



Curtin University

SHBBV ETHICS APPROVAL GUIDE

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SIREN
WA Sexual Health and Blood-borne Virus
Applied Research and Evaluation Network

SHBBV Ethics Reference Guide

This factsheet provides an introduction to planning and applying for ethics approval. It answers the questions: Why do I need ethics? Where do I apply for ethics? Where can I get help with ethics?

Why do you need ethics approval?

All research involving humans must be reviewed and approved by a suitably qualified ethics committee before data collection begins. All major health providers, health organisations and universities have Human Research Ethics Committees (HREC), which regularly report to the National Health and Medical Research Council (NH&MRC).

The ethics review process ensures the protection of the welfare and rights of participants in research. The ethical and legal responsibilities which researchers have towards participants reflect four basic ethical values:

Integrity

Consistency of actions, values, methods, measures, principles, expectations and outcomes.

Respect for Persons

All people deserve the right to fully exercise their autonomy.

Beneficence

Actions designed to positively benefit the wellbeing of others and impose a moral obligation to do minimal harm.

Justice

The fair and equitable distribution of benefits, burdens, and duties among and between members of society.

The ethics review process is intended to offer a level of assurance to research participants, the investigators and the institution/s sponsoring the research that participants will be involved in research that is ethically sound. In turn, this assurance provides the general public with confidence in both the conduct and outcomes of the research (Freegard, 2006).

Typical ethics application

A typical ethics application will include:

Project overview / plan

Information sheet and consent form for participants

Details of number of participants in sample and how they will be recruited

Interview/survey questions and study topics participants will be asked about

Completed ethics application form



Start thinking about your ethics application as soon as you have a project in mind. Allow 2-8 weeks for approval depending on the level of risk to participants.

What is human research?

Human research is conducted with or about people, or their data or tissue. Human participation in research includes:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database (National Health & Medical Research Council, 2013).

Australian law states that you must obtain ethics approval for any activity that collects, uses, or discloses information about any individual (Office of the Health Services Commissioner, 2002).



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Human Research Ethics Committee (HREC)

The main HRECs are listed below along with the web address where each of the ethics forms can be accessed.

National HREC

Name	Function / Information	Link
National Health and Medical Research Council	Issue advice & guidelines on ethics and related issues in the fields of health, human research & animal research.	www.nhmrc.gov.au/health-ethics

Western Australian HRECs

Name	Function / Information	Link
Metropolitan		
North Metropolitan Health Service, Mental Health Human Research Ethics Committee	Advise on research involving North Metropolitan Health Service, Mental Health service patients or staff.	www.nmahsmh.health.wa.gov.au/ethics/index.cfm
Princess Margaret Hospital (PMH) for Children Ethics Committee	Advise on and carry out the ethical review of all research involving the staff, patients or resources of the Child and Adolescent Health Service, primarily encompassing research conducted at PMH and affiliated organisations.	www.pmh.health.wa.gov.au/development/resources/ethics.htm
Women and Newborn Health Service Ethics Committee	Advise on and carry out the ethical review of all research involving the staff, patients or resources of the Women and Newborn Health Service, primarily encompassing research conducted at King Edward Memorial Hospital and affiliated organisations.	www.kemh.health.wa.gov.au/development/resources/ethics.htm
South Metropolitan Health Service Human Research Ethics Committee	Review research projects involving human participants (patients or staff), their data, or tissue, in the catchment area of the South Metropolitan Health Service (excluding Royal Perth Hospital).	www.fhhs.health.wa.gov.au/education/research.aspx
Regional		
WA Country Health Service Research Ethics Committee	Assess the ethical implications of all research protocols undertaken within the WA Country Health Service.	www.wacountry.health.wa.gov.au/researchethicscommittee
Specialist		
Human Research Ethics Committee – Department of Health	Special responsibility oversee the use and disclosure of personal health information held in the Department of Health data collections.	www.health.wa.gov.au/healthdata/HREC/
Western Australian Aboriginal Health Ethics Committee (WAAHEC)	<u>ALL</u> projects involving Aboriginal people must receive approval from WAAHEC. In addition, local research committees may require an overview of proposed research to be submitted	www.ahcwa.org.au/index.php/programs/ethics

University HRECs

Name	Link
Curtin University	Contact SiREN research.curtin.edu.au/guides/ethics.cfm
Edith Cowan University	intranet.ecu.edu.au/research/research-ethics/
Murdoch University	our.murdoch.edu.au/Research-Ethics-and-Integrity/
Notre Dame University	www.nd.edu.au/research/hrec/committee.shtml
University of Western Australia (UWA)	www.research.uwa.edu.au/staff/human-research/management/hrec



Remember to check how often the HREC meets and the date of the next HREC meeting (HREC typically meets monthly or bimonthly).



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Note: From the 1 September 2013, the following ethics forms are to be used throughout WA Health for the ethical and scientific review of research projects:

- NEAF & WA-Specific Module. The NEAF is available from www.neaf.gov.au.
- WA Health Ethics Application Form (for research conducted within WA Health). Available from www.health.wa.gov.au/researchdevelopment/home/hrec.cfm.

National Ethics Application Form (NEAF)

NEAF is an interactive, web-based tool for researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees.

To access a NEAF, go to the independent NEAF website at www.neaf.gov.au. This website also provides you with a map of the NEAF structure (Quick Reference Map) – this is a listing of all the sections in an NEAF. The sections you will be required to answer will depend on the type of research you are undertaking.

There are two methods of applying for ethical clearance: [Low Risk Review](#) (for projects involving negligible or low risk, as defined by the [National Ethical Conduct in Human Research \(2007\)](#)), or completion of the full NEAF – for ethical and scientific review relating to research in which the risk to participants is more serious than discomfort.

Essential Reading

Ethics forms will expect you to indicate how your project complies with the requirements set out in the NHMRC code of ethical conduct; therefore it is important that you read the following documents.

- NHMRC Health and Research Ethics 2013 <http://www.nhmrc.gov.au/health-ethics>
- National Statement on Ethical Conduct in Human Research 2007 (Updated May 2013) by the National Health and Medical Research Council http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e72_national_statement_130813.pdf

Example ethics process

Each ethics committee will have its own process and requirements for ethics applications and approval. An example of a 'typical' ethics application process is outlined below. However, it is important you understand the full details and requirements of the ethics committee to which you are applying.

Develop a project plan. Investigate and decide on which ethics committee you will need to apply to for your project.

Download and complete the appropriate forms and other required documents.

Submit application. Your application will be reviewed and you may receive feedback to make changes or address queries.

Make the relevant changes and re-submit your application.

You will be advised of the outcome of your application (approved / not approved) by the ethics committee (if necessary).

Help

For help with ethics submissions please contact SiREN. <http://siren.org.au/contact-us/>

See the 'How to write a good ethics application' page on the UWA website for some useful tips.

www.research.uwa.edu.au/staff/human-research/good-application

References

- Freeguard, H. (2006). Ethics of research *Ethical practice for health professionals* (pp. 192-208). Victoria, Australia: Cengage Learning Australia Pty Limited.
- National Health & Medical Research Council. (2013). National statement on ethical conduct in human research 2007 (updated May 2013) NHMRC.
- Office of the Health Services Commissioner. (2002). *Health records act 2001 (Vic): statutory guidelines on research*. Melbourne.