

	Human Research Ethics Committee Appeals Protocol	
Scope	All Departments, All staff	
Responsible Department	Research and Development, Clinical Support Services	
Approved By	Group Executive	May 2017

INTRODUCTION

Bendigo Health Care Group (Bendigo Health) is committed to maintaining the highest standards of ethical review, approval, monitoring and audit of research projects. It adheres to the guidelines on research conduct established in the Joint National Health Medical Research Council / Australian Vice Chancellors Committee Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research. Bendigo Health further articulates its operating framework relating to research in a series of adopted policies and procedures. This procedure is one in the series.

POLICY

- The Human Research Ethics Committee (HREC) is responsible for ethical review, approval, monitoring and audit of research conducted within Bendigo Health.
- Quality Assurance activities may also be subject to HREC approval under the terms described in the Bendigo Health policy “Identifying Quality Assurance Activities that require HREC Approval.”
- Where a researcher wishes to appeal a decision of the HREC in relation to their research or quality assurance application or project they are entitled to appeal against that decision using the Appeals Procedure.

APPEALS PROCEDURE

1. Research and Quality Assurance Applications

- 1.1 A researcher may appeal against a decision of the HREC concerning:
 - (a) A request for an amendment to part of an application for ethics approval.
 - (b) A request for substantial changes to an application for ethics approval.
 - (c) A request for a resubmission of an application for ethics approval.
 - (d) Non-approval of a research or quality assurance application.
- 1.2 Should a researcher believe a request for amendment, substantial change, resubmission or non-approval is unfair or unwarranted, they should initially confer with the HREC Secretary or the Chair for clarification of the reasoning of the HREC.
- 1.3 If, after consultation with the HREC Secretary or the Chair the researcher is not satisfied, the researcher can put their concerns in writing for consideration

by the Committee at the next scheduled meeting. The Committee may invite the researcher to attend this meeting.

2. Monitoring and Audit function

- 2.1 A researcher may appeal a decision of the HREC in relation to the outcome of an audit of a current approved project including the monitoring of compliance.
- 2.2 Should a researcher believe a decision or conclusion is unfair or unwarranted they should initially confer with the HREC Secretary or the Chair for clarification of the reasoning of the HREC.
- 2.3 If, after consultation with the HREC Secretary or the Chair, the researcher is not satisfied, the researcher can put their concerns in writing for consideration by the Committee at the next scheduled HREC meeting. The Committee may invite the researcher to attend this meeting.

3. Appeal to CEO

- 3.1 If a researcher is not satisfied following firstly, the consultation with the HREC Secretary or the Chair; and secondly, a further consideration by the Committee; and believes that the HREC, in reaching its decision, has not complied with policies and procedures in effect, the researcher may request the Chief Executive of Bendigo Health (CEO) to review the decision of the HREC. This request must be made in writing giving full details of the project, and reasons for the request.
- 3.2 The CEO will make a recommendation to the Chair of the HREC following the review. This recommendation will be considered by the HREC at the next scheduled HREC meeting.

REFERENCES AND ASSOCIATED DOCUMENTS

- Identifying Quality Assurance Activities that require HREC Approval
- Flowchart – when is Human Research Ethics Committee (HREC) approval required? National Health & Medical Research Council's (NHMRC)/ Australian Vice Chancellors' Committee National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015), (The National Statement)
- NHMRC/ Australian Research Council (ARC)/Universities Australia Australian Code for Responsible Conduct of Research (The Code)

Personal information and health information as defined in the relevant Victorian law, which is required to be collected, used, disclosed and stored by BHCG in order to achieve the Purpose of this policy, will be handled by the Group and its employees in accordance with their legal obligations.

When developing this policy, BHCG has taken all reasonable steps to make its content consistent with the proper discharge of its obligations under the Charter of Human Rights and Responsibilities Act 2006.