BENDIGO HEALTH	**Conduct of Human Research Protocol**	
Scope	• All Departments • All Researchers	
Responsible Department & Position	Research and Development - Research Manager	
Approved By	Clinical Support Services Senior Management Group	18/07/17
Authorised or noted by	Policy, Strategy and Risk Committee	27/09/17

PURPOSE

Bendigo Health Care Group (BHCG) wishes to ensure that research conducted at BHCG is of high quality, has the highest ethical standard, is purposeful, and that the collection and reporting of data is both valid and accurate and thus requires that all researchers are committed to high standards of professional conduct. In addition, both BHCG and researchers are responsible for ensuring, as far as is reasonably possible, the safety of all those associated with research.

Accordingly BHCG has developed this protocol to ensure sound research procedures, the protection of all individuals concerned and the institution.

DEFINITIONS

Confidentiality – the obligation of people not to use private information, whether private because of its content or the context of its communication, for any purpose other than that for which it was given to them, (see Privacy below).

Data – pieces of information that can be collected stored or disclosed as either individually identifiable data, re-identifiable data or non-identifiable data.

Human Research Ethics Committee – designed to protect the welfare and the rights of participants in research.

Privacy – a domain within which individuals and groups are entitled to be free from the scrutiny of others.

Research – although there is no universally agreed definition, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers.

Research participant – anyone who is the subject of research broadly, including involvement through:

- taking part in surveys, interviews or focus groups
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers

- researchers having access to their personal documents or other materials
- the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

The term 'participants' therefore includes those who may not even know they are the subjects of research; for example, where the need for their consent for the use of their tissue or data has been waived by a HREC.

Researcher – someone who performs research at BHCG, or under the auspices of BHCG, including visiting, honorary, adjunct and short-term appointments, students or external researcher.

Risk – in the case of research a risk is a potential for harm, discomfort or inconvenience. It involves the likelihood that a harm, discomfort or inconvenience will occur and the severity of the harm, including its consequences.

AHEC – Australian Human Ethics Committee
HREC – Human Research Ethics Committee
NHMRC – National Health and Medical Research Council
NS/National Statement –National Statement on Ethical Conduct in Human Research 2007 (UpdatedMay 2015) – developed jointly by National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) and Australian Vice-Chancellors' Committee (AVCC)
The Code – the Australian Code for the Responsible Conduct of Research 2007– issued jointly by National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia

POLICY

1. Ethics Approval

The *National Statement on Ethical Conduct in Human Research* (2007) (*NS*) requires that all research proposals involving human participants be reviewed and approved by a Human Research Ethics Committee (HREC) and sets out the relevant ethical principles and values by which research should be designed and conducted. Therefore, all research projects at BHCG which involves humans and/or access to their records, files or specimens must be reviewed by the BHCG HREC or by an accredited reviewing HREC in the streamlined ethical review system for public health organisations. This includes all types of projects, whether funded or unfunded, as well as student research projects. Researchers must submit an application to an HREC, and have obtained approval from it, before proceeding. Retrospective HREC approval cannot be granted, and in the event that research has commenced without prior approval, this action is considered a breach of this Policy.

Please note that ethical approval is not required where research only involves the use of existing collections of data or records that contain only non-identifiable data about human beings. However, researchers must conduct their research according to the requirements of the National Statement (*NS* 5.1.23).

In addition to ethical review, research is subject to a site specific assessment at BHCG. This is where BHCG decides whether or not to authorise ethically approved research, taking into consideration issues such as resourcing, funding, risk management and all legal, regulatory and administrative requirements. After obtaining ethical approval, researchers must submit site specific documents for assessment and gain authorisation from BHCG before proceeding.

2. Ethical Principles

Researchers should be aware of and adhere to the following ethical principles as found in the National Statement (*NS*, Section 1).

- research merit and integrity
- beneficence
- respect for human beings
- justice.

3. External Research

If BHCG is requested to distribute information related to research conducted at another institution, such as a brochure, the following applies:

- Prior to agreeing, evidence of HREC approval must be sighted and
- Relevant Executive Director approval must be obtained
- No other information must be given by BHCG staff.

4. Standards

It is the researcher's responsibility to comply with all relevant legislation and guidelines including:

- The National Statement
- The Australian Code for the Responsible Conduct of Research (The Code)
- The NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods 2016.
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)
- All BHCG policies and procedures relating to human research
- The terms of approval as set by the relevant HREC and BHCG authorisation.

5. Researcher Training and Competence

All researchers must receive training on and comply with research ethics as found in the *NS*, the Code and relevant BHCG research policies and procedures. They must also respect the terms of approval set by the relevant HREC and BHCG authorisation. In addition to this, researchers must be trained in any other relevant legislation and guidelines specific to their area of research, particularly if it involves vulnerable populations as defined in Section 4 of the NS such as Aboriginal and Torres Strait Islander Peoples, those with a cognitive impairment, an intellectual disability or mental illness individuals, or children. Researchers and supervisors must accept that undertaking research requires dedication and accountability and involves responsibilities. They should endeavour to be good role models to others, particularly junior colleagues, therefore contributing to a BHCG research culture of excellence, integrity, professionalism and mutual respect.

6. Privacy and Confidentiality

Researchers must comply with the legal and ethical obligations of confidentiality and the relevant legislation relating to privacy and common law. Confidentiality must be maintained for both participants and institutions. Researchers should make themselves aware of the BHCG policy regarding confidentiality.

7. Intellectual Property

Applications for approval of projects should specifically address the issue of intellectual property ownership, to comply with BHCG policy on intellectual property.

8. Publications

All research publications by BHCG staff or reporting of research conducted at BHCG must be approved by the appropriate Executive Director, and make appropriate acknowledgment of BHCG.

9. Supervised Research

Supervisors must provide adequate guidance in all areas of research practice, and ensure the validity of research data obtained by a student under his/her supervision.

10. Disclosure

Researchers have an obligation to disclose at the time of proposing, or subsequently reporting research (if the issue was not previously identified), any conflict of interest or financial incentives which have the potential to influence research and investigations, publication and media reports, grant applications, applications for appointment and promotion. Disclosure should be made to the HREC, editors of journals, to the readers of published work, and to external bodies from which funds are sought.

11. Protection of Participants in Research

To protect the privacy of research participants researchers have an obligation to observe ethical guidelines, such as those issued by the NHMRC and relevant legislation. BHCG's HREC has a procedure for managing complaints from participants and researchers should inform participants of this.

12. Research Misconduct

Research misconduct is a serious issue and will not be tolerated. Researchers should be aware that research misconduct includes but is not limited to fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. Approval to conduct research may be withdrawn in such cases. Exceptions include honest errors or honest differences in interpretation or judgements of data. In certain circumstances a researcher may appeal a decision of the HREC and there is a procedure in place for managing these appeals.

13. Management and Retention of Research Data and Materials

The responsible conduct of research includes the proper management and retention of research data and primary materials. The purpose of retaining data is mainly to support any reported or published outcomes and to justify them if challenged. While it may not be practical to keep the primary material (such as biological samples,

questionnaires or recordings), any records derived from them (such as test results, transcripts, and laboratory and field notes) must be retained and accessible. The researcher is responsible for deciding which data and materials should be retained, taking into account BHCG, regulatory and legal requirements and those set by funding agency or publisher. The potential value of the material for further research should also be considered, particularly where the research would be difficult or impossible to repeat.

14. Funding and Financial Management

Good financial management of research funds is the responsibility of all researchers, with ultimate responsibility resting with the Principal Investigator. Funding for research projects must be disclosed to relevant parties. BHCG employees must ensure that the responsible Executive Director approves all proposals and applications for funding of research projects. Any fees/costs incurred by BHCG shall be recognised in the disbursement of funds provided; however it is acknowledged that many funded projects do not recognise corporate/overhead costs. Accurate and timely records of all expenditure must be kept and the budgetary position of research projects monitored at regular intervals.

REFERENCES and ASSOCIATED DOCUMENTS

Bendigo Health Policies and Protocols

- HREC Information and Application Forms
- Identifying quality assurance activities that require Human Research Ethics Committee approval
- Flowchart – when is Human Research Ethics Committee (HREC) approval required?
- Confidentiality Policy
- HREC Complaints Protocol
- HREC Appeals Protocol
- Intellectual Property Policy
- Research Governance Toolkit

State and Commonwealth Legislation

- Health Records Act 2001
- The Privacy and Data Protection Act 2014
- Privacy Act 1988\

Standards / Codes of Practice / Industry Guidelines

- Code of Conduct issued by the Public Sector Standards Commissioner
- National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* 2007
- Australian Code for the Responsible Conduct of Research 2007
- NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods 2016
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)

MANDATORY INCLUSION

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.