1.0 PRINCIPLES OF ETHICAL RESEARCH CONDUCT

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In Australia, The National Health and Medical Research Council (NHMRC) website provides the key document for informing and understanding ethical research processes. The National Statement on Ethical Conduct in Research Involving Humans is an excellent place to start to understand the ethics review process, as it provides easy-to-read and use guidance and advice for researchers, practitioners and ethics committee members.

According to the National Statement,¹ ethical conduct of research is based on the principles of respect, merit, justice and beneficence.

Respect is the concept that all people deserve the right to fully exercise their autonomy. Issues such as informed consent to participate in research fall into this category.

Research merit is dependent on balancing the potential benefits of the research against possible risk to research participants (and researchers).

Justice assumes that the risk and benefit associated with research will be evenly distributed and no group will be disadvantaged by participation in the research.

Beneficence goes beyond the concept of "doing no harm". Essentially it is the expectation that the research will generate "good" or benefit. Individual participants may not benefit directly from the "good," but overall the project must benefit the wider community.

Application of the principles of ethical conduct must be inherent throughout research – from the conception and design of the project through to participant selection, data collection, analysis and interpretation, and dissemination of research results.

What is informed consent?

Informed consent is a voluntary agreement to participate in research. It is not merely a form that is signed but a process in which the participant has an understanding of the research and its risks. It is essential to obtain informed consent prior to recruiting participants. Informed consent must be obtained for all types of human participant research, and for research conducted domestically or abroad. Obtaining consent involves informing the participant of his or her rights, the purpose of the study, the procedures to be undergone, and the potential risks and benefits of participation. Participants in the study must take part willingly. Vulnerable populations (e.g. prisoners, children, pregnant women) must receive extra protections. The goal of the informed consent process is to provide sufficient information for a participant to make an informed decision about whether or not to enrol in a study or to continue participating. The informed consent document must be written in a language easily understood by the participant, it must minimise the possibility of coercion or undue influence, and the participant must be given sufficient time to consider taking part.2