

6.2 To which ethics committee do I forward my application?

The review process associated with individual research proposals involving humans is dependent on the risks to which research subjects may be exposed and is governed by the *National Statement on Ethical Conduct in Human Research 2007*.

The review system developed by La Trobe University is aimed at providing the most appropriate and effective review process to meet the requirements of the National Statement.

The following committees deal with the review and approval of Human Ethics applications proposed by La Trobe University researchers:

- University Human Ethics Committee (UHEC)
- Faculty of Education Human Ethics Committee
- Faculty of Health Sciences Human Ethics Committee
- Faculty of Humanities and Social Sciences Human Ethics Committee
- Faculty of Law and Management Human Ethics Committee
- Faculty of Science, Technology and Engineering Human Ethics Committee

The relevant Faculty Human Ethics Committee (FHEC) should be the point of contact if the study involves:

- **Negligible risk:** no review is required. However, researchers are required to submit a brief summary of human research that involves only 'negligible risk' as defined by the National Statement to their FHEC prior to the commencement of studies, and FHECs are requested to provide summaries of all 'negligible risk' projects to the UHEC on a regular basis.
- **Low risk:** the application should be submitted for review to the relevant FHEC if the risks to human subjects are 'low risk' as defined by the National Statement. The FHEC should forward the application to the UHEC if the risks are perceived to be greater than estimated by the chief investigator of the research project.

The University Human Ethics Committee (UHEC) should be the point of contact if the study involves:

- **More than low-risk:** the application should be reviewed by the UHEC if the risk involved is 'more than low-risk' as defined by the National Statement.

Note that it is a requirement that all members of the UHEC and FHECs must be familiar with the National Statement on Ethical Conduct in Human Research (National Statement Section 5.1.19a).

Also note that the removal of **Negligible Risk** projects from formal human ethics review has been decided by the University and the UHEC as outlined in the UHEC

Terms of Reference, provided that the procedures fulfill the obligations outlined above and in Sections 5.1.10 to 5.1.17 of the NHMRC National Statement on Ethical Conduct in Human Research (2007).

In the case of research centres or institutes not aligned with faculties, all matters should be referred to the UHEC.

6.3 How do I assess the risks involved in my research proposal?

6.3.1 'Negligible risk' classification:

The proposed research carries only negligible risk if it meets the requirements outlined in Sections 2.1.7, 5.1.6-8 and 5.1.22-23 of the National Statement.

Research involving negligible risk should either (a) contain no foreseeable risk of harm or discomfort or (b) be such that any foreseeable risk should be no more than inconvenience. Research which involves risk, even if unlikely, which may be more serious than inconvenience, is not classified 'negligible risk'.

Negligible-risk studies that may be exempt from review include research utilizing existing collections of data or records that contain only non-identifiable data about human beings.

6.3.2 'Low risk' classification:

Research carries low risk only if it meets the requirements of the Sections 2.1.6 and 5.1.7 as well as 5.1.18-21 of the National Statement.

Research involving 'low risk' only allows for risks no more serious than discomfort to the research participants (National Statement Section 2.1.6). Research which involves risk, even if unlikely, which may be more serious than discomfort, is not classified 'low risk'.

Examples of low-risk studies may include:

- research involving the use of standard tests and questionnaires administered appropriately to normal adult populations, and where data are recorded in such a manner that the participants are not and cannot be identified;
- research or evaluative procedures involving observation of public behaviour on unidentified participants, where data are recorded in such a manner that participants are not and cannot be identified;

- research or evaluative procedures involving collection of existing publicly available data, documents, records or specimens;
- research carried out in an educational setting using groups of participants (rather than individual participants), where data are recorded in such a manner that participants are not and cannot be identified.
- diagnostic ultrasound and magnetic resonance imaging (MRI) aside from other factors which may warrant a higher risk classification and as long as the research protocol meets acceptable clinical standards;
- research that may cause discomfort (either physical, psychological or social) beyond normal levels of inconvenience.

6.3.3 'More than low risk' classification:

The classification of 'more than low risk' research applies to all research which may involve risk to participants of more than discomfort as outlined in Sections 5.1.6 and 5.1.24 of the National Statement. This includes research which:

- uses intrusive techniques, including some personality assessment tests;
- examines potentially sensitive or contentious areas, such as studies of body image or sexuality;
- involves minors as participants where there is individual or one-to-one interaction between investigators and participants;
- uses therapeutic techniques;
- involves secondary use of specimens or data collected for another study or purpose;
- seeks disclosure of information that may be prejudicial to participants (for example, which has the potential to be incriminating);
- involves any physical intervention or removal of body fluids or tissues (such as blood or urine samples, biopsies);
- involves a clinical trial of any drug, therapeutic product or biomaterial;
- involves qualifying the conditions of consent , *ie* circumstances where the purpose of the study is not fully disclosed to participants;

- uses a highly vulnerable participant population, for example - intellectually disabled individuals, people who have undergone trauma, psychologically disturbed individuals;
- involves the collection, use or disclosure of identified personal, health or sensitive information without the consent of the individuals in question.

Examples of categories of 'more than low risk' research to be reviewed by the UHEC include:

- risk of physical, mental, or social harm;
- deception;
- possible breaches of legislation (usually relating to access to sensitive personal information);
- secondary use of existing human specimens;
- research involving Indigenous Australian (Aboriginal and / or Torres Strait Islander) participants or subject matter;
- research conducted overseas (National Statement Chapter 4.8).

If an investigator is in doubt, the application may be submitted to a FHEC for risk assessment.

If your research unit is not affiliated with any of the La Trobe University faculties (as is the case of some research centres) the application should be submitted to the UHEC.

6.4 Expedited review by the UHEC

Expedited reviews by the Chair of the UHEC without circulation to other members of the Committee may occur for modifications to projects, progress reports and final reports.