

HUMAN RESEARCH ETHICS 2009

MELBOURNE RESEARCH OFFICE

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THE UNIVERSITY OF
MELBOURNE

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All human research carried out by staff and postgraduate students at the University of Melbourne requires ethics approval. The University's Code of Conduct for Research prescribes the standards and ethical conduct expected of those engaged in research at this institution. Staff and students are to be aware of the ethical framework governing research at the University and to comply with institutional and regulatory requirements. The Australian Code for the Responsible Conduct of Research guides institutions and researchers in responsible research practice and promotes integrity in research. The NHMRC National Statement on Ethical Conduct in Human Research (2007) sets out the national standards of ethical conduct for research involving humans and should be used by researchers when developing their projects.

WHAT ARE THE ESSENTIAL VALUES THAT GUIDE ETHICAL RESEARCH?

The values of respect for human beings, research merit and integrity, justice and beneficence guide the design and conduct of human research and help shape a relationship of trust, mutual responsibility and ethical equality between researchers and research participants.



DO I NEED ETHICS APPROVAL?

If you are a staff member or a student doing a PhD, Doctorate, Masters or Honours, and your research involves humans or their data, you will need University ethics approval before you commence. Research projects requiring ethics approval include surveys, interviews, certain types of observational studies, administration of tests or stimuli, collection or use of human tissue, bone, blood or other body fluids and clinical trials.

If you are an undergraduate student (not in Honours year) the projects you undertake will usually have an education, training and practical experience focus and will not normally require ethics approval. Your Course Coordinator can give you advice about this.

Left: Studying musculoskeletal conditions and treatments - Professor Kim Bennell, (Director, Centre for Health, Exercise & Sports Medicine, School of Physiotherapy).

WHAT DO I DO FIRST?

Visit the Research Office Human Ethics website at www.research.unimelb.edu.au/humanethics/ where you will find the relevant policies, application and reporting procedures, important contacts and resources.

If you are a student, discuss your project with your supervisor(s). Your supervisor is there to advise you, to help you develop your project and give due consideration to the ethical issues involved. The supervisor also oversees the project once it is underway.

You can also seek assistance from members of your Human Ethics Advisory Group (HEAG). Your HEAG provides advice to researchers and to the Human Ethics Sub-Committee (HESC) about the academic validity of research projects, their ethical implications as well as compliance with guidelines and legislation. A list of HEAGs and the relevant contact person is also available on the ethics website.

HOW DO I SUBMIT AN ETHICS APPLICATION?

Human Ethics applications are to be submitted electronically via Themis (see www.themis.unimelb.edu.au) and, specifically, the Human Ethics Workbench. Hard copies of these applications, appropriately signed, are also required.

University of Melbourne researchers including Higher Doctorate, Doctorate by Research, Masters by Research, Doctorate by Coursework, Masters by Coursework and Bachelors Honours have ready access to Themis, however other students requiring access may need to arrange this through their faculty or department HEAG. For further details regarding access to Themis see www.themis.unimelb.edu.au/starting/new_user.html.

MINIMAL RISK PROJECTS – HEAG APPROVAL

A research project that presents low or minimal risk, according to a set of checklist items concerning the nature of the project, its research methodology and participants, can be approved by the HEAG in your faculty or school. The only foreseeable risk to participants in these projects is to be no more than discomfort. Note that the HEAG (not the researcher) decides whether the application is eligible for minimal risk review.

A minimal risk application is submitted via Themis then a hardcopy is provided to your HEAG for review. You may be asked to make some changes to your project before it is given final approval. You will receive notification from the HEAG that your project has been approved as minimal risk. You may then commence your research.

MEDIUM OR HIGH RISK PROJECTS – HESC APPROVAL

In cases where the research involves moderate or high risk, where foreseeable risks are greater than discomfort, or where the funding body, research site or host organisation requires it, you will need to obtain ethics approval from one of the University's Human Ethics Sub-Committees. In this case you will need to complete a Standard Project application via Themis then submit a hardcopy to the HEAG. The HEAG will consider the project, perhaps request some changes, then make a recommendation to the relevant HESC to formally review and approve your application. At this point you will then forward the endorsed application, with the required number of copies, to the Melbourne Research Office for HESC review. Following its review, the HESC may ask you to clarify certain aspects of your project or to make some changes

before it is given final approval. You will receive written notification from the HESC advising that the project has been approved. You may then commence your research.

There are three HESCs (Behavioural & Social Sciences, Humanities & Applied Sciences, Health Sciences) which meet monthly during semester – see meeting schedule overleaf. Generally you should allow four to six weeks for HESC approval after your application has been submitted.

WHEN CAN I COMMENCE MY RESEARCH?

Researchers may not commence their research until they have written advice that their project has ethics approval. The principal researcher will receive a formal letter advising that the project, identified by a unique HREC number, has been approved. Students should contact their supervisor for a copy.

WHAT ELSE MUST I DO?

Researchers are required to submit an annual report regarding the status of their research project. You will be asked to submit the report via Themis at the end of each year. Researchers must advise the ethics committee of any serious or adverse event that occurs during the course of the research, and must obtain ethics approval if they wish to make any amendments to approved projects. It is also the responsibility of researchers to be aware of both general and specific legal requirements pertaining to their research wherever relevant.

Right: Studying well-taught mathematics classrooms - Professor David Clarke (Director, International Centre for Classroom Research, Melbourne Graduate School of Education).



WHERE CAN I GET FURTHER INFORMATION, THE GUIDELINES AND FORMS

Visit the human ethics website at www.research.unimelb.edu.au/humanethics/, contact your Human Ethics Advisory Group (HEAG), or contact one of the human research ethics team at the Melbourne Research Office:

Kate Murphy

Executive Officer

Human Research Ethics Committee and Health Sciences HESC

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USEFUL WEBSITES

Human Research Ethics website (University of Melbourne)

www.research.unimelb.edu.au/humanethics/

University of Melbourne - Code of Conduct for Research (Regulation 17.1.R8)

www.unimelb.edu.au/ExecServ/Statutes/r171r8.html

Australian Code for the Responsible Conduct of Research

<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>

National Statement on Ethical Conduct in Human Research (2007)

www.nhmrc.gov.au/publications/synopses/e72syn.htm

Human Research Ethics Handbook - Commentary on the National Statement (2000)

www.nhmrc.gov.au/publications/synopses/e42syn.htm

Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)

www.nhmrc.gov.au/publications/synopses/e52syn.htm

MEETING DATES

	Behavioural and Social Sciences Human Ethics Sub-Committee		Humanities and Applied Sciences Human Ethics Sub-Committee		Health Sciences Human Ethics Sub-Committee	
Meeting Number	Research Office Application Deadline	Meeting Date	Research Office Application Deadline	Meeting Date	Research Office Application Deadline	Meeting Date
1/09	29 Jan	13 Feb	3 Feb	19 Feb	2 Feb	17 Feb
2/09	19 Feb	6 Mar	24 Feb	12 Mar	2 Mar	17 Mar
3/09	19 Mar	3 Apr	24 Mar	9 Apr	15 Apr	28 Apr
4/09	16 Apr	1 May	28 Apr	14 May	4 May	19 May
5/09	21 May	5 Jun	25 May	11 Jun	29 May	16 Jun
6/09	23 Jul	7 Aug	28 Jul	13 Aug	3 Aug	18 Aug
7/09	20 Aug	4 Sep	25 Aug	10 Sep	31 Aug	15 Sep
8/09	17 Sep	2 Oct	22 Sep	8 Oct	5 Oct	20 Oct
9/09	22 Oct	6 Nov	27 Oct	12 Nov	2 Nov	17 Nov
10/09	19 Nov	4 Dec	17 Nov	3 Dec	23 Nov	8 Dec

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