



Cabrini Human Research Ethics Committee

Processes for Review of Human Research Applications

Background

1. The *National Statement on Ethical Conduct in Human Research (2007)* requires that research involving certain categories of participants and research that involves more than low risk to participants be reviewed by an HREC (para 5.1.6).
2. The *National Statement* further provides that institutions may establish other levels of ethical review for research that carries only low risk (para 5.1.7), and that research involving only negligible risk may be exempted from ethical review (para 5.1.8).

Purpose

3. This policy describes the process used by Cabrini to determine the appropriate level of review to be applied to applications for ethical approval of human research.

Guidelines

4. The level of review must be appropriate to the level of risk of the proposed study (para 5.1.10). Under delegation from the CHREC, the Manager (not the researcher) shall determine the risk to the participants and the appropriate level of review for each study (Chapter 2.1 p15).
5. The steps for determining the various levels of risk are described below and set out in the attached flow charts.

Review Level 1 – Quality Assurance projects

6. Research involving the use of existing collections of data or records that contain only non-identifiable data about human beings and are deemed to be of negligible risk may be considered as quality assurance studies (Para 5.1.22).
7. The NHMRC document "*When does quality assurance in health care require independent ethical review?*" provides advice on this matter. It is available at: <http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>
8. Following receipt of the appropriate application described below the CHREC Manager may approve the study on behalf of the CHREC.

Review Level 2 –Projects involving only negligible or low risk

9. The CHREC Manager may approve research determined to involve negligible or low risk for participants. This would include studies that use patient data within the guidelines of the Cabrini inpatient registration forms and the Cabrini privacy statement "What happens to information about you?"
10. The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk. (Chapter 2.1 page 16)
11. The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. (Chapter 2.1 page 16)
12. The appropriate paperwork to submit for low risk projects is listed in section 16 of this document. The approval process is described in the attached flow charts.

Review Level 3 –Expedited Review by Partnering Agreement

13. Under Chapter 5.3 of the *National Statement on Ethical Conduct in Human Research*, review by the full CHREC is not required when this would be duplicating the review of one of our partner universities with whom we have a mutual recognition agreement for ethical approval unless there are clinical, resource or risk issues for Cabrini.
14. At present the following agreements are in force:
 - Deakin University
 - Monash University
15. Following receipt of the appropriate application described in Para 16 below the CHREC Manager may approve the study on behalf of the CHREC.

Review Level 4 – Project involving more than low risk for participants

All research unless otherwise specifically exempted. This includes, for example, studies involving:

- human stem cells;
- women who are pregnant;
- the human foetus;
- ionising radiation;
- people highly dependent on medical care who may be unable to give informed consent;
- Aboriginal or Torres Strait Islander peoples;
- interventions and therapies;
- human genetics;
- people with a cognitive impairment, an intellectual disability or a mental illness;
- people who may be involved in illegal activities;
- people in other countries;
- people who are economically disadvantaged, exploited or marginalised;
- potential for risk to outweigh benefit;
- privacy legislation and guidelines;
- Cabrini resources.

Reduced paper work

16. To apply for CHREC approval under Review Levels 1 to 3, Principal Investigators shall:

- complete a Cabrini supplementary application form;
- complete the appropriate checklist;
- attach project protocol; resourcing details; and any information for participants (including any Participant Information and Consent Forms);
- attach any letters of support/approval;
- sign a declaration at the end of a Cabrini supplementary application form;
- submit to the Manager, CHREC for consideration.

Notification of delegated approvals to CHREC

17. The CHREC Manager shall report each approval granted under Review Levels 1 to 3 to the following full CHREC meeting for endorsement.

Summary of Delegations

<i>Responsibility</i>	<i>Delegate</i>
Determine Study level of risk	CHREC Manager
<i>Risk & Review Level</i>	<i>Approval granted by</i>
1 – Quality assurance	CHREC Manager
2 – Negligible or low risk	CHREC Manager
3 – Mutual agreement	CHREC Manager
4 – More than low risk	CHREC

Variations to this policy

The CHREC Chair and Manager may jointly authorise exceptions to this policy if in their opinion such action is in the best interests of Cabrini Health, study participants and the achievement of the CHREC's objectives. These exceptions shall be reported to the following full CHREC meeting for endorsement.

Action Policy developed Reviewed 13 August 2010	By: Glenn, Anne, Stephanie, Glenn, Anne	Date Adopted: 14 April 2008
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