

Ethical Issues Checklist Research Involving humans

Research involving humans should always comply with current ethical standards. In Australia, the ethical standards for such research are set by the National Health and Medical Research Council (*the NHMRC*) *National Statement on Ethical Conduct in Human Research* and those proposing to carry out research should be familiar with publications of the NHMRC.

Refer to: <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

The aim of ethical review of human research is to ensure that participants in research are not put at risk of harm, are not disadvantaged and are made aware that they may withdraw without prejudice.

Broadly, the process of ethical review concentrates on three main areas:

A Gathering informed consent to participate in research projects

B Protection of privacy and confidentiality of records

C Risk of harm to subjects or to groups in the community

In the following section you are asked to answer a number of questions under each of these three headings in order to identify any ethical considerations that may arise from your proposed research. Following this set of questions there is a further check list relating to types of research that have previously been identified as likely to raise ethical questions. In the second check list each of the types of research is cross referenced to a chapter of the NHMRC guidelines for you to read.

The following checklist is designed to alert you to the major types of ethical issues in your research. If you answer Yes to any of these questions, be sure to explain and clarify the issue elsewhere in the document.

A: Informed consent.

Research subjects must be able to give consent to their participation in research in such a way that ensures that they are fully informed of relevant aspects of the research and that they are confident to give consent for the research to be undertaken.

Researchers should ensure that individuals are not directly or indirectly pressured or coerced into participation through unequal power relationships or payments or inducements. The use of deception in any form in a research protocol has the potential to prevent the subject from giving consent that is truly well-informed.

Does your research involve:

(please tick)

1	Processes that potentially exclude and/or disadvantage a person or group, such as the collection of information which may expose the person/group to discrimination or misrepresentation?	YES <input type="checkbox"/> NO <input type="checkbox"/>
2	Collection or disclosure of personal information by a Commonwealth, State or Territory agency that might involve a breach of an Information Privacy Principle (as defined by the Commonwealth Privacy Act 1988 and the Australian Standard)?	YES <input type="checkbox"/> NO <input type="checkbox"/>
3	Collection or disclosure of personal information by a private sector organisation [that might involve a breach of a National Privacy Principle (as defined by the Commonwealth Privacy Act 1988)]?	YES <input type="checkbox"/> NO <input type="checkbox"/>
4	Payments or inducements, other than reasonable recompense, to participants for their participation?	YES <input type="checkbox"/> NO <input type="checkbox"/>
5	Deception of the participants including concealment and covert observation?	YES <input type="checkbox"/> NO <input type="checkbox"/>
6	Disclosure of the response outside the research which could place the participants at risk of criminal prosecution or civil liability or be damaging to their financial standing, employability, professional or personal relationships?	YES <input type="checkbox"/> NO <input type="checkbox"/>
7	Any form of passive consent?	YES <input type="checkbox"/> NO <input type="checkbox"/>

B: Risks to privacy and confidentiality.

The privacy of individuals and the confidentiality of data are both vital. The research must take special care to protect the privacy and confidentiality of subjects and the data obtained from them.

Does your research involve:

8	The participation of minors (under 18 years), other than in the observation of normal school activity?	YES <input type="checkbox"/> NO <input type="checkbox"/>
9	Participants who are in a dependent situation, such as students or residents of an institution (such as a hospital, nursing home or prison or patients highly dependent on medical care), other than those who are being observed in their normal environment where such observation is considered innocuous?	YES <input type="checkbox"/> NO <input type="checkbox"/>
10	Participants who may be unable to give or are incapable of giving informed consent?	YES <input type="checkbox"/> NO <input type="checkbox"/>
11	The participation of Aboriginal or Torres Strait Islanders, or other peoples from identifiable cultural, ethnic or minority groups?	YES <input type="checkbox"/> NO <input type="checkbox"/>
12	a) Acquisition of data about organisations or individuals through any form of database at any stage of the research? b) Organisations or individuals who are directly or indirectly identifiable by the researcher within the database?	YES <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/>
13	Use of questionnaires or interviews which may be linked either directly (eg through recording of names) or indirectly (eg through a cross-linked code) to the individual/participant/researcher at any stage of the research, including the obtaining of data?	YES <input type="checkbox"/> NO <input type="checkbox"/>
14	Use of questionnaires, interviews, or procedures, irrespective of the recording of the individual's identity, which might reasonably be expected to cause discomfort, embarrassment, or psychological or spiritual harm to the participants?	YES <input type="checkbox"/> NO <input type="checkbox"/>

C: Is there a risk of harm to subjects or groups in the community?

Individuals may be put at risk through the use of new and untried procedures, invasive procedures, the administration of drugs, or the use of procedures likely to cause pain or suffering. Individuals and groups in the community may also be harmed through damage to their cultural security or through processes which might expose them to discrimination or misrepresentation.

Does your research involve:

15	Any novel procedure in the therapy or management of patients in a clinical setting?	YES <input type="checkbox"/> NO <input type="checkbox"/>
16	Any form of physically invasive procedure such as blood collection, exercise regimens or physical examination, and which is not part of clinical management?	YES <input type="checkbox"/> NO <input type="checkbox"/>
17	Any form of physically invasive procedure on volunteer participants such as body fluid collection (eg blood, urine, semen), exercise regimens or physical examination?	YES <input type="checkbox"/> NO <input type="checkbox"/>
18	The administration of any form of drug, medicine (other than in the course of standard medical procedure) or placebo?	YES <input type="checkbox"/> NO <input type="checkbox"/>
19	Physical pain, beyond mild discomfort?	YES <input type="checkbox"/> NO <input type="checkbox"/>
20	Obtaining and storage of blood, body fluid or tissue samples from the participants?	YES <input type="checkbox"/> NO <input type="checkbox"/>
21	Any other ethical issue of the study which has not been addressed in this Checklist?	YES <input type="checkbox"/> NO <input type="checkbox"/>

If Yes, please indicate:

FINAL CHECKLIST

As a final check, please respond to the following list of research areas that commonly raise ethical concerns. Research involving any of the categories listed below is subject to compliance with the provisions of the NH&MRC *National Statement on Ethical Conduct in Human Research*. If you answer Yes, or Probably, please ensure that you have explained and clarified each item elsewhere in the document and that you have both read the relevant chapter of the National Statement (<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>) and addressed the specific considerations therein.

Does this proposal involve: -

Please tick answers to ALL questions

1. minors i.e., under the age of 18 (chapter 4.2)?
2. persons with an intellectual or mental impairment (chapter 4.5)?
3. persons highly dependent on medical care (chapter 4.4)?
4. persons in dependent or unequal relationships (chapter 4.3)?
5. collectivities (such as other specified racial groups) (chapter 4.8)?*
6. separate identification of, or focus on, Aboriginal and Torres Strait Islander peoples (chapter 4.7)?*
7. ionising radiation (X-rays, fluoroscopy or radioisotopes) (chapter 3)?**
8. assisted reproduction technology (chapter 3)?
9. clinical trials (chapter 3)?
10. innovative therapy or intervention (chapter 3)?
11. epidemiological research (chapter 3)?
12. use of human tissue samples (chapter 3.4)?
13. human genetic research (chapter 3.5)?
14. any perceived, possible or actual conflicts of interest

YES	POSSIBLY	NO
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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*If you answered yes to questions 5 or 6, have you consulted the Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. (<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>) This provides good guidance on dealing with cultural groups and their sensitivities

YES NO

**For research involving ionising radiation, microwaves, lasers or ultraviolet light, researchers must submit a separate application to the Radiation Safety Officer, for consideration of approval by the Radiation Safety Committee. Research cannot commence without such approval.

Please indicate the National Statement chapters you have consulted.

For each item to which you have ticked **Yes** or **Possibly**, please state briefly how your research complies with the relevant section of the National Statement.

If you answer YES to any of the questions in the checklist, you will be required to submit an application for ethics approval. Even if all questions are answered NO, your school or faculty may still require that an ethics application be submitted.

For Application Forms please refer to <http://research.curtin.edu.au/ethics/human.cfm>