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 *National Statement*) 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.

Principles and Objectives

1.

The Deputy Vice-Chancellor (Research & Enterprise)(DVCRE) and the Pro Vice-Chancellor (Research)(PVCR) 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 DVCRE or PVCR unless the research is conducted elsewhere and approved by another NHMRC-registered HREC or delegated review body.

- 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 PVCR

- 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

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 regulatoryac

The notification requirements in the *Complaints Management and Investigations Policy and procedure* will be adhered to for matters identified during monitoring. Matters that uncover breaches of the UNSW *Code of Conduct and Values*, the *Australian Code for the Responsible Conduct of Research* or the *National Statement* are immediately referred to the DVCRE or PVCR. The DVCRE or PVCR 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 PVCR r

Appendix

Legislative compliance

1. This procedure supports the University's compliance with the following legislation:
    1.1. Human Tissue Act 1983 (NSW)
    1.2. State Records Act 1998 (NSW)
    1.3. Privacy and Personal Information Protection Act 1998 (NSW)
    1.4. Health Records and Information Privacy Act 2002 (NSW)

Related 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.
- Australian Code for the Responsible Conduct of Research, 2018
- National Statement on Ethical Conduct in Human Research 2007 (updated 2018)
- Code of Conduct and Ethics
- Complaints Management and Investigations Policy and Procedure
- Conflict of Interest Disclosure and Management Procedure
- Intellectual Property Policy