



| Version | Approved by | Approval date | Effective date | Next full review |
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| 2.1 | Deputy Vice-Chancellor Research & Enterprise | 4 July 2023 | 4 July 2023 | November 2025 |
| Procedure Statement | | | | |
| Purpose | This procedure sets out the responsibilities and bodies governing human research and its ethical considerations following the National Statement's requirements on Ethical Conduct in Human Research (henceforth referred to as the <i>National Statement</i>) and other relevant codes and legislation. | | | |
| Scope | The procedure applies to all staff and research students at UNSW and affiliated centres and institutes conducting human research in Australia and overseas. | | | |
| Are Local Documents on this subject permitted? | <input type="checkbox"/> Yes, however, Local Documents must be consistent with this University-wide 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 public trust in research. Consequently, codes and legislation evolve to reflect public expectations of how human research is conducted and the benefits of such

research. This procedure details the mechanisms set in place by UNSW to ensure that human research is conducted so as to minimise the risk posed to participants, researchers, the University, and the broader community while affirming researchers' right to carry out legitimate investigations.

2. Regulatory Environment

The Deputy Vice-Chancellor Research & Enterprise and the Pro Vice-Chancellor (Research) oversee the conduct of human research at UNSW with the 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 following 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 are reviewed by the HRECs or HREAPs and approved by the Deputy Vice-Chancellor Research & Enterprise (DVCRE) or Pro Vice-Chancellor (Research) PVC(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), the *Health Records and Information Privacy Act 2002* (NSW) and the *Therapeutic Goods Act 1989*. In addition, university procedures, guidelines and training are developed by Research Ethics & Compliance Support (RECS) in consultation with the Presiding Member, HRECs/HREAPs and the research community, and approved by the Deputy Vice-Chancellor Research & Enterprise or the Pro Vice-Chancellor (Research).

3. Principles of Ethical Review at UNSW

Human ethics approval must be obtained before commencing any human research at negligible or greater risk and involving human participants, their data, and biospecimens. Research involving publicly available datasets must be notified as requested on the UNSW Human Research Ethics [website](#).

HREAPs review human research proposals involving negligible and low risk (as defined in the *National Statement*), and NHMRC-registered HRECs review human research proposals involving more than low risk. Section 6 of this procedure establishes the requirements for situations where ethical approval is obtained elsewhere.

The UNSW HRECs/HREAPs apply the principles outlined in the *National Statement*, including research merit and integrity, justice, beneficence, and respect. It is the role of these ethical review bodies 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 as available on the UNSW Human Research [website](#)*.

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:

- Review proposals for more than low-risk research submitted by staff and students of the University or its affiliates to determine whether they are ethically acceptable and follow relevant standards and guidelines;
- Provide the DVCRE or PVC(R) with a recommendation on whether the research should be approved, modified before 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 by receiving annual and final reports, audits of compliance with the approved protocol, and site visits and interviews with research participants or complainants. The method will depend on the level of risks identified in individual projects.
- Where deemed appropriate, provide recommendations to the DVCRE or PVC(R) to withdraw, suspend or terminate the approval of any project where non-compliance with the approved protocol has been identified. Alternatively, where an event impacts the participants' safety, advise on how

the project would need to be modified to ensure participants' safety and protection before a project is allowed to resume.

- Refer such alleged non-compliance and other possible breaches of the UNSW *Research Code of Conduct*, including human research, to the Conduct & Integrity Office at UNSW and inform the DVCRE or the PVC(R);
- Review any requests for amendments to approved more-than-low-risk projects through the HREC Executive and recommend to the DVCRE or PVC(R) as to whether the modifications should be approved, modified before 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 DVCRE or PVC(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 by participating in formal human ethics member training and/or assisting RECS with the development or delivery of student/researcher education sessions/materials; and
- Provide advice and recommendations to the DVCRE or PVC(R) on any measures needed to ensure that UNSW, its researchers and research students maintain the *National Statement's* standards.

4.2. Composition of the HRECs

The composition of the UNSW HRECs follows the requirements of the *National Statement*. Gender diversity should be represented in equal numbers, and at least one-third of the members will be from outside the University. The membership of each HREC comprises representatives from the following categories and other additional members:

- **Chairperson** with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*;
- **Lay Persons (at least two)** who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work, and who are of a different gender from the other lay person so as to achieve gender diversity;
- **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;
- **A lawyer** who is not engaged in advising the University; and
- **Researchers/Content Specialists** (at least two) with current research experience relevant to research proposals to be considered for review.

More than the required number of persons per category may represent membership categories to ensure that each HREC is equipped to address all relevant considerations from the research disciplines reviewed. Also, the committees may seek confidential expert advice from outside the HREC membership to assist the HRECs in making the appropriate decisions.

Should the chairperson expect to be unavailable, they may deputise an HREC member to the role of Acting Chair for this occasion.

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*, 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 must declare any current interest and facts that may preclude them from the nominated category and sign the University's confidentiality agreement. RECS will assess declared interests to determine whether they reflect a real or potential Conflict of Interest. External candidates are asked to attend an interview, which may be followed by a referee check by the Director RECS.

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

Memberships may be terminated by the DVCRE or PVC(R) by providing not less than 24 hours' notice in writing. Members may voluntarily retire during their appointment by providing notice in writing to the DVCRE or PVC(R). Staff members of UNSW may need approval from their Head of School or Dean before submitting a retirement notice.

UNSW offers an allowance for HREC members external to the University and professional development for HREC members in general as determined by the DVCRE or PVC(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 relevant to their terms of reference. The minimum attendance for these meetings is the eight representatives from the minimum membership categories as required by the *National Statement*, noting that the eight representatives required from the minimum membership categories must either attend the meeting when any decision is taken or submit their input in writing prior to the meeting. These reports must then be circulated to everyone attending the meeting with sufficient opportunity for consideration before the meeting and not just considered by the Chair. Normally, the Presiding Member has the dual role of Chair of HREC A, which does not contradict the *National Statement's* requirements.

HRECs should strive to reach decisions on agenda items by general agreement; this need not involve unanimity. If a general agreement is not reached, the Chair will facilitate a discussion to decide the review's outcome. As the *National Statement* requires, all key discussion points and decisions made at HREC meetings are recorded in minutes for the formal university record.

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 during the consideration of the proposal or other agenda item until decision-making processes relating to the matter have been completed.

The HRECs may consider human research ethics applications from applicants not associated with UNSW. The decision to accept such external applications for review will be at the discretion of the Presiding Member following the external research review guideline. A fee for review and subsequent monitoring applies as determined by the DVCRE or PVC(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 the HREC Chairs under the leadership of the Presiding Member. However, should a Chair be unavailable the Presiding Member may if required, deputise an HREC member to the Executive for this occasion, or alternatively another Chair can review executive items, with these decisions to be noted by the initial Chair once available.

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.

As required by the *National Statement*, all key discussion points and decisions made at HREC Executive meetings are minuted for the formal university record. HREC Executive recommendations and minutes are submitted to the DVCRE or PVC(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 to:

- Review proposals for negligible and low-risk research to be undertaken by staff and students, or on the premises of the University or its affiliates, so as to determine whether they are ethically acceptable and follow relevant standards and guidelines;

- Provide the DVCRE or PVC(R) with a recommendation on whether the research should be approved, modified prior to approval, approved with conditions, deferred for further review or rejected;
- Refer ethics applications 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 by receiving annual and final reports, audits of compliance with the approved protocol, and site visits and interviews with research participants or complainants. Additionally, where deemed appropriate, provide recommendations to the DVCRE or PVC(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 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 such alleged non-compliance and other possible breaches of the UNSW *Research Code of Conduct*, including human research, to the Conduct & Integrity Office (CIO) at UNSW and inform the DVCRE or PVC(R);
- Review any requests for amendments to approved negligible and low-risk projects through the HREAP Executive and recommend to the DVCRE or PVC(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 members by participating in formal human ethics training or assisting RECS with the development or delivery of student/researcher education sessions/materials.

5.2. Composition of the HREAPs

HREAPs are review bodies established to enable review mechanisms for negligible and low-risk research proposals under the *National Statement's* provisions.

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

- **Convenor** with suitable leadership and research 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 relevant to the human research ethics applications will be considered for review.

Should the Convenor expect to be unavailable, they may deputise an 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 to the DVCRE or PVC(R) negligible risk proposals for approval, 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 *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 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 *National Statement* or other relevant legislation requirements or 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

cannot 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 the recommendation of approval for the remaining sites and activities as requested on the UNSW Human Research Ethics [website](#).

7. Research Conducted Overseas

UNSW employees, research investigators, or students must establish UNSW ethical approval for human research proposals that UNSW is responsible for and where that research involves in-person data collection conducted overseas. Additional Human ethics approval must also be obtained for those proposals where relevant ethical review processes exist within the countries where data collection will occur. In the absence of relevant ethical review processes or for other research involving online participation of participants recruited overseas, the human research ethics proposal must include evidence of engagement with relevant organisations on the research design, methodology and relevant in-country support services where applicable.

Where UNSW employees, researchers or students are participating in research approved overseas and where UNSW is not responsible for the research, evidence of the external review and approval must be provided as per the requirements of section 6. Relevant legal agreements must also be established between overseas institutions and UNSW before transferring any data or tissue collected for approved human research.

The University reserves the right to request that the *National Statement* requirements are met and that any tensions with overseas legal or other processes are resolved as set out in the *National Statement*.

Advice may also be required from UNSW Risk Management, Legal or Insurance where proposed projects involve people in politically unstable countries, where human rights are restricted, and where the research involves economically disadvantaged, exploited or participants from such countries.

Research students must be supervised when working with human participants, conducting fieldwork, or collecting their data or tissue overseas. Supervision may include an 'in-country supervisor' appointment or developing a protocol for supervision between the supervisor in Australia and the research student overseas.

8. Clinical Trials

A trial sponsor ensures that any proposed clinical trials are designed, conducted and monitored according to all regulatory requirements. Sponsors of clinical trials can be pharmaceutical or biotechnology companies, research institutes, or universities. In addition, an Australian entity must sponsor clinical trials conducted in Australia.

Where UNSW researchers, staff and students intend to participate in a clinical trial or where UNSW is intended to act as a clinical trial site, evidence of the external review and approval must be provided by the UNSW researcher to UNSW prior to the commencement of the clinical trial as requested on the UNSW Human Research Ethics website

UNSW may act as the sponsor of clinical trials initiated by staff or students where the UNSW Sponsor's Delegate has confirmed that the clinical trials research governance requirements outlined on the UNSW Human Research Ethics [website](#) have been met. The Director RECS is the *ex officio* UNSW Sponsor's Delegate as nominated by the DVCRE.

9. Monitoring of Research

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 the research project may compromise 'participants' welfare.

Chief investigators must report incidents that present an undue risk to the health, safety or wellbeing of human participants or those that have the potential to affect the ethical acceptability of approved human research as soon as possible, following the requirements outlined in the UNSW Human Research Ethics [website](#). UNSW may request additional monitoring and other actions as deemed appropriate.

The notification requirements in the Research Misconduct Procedure will be adhered to for matters identified during monitoring. Matters that uncover breaches of the UNSW Research Code of Conduct are immediately referred to the DVCRE or PVC(R). The DVCRE or PVC(R) may withdraw, suspend, or terminate the project's approval on the advice of the relevant HREAP or HREC.

HRECs will fulfill all reporting requirements with the support of RECS so that institutional and external obligations by the institution can be met. HREC reporting includes but is not exclusive to: Annual report to Risk Committee of Council, Quarterly update to the Pro Vice-Chancellor (Research), reporting to national and international funding and compliance bodies, close liaison with UNSW Conduct & Integrity and the University on matters of possible deviations from approved protocols and complaints about human research, and responding to internal and external audits of human research ethics processes.

10. Complaints, Grievances and Allegations of Non-Compliance

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

Complaints about UNSW staff, research investigators, personnel or students' conduct involving human research should be directed to the Director Research Ethics and Compliance Support (RECS) (humanethics@unsw.edu.au). Allegations involving possible breaches of the *Australian Code for the Responsible Conduct of Research* are referred to the Conduct & Integrity Office (research.integrity@unsw.edu.au) to be reviewed following the UNSW *Research Code of Conduct*.

Grievances about ethics review and processes by UNSW staff and students should be addressed to the Director RECS (humanethics@unsw.edu.au).

11. Additional Operating Guidelines

Human Research Ethics operating guidelines supporting 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 Director RECS or PVC(R) and displayed in their current form on the UNSW Human Research Ethics [website](#).

| Accountabilities | |
|---------------------------------|---|
| Responsible Officer | Director, Research Ethics & Compliance Support |
| Contact Officer | Human Research Manager E: humanethics@unsw.edu.au T: +61 2 9385 6222 |
| Supporting Information | |
| Legislative Compliance | This procedure supports the University's compliance with the following legislation: <i>Human Tissue Act 1983</i> (NSW) <i>State Records Act 1998</i> (NSW) <i>Privacy and Personal Information Protection Act 1998</i> (NSW) <i>Health Records and Information Privacy Act 2002</i> (NSW) |
| 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, 2018 National Statement on Ethical Conduct in Human Research 2007 (updated 2018) Conflict of Interest Disclosure and Management Policy Conflict of Interest Disclosure and Management Procedure Intellectual Property Policy Privacy Policy Research Misconduct Procedure Research Data Governance & Materials Handling Policy Handling Research Material and Data Procedure |
| Superseded Documents | Human Research Ethics Procedure, version 1.1 |

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| File Number | 2022/077579 | | | |
| Definitions and Acronyms | | | | |
| Compliance | following 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. When a person's reactions exceed discomfort and become distressed, they should be viewed as harmful. | | | |
| More than low-risk research | research that may plausibly lead to 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 |
| Version 1.0 of this Procedure superseded the Operations Manual of the UNSW Human Research Ethics Committees (2010) | | | | |
| 1.0 | Deputy Vice-Chancellor Research | 9 August 2016 | 15 August 2016 | New Document |
| 1.1 | Deputy Vice-Chancellor Research | 31 July 2017 | 15 August 2017 | Administrative update to senior positions |
| 2.0 | Deputy Vice-Chancellor Research & Enterprise | 30 November 2022 | 30 November 2022 | Full review with minor changes |
| 2.1 | Deputy Vice-Chancellor Research & Enterprise | 4 July 2023 | 4 July 2023 | Minor amendments to governance processes in sections 4.2, 4.3, 4.4 and 9 as requested and agreed by the National Health and Medical Research Council (NHMRC) |