



## CALVARY HEALTH CARE BETHLEHEM HUMAN RESEARCH & ETHICS COMMITTEE

### CHECKLIST

#### 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 publication "*When does quality assurance in health care require independent ethical review?*", which served as the basis for this checklist, can be downloaded from the NHMRC website <http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>

*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:

2. Does the proposal pose any risks for participants beyond those of their routine care, treatment or activity?  
 Yes       No

If yes, provide details:

3. Does the proposal impose a burden on participants beyond that experienced in their routine care, treatment or activity?  
 Yes       No

If yes, provide details:

4. Does the proposal seek to gather information beyond that collected in routine care or service?  
 Yes       No

If yes, provide details:

5. 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:

6. (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

7. 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:

8. Does the proposal involve randomization or the use of a control group or placebo?  
 Yes       No

If yes, provide details:

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

Yes       No

If yes, provide details:

If all of the above questions can be answered “no”, then the proposal does not need consideration by an HREC. 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.

**If an application for ethical review is submitted to the Calvary Health Care Bethlehem RE&EC, please include this completed checklist with the application.**