part (b) **and** did not tick any of the boxes for part (c), then you can count this as an overall “no” to this question.