If you are considering participation in a research study, you will be asked to give informed consent. Informed consent is a process, not just a form.

At a minimum, this should include receiving both an information sheet and a consent form, however the researcher should also take the time to explain the research to you and answer any of your questions.

The information provided should be given without undue inducement or any element of force, fraud, duress or any other form of constraint or coercion. Participants should always be given adequate information on both the possible risks and the potential benefits of their involvement to allow them to make informed decisions about whether or not to participate in the research.

**Research ethics**

Research that involves people raises unique and complex ethical, legal and social issues. Research ethics allows us to analyse ethical issues that are raised when people are involved as participants in research.

There are three main objectives in conducting an ethical review of research. The first is to protect participants. The second is to make sure that the research being conducted serves interests of patients, groups and/or society as a whole. The third objective is to examine specific research activities and look at issues such as the management of risk, protection of privacy and confidentiality and the process of informed consent.

**Human Research Ethics Committees**

Human Research Ethics Committees (HREC) operate in accordance with the The National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (the National Statement). When a researcher wants to conduct a study involving humans, they submit an application to one of the 200+ HRECs in Australia for ethical review. HRECs are required to have a minimum membership which includes a Chairperson with suitable experience, at least two lay people, at least one person with knowledge of and current experience in the professional care, treatment or counselling of people, e.g. a nurse, doctor or allied health professional, at least one person who performs a pastoral care role in a community, e.g. an Aboriginal elder or minister of religion and at least one lawyer.

If you are a participant in a research study and have a concern about the conduct of a research, you can raise your concern with the researcher responsible for the project, however if you are not comfortable discussing your concern with the researcher or are not satisfied with the response, you can contact the HREC that approved the research project. The contact details for the HREC will have been given to you on either the written information sheet or consent form.

# Low risk research

The NHMRC National Statement recognises that human research involves a wide range of activities that have variable risks and potential benefits. The National Statement establishes different levels of ethical review, based on the degree of risk involved.

There are three levels of risk:

•Harm;
•Discomfort; and

•Inconvenience

Researchers are required to determine the existence, likelihood and severity of these risks based on the research methodology and design, participant population and research activity.

The National Statement, sections 2.1.6-2.1.7 holds that:

2.1.6 Research is ‘Low Risk’ where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk;

2.1.7 Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk’

Research that involves the risk of harm or the likelihood of harm must be reviewed by a fully constituted HREC. For research involving only the risk of inconvenience, or discomfort (i.e. low or negligible risk), or service evaluations, research institutions may establish alternative ethical review process.

It should be noted that research involving certain groups, methodologies or procedures, regardless of the level of risk, must be reviewed by a full HREC (Clause 5.1.6 of the National Statement), for example, research involving children.

**Your notes**

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| Information prepared by the Centre for Community-Driven Research (CCDR). Contact npon@cc-dr.org [Version:10 January 2024] |