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|  | <h2>Human Research Complaints Protocol</h2> | |
| Scope | <ul style="list-style-type: none"> • All Departments <li style="margin-left: 300px;">• All Staff | |
| Responsible Department & Position | Research & Development – Research Manager | |
| Approved By | Clinical Support Services Senior Management Group | April 2018 |
| Authorised By | Group Executive Policy, Strategy & Risk Committee | July 2018 |

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.

The Human Research Complaints Protocol governs the management of complaints about researchers, or research carried out under the jurisdiction of the Human Research Ethics Committee (HREC). Complaints about research within BHCG involving humans may either be directed to the HREC or to the Health Complaints Commissioner of Victoria.

A separate appeals protocol is available in the event that a complaint is made about the conduct or decisions of the BHCG HREC itself.

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.

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.

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.

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.

POLICY

1. Complaints under this protocol may be about, but are not limited to, allegations of:
 - Research being conducted in a way that the complainant believes to be unethical or contrary to existing policy or legislation
 - Research involving human participants being conducted without formal HREC approval
 - Research being conducted in a manner contrary to that approved by the HREC or not complying with other conditions placed on the research
 - Violation or compromise of confidentiality or privacy in recruitment, conduct and publication of research
 - Misuse of data.
2. Where an individual or organisation has a complaint about research involving human participants a complaint to the Secretary of the HREC may be made either verbally or in writing.
3. Complaints, whether written or verbal, must specify:
 - The name of the researcher
 - The institution of the researcher
 - The title of the research project, or a description of the project
 - The HREC reference number (if known)
 - A description of the circumstances surrounding the complaint
 - The resolution sought.
4. Complainants should identify themselves to the HREC, unless they specifically request to remain anonymous, or have their identity suppressed; this will not affect the management of the complaint.
5. Complaints will be dealt with in confidence and in accordance with BHCG information services policies (see associated documents).
6. Complaints will be acknowledged in writing within 7 working days, and referred to the Chair of the HREC, who will lead the investigation in association with other members as seen fit by the Chair.
7. The investigation may include discussion with the researcher, and, if necessary, the institution sponsoring the research or the investigator.

8. A written response will be provided to the complainant regarding the outcome of the investigation, within 90 days of receiving the complaint. It may or may not be necessary for the full committee to meet to consider the complaint before a written response is provided.
9. Complaints about the HREC itself, or appeals about a decision of the HREC, will be dealt with in accordance with the HREC Appeals Protocol and should be addressed in writing to the Chair of the HREC.

Complaints may also be directed to the
Health Complaints Commissioner
Level 26, 270 Bourke Street
Melbourne Victoria 3000
Toll Free: 1800 582 113
Fax No: (03) 8601 5219
E-mail: hcc@hcc.vic.gov.au

REFERENCES and ASSOCIATED DOCUMENTS

Bendigo Health Policies and Protocols

- [Human Research Ethics Committee Appeals Protocol](#)
- [Research Governance Toolkit 2015](#)
- [Conduct of Human Research Policy](#)
- [Confidentiality Policy](#)
- [Privacy of Health Records Policy](#)
- [Privacy of Personal Records Policy](#)

State and Commonwealth Legislation

- [Health Records Act 2001](#)
- [The Privacy and Data Protection Act 2014](#)
- [Privacy Act 1988](#)
- [Medical Treatment Planning and Decisions Act 2016](#)

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*](#)
- [Australian Code for the Responsible Conduct of Research](#)

MANDATORY INFORMATION

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.