### Abstract
This Directive outlines the responsibilities of UTS researchers whose research activities involve interaction with human participants. It also highlights the role and functions of the UTS Human Research Ethics Committee (HREC) in relation to human research and the University's requirements to ensure compliance with government regulations and directives.

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<td>20/02/2014</td>
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<th>Implementation Officers</th>
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| Relevant to                                | Researchers at UTS, including staff and students |

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<tr>
<th>Related documents</th>
<th>Australian Code for the Responsible Conduct of Research (the Code)</th>
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### 1. Purpose

The purpose of this Directive is to outline the responsibilities of UTS researchers whose research involve interaction with human participants. This Directive highlights the function of the UTS Human Research Ethics Committee (HREC) in relation to human research and the University’s requirements to ensure compliance with government regulations and directives.

This Directive is supplementary to and should be read in conjunction with the UTS [Responsible Conduct of Research Policy](#).

### 2. Scope

This Directive applies to any person conducting research involving human subjects under the auspices of UTS, whether that person is a staff member, student or non-staff member. The Directive also applies to UTS centres, institutes or research groups who are holders of program approval. Research in this context is understood broadly to encompass both funded and unfunded research.
3. Definitions
The following definitions define terms that are specific to this Directive. These are in addition to terms defined in Schedule 1, Student Rules and those provided in the Responsible Conduct of Research Policy.

Chief investigator is the person who takes responsibility for the conduct of the research on a day to day basis.

A clinical trial (as defined by the National Health and Medical Research Council (NHMRC)) describes research in which ‘a therapeutic, preventive or diagnostic intervention is tested’. Clinical trials at UTS must be conducted in accordance with relevant ethical guidelines and legislation.

Program ethics approval refers to particular body or program of research in which the same general methods of data collection and analysis are employed, such as research undertaken by a research centre.

The UTS Human Research Ethics Committee (HREC) is a Vice-Chancellor’s committee established in accordance with the requirements of the National Statement to ensure that all research undertaken by UTS staff and students conform to the highest ethical standards and to the guidelines of the Australian Health Ethics Committee (AHEC), which is a principal subcommittee of the NHMRC.

The role of the HREC and the ethics review process is to protect the interests of human participants of research, researchers and UTS, and to facilitate and enhance the research process within the University. HREC membership is published on the committee membership webpage (restricted access: UTS login only).

Responsible Academic means an academic from a research centre/research group with adequate administrative capacity to ensure ethical integrity of research projects, staff awareness of the National Statement and the Code, and compliance with internal standard operating procedures and codes.

4. Directive principles
In the Responsible Conduct of Research Policy, the University has endorsed the general principles of responsible research as set out in part A, section 1 of the Code and adopted them as a requirement for good research practice at UTS. These principles are also applicable to this Directive.

Further, the Code states that researchers must ‘maintain high standards of responsible research’ and ‘follow proper practices for safety and security’. This is also an expectation in conducting research at UTS.

5. Directive statements
5.1 General requirements for research involving human participants
When undertaking research involving human participants, the University requires researchers to:
a. adhere to UTS and relevant national policy and guidelines
b. conform to the principles of natural justice (PDF 505kb): fairness, transparency, equality before the law, freedom from bias, and the right to be heard
c. plan the research carefully so as not to waste participants' time (for example, ensure the information sought is relevant and necessary for the research) and to minimise any adverse consequences for the subjects/participants (for example, minimise disruption, intrusion, risk, discomfort)
d. identify themselves as either staff or student of UTS
e. provide sufficient information to participants so that they are informed about all relevant aspects of the research
f. obtain appropriate informed consent
g. accept any participants' right to withdraw from research projects at any time during the course of the project and along with any implications of withdrawal, and whether it will be possible to withdraw data
h. ensure that any information/data is recorded in accordance with the Privacy Principles as outlined in the Privacy and Personal Information Protection Act 1998 (NSW)
i. ensure that confidentiality is maintained (that is, any information obtained through the research is not divulged without permission of the subjects/participants)
j. reveal any financial or funding interest (such as commercial sponsorship) arising from the research to the HREC (if submitted for approval) and to participants/subjects
k. reveal any potential conflict of interest arising from the research to the HREC (if submitted for approval) and to participants/subjects.

Note: For research conducted outside of NSW researchers must comply with the governing principles of this Directive and the Responsible Conduct of Research Policy, provided that such compliance does not breach relevant local legislation.

Research should not be conducted in other countries as a mechanism of avoiding compliance with this policy and local legislation.

5.2 HREC ethics approval requirements
5.2.1 Human research approval
HREC approval is required when research involves humans as subjects or participants or use of their body organs, tissues or fluids, and:

a. may involve significant risk for the participant, researcher or institution
b. involves direct interventions with human participants which may have significant consequences for them or cause awkwardness, embarrassment or distress, changes of treatment protocols, teaching interventions, etc.
c. involves significant issues of privacy (for example, access to medical, staff or student records or collection of sensitive information)
d. involves collection and use of their body organs, tissues or fluids (for example skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath
e. involves another institution which requires formal ethics approval from UTS (for example schools, hospitals, nursing homes)
f. involves significant ethical issues (for example, conflict of interest, deception, limited disclosure)
g. involves human participants with whom the researcher has an existing or prior relationship which may be open to exploitation, such as student, employee, or family member
h. when there is a risk of disclosure of commercially sensitive information
i. when the relevant professional codes require such formal ethics approval.

5.2.2 Program ethics approval
Program ethics approval is granted to a program of research in which the same general methods of data collection and analysis are employed, such as research undertaken by a research centre.

In order to qualify for program approval, one person must be prepared to act as a Responsible Academic for all research included in the application and must demonstrate that it has the administrative capacity to manage the research to the satisfaction of the HREC and to ensure that all staff and students covered under the program approval are familiar with the National Statement and the Code. In addition, the HREC must be satisfied that the research does not involve high risk (such as clinical trials, vulnerable populations, etc.).

Program approval may only be applied for after consultation with the HREC Chair and the Research Ethics Manager.

5.2.3 Research involving UTS students and/or staff
HREC approval is necessary whenever the research involves use of UTS staff or students participants or where access to their records is required. Approval may not be necessary where:

- the research is anonymous and respondents will not be identifiable as a result of their participation, and
- the researcher does not have an existing or prior relationship which may be open to exploitation, such as student–teacher or employee–supervisor.

In all instances where research is conducted using staff or students of UTS as participants, approval must be obtained from an appropriate academic officer (for example, the head of the academic unit, the Associate Dean (Research), Dean, faculty research committee, etc.).

All access to staff and students’ records for the purposes of research must be in accordance with the Privacy Vice-Chancellor’s Directive.

5.2.4 Research where review by HREC is not required
Researchers do not require HREC review and approval in cases where the research is:

a. assessed as nil/negligible risk (likely to cause no more than inconvenience to participants or subjects)
b. teaching and learning evaluation activities
c. quality improvement/assurance activities.

Nil/negligible risk
For this assessment to take place, researchers must submit a Nil/Negligible Risk Declaration form via ResearchMaster (restricted access: UTS login only) to their faculty or unit research office. Up-to-date information about determining level of risk and faculty/unit review and approval processes is available from human research ethics — submission dates, processes and forms (restricted access: UTS login only).
**Teaching and learning evaluation activities**

Generally, teaching and learning evaluations (for example, course or subject evaluations) will not require HREC approval. Each faculty/unit is responsible for managing internal teaching and learning evaluations.

It is recommended that, where possible, student participation in any such teaching and learning activity is anonymous and that a decision by an individual student to participate in the evaluation or not should not affect subject results or course progression in any way.

The HREC has developed a Teaching and Learning (T&L) Evaluation Declaration to allow teaching and learning evaluation activities which extend beyond that broadly covered by the UTS Student Feedback Survey, for example, course or subject evaluation to be reviewed in terms of ethical implications. An example may be where researchers are planning to report or publish results of student evaluation and need to show evidence of ethical review.

Categories of teaching and learning evaluation activities and the requirements for an ethical review are available in the teaching and learning guidelines (restricted access: UTS login only). Some examples that require submission of a T&L Evaluation Declaration include:

- formal extensive evaluation of teaching and learning activities via obtaining feedback from students using questionnaires
- interviews or focus groups
- asking students/tutors to keep journals, and
- peer observation or video recording of lectures/tutorials for later analysis.

It is not intended that the T&L Evaluation Declaration cover research into teaching and learning — which could be of nil/negligible, low, medium or high risk. Depending on the level of risk identified, such research will require submission of a Nil/Negligible Risk Declaration (restricted access: UTS login only) or a full ethics application.

Refer to human research ethics — teaching and learning guidelines (restricted access: UTS login only) for guidelines and access to the T&L Evaluation Declaration form.

**Quality improvement/assurance activities**

HREC approval is not required where research being undertaken involves simple quality assurance assessments that are normally carried out in the classroom or laboratory, provided adequate protocol/safety procedures are used and relevant guidelines are taken into account.

**5.2.5 Retrospective ethics approval is not permitted**

As outlined in the Responsible Conduct of Research Policy, retrospective HREC approval is not permitted, and research involving human participants conducted without prior ethics approval is therefore considered a breach of the Responsible Conduct of Research Policy and this Directive.

**5.3 Students and ethics approval**

Each faculty, school and department is responsible for ensuring that its students carry out research in an ethical manner in accordance with University policy, directives and guidelines. Responsibility for ensuring that research students are adequately prepared to carry out their research in a responsible and ethical manner rests with the Dean and the Associate Dean (Research) of each faculty.
The staff responsible for supervising higher degree research, postgraduate and undergraduate research students should ensure compliance with the Responsible Conduct of Research Policy and this Directive, to ensure the ethical conduct of research involving humans.

Under normal circumstances, only doctoral and masters by research projects will require formal HREC review and approval. However, research projects conducted by undergraduate, honours and masters by coursework students are not universally exempt from HREC review. Due to the short timeframes available for the completion of these projects, at a minimum, every effort should be made to ensure that these projects are of nil/negligible or low risk. It is expected that these projects be reviewed for level of risk at faculty level.

An undergraduate, honours or masters by coursework research project can be submitted for review by the HREC where there is a particular reason, including but not limited to, a request for HREC approval from an external organisation (for example, hospital or school) and the involvement of vulnerable groups and communities.

The HREC recommends that all undergraduate and postgraduate subjects that contain a research element also contain references to policies and guidelines for the ethical conduct of research, including any relevant professional guidelines.

Faculties are to establish appropriate methods for dealing with ethical considerations of student research applicable to their particular disciplines (for example, they may establish their own faculty research ethics subcommittee that can liaise with the HREC).

Alternatively, where a particular subject involves a number of students undertaking similar research projects, the course coordinator may wish to seek ethics approval for the subject as a whole.

5.4 Communication and monitoring

5.4.1 Communication to the UTS HREC

All communication to the HREC must be made in writing to the Ethics Secretariat (restricted access: UTS login only). All applications need to be received by the Ethics Secretariat by the closing date. Information about application deadlines and meeting dates are available from human research ethics — submission dates, processes and forms (restricted access: UTS login only). Any application not received by this date will be held over until the meeting after. Only UTS staff may be listed as the chief investigator.

5.4.2 Communication from the UTS HREC

Correspondence from the UTS HREC is sent to the chief investigator of the research project and nominated researchers by email from the Ethics Secretariat (on behalf of the HREC). Outcomes of research applications reviewed by the HREC are sent within five working days of the meeting date. Researchers should not approach individual members of the HREC to discuss the progress of pending applications. If outcomes are not sent within five working days, researchers should contact the Ethics Secretariat (restricted access: UTS login only) with any queries or concerns.

5.4.3 Official records of the UTS HREC

After each meeting, copies of HREC meeting minutes are circulated to the Vice-Chancellor and Deputy Vice-Chancellor (Research). These minutes documents are
confidential and access is made available only to aforementioned personnel, the Ethics Secretariat and HREC.

The UTS HREC annual report is submitted to the Vice-Chancellor and the Deputy Vice-Chancellor (Research) and is available from human research ethics — committee membership and reports to the VC (restricted access: UTS login only).

5.4.4 Monitoring of research
In accordance with chapter 5.5.3 of the National Statement, ‘researchers have a significant responsibility in monitoring [their research activity] as they are in the best position to observe any adverse events or unexpected outcomes’. Researchers are expected to ‘report such events or outcomes promptly to the relevant institution(s) and ethical review body(ies), and take prompt steps to deal with any unexpected risks’. As a result, it is expected that researchers must submit the following information to the UTS HREC:

a. annual progress reports whilst the project is in progress (including compliance with any conditions of approval and maintenance and security of records)
b. final report on completion, project termination or withdrawal (including a copy of the results, information sent to participants and any publications)
c. amendments to the research protocol or changes to participant materials
d. reports of adverse/serious adverse events.

The UTS HREC and the Research Ethics Manager may conduct random audits of approved research projects as part of this monitoring activity.

5.5 Clinical trials
Clinical trials are a specific type of research involving human participants and have additional regulatory requirements.

When conducting clinical trials, UTS researchers are required to:

a. adhere to the Responsible Conduct of Research Policy, this Directive and relevant national and international policy and guidelines related to conduct of clinical trials, such as TGA’s note for guidance on good clinical practice (CPMP/ICH/135/95), the Declaration of Helsinki and any other guidelines specific to the research area
b. comply with the principles of NHMRC’s Good Clinical Practice (GCP) and UTS’s requirements for clinical trials (restricted access: UTS login only).

Before initiating a clinical trial, UTS researchers should have the essential clinical trial documents, insurances and signed contracts (if applicable), and have obtained written approval or ratification of external approval from the UTS HREC for the trial protocol. Refer to human research ethics — clinical trials (restricted access: UTS login only).

5.6 Resolving breaches of the Directive
Breaches of this Directive should be resolved through the processes outlined below and in accordance with the UTS Code of Conduct.

5.6.1 Complaints and grievances
Complaints or concerns can originate from individuals internal or external to UTS. Complaints may fall into the following categories:

• complaints from individuals who are not associated with research (may include members of the public and visitors to the University)
• complaints by UTS staff or students
• disputes between investigators and the Ethics Committee
• serious disagreements between members of the Ethics Committee
• disagreements between the Ethics Committee and UTS senior managers.

5.6.2 General complaint principles
The following general principles guide the resolution of Directive breaches:

• The ultimate goal in considering any complaints is to ensure the wellbeing of the human participants.
• All complaints must be treated confidentially and can be submitted anonymously if desired by the complainant.
• Any person who makes a complaint in good faith will not be disadvantaged.
• In the first instance, all enquiries, concerns and complaints should be directed to the Research Ethics Manager. The complaint, with or without resolution, will be notified to the Director, Research and Innovation Office, and the HREC for resolution.
• All complaints will be taken seriously and resolved in a timely manner.
• All complaints, except those which are minor and do not involve a breach of this Directive, need to be reported to the Research Ethics Manager.
• Any member of the HREC receiving a complaint about a breach of this Directive is obliged to raise the matter with the Research Ethics Manager and/or HREC Chair as soon as possible.
• Staff and students of the UTS must be made aware of what complaints management procedures exist.

5.6.3 Complaints management procedures
a. The Research Ethics Manager is authorised by the UTS HREC to monitor projects involving human participants to ensure they are proceeding in compliance with the Code, the National Statement and the decisions of the UTS HREC.

b. Concerns or complaints from internal and external stakeholders received via email, telephone or in a face-to-face conversation are recorded in writing by the Research Ethics Manager and kept in a separate file to which only the Research Ethics Manager will have access.

c. The Research Ethics Manager undertakes a preliminary investigation regarding the issues raised by the complainant.

d. The HREC Chair is notified about the complaint and the results of the preliminary investigation and if necessary provides advice about the appropriate resolution of the concern or complaint.

e. The Chair and the HREC endorse the resolution of the complaint.

f. The complaint and its proposed or actual resolution are notified to the Director, Research and Innovation Office, the HREC (at its next meeting) and the faculty Associate Dean (Research).

g. The Research Ethics Manager informs the complainant and the researcher to whom the complaint has been made of the outcome.

In exceptional cases, the HREC Chair, Deputy Chair or Research Ethics Manager may place an immediate suspension on a project upon receipt of a complaint. The researcher will be notified immediately if this occurs.

The HREC may recommend to the Deputy Vice-Chancellor (Research) the withdrawal of a study if there is a major deviation from the HREC approved protocol.
or proven misconduct. Where appropriate, or deemed necessary by the HREC, the responsible researcher(s) may be subject to disciplinary action in relation to the complaint. In this instance, the matter will be referred to the UTS Adviser on Integrity in Research (restricted access: UTS login only) (usually the relevant faculty's Associate Dean (Research)), and the Designated Person to Receive Formal Complaints (restricted access: UTS login only) (the Deputy Vice-Chancellor (Research)) related to the Code.
## 6. Roles and responsibilities

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<th>Accountable Officer</th>
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<th>Researchers, supervisors</th>
<th>Research students</th>
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</table>
| Deputy Vice-Chancellor (Research) | Deans, Associate Deans (Research) of faculties and centre directors are responsible for:  
  - promoting the awareness of policies, procedures and guidelines related to the ethical conduct of research involving human participants  
  - training researchers and students in responsible and ethical research practice.  
  Director, Research and Innovation Office (RIO) is responsible for:  
  - providing advice on implementing and administrating the Directive  
  - managing the processes through which a research project gains approval to be conducted, including the approval from HREC  
  - ensuring HREC is appropriately constituted  
  - facilitating access to information about the ethical conduct of research and the procedures for seeking approval and reporting on the completion of research. | All researchers are responsible for ensuring that their conduct of research complies with the statements in this Directive as well as with state and federal legislation. Research supervisors are responsible for ensuring that research students are aware of the requirements of the research they will be conducting and have complied with the requirements of HREC. | Research students are responsible for ensuring that their conduct of research complies with this Directive and the associated Responsible Conduct of Research Policy as well as with state and federal legislation. Research students should be aware of the requirements of the research they will be conducting and have complied with the requirements of HREC. |
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<td><strong>6.2 HREC ethics approval</strong></td>
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<td>Deputy Vice-Chancellor (Research)</td>
<td>UTS Human Research Ethics Committee (HREC) is responsible for:</td>
<td>All researchers and supervisors are responsible for:</td>
<td>Research students are responsible for:</td>
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<td>- proposing amendments to the Directive, and</td>
<td>- seeking ethics approval when required and for keeping clear and accurate records of the research process, including methodologies and data sources and any approvals granted</td>
<td>- actively engaging with the research training opportunities offered through the Graduate Research School and their faculty/research strength</td>
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<td>- provision of comments and feedback in the consultation process when the Directive is due for review.</td>
<td>- ensuring that the design and conduct of their research complies with UTS policies, directives and guidelines on ethical conduct and the responsible conduct of research.</td>
<td>- seeking guidance from their supervisor on the ethical conduct of their research</td>
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<td>Ethics Secretariat is the primary point of contact for:</td>
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<td>- ensuring that the design and conduct of their research complies with UTS policies, directives and guidelines on ethical conduct and the responsible conduct of research.</td>
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<td>- establishing and maintaining the official file of the Directive</td>
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<td>- proposing amendments as required, and</td>
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<td>- managing the consultation process when the Directive is due for review.</td>
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<td><strong>6.3 Communication and monitoring</strong></td>
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<td>Deputy Vice-Chancellor (Research)</td>
<td>Research Ethics Manager and the Ethics Secretariat are responsible for:</td>
<td>Researchers and supervisors of research students are responsible for:</td>
<td>Research students are responsible for:</td>
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<td>- communicating the decisions of the UTS HREC to the researchers and senior management</td>
<td>- responding to the HREC comments in a timely matter (within three months) to enable finalisation of the ethics approval</td>
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<td>- promoting the awareness of policies, procedures and guidelines related to the ethical conduct of research involving human participants.</td>
<td>- identifying and providing appropriate supervision and training for research students, for example, through using the opportunities provided through the Graduate Research School.</td>
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<td><strong>6.4 Students and ethics approval</strong></td>
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| Deans, Associate Deans (Research and Teaching and Learning) of faculties and Centre Directors | Deans and Associate Deans (Research and Teaching and Learning) of faculties are responsible for:  
- establishing appropriate methods for dealing with ethical considerations of student research as applicable to their particular disciplines, for example, research ethics subcommittee or subject related ethical review  
- ensuring all programs that teach principles of research methodology include an ethics component to acquaint students with the relevant issues and appropriate professional codes and guidelines. | Supervisors of research students are responsible for:  
- ensuring compliance with UTS policy, directives and guidelines for the ethical conduct of research involving human participants.  
Course coordinators are responsible for:  
- seeking ethics approval for the subject as a whole if the subject involves a number of students undertaking similar research projects  
- providing research students and staff with support, assistance and mentoring in matters of authorship and the dissemination of research outputs as appropriate. | Research students are responsible for:  
- seeking ethics approval when required and for keeping clear and accurate records of the research process, including methodologies and data sources and any approvals granted. |
| **6.5 Clinical trials** |
| Deputy Vice-Chancellor (Research) | Director, Research and Innovation Office is responsible for:  
- developing procedures to assist researchers and the University in conducting clinical trials.  
Research Ethics Manager and the Ethics Secretariat are responsible for:  
- promoting awareness of the UTS clinical trials procedures and guidelines and making them available to researchers. | Researchers are responsible for:  
- ensuring that the conduct of their clinical trial complies with the statements in this Directive as well as with relevant UTS, state and federal regulations relating to clinical trials  
- having all essential clinical trial documents and relevant approvals before initiating a clinical trial. | Research students are responsible for:  
- ensuring that the conduct of their clinical trial complies with the statements in this Directive as well as with relevant UTS, state and federal regulations relating to clinical trials  
- having all essential clinical trial documents and relevant approvals before initiating a clinical trial. |
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<td><strong>Researchers</strong> are responsible for:</td>
<td><strong>Research students</strong> are responsible for:</td>
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<td>● ensuring that processes outlined in this Directive and in the UTS Responsible Conduct of Research Policy are implemented.</td>
<td>● being aware of and complying with this Directive and relevant UTS policies and agreements.</td>
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<td><strong>Designated Person</strong> in research integrity who receives formal complaints under the Code (Deputy Vice-Chancellor (Research)) is responsible for:</td>
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<td>● ensuring that processes outlined in this Directive and in the UTS Responsible Conduct of Research Policy are implemented.</td>
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7. Acknowledgements

AHEC
NHMRC
National Statement

8. Version control and change history

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<tr>
<th>Effective date</th>
<th>Version</th>
<th>Approved by, resolution no. (date)</th>
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<td>20/03/2014</td>
<td>1</td>
<td>Vice-Chancellor (22/02/2014)</td>
<td>New Directive.</td>
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<td>23/08/2016</td>
<td>1.1</td>
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