

Version	Approved by	Approval date	Effective date	Next review date
1.0	Deputy Vice-Chancellor (Research)	9 August 2016	15 August 2016	9 August 2019

Procedure Statement

Purpose	This document sets out the responsibilities and bodies governing human research and its ethical considerations in accordance with the requirements of the <i>National Statement on Ethical Conduct in Human Research</i> (henceforth referred to as the <i>National Statement</i>) and other relevant codes and legislation.		
Scope	The content of the document applies to all staff and research students at UNSW Australia and affiliated centres and institutes conducting human research in Australia and overseas.		
Are Local Documents on this subject permitted?	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes, subject to any areas specifically restricted within this Document	<input checked="" type="checkbox"/> No

Procedure Processes and Actions
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1. Preamble

Human research, including research with or about people or their data or tissue, is governed by ethical principles embedded in codes and legislation. History has shown that wilful or inadvertent research conduct can harm participants and erode the public trust in research. Codes and legislation evolve over time to reflect public expectations about the conduct of human research and the benefits of the research for people. This Procedure details the mechanisms set in place by UNSW Australia to ensure that human research is conducted to minimise the risk posed to participants, researchers, the university, and the broader community while affirming the right of researchers to carry out legitimate investigations.

2. Regulatory Environment

The Deputy Vice-Chancellor (Research) oversees the conduct of human research at UNSW Australia with support of the Presiding Member for Human Research Ethics, the Human Research Ethics Committees (HRECs) and Human Research Ethics Advisory Panels (HREAPs), and Research Ethics & Compliance Support (RECS). HRECs and HREAPs are established in accordance with the requirements of the National Statement. All human research at UNSW and its affiliated centres and institutes at the level of negligible risk and above is reviewed by the HRECs or HREAPs and approved by the DVC(R) unless the research is conducted elsewhere and approved by another NHMRC-registered HREC or delegated review body.

The principal guidance for policy development is provided by the *National Statement* and by State legislation, including the *Human Tissue Act 1983* (NSW), the *Privacy and Personal Information Protection Act 1998* (NSW) and the *Health Records and Information Privacy Act 2002* (NSW). University procedures, guidelines and training are developed by Research Ethics & Compliance Support (RECS) in consultation with the Presiding Member, ethics committees and the research community and approved by the DVC(R).

3. Principles of Ethical Review at UNSW

All human research and teaching involving negligible risk and above is reviewed prior to commencement and, upon approval, monitored until project closure. HREAPs consider human research proposals involving negligible and low risk (as defined in the *National Statement*), and HRECs consider human research proposals involving more than low risk.

Both HRECs and HREAPs apply the principles outlined in the *National Statement*, including research merit and integrity, justice, beneficence and respect. It is the role of the HRECs and HREAPs to ensure that projects promote and facilitate ethically sound research that is of benefit to the community, that researchers and research students respect the rights and welfare of human participants in research, and that any risk of unfair burden or harm from research procedures is minimised.

The principles of ethical review at UNSW are outlined in the *Guidelines for HREC and HREAP Members: A structured approach to ethical review of human research at UNSW Australia*.

4. University Human Research Ethics Committees

4.1. HREC Terms of Reference

Each UNSW HREC will operate in accordance with the following terms of reference in order to:

- Review proposals for more than low risk research to be undertaken by staff and students or on the premises of the University or its affiliates, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines;
- provide the DVC(R) with a recommendation as to whether the research should be approved, modified prior to approval, approved with conditions, deferred for further review or rejected;
- refer ethics applications that are identified as negligible or low risk to a UNSW HREAP for ethical review;
- monitor the conduct of approved more than low risk human research projects through the receipt of annual and final reports, audits of compliance with the approved protocol, and site visits and interviews with research participants or complainants;
- provide recommendations to the DVC(R) to withdraw, suspend or terminate the approval of any project where possible non-compliance with the approved protocol has been identified or where an adverse event impacts on the safety of the participants, and advise on how the project would need to be modified to ensure participant safety and protection of participants before a project is allowed to resume;
- refer the alleged non-compliance and other possible breaches of the UNSW Research Code of Conduct, including human research, to the Research Integrity Office at UNSW and inform the DVC(R);

- review any requests for amendments to approved more than low risk projects through the HREC Executive and recommend to the DVC(R) as to whether the modifications should be approved, modified prior to approval, approved with conditions, deferred for further review or rejected;
- maintain records of all more than low risk human research ethics projects and correspondence in accordance with the requirements of the National Statement and relevant legislation;
- provide advice to the DVC(R) on draft and existing institutional human ethics policies, procedures and guidelines and on the implication for the university of new and revised codes and legislation updates affecting the conduct of human research;
- contribute to the professional development of researchers, research students and the induction of new committee members; and
- provide advice and recommendations to the DVC(R) on any measures needed to ensure that the standards of the National Statement are maintained by UNSW and its researchers and research students.

4.2. Composition of the HRECs

The composition of the UNSW HRECs is in accordance with the requirements of the National Statement. As far as possible, men and women will be represented in equal numbers and at least one third of the members are from outside the university. The membership of each HREC comprises at least eight representatives from the following categories:

- **Chairperson** with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- **Lay Woman** who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work;
- **Lay Man** who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work;
- **Health Professional** with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- **Pastoral Care Person** who performs a pastoral care role in the community;
- **Lawyer** who is not engaged to advise the university; and
- **Researchers/Content Specialists** (at least two) with current research experience that is relevant to research proposals to be considered for review.

Membership categories may be represented by more than one person per category to ensure that each HREC is equipped to address all of the relevant considerations arising from the range of research disciplines reviewed. In addition, the committees may seek confidential expert advice from outside the HREC membership to assist the HRECs in making the appropriate decisions.

4.3. Appointment of HREC Members

HREC members are recruited by direct approach, nomination or advertisement. Prospective members are asked to provide a written expression of interest and current *curriculum vitae*, along with a letter of support from the Head of School or Institute for academic members, or contact details for professional referees for external members.

As part of the nomination process, potential members are required to declare current and potential conflicts of interest and facts that may preclude them from the nominated category and sign the University's confidentiality agreement. External candidates are asked to attend an interview, followed by background and referee check by the Director of RECS.

All HREC members are formally appointed by the DVC(R) following a recommendation for appointment from the Presiding Member for Human Research Ethics and the Director of RECS. Members are appointed for a term of three years, with the possibility to renew membership for a maximum of one more term as decided by the DVC(R).

Memberships may be terminated by the DVC(R) at any time by providing not less than 24 hours' notice in writing. Members may voluntarily retire during their appointment by providing not less than 24 hours' notice in writing to the DVC(R). Members who are staff of UNSW may need to seek approval from their Head of School or Dean prior to submitting a notice of retirement.

UNSW offers remuneration for HREC members external to the University and professional development for HREC members in general as determined by the DVC(R) to allow members to fulfil their duties according to the National Statement and UNSW policies and procedures.

4.4. HREC Meetings and Decision-Making

HRECs meet as required, normally monthly from February to December, to review more than low risk applications and discuss other agenda items as relevant to their terms of reference. The quorum for these meetings is at least eight representatives from the above categories as required by the National Statement, with each member representing one membership category only. Normally the Presiding Member has the dual role of Chair of HREC A which does not contradict the requirements of the National Statement. In circumstances where a member cannot be present, written comments may be submitted for consideration at the meeting to attain quorum.

HRECs should strive to reach decisions on agenda items by general agreement; this need not involve unanimity. In circumstances where a general agreement is not reached the Chair will facilitate a discussion in order to decide the outcome of the review. All key discussion points and decisions made at HREC meetings are minuted for the formal university record as required by the National Statement.

Any HREC member who has an interest, in the form of research collaboration or otherwise, in a proposal or other agenda item considered by the HREC, should as soon as practicable, declare such interest and withdraw from the meeting until the consideration of the matter has been completed.

Human research ethics applications from applicants not associated with UNSW may be considered by the HRECs, the decision to review will be at the discretion of the Presiding Member. A fee for review and subsequent monitoring applies as determined by the DVC(R).

4.5. HREC Executive Committee

HRECs may delegate decision-making on some items not requiring full HREC review to the HREC Executive which normally comprises of the HREC Chairs under the leadership of the Presiding Member. Should a Chair be unavailable, the Presiding Member may deputise a HREC member to the Executive for this occasion.

Items reviewed by the HREC Executive include responses to HREC requests for further clarification as recommended by the HRECs at their meetings, requests for modifications to HREC-approved projects, annual progress and final reports, and Serious Adverse Events, complaints and protocol deviations.

All key discussion points and decisions made at HREC Executive meetings are minuted for the formal university record as required by the National Statement. HREC Executive recommendations and minutes are submitted to the DVC(R) for approval and added to the agenda of the next HREC meeting for ratification.

5. University Human Research Ethics Advisory Panels

5.1. HREAP Terms of Reference

Each UNSW HREAP will operate in accordance with the following terms of reference in order to:

- Review proposals for negligible (through the HREAP Executive) and low risk research to be undertaken by staff and students or on the premises of the University or its affiliates, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines;
- provide the DVC(R) with a recommendation as to whether the research should be approved, modified prior to approval, approved with conditions, deferred for further review or rejected;
- refer ethics applications that are identified as more than low risk to the UNSW HRECs for ethical review;
- monitor the conduct of approved negligible and low risk human research projects through the receipt of annual and final reports, audits of compliance with the approved protocol, and site visits and interviews with research participants or complainants;
- provide recommendations to the DVC(R) to withdraw, suspend or terminate the approval of any project where possible non-compliance with the approved protocol has been identified or where an adverse event impacts on the safety of the participants, and advise on how the project would need to be modified to ensure participant safety and protection of participants before a project is allowed to resume;

- refer the alleged non-compliance and other possible breaches of the UNSW *Research Code of Conduct*, including human research, to the Research Integrity Office at UNSW and inform the DVC(R);
- review any requests for amendments to approved negligible and low risk projects through the HREAP Executive and recommend to the DVC(R) as to whether the modifications should be approved, modified prior to approval, approved with conditions, deferred for further review or rejected;
- maintain records of all negligible and low risk human research ethics projects and correspondence in accordance with the requirements of the *National Statement* and relevant legislation; and
- contribute to the professional development of researchers, research students and the induction of new committee members.

5.2. Composition of the HREAPs

HREAPs are bodies established to enable expedited review mechanisms for negligible and low risk research proposals under the provisions of the *National Statement*. This recognises that research involving negligible and low risk involves, by definition, less risk to research participants, researchers and/or the university.

HREAPs are composed of two categories of members appointed under the same terms and conditions outlined for HREC members:

- **Convenor**, with suitable experience, whose other responsibilities will not impair the HREAP's capacity to carry out its obligations under the National Statement; and
- **Researchers** (at least two) with current research experience that is relevant to the human research ethics applications to be considered for review.

Should the Convenor be expected to be unavailable, he/she may deputise a HREAP member to the role of Acting Convenor for this occasion.

The HREAP Executive, in the form of the HREAP Convenor or deputised HREAP member, is delegated to review and recommend for approval to the DVC(R) proposals for negligible risk research, responses to HREAP requests for further clarification as recommended by the HREAPs, requests for modifications to HREAP-approved projects, annual progress and final reports, and complaints and protocol deviations.

6. External and Multi-centre Ethical Review

UNSW has adopted the recommendation of the *National Statement* to minimise the duplication of ethical review and therefore recognises approvals issued by other NHMRC-registered HRECs and their delegated negligible and low-risk review bodies.

This means that UNSW staff and research students do not need to seek ethical review by UNSW HRECs or HREAPs if the research is conducted elsewhere and an external, NHMRC-registered HREC or delegated review body provides the review, approval and monitoring of the research according to the requirements of the *National Statement*.

However, evidence of the external review and approval must be provided by the lead UNSW researcher to UNSW prior to the commencement of the research or participation in an external project as requested on the UNSW Human Research Ethics [website](#). UNSW reserves the right to place conditions on involvement or refuse involvement should approved proposals not conform to the requirements of the *National Statement*, other relevant legislation or potentially expose the university to undue risk.

UNSW HREC or HREAP review is still required where the external HREC or delegated review body is not registered with NHMRC. UNSW HREC or HREAP review is also required where the external HREC is unable to approve UNSW as a research site for specific study activities. In this case the relevant UNSW HREC or HREAP will review the existing application to consider recommendation of approval for the remaining sites and activities as requested on the UNSW Human Research Ethics [website](#).

7. Research Conducted Overseas

Where a research project involving human participants, their data or tissue, including negligible risk research, is to be conducted overseas and the personnel responsible is a UNSW researcher or employee of an affiliated centre or institute, UNSW HREC or HREAP ethical review is required. In addition, approval must be obtained from overseas ethics committees or equivalent bodies where required or appropriate. Applications are reviewed with reference to the specific considerations in the *National Statement*. Particular care is taken where proposed projects involve people in countries that are politically unstable, where human rights are restricted, and/or where the research involves economically disadvantaged, exploited or marginalized participants from such countries.

Research students need to be adequately supervised when working with human participants or collect their data or tissue overseas. This may include the appointment of an 'in-country' supervisor or the development of a communications plan between the supervisor in Australia and the research student overseas.

Where UNSW or affiliated centre and institute researchers and research students intend to participate in human research approved overseas they need to provide evidence of the external review and approval as requested on the UNSW Human Research Ethics [website](#). The University reserves the right to request that the requirements of the *National Statement* are met and that any tensions with overseas legal or other processes are resolved as set out in the *National Statement*.

8. Monitoring of Research and Adverse Events

Human research approved by UNSW is monitored by UNSW and its delegated bodies through mechanisms described in the *National Statement*, including annual progress and final reports for each approved project, internal and external audits of compliance with the approved protocols, and site visits and interviews with research participants. UNSW may suspend or withdraw approval for human research where it is reasonable to believe that continuation of the research project may compromise participants' welfare.

Chief investigators are required to report unexpected adverse events to the relevant HREC or HREAP as soon as possible in accordance with the requirements outlined on the UNSW Human Research Ethics [website](#) and the committee or panel may request additional monitoring and other actions as deemed appropriate. This includes Serious Adverse Event, Suspected Unexpected Serious Adverse Event and Protocol Violation Reporting in clinical trials.

Issues identified during monitoring or adverse event reporting which may possibly involve breaches of the UNSW *Research Code of Conduct* are immediately referred to the SDVC and dealt with according to the UNSW Procedure for Handling Allegations of Research Misconduct. The DVC(R) may, on advice of the relevant HREAP or HREC, withdraw, suspend or terminate the approval for the project.

9. Complaints and Grievances

UNSW has established a complaints and grievances mechanism for UNSW personnel, students and persons external to the university. This process allows the voicing of concerns regarding human research and the ethical review process.

Complaints about the conduct of research by UNSW Australia staff, affiliates and research students should be directed to the DVC(R). Allegations involving possible breaches of the *Australian Code for the Responsible Conduct of Research* are dealt with by the Research Integrity office at UNSW in accordance with the *UNSW Research Code of Conduct*.

Grievances about ethics review and processes by UNSW Australia staff, affiliates and research students should be addressed to the Director of RECS. Concerns are addressed in reference to this Procedure and the *Guidelines for HREC and HREAP Members: A structured approach to ethical review of human research at UNSW Australia* available on the UNSW Human Research Ethics [website](#).

10. Additional Operating Guidelines

Human Research Ethics operating guidelines in support of this Procedure, such as rulings on recordkeeping, risk assessment, practical exercises involving human participants, and guidelines for staff and student surveys and participant information are approved by the DVC(R) and displayed in their current form on the UNSW Human Research Ethics [website](#).

11. Review & History

Version 1.0 of this Procedure replaces the *UNSW Operations Manual for the Human Research Ethics Committees (HRECs) 2010*. The Procedure is scheduled for review every three years.

Accountabilities	
Responsible Officer	Director, Research Ethics & Compliance Support
Contact Officer	Coordinator Human Ethics <i>E:</i> humanethics@unsw.edu.au <i>T:</i> +61 2 9385 6222
Supporting Information	
Parent Document (Policy)	Research Code of Conduct
Supporting Documents	Human Research Adverse Event Reporting Standard Operating Procedure Guidelines for HREC and HREAP Members: A structured approach to ethical review of human research at UNSW Australia.
Related Documents	Australian Code for the Responsible Conduct of Research 2007 National Statement on Ethical Conduct in Human Research 2007 Conflict of Interest Policy Intellectual Property Policy Privacy Management Plan Procedure for Handling Allegations of Research Misconduct Procedure for Handling Research Material and Data
Superseded Documents	Operations Manual of the UNSW Human Research Ethics Committees (2010)
UNSW Statute and / or Regulation	Nil
Relevant State / Federal Legislation	<i>Human Tissue Act 1983 (NSW)</i> <i>State Records Act 1998 (NSW)</i> <i>Privacy and Personal Information Protection Act 1998 (NSW)</i> <i>Health Records and Information Privacy Act 2002 (NSW)</i>
File Number	2016/24354
Definitions and Acronyms	
Compliance	acting in accordance with the <i>National Statement</i> , relevant legislation and UNSW Policies and Procedures.
Discomfort	a negative accompaniment or effect of research, less serious than harm.
Ethics	the concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.
Human research	research conducted with or about people, or their data or tissue.

Low risk research	research in which the only foreseeable risk is one of discomfort. Discomfort includes, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.			
More than low risk research	research which may plausibly lead to harm, including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.			
Negligible risk research	research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.			
Serious adverse event	serious or unexpected physical, psychological, financial, social or cultural harm to a research participant or researcher.			
Revision History				
Version	Approved by	Approval date	Effective date	Sections modified
1.0	Deputy Vice-Chancellor (Research)	9 August 2016	15 August 2016	New Document

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