ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

***RESEARCH GOVERNANCE UNIT***
*St. Vincent's Hospital (Melbourne)*
*Caritas Christi Hospice*
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*Prague House*
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# QUALITY ASSURANCE ACTIVITY

## ***Statement of Intent and Outcomes***

The St Vincent's Hospital (Melbourne) Human Research Ethics Committee is committed to fulfilling Section 5 of The National Statement on Ethical Conduct in Human Research (2007) by ensuring Quality Assurance activities are well defined, and that the review process for such activities is appropriately expedited to reflect the low level of risk involved.

## ***Definitions***

**Quality Assurance (QA)** is defined as an activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (individual, service or an organisation), that may be presented, published, or serve as an item of general interest.

## ***Procedure***

St Vincent's Hospital (Melbourne) considers QA as an integral process for the improvement of health care delivery. As a result, such activities must be fostered and encouraged.

The distinction between QA from research may be difficult; however, for the purposes of this procedure:

a) To be classified as QA, the activity must be low risk, and undertaken for a valid purpose for which its outcomes will be used to improve health care;
b) The conduction of QA activities must adhere to relevant ethical principles including integrity, respect for persons, beneficence and justice, as well as State, Territory and Commonwealth legislation; and
c) Where QA proposals could infringe ethical principles that guide human research, independent ethical scrutiny of such proposals must be sought.

Sections 5.1.22 and 5.1.23 of the National Statement on Ethical Conduct in Human Research (2007 – Updated 2018) allow Institutions to implement procedures which exempt QA activity from ethical review. At St Vincent's Hospital (Melbourne), QA activities are reviewed by the Research Governance Unit.

Any QA activity which causes concern will be referred for full review to the Human Research Ethics Committee constituted and operating in accordance with the National Statement on Ethical Conduct in Human Research (2007 – Updated 2018).

For the purpose of this procedure, QA activity can proceed without review by a Human Research Ethics Committee, as long as the following principals apply:

**Consent**

Appropriate consent must be sought from participants, where applicable. Where consent is not required (including chart reviews and clinical audits), the activity must ensure all information that is collected and utilised is non-identified, and is collected, stored and utilised in adherence to the National Statement on Ethical Conduct in Human Research (2007 – Updated 2018), the Privacy Act (1988), and the Health Records Act 2001 (Vic), as applicable.

**Risks and burdens**
Risks include not only those of a physical nature, but those relating to psychological, spiritual and social harm and/or distress, including stigmatisation or discrimination. QA activities must not pose any risks for patients beyond those associated with routine care.

QA activities must also not impose any further burden on participants beyond that associated with routine care. Burden may include intrusiveness, discomfort, inconvenience or embarrassment, including persistent phone calls, additional hospital visits or lengthy questionnaires.

**Privacy and confidentiality**
QA activities must be conducted by a person who has usual access to the information, for the purpose/s under which it was collected. This includes access to a clinical record by any member of the treating team. The involvement of a clinical student who is a member of the team in any clinical setting or involvement of an authorised quality assurance officer would also be acceptable. However, the involvement of a student external to the clinical team would need further consideration by the Research Governance Unit.

The review of medical records by anyone who would not normally have access to information contained therein is considered in breach of privacy principals, and is inappropriate for QA activities. All such activities must be subject to full ethical review.

QA activity must also ensure the protection and confidentiality of all personal information. For example, activities that require written communication to be sent to participants that includes sensitive health information, could lead to a breach of confidentiality if the communication is read by someone other than the proposed recipient. As a result, quality assurance activities should ensure anonymity and protection of privacy and confidentiality at all times. All activities which pose a potential risk to the breach of privacy and confidentiality must be subject to full ethical review.

**Clinical Activities**
QA activities must not involve any clinically significant departure from the routine clinical care. The application and evaluation of an approved technology that is utilised as standard care elsewhere, but not previously used at St Vincent's Hospital may be assessed as quality assurance on the condition that appropriate support is provided by the Head of Department, and any other persons as applicable.

Clinical activities which involve randomisation and/or the use of a control group or a placebo are not considered quality assurance activities, and must be subject to full ethical review. However, activities involving comparison with published or prior treatment results with other groups are acceptable if the proposals do not involve randomisation.

Where clinical information is required, the proposed quality assurance activity must not include the collection of information beyond that which is already collected for the purposes of routine clinical care. Any activities which include the collection of additional information must be subject to full ethical review.

Studies that adhere to the above, but relate to the collection and use of genetic information may be classified as quality assurance; however, the Research Governance Unit retains the right to re-direct such activity to full ethical review.

**Accountability and Record Management**
For the purposes of record management, the Research Governance Unit will ensure a copy of the application form and any other associated documentation is held on file, and identified by a QA reference number. All records will be retained for a period of 15 years.

All QA applications must be responded to in writing, and must confirm that the activity has been confirmed as quality assurance, and may be conducted and published with the support of the Institution. This will allow the submission of articles to applicable journals for publication, and obviate any need for requests for retrospective ethical approval.

For the purposes of accountability, a listing of all confirmed quality assurance activities for the previous month will be circulated to, and noted by the Human Research Ethics Committee at each meeting.

The review of QA activities will not incur a fee. This practice will ensure quality assurance activity is encouraged.

***Associated Procedures/Instructions***
Nil

***Reference Documents***

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 – Updated 2018 (Cth)
- Australian Code for the Responsible Conduct of Research (2018)
- Privacy Act (1998)
- Health Records Act (2001) (Vic)

Authorized by:

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