BENDIGO HEALTH	**Identifying Quality Assurance Activities that require Human Research Ethics Committee Approval**	
Scope	• All Departments • All Staff	
Responsible Department	Research & Development – Research Manager	
Approved By	Clinical Support Services Senior Management Group	April 2018
Authorised By	Group Executive Policy, Strategy & Risk Committee	July 2018

POLICY

The purpose of this policy is to ensure that all quality assurance (QA) activities or projects receive review, as appropriate by the Bendigo Health Care Group (BHCG) Human Research Ethics Committee (HREC) prior to commencement.

DEFINITIONS

Biospecimens – any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.

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.

Health Information - under the Victorian Health Records Act 2001 means:

(a) Information or an opinion about:
   i. the physical, mental or psychological health or a disability (at any time) of an individual; or
   ii. an individual's expressed wishes about the future provision of health, disability or aged care services to him or her; or
   iii. a health, disability or aged care service provided, or to be provided, to an individual;

(b) Other personal information collected to provide, or in providing, a health, disability or aged care service; or

(c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or

(d) Personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or any of his or her descendants.

Personal Information - generally means information or an opinion (including information or an opinion forming part of a database), whether true or not, and

whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

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

Sensitive Information - means information or an opinion about an individual's:

- racial or ethnic origin; or
- political opinions; or
- membership of a political association; or
- religious beliefs or affiliations; or
- philosophical beliefs; or
- membership of a professional or trade association; or
- membership of a trade union; or
- sexual preferences or practices; or
- criminal record;

that is also personal information; or (in the Commonwealth Privacy Act only): health information about an individual.

QA activities – An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation). Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably.

PROCEDURE

QA activities are those in which the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation). QA activities do not usually require prior approval of the HREC except if any of the following is to occur:

1. The QA activity poses risks for patients beyond those of their routine care, including psychological, spiritual and social harm or distress.
2. The QA activity imposes a burden on patients beyond that experienced in their routine care. Burdens may include intrusiveness, discomfort, inconvenience or embarrassment.
3. The QA activity involves the testing of non-standard (innovative) protocols or equipment.
4. The QA activity is to be conducted by a person who does not normally have access to the patient's records for clinical care or a directly related secondary purpose.
5. The QA activity risks the privacy and/or confidentiality of the individual beyond that experienced in the provision of routine care.
6. The QA activity involves the secondary use of data – using data or analysis from QA or evaluation activities for another purpose.
7. The QA activity involves the comparison of cohorts, randomisation or the use of a control group or placebo.
8. The QA activity involves the gathering of information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations.

9. The QA activity involves targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA activity.
10. The consent from participants, where required, is inadequate or the activity is inconsistent with Australian Privacy Principles 3.2 and 3.3:
    a) APP 3.2. An organisation must not collect personal information (other than sensitive information) unless the information is reasonably necessary for one or more of its functions or activities.
    b) APP 3.3. An organisation must not collect sensitive information about an individual unless the individual consents and the information is reasonably necessary for one or more of its functions or activities or a permitted health situation exists in relation to the collection of the information.
11. The proposed QA activity potentially infringes the rights, privacy or professional reputation of participants, carers, health care providers or the organisation.

Staff requiring assistance with QA activities should contact the Quality Unit. To determine if HREC approval is required, contact the Quality Unit or HREC secretary. It should be noted that there are circumstances where ethical approval for QA activities is required by external organisations, for example where there is an intention to publish the outcomes in a peer reviewed or professional journal. The HREC does not provide retrospective approval.

REFERENCES and ASSOCIATED DOCUMENTS

Bendigo Health Care Group Policies and Protocols

- Confidentiality Policy
- Intellectual Property Policy
- Flowchart - when is Human Research Ethics Committee approval required?
- HREC Information and Application Forms
- Quality Assurance Plan

Standards / Codes of Practice / Industry Guidelines

- National Health and Medical Research Council (NHMRC) (2007) National Statement on Ethical Conduct in Research Involving Humans
- National Health and Medical Research Council (NHMRC) Ethical Considerations in Quality Assurance and Evaluation Activities May 2015
- National Health and Medical Research Council (NHMRC) / Australian Research Council (2007) Australian Code for the Responsible Conduct of Research

State and Commonwealth Legislation

- Health Records Act 2001
- The Privacy and Data Protection Act 2014
- Privacy Act 1988
- Code of Conduct issued by the Public Sector Standards Commissioner
- Medical Treatment Planning & Decisions Act 2016

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.