

BOND UNIVERSITY HUMAN RESEARCH ETHICS POLICY

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Policy name	Bond University Human Research Ethics Policy (Issue Three)
Applicability	Bond University Staff and Students; External stakeholders
Policy owner	Chair, Academic Senate
Contact person	Director of Research, Office of Research Services
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Related policies and documents	<p>Research Code of Conduct Policy (TLR 5.06)</p> <p>Bond University Animal Research Ethics Committee Policy (TLR 8.02)</p> <p>Bond University Human Research Ethics Application Process website</p> <p>Research Misconduct Policy (TLR 8.07)</p> <p>Research Data Management and Sharing Policy (TLR 5.12)</p> <p>National Statement on Ethical Conduct in Human Research (2018) (National Statement)</p> <p>Australian Code for the Responsible Conduct of Research (2018) (Australian Code)</p> <p>National Health and Medical Research Council Act (1992)</p> <p>Privacy Act 1988</p> <p>Privacy Amendment (Enhancing Privacy Protection) Act 2012</p> <p>NHMRC Ethical issues website</p> <p>NHMRC publications relating to Human Research Ethics website repository</p> <p>The Therapeutic Goods Act (1989)</p> <p>Therapeutic Goods Amendment (2009 Measures No 2) Act 2009</p> <p>Australian clinical trial handbook (2018)</p> <hr/> <p>The Australian New Zealand Clinical Trials Registry (ANZCTR)</p> <p>Guidelines for Ethical Research in Australian Indigenous Studies (2012)</p> <p>Values and Ethics: Guidelines for Ethical conduct in Aboriginal and Torres Strait Islander Health Research (2003)</p> <p>Bond University Research Data Management website</p>

1. INTRODUCTION AND OBJECTIVES

- 1.1. Bond University is committed to assisting its researchers and students to undertake their research in an ethical manner. To that end, the University has established a research ethics process which helps its researchers to comply with Commonwealth and State regulations and legislation, as well as Bond University policy. The University's Research Ethics Committee also serves as a source of advice to researchers and students on research ethics matters.
- 1.2. Through a recommendation of Academic Senate, Bond University established a central Research Ethics Committee in July 1998, known as BUHREC (Bond University Human Research Ethics Committee). BUHREC was first registered with the Australian Health Ethics Committee in 1999. Staff and students of Bond University must receive written approval from BUHREC prior to commencing any research projects through the University, involving human participation. BUHREC has the responsibility for the approval and monitoring of research conducted through Bond University. It is the Committee's responsibility to ensure that research is conducted in accordance with the principles of the *Australian Code for the Responsible Conduct of Research (2018)*, to promote a strong research culture. A strong research culture is defined in that document as having:
- Honesty and integrity;
 - Respect for human research participants, animals and the environment;
 - Good stewardship of public resources used to conduct research;
 - Appropriate acknowledgement of the role of others in research; and
 - Responsible communication of research results.

2. NATURE AND PURPOSE

2.1. The National Statement

- 2.1.1. In Australia, the conduct of research involving the participation of humans must comply with the provisions of the *National Statement on Ethical Conduct in Human Research (2018)* (hereafter shortened to the *National Statement*). The *National Statement* was produced by the National Health and Medical Research Council (NHMRC), is endorsed by the Australian Vice-Chancellor's Committee, Australian Research Council (ARC), Australian Academy of the Humanities, Australian Academy of Science, and the Academy of the Social Sciences in Australia, and is supported by the Academy of Technological Sciences and Engineering. Bond University acknowledges the *Australian Code for the Responsible Conduct of Research (2018)* (hereafter shortened to the *Australian Code*) and aligns itself with the institutional responsibilities outlined therein.
- 2.1.2. Researchers may have additional ethics burdens placed upon them by professional codes of ethics in their disciplines (e.g. the Australian Psychological Society code of ethics specifies a longer archival period than does the *Australian Code*), or when conducting clinical trials. Where the discipline and the NHMRC code diverge, researchers must adhere to the more stringent standard.

2.2. Consequences of not complying with the *National Statement*

- 2.2.1. Institutions that fail to comply with the provisions set out by the NHMRC risk losing all nationally competitive research funding from NHMRC and ARC sources and may be found to be in breach of the *Australian Code*. Individual researchers and students who fail to comply with the provisions of the *National Statement* risk facing serious professional and legal consequences. Accusations of a breach of the *Australian Code* will be investigated in accordance with Part B of the *Australian Code* and the disciplinary processes of the University.
- 2.2.2. It should be noted that, in the event of any action against a researcher, student, or the University, the *Australian Code* will be regarded as the minimum standard required for the conduct of research involving humans.

2.3. Definition of research ethics at Bond University

The term 'research ethics' at Bond University refers specifically to those issues covered by the provisions set down by the NHMRC and Bond University Policies. The *National Statement* provides the following as the principles of ethical conduct in research:

- a) **Research Merit and Integrity** – Research must be justifiable on the basis of its potential for contribution to knowledge. It must reflect a genuine search for knowledge or contribution to social welfare, adherence to recognised principles of research conduct as outlined in the *Australian Code*, and the dissemination and communication of results. Where prior peer review has judged that a project has research merit, its methodology may not be subject to ethical review to the extent that the methodology has not been altered from that presented for peer review. Consistent with the objectives of the National Approach to Single Ethical Review of Multi-Centre Research (National Approach) and section 5.3 of the *National Statement*, Bond University acknowledges the expertise of other Australian Ethics Committees (AEC) and seeks to avoid duplication of the review process.
- b) **Justice** – There must be a fair distribution of the benefits and burdens associated with participation in the research, and any inclusion / exclusion of subjects on the basis of gender, race, age, etc. must be essential to the purposes of the research.
- c) **Beneficence** – The benefit of the research to participants must justify any risks of harm or discomfort to participants (the University absolutely endorses the principle that respect for the dignity and well-being of participants must take precedence over the expected benefits to knowledge).
- d) **Respect** – A regard for the welfare, rights, perceptions, customs, and cultural heritage of participants (both individuals and collectives). Where participants are unable to make their own decisions, or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary. Respect is usually demonstrated by ensuring that participants have the opportunity to make an informed judgement to participate in research and the right to withdraw from research at any stage without penalty.

3. RESPONSIBILITY FOR ETHICS AT BOND UNIVERSITY

- 3.1. Principle responsibility for the ethical conduct of research lies with the individual researcher. In the case of students, part or equal responsibility will reside with the supervisor, unit coordinator and Executive Dean.
- 3.2. The University has established the Bond University Human Research Ethics Committee (BUHREC) to consider applications for ethical clearance, monitor the conduct of projects, and advise the University of Research Ethics Policy Matters. This Committee is established in accordance with the *National Statement* and includes members from both within and outside the University.

- 3.3. The Bond University Office of Research Services provides secretariat support to BUHREC.
- 3.4. The Bond University Research Website: <https://bond.edu.au/researchers> explains and clarifies the University's research ethics arrangements, the operation of BUHREC, as well as the roles and responsibilities of its members.
- 3.5. In addition, the Bond University Research website provides details of the University's research ethics clearance processes as well as explaining the principles which underlie them. It provides advice in relation to planning research, applying for ethical clearance, and conducting research in an ethical manner.
- 3.6. The website also provides details of the contact for complaints regarding the conduct of research and links to the Research Code of Conduct Policy (TLR 5.06), and the Library's guidance on research data management, including issues of data security and privacy.

4. TERMS OF REFERENCE FOR BUHREC

- 4.1. The following terms of reference accord with the requirements set out in the *National Statement*:
 - 4.1.1. To provide a system for ethical review of research projects which has the potential to cater for all human research ethics approval at Bond University;
 - 4.1.2. To consider the ethical implications of all proposed research projects which involve or impact upon humans and approve only those projects which conform to the standards set by the NHMRC in the *National Statement*;
 - 4.1.3. To provide researchers with feedback to assist them in complying with the ethical standards set in the *National Statement*;
 - 4.1.4. To consider the ethical implications of all proposed teaching exercises which use students as participants for the purpose of research, and approve only those exercises which conform to the *National Statement*;
 - 4.1.5. To consider whether the conduct of the research that is approved may contravene the law;
 - 4.1.6. To maintain a record of all research projects received and reviewed, with decisions and conditions;
 - 4.1.7. To monitor the progress of research projects so as to be satisfied that they continue to conform with approved ethical standards;
 - 4.1.8. To establish and administer mechanisms for receiving and handling complaints or concerns about the conduct of an approved research or teaching project;
 - 4.1.9. To establish a mechanism for handling any serious breach of ethical guidelines;
 - 4.1.10. To advise the University administration regarding ethical approval for research projects;
 - 4.1.11. To inform the University of Institutional responsibilities arising from the *National Statement*;
 - 4.1.12. To report annually to the Australian Health Ethics Committee (AHEC) information relevant to its procedures;
 - 4.1.13. To provide AHEC with access, upon request, to information in the Committee's register.

5. COMMITTEE MEMBERSHIP

- 5.1. The *National Statement* (5.1.29) states that an HREC must have a minimum of eight (8) members, fulfilling the requirements of stated categories of membership. Members are appointed for their knowledge and expertise and not as representatives of particular groups or interests. At a minimum one third of the membership of the committee should be non-institutional members.
- 5.2. BUHREC membership consists of:
 - 5.2.1. One (1) senior academic staff member nominated by the Bond University Research Committee
 - 5.2.2. One (1) minister of religion, or a person who performs a similar role in a community such as an Aboriginal elder, appointed by the Chair of BUHREC
 - 5.2.3. At least two (2) members with knowledge of, and current experience in, research in one or more disciplinary areas of the nominating Faculty, nominated by the Executive Dean of their Faculty.
 - 5.2.4. Lawyer appointed by the Chair of BUHREC
 - 5.2.5. Laywoman appointed by the Chair of BUHREC
 - 5.2.6. Layman appointed by the Chair of BUHREC
 - 5.2.7. One (1) member with knowledge of and current experience in medical practice or nursing appointed by the Chair of BUHREC
 - 5.2.8. One (1) member with knowledge of and current experience in counselling, clinical psychology or social work appointed by the Chair of BUHREC
 - 5.2.9. One (1) member who is a current HDR student.
 - 5.2.10. One of the members may be appointed as a Deputy Chair to operate in the Chair's stead in the event of illness or unavailability.

5.3. In addition to these members, BUHREC has established a pool of inducted members with relevant expertise in accordance with section 5.1.30 of the *National Statement*, who may be called upon for expert advice or to serve on sub-committees. It is important that the selection of members follows an open and accountable procedure. These are set out in the BUHREC Terms of Reference document.

5.4. Term of appointment

Each member will have a two-year appointment with the possibility of re-appointment. Appointments will be staggered, approximately half the members completing their terms at the end of any one (1) year.

5.5. Removal of members

The Deputy Vice Chancellor and Chair of BUHREC, by joint agreement, may remove a member from BUHREC if he/she has not discharged the responsibilities of membership in an acceptable manner. In this circumstance, the person will be offered natural justice.

5.6. Replacement of members

Members will be replaced, as necessary, by following the procedure described in 5.3 above.

5.7. Remuneration of BUHREC members

Members cannot be paid for Committee work (preparation and attendance at meetings). The University may undertake to reimburse members' reasonable expenses such as travel costs and may choose to recognise their contribution by offering an honorarium.

5.8. Legal Protection for those involved in ethical review of research

The University provides an assurance of legal protection to all those involved in ethical review of research for liabilities that may arise from the *bona fide* conduct of their duties in this capacity (section 5.1.9 of the *National Statement*).

6. REPORTING

6.1. BUHREC reports to the Academic Senate annually, through the Bond University Research Committee (BURC). The Committee also reports, through the Chair of BUHREC and Office of Research Services to external bodies, such as the Australian Health Ethics Committee, as required.

6.2. Annual reports to the Academic Senate address numbers and types of activities considered for approval and the outcomes, risk management, any administrative or other difficulties being experienced, and any requirements for training staff.

7. MODE OF OPERATION

7.1. BUHREC meetings

Most business will be conducted at Committee and Sub-committee meetings. It is important that these follow a consistent pattern as researchers need to know the time frame for processing applications.

7.2. BUHREC Chair's discretion

Provision is also made for the approval process to be hastened by Chair's review when exceptional circumstances present an unforeseen opportunity to carry out important research. Chair's review may be delegated to the Deputy Chair or a member with specific technical expertise relevant to the research. Chair's review decisions are ratified at the subsequent meeting of the Full Committee.

7.3. Approval for lower risk projects

The Bond University Research Ethics webpages include guidance on additional opportunities to approve projects whose risk profiles are low or negligible, by use of the BUHREC Subcommittee and, exceptionally, through Chair's approval (see 7.2 above). Low risk reviews may be conducted by designated low risk reviewing officers as appointed by the Chair. Low risk reviewing officers will have a knowledge of ethics committee operating procedures and the *National Statement*. Low risk reviews may be approved subject to ratification at the subsequent meeting of the Full Committee. Low risk reviewers may elect to elevate the review from a low risk status to Full Committee review, in which case the low risk application will be considered at the next Full Committee meeting.

7.4. Changes in policies/procedures

Changes in policies or procedures will require:

7.4.1. Endorsement by a quorum of BUHREC; and

7.4.2. Advice to, and assent of, Bond University Research Committee.

7.5. Files and archiving

Project and general files will be held in secure storage in the Office of Research Services and will be archived in accordance with the *Australian Code* and the University's procedures for records management, set out in the [Research Data Management Toolkit](#).

8. WORKING PROCEDURES

8.1. Section 5.2 of the *National Statement* requires that BUHREC establish detailed working procedures. These procedures are located on the University's Research Ethics website.

8.2. Concerns or complaints

The procedure for handling concerns or complaints is set out on the Bond University's Research Ethics Webpages and the University's practice follows requirements set out in the *National Statement* and Part B of the *Australian Code*.

9. RELATED PROCEDURES

BUHREC advises researchers of their responsibilities under the *National Statement*, and additional requirements arising from other legislation or University requirements, including but not limited to:

- 9.1. The expectation for clinical trials to be registered with an appropriate clinical trials registry;
- 9.2. The need for researchers to have received appropriate indemnity for medical or other therapeutic research prior to application for ethics approval;
- 9.3. The need for researchers to manage data according to best practice, as set out in Bond University's Data Management Toolkit, including the secure preservation of data for at least the minimum periods specified under the *Australian Code* or the relevant professional associations' requirements. When there is a disagreement between *National Statement* and professional associations requirements, the longer period shall apply;
- 9.4. Intellectual Property agreements relating to research should be arranged prior to an application's submission to BUHREC for ethical review.

10. RELATED GUIDELINES AND FORMS

Refer Related Policies and Document (above)
[Bond University Authorship Agreement](#)