

ADDITIONAL INFORMATION

1. Researchers are reminded that their research must implement not only the “Code of Ethical Conduct for Research, Teaching and Evaluations Involving Human Participants” but also all other relevant University codes and policies, including the “Research Use of IT Infrastructure Policy” and the “Policy and Procedures for Course Related Student Travel Overseas”.

2 **Support from Massey University**

Provided researchers have made every effort to implement the “Code of Ethical Conduct for Research, Teaching and Evaluations Involving Human Participants” and other relevant codes and policies, the University will provide support in the event of complaints from participants. However, any researcher who proceeds with a project which does not comply with the Code should be aware that Massey University may be unable to provide protection should a complaint be laid.

Researchers/supervisors should be aware that if a participant advises them of a physical injury suffered as a result of taking part in the research project, they should advise:

- 2.1 The participant to visit a treatment provider to make a claim to ACC as soon as possible.
- 2.2 Their Head of Institute/School/Department of the incident.
- 2.3 The University’s Insurance Officer of the incident.
- 2.4 The Research Ethics Office of the incident.

Please be reassured that in the case of ACC not accepting the claim, the University’s Insurance Policy would be invoked. Researchers would not be individually liable unless it could be shown that the University’s policies and procedures had not been observed.

3. **Discussion and Analysis of Ethical Issues**

Researchers/teachers are required to assess the ethical issues of their projects in discussion with colleagues, preferably independent of the project, and with reference to appropriate ethical and professional codes.

Supervisors should ensure that research students are instructed in the Code and that they undertake an ethical analysis of their project, which is then discussed with the supervisor.

4 **Applications**

A Massey University Human Ethics Committee makes its decisions on the basis of the information supplied. It is the responsibility of applicants to present such information as clearly as possible. In particular, jargon and technical terminology should be avoided. Where such language is unavoidable, an adequate explanation of the terms should be included. Every document **must** be written in such a way as to be understood by the participants in the research.

4.1 Projects involving the collection of tissue, blood, other body fluids or physiological tests or the use of hazardous substances, procedures or equipment

It is a requirement that applicants must identify, assess and mitigate potential risks and hazards, and use appropriate, approved procedures in their research at all times. Researchers must cite existing standard operating procedures (SOPs) or propose a new SOP where none exists. The University has various health and safety policies and protocols with which researchers should be familiar (http://www.massey.ac.nz/massey/staffroom/national-shared-services/health-safety/managing-hazards/hazards_home.cfm) .

4.2 Projects involving the use of radiation (x-ray, CT scan, bone densitometry (DEXA))

Where an applicant intends to use a non-Massey Licensee of radiology facilities, it is not necessary to attach a copy of the Licensee's Radiation Safety Plan.

Applicants must, however, attach a copy of the participant dose assessment calculation sheet and approval of the dose assessment from the relevant authority.

In order to access Massey IFNHH radiology facilities applicants must contact and consult the Massey Licensee prior to submission of an application.

In the case of applications involving the proposed use of DEXA, it is not necessary for applicants to provide a copy of the Radiation Safety Plan as this is held by the Research Ethics Office.

Applicants must, however, attach a participant dose assessment calculation sheet and approval of the dose assessment from the relevant authority (as advised by the Massey Licensee). In addition, applicants should ensure that the risks of radiation have been considered and addressed in Section C of the application form and that detail about the use of the DEXA is outlined in the information sheet to potential participants.

In the case of applications involving the proposed use of other Massey radiology services and equipment, applicants must attach a copy of the Radiation Safety Plan, a participant dose assessment calculation sheet and approval of the dose assessment from the relevant authority (as advised by the Massey Licensee). In addition, applicants should ensure that the risks of radiation have been considered and addressed in Section C of the application form and that detail about the use of the radiology equipment and procedures is outlined in the information sheet to potential participants.

4.3 Submission of Applications

Applications are to be submitted as follows:

4.3.1 Academic/General Staff applicant

Applications are to be submitted to the Human Ethics Committee where the applicant is located.

4.3.2 Student applicant

Applications are to be submitted to the Human Ethics Committee where the Chief Supervisor of the applicant is located.

5 Approvals

5.1 Approval of Changes to Applications

If the nature, content, procedures, location, or personnel of a research project changes after a Massey University Human Ethics Committee has approved it, the applicant must seek a further approval from the Committee. Applicants are responsible for informing the Committee if any of these changes occur.

The Chairperson of the Committee has the power to approve amendments when these are of a minor nature.

5.2 Retrospective Approval

In no case will retrospective approval be given.

5.3 Approval of research in which the researcher is a participant

5.3.1 The researcher should follow standard notification/application procedures, indicating in the notification/application form that he/she will be either the sole participant or one of the study participants.

5.3.2 Researchers considering subjecting themselves to an invasive experimental procedure in order to establish its feasibility or utility for research purposes must discuss this with their Head of Academic Unit and the Health and Safety Officer. Provided that no data will be gathered for research purposes, an ethics application is not required.

5.4 Approval of Staged/Long Term Research

Where there are different stages to the research project, separate consents should be obtained for each stage. When there is a significant time gap between different research activities (for example, follow up testing or interviewing), a separate consent for each of the research activities may be appropriate, even if this involves the same research process.

5.5 Approval of Team Research

Approval of research applications for research teams will normally be delegated to the ethics committee of the institution of the principal researcher, with the research conducted according to the policy and procedures of the researcher's institution. However, where the research is carried out for the purpose of gaining a qualification from Massey University, the application must be carried out according to the Massey University Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants.

5.6 Approval of research undertaken as a contract

5.6.1 If the staff member is the contractor, approval must be obtained in the usual manner from Massey University.

5.6.2 If the staff member carrying out the research is a sub-contractor, ethical approval is the responsibility of the main contractor. Where that has not occurred, the staff member should seek advice from their Head of Academic Unit.

5.7 Transfer of Approval by New Staff/Staff from other Universities

If a new staff member brings a grant/research project to Massey University from another organisation the original ethics application and approval should be forwarded to the Secretary of a Massey University Human Ethics Committee for noting.

5.8 Approval of Projects conducted by Massey Staff enrolled in Degree Programmes in other Universities

Ethics approval should be sought through the degree-granting university.

A copy of the documentation must be lodged with the Secretary of a Massey University Human Ethics Committee for noting.

5.9 Collaborative Research

Because the circumstances associated with collaborative research vary widely and may involve researchers in different countries, staff involved should seek advice from the Director, Research Ethics.

5.10 Approval of research conducted overseas

All research conducted overseas must comply with the Code of Ethical Conduct for Research, Teaching and Evaluations involving Human participants and be either approved by a Human Ethics Committee or be notified as a Low Risk project. Research conducted overseas must also comply with any requirements of the host country. This may involve local ethical review or government approval. Researchers are advised to check for any specific visa requirements for research conducted overseas.

Travel undertaken by students must be approved by their supervisor and the relevant PVC and be in accordance with the Policy & Procedures for Course Related Student Travel Overseas. In addition, the supervisor must advise the University's Insurance Officer.

6 Reconsideration of Decision of a Massey University Human Ethics Committee

An applicant who is dissatisfied with a Massey University Human Ethics Committee's decision may request reconsideration of the decision. Requests should be sent to the Director, Research Ethics who will convene a meeting of an Appeals Committee set up by the Assistant Vice-Chancellor (Research) for this purpose.

7 Expedited Review of an Application

If you believe there are circumstances that make it inappropriate for your application to be considered at the next regular Human Ethics Committee meeting, you may make a written request to the Chair for an expedited review. You must justify this request.

Requests for an expedited review should be sent to the Secretary of the Human Ethics Committee.

Expedited review will **not** be given where a project involves invasive procedures; or participants who are in a dependent relationship with the researcher, such as prisoners, or hospital patients, children fifteen (15) years old or younger or those who are not fully capable of giving informed consent for themselves.

8. Media communications

Researchers may wish to publicise the fact that their research is about to start or is underway in order to increase the recruitment of participants. University communication staff may wish to publicise the research before completion because it is judged to have wider public interest. Media and other organisations may also become interested in the research before it is completed and wish to interview the researcher.

Where the proposed communication relates to research that has been notified to the Research Ethics Office or approved by an HEC, researchers should normally take advice from the Director of Research Ethics or the Chair of the relevant HEC before drafting a release or agreeing to be interviewed. Postgraduate students and inexperienced researchers should not interact directly with media organisations except under the close supervision of an experienced researcher. Where the research involves external funding, or potential intellectual property commercialisation opportunities, particular care must be taken not to breach any confidentiality agreements.

Researchers should attempt to ensure that the content of any media communication is factual and consistent with the aims of the study. Specific advice should be sought from the Communications Advisor for the College or the University's Communications Director regarding radio and television interviews. Media releases are official University communications and must be approved by the Communications Director.

It is permissible for researchers to use media releases in order to attempt to increase recruitment. Email or phone contact details may be included so that anyone who may be interested in participating is able to request further information. However, a media release is not a substitute for an information sheet.

Researchers should, in general, avoid media communications until the research has been completed and a peer reviewed research report is available on which to base their factual comments. In this respect, senior researchers and supervisors have a particular duty of care toward less experienced colleagues and students.

In media releases concerning completed studies, researchers must clearly distinguish between findings and opinions and should limit comments to the research study and/or areas of personal scholarly expertise.

9 Definition of Terms

9.1 Feasibility Assessment

In some studies, researchers need to establish the feasibility of their research prior to formally seeking access, recruiting participants or data gathering. Prior ethics committee approval is *not* normally required for this phase of the research. In addition to ensuring that their proposed research meets the requirements of the MUHEC Code, if the study is to be conducted within a particular locality, community or organisation, researchers may undertake preliminary inquiries about relevant local arrangements. This is not the same as a formal request for access to research settings or participants for data gathering which may only take place following notification or ethical approval. When submitting an ethics application, researchers should include a summary of preliminary inquiries undertaken or copies of relevant correspondence with, for example, community representatives, senior managers in an organisation, owners of datasets, or staff representatives.

9.2 **Pilot study**

The term pilot study is used in various ways by researchers: (i) In some studies, researchers wish to evaluate data gathering instruments for relevance, clarity, validity or ease of use with an individual or group of volunteers who share the same characteristics as the participants to be recruited for the main study; (ii) In some studies, limited researcher resources only permit data gathering from a smaller sample than is necessary to demonstrate the statistical power of results; (iii) In some studies, there is little or no prior knowledge of the phenomenon and researchers wish to undertake data gathering from a small sample in order to identify areas for more substantive investigation.

Provided that there is no risk of harm to anyone who agrees to evaluate instruments prior to a main study, prior ethical approval is not normally required as these volunteers are not research 'participants' as understood by the MUHEC Code. However, where researchers wish to gather, retain, analyse and/or report data from a pilot study, this clearly does involve volunteers as 'participants'. The risk to participants will vary according to the nature of the study and prior low risk notification or committee approval of the proposed study is therefore required prior to their recruitment and informed consent.

9.3 **Main study**

The term main study is used for research that follows a previous pilot study. Normally, participants in the pilot and the main study will share the same characteristics. In some instances, pilot and main study phases of the research will be the subject of separate notifications or applications. In other instances, the notification or application will cover both the pilot and the main study. In their low risk notification or application to a committee, researchers should clearly explain the relationship between pilot and main studies in any proposed research.

Researchers are asked to make clear the usage of terms such as 'pilot study' in their application.

10 **Monitoring of approved projects**

In instances where there may be an ongoing risk of harm to researchers, participants or researched communities, the ethics committee may require brief periodic updates or variance reports from researchers as is the practice with, for example, Health and Disability Ethics Committees (NZ) and Institutional Review Boards (USA).

11 **Submission of a Report**

Applicants are welcome to provide feedback to the reviewing committee on ethical issues encountered during the course of the research and also a brief summary of the findings. Such feedback assists the committees in their work.