Appendix A

CABRINI RESEARCH GOVERNANCE

PROCESSES FOR ETHICAL REVIEW OF HUMAN RESEARCH APPLICATIONS

Background

The *National Statement on Ethical Conduct in Human Research (2007)*, including subsequent updates, requires that research involving certain categories of participants and research involving more than low risk to participants be reviewed by a HREC (para 5.1.6).

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

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

The level of review must be appropriate to the level of risk of the proposed study (para 5.1.10). The CRGO (not the researcher) shall determine the appropriate level of review for each study (Chapter 2.1). The Principal Investigator can assume the level of risk of their project (as the application processes differ) as long as they recognise and accept that the CRGO may assess the application differently. The CRGO has final jurisdiction over determining level of risk.

The steps for determining the various levels of risk are described below and set out in the flow charts in Appendix B.

Review Level 1—Quality Assurance projects

Research that involves the use of existing data or records that contain only non-identifiable data about human beings and that is deemed to be of negligible risk may be considered quality assurance (Para 5.1.22).

Following receipt of the appropriate application (see below: **Reduced paperwork**), the CRGO may approve the study on behalf of the Cabrini Research Governance Committee.

Review Level 2—Projects involving only negligible or low risk

The CRGO is delegated to 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 policy '[The privacy of your personal information]'

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).

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).

The appropriate paperwork to submit for low risk projects is listed in **Reduced paperwork**, below. The approval process is described in Appendix B.

Review Level 3—Expedited Review by Partnering Agreement

Under Chapter 5.3 of the *National Statement on Ethical Conduct in Human Research*, review by Cabrini is not required when this would duplicate the review of another appropriate HREC. Only a governance review is required.

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

This includes all research unless otherwise specifically exempted according to the above criteria. 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.

These projects must obtain full HREC approval from a NHMRC approved HREC committee.

Reduced paper work

To apply for CRGO approval under Review Levels 1 to 3, Principal Investigators shall:

- complete a Cabrini Low Risk Governance Application Form (Attachment 2);
- complete the Level of Risk Checklist (Attachment 4) if appropriate;
- attach the 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 researchgovernance@cabrini.com.au for consideration.