Calvary | Health Care Bethlehem

Attachment 2

CALVARY HEALTH CARE BETHLEHEM (CHCB) RESEARCH ETHICS & ETHICS COMMITTEE CHECKLIST FOR IDENTIFYING LOW OR NEGLIGIBLE RISK PROJECTS

Some research and quality assurance projects may not require review by the full CHCB Research Ethics and Ethics Committee (REEC).

To assess whether or not your research or quality assurance project requires review by the REEC, please consider the advice given in the *National Statement on Ethical Conduct in Human Research* (2007), especially:

- Chapter 2.1, which defines low and negligible risk research;
    - Low risk describes research in which the only foreseeable risk is one of discomfort.
    - Negligible risk describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Inconvenience is less serious than discomfort. Examples may include filling in a form, participating in a survey or giving up time to participant in research Where the risk is more than inconvenience, the research is not negligible.
- Chapter 5.1.10 to 5.1.23 which discusses levels of ethical review and the types of research which can be exempted from ethical review.

Please also consider the NHMRC statement *Ethical Considerations in Quality Assurance and Evaluation Activities* ((March 2014). This document can be downloaded from http://www.nhmrc.gov.au/guidelines/publications/e111

In particular, note the 7 triggers for ethical review which are listed in Section 2(e) of this document. These triggers are:

- Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- Secondary use of data - using data or analysis from QA or evaluation activities for another purpose.
- Gathering information about the participant beyond that which is collected routinely. Information may include bio-specimens or additional investigations.
- Testing of non-standard (innovative) protocols or equipment.
- Comparison of cohorts.
- 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.

Criteria for Low or Negligible Risk Research: Does the research project involve ANY of the following?	**Y/N/NA**
Use of a product (drug or device) that is not registered with the Therapeutic Goods Administration (TGA)	
Use of a drug or device in a clinical trial, when the product is being used in the trial for an unapproved indication, in an unapproved age group or at an unapproved dose	
Use of a drug or device in a clinical trial, when such use in the trial is to gain further information about an approved use (e.g. pharmacokinetic or pharmacodynamic research)	
A randomised and/or control group trial assessing an intervention(s) i.e. drug/device, clinical, surgical, diagnostic, public health or mental health **(consider NS 3.1)**	
Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care **(consider NS 4.2)**	
Targeted recruitment of vulnerable groups e.g. children in the ICU, people with mental illness or those who may have been involved in criminal activities **(consider NS 4.2, 4.3 & 4.4, 4.5)**	
Invasive procedures outside of standard care e.g. collection of blood or tissue samples **(consider NS 3.4)**	
Examining potentially sensitive or contentious issues or deception of participants, concealment or covert observation **(consider NS 2.3.1-2)**	
Research which may show unknown disabilities; disease status or risk; or have the potential for the discovery of non-paternity **(consider NS 3.1 Element 5, NS 3.3)**	
Request for a Waiver of Consent **(NS 2.3.10 MUST be addressed, and researchers must identify the applicable APP's)** *Note: Retrospective chart review by the clinician is able to be done without consent for the purposes of improvement or evaluation of health services as per Health Privacy Principles 2.2 (f) (i) & (iv) & (v) & (vi) therefore a Waiver is not required in this instance*	
Request for Opt Out Approach **(NS 2.3.6 MUST be addressed, and researchers must identify the applicable APP's)**	
The data collected and analysed is not linked to individuals	
Data will not be obtained from other sources or organisations such as Medicare, Health Insurance.	
The activity does not involve • testing of non-standard protocol or equipment • comparisons of cohorts • control groups or placebo	
The activity is seeking consent for participants to engage in interviews, focus groups or other procedures related to the activity (if applicable)	
The activity is not seeking to establish a registry/databank	

If you ticked "No" to ALL items in Section 1 please submit a Low & Negligible Risk Application.

Whether or not your research or quality assurance project requires review by REEC, **access to medical records for audit and quality assurance purposes requires authorisation**