
Human research ethics committees

Research involving humans must be conducted in an ethical manner. All proposals for research involving human participants must be reviewed and approved by a Human Research Ethics Committee (HREC). There are also guidelines about accessing existing information and how it can be used by researchers.

An international code

The need for international standards governing the treatment of humans in research was highlighted after World War II. The Nuremberg military tribunal on war crimes set the foundation for ethical principles and many countries have since established their own guidelines. In most cases, the laws and codes are influenced by the 1964 *Declaration of Helsinki*, published by the World Medical Association and revised on numerous occasions since.

Guidelines for Australian research

The National Health and Medical Research Council (NHMRC) in Australia first published research ethics guidelines in 1999. These were revised in 2007 and the *National Statement on Ethical Conduct in Human Research* was fully implemented on 1 January 2008.

Each research application submitted to an HREC is now vetted to ensure that the proposed research is consistent with two sets of national Australian guidelines: the National Statement on Ethical Conduct in Human Research (2007) and the Australian Code for the Responsible Conduct of Research (2007). All research projects involving humans must be reviewed by a human research ethics committee and must not be undertaken until approval has been granted.

The Department of Health Victoria Human Research Ethics Committee

There are approximately 70 HRECs at various institutions (for example, in hospitals or universities) across Victoria. These review and approve research in their institutions. Department of Health Victoria HREC reviews research proposals which:

- Involve human participants in research being undertaken by DHS
- Are undertaken by other agencies throughout Victoria that are funded by Department of Health Victoria but do not have their own HREC or access to a more appropriate HREC
- Involve the clients of agencies throughout Victoria that are funded by Department of Health Victoria but do not have their own HREC or access to a more appropriate HREC.

The Department of Health Victoria HREC does not review proposals that have already been considered and approved by another HREC. External researchers requesting access to information held by Department of Health Victoria, its staff or clients must have the research approved by their institutional HREC. However, approvals from Department of Health Victoria program areas that hold data requested for research must be sought by researchers before any HREC considers the research proposal.

National Statement on Ethical Conduct in Human Research

The National Statement on Ethical Conduct in Human Research has guidelines for research involving specific **categories of participants** including:

- Pregnant women and the human fetus
- Children and young people

- People in dependent or unequal relationships
- People highly dependent on medical care who may be unable to consent for themselves
- People with an intellectual or mental impairment
- People involved in illegal activities
- Aboriginal and Torres Strait Islander people
- People in other countries.

These guidelines cover various **research methods or fields** including:

- Qualitative methods
- Databanks
- Interventions and therapies, including clinical and non-clinical trials, and innovations
- Use of human tissue samples
- Human genetic research
- Human stem cell research.

Ethical issues considered

Some of the issues covered in the National Statement on Ethical Conduct in Human Research include the following:

- A participant in any research project must be treated with respect as an autonomous human being.
- The research must be justifiable.
- The intended research must contribute to knowledge, using appropriate and honest methods, with a commitment to the pursuit and protection of truth.
- The potential for harm must be minimised, whether the harm is physical, psychological, emotional, economic, legal or social. The benefits likely to arise as a result of the research must justify any potential risks of harm or discomfort to participants.
- The research must take into account and respect individual and group beliefs, perceptions, customs and cultural heritage.
- The research must be fair and just and participants should have access to timely and clear research outcomes.
- Discussion of legal requirements is limited but it is highlighted that researchers and institutions should be aware of both general and specific legal requirements, wherever these are relevant.

Other important issues

The National Statement on Ethical Conduct in Human Research also requires that researchers and institutions meet certain strict standards, including:

- The research proposal must be based on a thorough study of current literature, prior observation, approved previous studies and, if relevant, laboratory and animal studies.
- The research must be conducted or supervised only by people or teams with experience, qualifications and competence appropriate to the research.
- Research must only be conducted using facilities appropriate for the research and where there are appropriate skills and resources for dealing with any contingencies that may affect the participants.
- The results of the research and the methods used should be published in ways that permit scrutiny and contribute to public knowledge.

Participants' rights

In most cases, potential research participants must give their consent before the research goes ahead. The researcher must provide information about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. The potential research participant has the right to decide against participating, without any need to justify themselves. Coercion, influence or pressure of any kind by the researchers or institution is unethical. If the individual decides to participate, they must record their agreement in some way, such as signing a consent form. Participants have the right to withdraw from the research and, in most types of research, this is possible.

Further information

For further information about human research ethics or participation in research, please contact the Human Research Ethics Committee at the Department of Health Victoria.

Where to get help

- Executive Officer, Human Research Ethics Committee, Department of Health Victoria Tel. (03) 9096 5239 or email:

Things to remember

- Research involving humans must be conducted in an ethical manner.
- All proposals for research involving human participants must be approved by a Human Research Ethics Committee.
- Each research application is vetted to ensure that the proposed research conforms to the National Statement on Ethical Conduct in Human Research, published by the National Health and Medical Research Council in 2007.

This page has been produced in consultation with, and approved by:

Department of Health - Office of the Chief Health Officer

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