

Contents

1. Establishing ethics approval for human research.....	2
2. Retrospective Approval.....	2
3. Minimising the Duplication of Ethical Review of research conducted within Australia	2
4. Research Conducted Overseas	2
5. Research Conducted Overseas where a UNSW researcher is responsible.....	2
6. Research Conducted Overseas where UNSW personnel are not responsible.....	4
7. Selection of appropriate ethical review body.....	4
8. Approval Period and Extensions.....	4
9. Research that can be exempted from review or does not require ethical approval.....	4

Human Research Establishment of Ethical Approval

1. Establishing ethics approval for human research

- 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. As per the [UNSW Research Misconduct Procedure](#) the conduct of research without ethics approval is considered a breach of the [UNSW Research Code of Conduct](#).
- In line with the [UNSW Research Code of Conduct](#) Human Research ethics approval must be established before any UNSW staff or students commence human research activity (e.g. recruitment, data collection, analysis or access to data, biospecimens). Approval must be established via an Australian NHMRC registered HREC or one of their delegated low or negligible risk HREAPs.

2. Retrospective Approval

- Requests for retrospective approval will not be granted for any human research conducted by UNSW staff or students without ethics approval or under approved project where the ethics approval period has expired. Any data collected using unapproved methods will need to be destroyed.
- Retrospective approval will not be granted for human research activities not approved or where the research team have deviated from the ethics approved protocol. Any data collected using unapproved methods will need to be destroyed.

3. Minimising the Duplication of Ethical Review of research conducted within Australia

- In line with the requirements of the National Statement institutions must adopt a review process that eliminates any unnecessary duplication of ethical review. Consistent with this requirement UNSW recognises the ethical review processes and approvals issued by Australian HRECs that are registered with the NHMRC and their delegated low or negligible risk review bodies. Before this type of research can commence ethical approval must be registered via the external ethics approval notification [process](#) (National Statement 5.3.1).
- Research submitted via the external ethics approval notification process will be reviewed by the HREC Executive. The application must indicate the role that UNSW will have in the research, the staff or students who will conduct the research, along with the name and location of the sites that are covered by external approval (National Statement 5.3.4 (a)).
- In line with the UNSW Human Research procedure, prior to the commencement of, or participation in, human research where external ethical approval via a NHMRC registered HREC has been established, UNSW, via RECS, reserves the right to place conditions on involvement or refuse involvement in circumstances where the approved proposals do not conform to the requirements of the National Statement, the UNSW human research procedures, or other relevant legislation, and/or where the approved proposals may potentially expose the university to undue risk.

4. Research Conducted Overseas

- When research projects involving human participants, or their data or tissue, is to be conducted overseas, and a UNSW researcher or employee of an affiliated center or institute is *responsible* for the conduct of the project, UNSW HREC or HREAP ethical review is required before travel is booked and recruitment or data collection commences.
- A person is considered responsible when a UNSW researcher is listed as the Chief Investigator of the research, UNSW is the sponsor of the research, UNSW has developed the clinical trial protocol, or a UNSW researcher is responsible for the collection of data, administration of research procedures, or conduct of research activity in-country during fieldwork activities.

5. Research Conducted Overseas where a UNSW researcher is responsible

- A UNSW Human Research Ethics application must be submitted for low or more than low risk review.
- In-country ethics approval must be established in circumstances where there are local ethics approval processes relevant to the research and these processes are mandatory. A copy of the human ethics approval must be provided before recruitment and data collection in-country commences.
- In countries where there are no ethics approval processes relevant to the research, or where these processes are voluntary, researchers must identify whether there are additional ethical considerations arising from the beliefs, customs, and cultural heritage of the local participant population in the country in which they intend to conduct their research.

Human Research Establishment of Ethical Approval

5.1. If so, **researchers must demonstrate how they have engaged with local organisations and/or communities during the development of the research methodology, the recruitment strategy, the safety protocols and the provision of local appropriate support services** (National Statement 4.8.2, 4.8.13, 4.8.15). The HREC/HREAPs will accept the following as evidence of engagement in-country in lieu of ethics approval:

- An email or letter from the research team to local ethical review boards and/or organisations that provide support or advisory services to the target population with the research proposal attached seeking confirmation of the following:
 - There are no relevant ethics review processes available and in-country human ethics approval is not required; and
 - A review of the research proposal has been completed and either suggestions for revision have been made or the proposal is appropriate for the setting that it will be conducted in.
- The researchers must confirm in their application that emails/letters of support will be provided before recruitment and data collection in-country commences, and any recommended revisions to the protocol must be submitted via a modification request.
- The researchers must confirm that the research that is planned in another country is lawful in that country and in Australia (National Statement 4.8.13, 5.7.3(b)).

If applicable:

- For student researchers travelling to the country to undertake data collection, a Human Research Fieldwork Safety Protocol, including academic supervision arrangements, must be provided for review with the human ethics submission (National Statement 4.8.8, 4.8.18).
- Overseas research being conducted in a high-risk country with a DFAT warning level of 3 (reconsider your need to travel) or 4 (do not travel) cannot be reviewed by the low risk Panels and must be reviewed by the more than low risk HREC. This type of research must be approved by the Director, Risk Management. Evidence of approval must be provided to the HREC before booking travel, travelling to the country, commencing recruitment or data collection (National Statement 4.8.18). In addition, insurance coverage for travel and the research activity must be checked with [UNSW insurance](#) before travel. Supporting documentation confirming that this process has occurred must accompany the ethics application before approval is issued.

5.2. If there are **not** additional ethical considerations arising from the beliefs, customs, and cultural heritage of the local participant population in the country in which the researchers intend to conduct their research, **researchers must justify the following five/six points within their application using examples from their project to support each statement:**

- The researchers have investigated the requirement for local ethics approval and/or local support (explain how) and have found that this is not required for the project (National Statement 4.8.4);
- The beliefs, customs and cultural heritage of the target participant population in the country in which the researchers intend to conduct their research does not involve additional ethical considerations to ensure that participants are accorded no less respect and protection than this National Statement requires (National Statement 4.8.2; 4.8.5);
- The researchers have enough experience or access to expertise to enable them to engage with participants in ways that accord them due respect and protection (National Statement 4.8.7, 4.8.15, 5.7.3(b));
- The research that is planned in another country is lawful in that country and in Australia (National Statement 4.8.13, 5.7.3(b)); and
- Research conducted overseas by UNSW researchers will comply with the National Statement (National Statement 4.8.5).

If applicable:

- For student researchers travelling to the country to undertake data collection, a Human Research Fieldwork Safety Protocol, including academic supervision arrangements, has been provided for review with the human ethics submission (National Statement 4.8.8, 4.8.18).
- Overseas research must not commence until UNSW HREAP/HREC approval has been established and, where applicable, in country ethics approval or letters of support have been noted by the UNSW HREAP/HREC.

Human Research Establishment of Ethical Approval

6. Research Conducted Overseas where UNSW personnel participate in research but are not responsible

- Research conducted overseas where UNSW personnel participate in research but are not responsible for its conduct must be registered via the [external ethics approval](#) notification process.
- A data sharing agreement must be established between the institution responsible for the research and UNSW in circumstances where data will be transferred to UNSW for analyses as approved by the international ethics review board. A copy of the signed data sharing agreement must be submitted as a supporting document via the external ethics approval process. All data sharing agreements must be negotiated via the UNSW Research Grants and Contracts or Legal Office.

7. Selection of appropriate ethical review body

- If human research activity involves the recruitment of participants, staff, access to resources or facilities of public health organisations, correctional services, defence force organisations, veterans or indigenous populations, ethical approval must be established via a HREC that has direct oversight to the activities being conducted. This may not be via one of the UNSW ethical review bodies.

8. Approval Period and Extensions

- The HREC and HREA Panels provide approval for up to five years. Ethics approval will remain valid for the five-year period if all a monitoring report forms are provided annually; any other conditions of approval are adhered to; and notification from the Deputy Vice Chancellor Research has not been issued to withdraw approval for safety reasons.
- The Chief Investigator responsible for an approved Human Research project can apply for an extension before the end date of an approved project. A project modification form must be completed to seek approval for an extension of approval.
- Requests for extension can only be granted during the approval period and retrospective extensions will not be granted.
- Requests for extensions for periods of longer than 12 months should be submitted as a new application. The approving HREC/HREAP may grant a 3-month extension to allow the researcher additional time to generate a new application for ethical review.
- Requests to extend the approval period for a further 12 months should be submitted as a modification request if recruitment and data collection will cease within a 12-month period. Extension requests for 12 months or less will be subject to the following conditions:
 - Additional extensions cannot be requested once an extension has been approved.
 - Projects with a high number of modifications submitted during the initial approval period may have to be submitted as a new application.
 - Requests for extensions can only be granted if all annual reporting and approval conditions have been met.

9. Research that can be exempted from review or does not require ethical approval

The following activities are exempt from review or do not require ethical approval. In line with the requirements of the National Statement institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable. It is for this reason that the use of existing collections of data or records that contain only non-identifiable data about human beings must be submitted for review via the negligible risk process for ethical review (National Statement 5.1.23).

9.1. Literature Reviews

- Literature reviews and meta-analyses do not require ethical approval. While meta data per se do not require ethical approval, there are some instances where you will be required to obtain ethical approval prior to accessing the data set. For example, the data custodian may require you to obtain ethical approval to access the data, or ethical approval may be required as part of the data access licencing agreement.
- If you are required to establish ethical approval prior to accessing a publicly available dataset then you will be required to follow the data extraction process and licencing requirements of the data custodian in order to gain access to the information. In order to gain ethical approval to access publicly available datasets, please complete the [UNSW Human Ethics Negligible Risk Application](#)

[Form.](#)

9.2. Coursework

At UNSW, coursework designed for teaching or learning purposes does not require review or approval via the UNSW ethical review process. Coursework projects conducted without human research ethics approval cannot be published for a research purpose at any stage. Faculties and Schools are responsible for implementing a process for assessing coursework projects to ensure that:

- The activities comply with any relevant privacy and/or confidentiality requirements. (e.g. a process of informed consent);
- Relevant health and safety requirements are adhered to (e.g. blood collection procedures, personal safety procedures, interview protocols etc.);
- Information will not be disseminated or published for a research purpose;
- Participants from a vulnerable population are not the focus of the project (as outlined in section 4 of the National Statement on Ethical Conduct in Human Research, 2015);
- The project does not aim to explore contentious or sensitive topics.
- There is no potential for participants to be exposed to harm as a result of the project including physical, psychological, social, economic or legal harm.

9.3. Projects involving portraiture at UNSW

At UNSW, portraiture undertaken for the purpose of coursework is not deemed to constitute human research and as such does not require human research ethics approval. Portraiture is defined here as either:

- The recording and representation of still image, audio and/or moving images recordings of actors or other performers, performing for the purposes of course-related work;
- The recording and representation of still or moving images of people for the purposes of creative arts practices, where the construction, manipulation and presentation of these portraits images constitutes the primary coursework outcome.
- Faculty-specific Image Release Agreements (a.k.a. “Model Release Forms”) should be used to provide portrait participants with information about the portrait being made, the types of situations a participants image could be shown in, licencing arrangements and limitations on use by (or sale to) third parties, as well as a description of what will happen portraits in the event that a person no longer wants their portrait to be available for publication/exhibition/circulation. A signed copy of agreements should be given to portraiture participants to keep in the event that they might wish to withdraw their agreement. Faculty- specific Image Release Agreements can be obtained via your supervisor, course-convenor or Head of School.
- Activities where the intention is to record statements made by a performer (also referred to as the model / sitter / subject) in which they contribute their personal insights, experiences and/or opinions would be considered an interview and would require UNSW human research ethics approval.
- Activities where the intention is to conduct a survey, an interview or focus group discussion in order to seek feedback about the portrait for a research purpose, would also be considered human research and therefore ethical approval would be required.

9.4. Quality Assurance and Evaluation Activities

Quality Assurance and Evaluation work is defined at UNSW as any activity where the data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols. For example, data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained. If one or more of the points below apply the activity will not be considered QA or evaluation work and ethical review via one of the UNSW processes is required:

- The data will be used to answer a research aim(s), question(s) or be published for a research purpose.
- The data being collected and analysed will be linked to individuals.
- Data will be obtained by individuals that do not have access as part of standard operating procedures and routine care.
- The activity has the potential to infringe on the privacy or professional reputation of participants, providers or organisations.
- The data collected and/or analysed will be used for or shared for a secondary purpose unrelated

Human Research Establishment of Ethical Approval

to the standard operating procedures or protocols that it was collected for.

- The activity involves the collection of data, biospecimens or requires the conduct of additional investigations beyond that which is collected routinely.
- The activity involves testing of non-standard (innovative) protocols, equipment or the comparison of cohorts
- The activity involves randomisation or the use of control groups or placebos.
- The activity involves targeted analysis of data involving minority/vulnerable groups.

The UNSW HREAPs and HRECs do not provide retrospective approval for any research conducted without ethics approval or under an expired ethics project. The guidance on whether or not ethical approval is required should be sought by contacting the Human Ethics Team via email humanethics@unsw.edu.au.