1. PRINCIPLES OF ETHICAL CONDUCT

The primary purpose of this Statement of ethical principles and associated guidelines for research involving humans is the protection of the welfare and rights of participants in research. The ethical and legal responsibilities which researchers have towards participants in research reflect basic ethical values of integrity, respect for persons, beneficence and justice. The responsibilities set out below accord with accepted moral and scientific principles set out in declarations, conventions and guidelines listed in Appendix 1. The principles in 1. Principles of Ethical Conduct are intended to apply to the interpretation and the use of all subsequent parts of this Statement.

INTEGRITY, RESPECT FOR PERSONS, BENEFICENCE AND JUSTICE

1.1 The guiding value for researchers is integrity, which is expressed in a commitment to the search for knowledge, to recognised principles of research conduct and in the honest and ethical conduct of research and dissemination and communication of results.

1.2 When conducting research involving humans, the guiding ethical principle for researchers is respect for persons which is expressed as regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage, both individual and collective, of persons involved in research.

1.3 In research involving humans, the ethical principle of beneficence is expressed in researchers' responsibility to minimise risks of harm or discomfort to participants in research projects.

1.4 Each research protocol must be designed to ensure that respect for the dignity and well being of the participants takes precedence over the expected benefits to knowledge.

1.5 The ethical value of justice requires that, within a population, there is a fair distribution of the benefits and burdens of participation in research and, for any research participant, a balance of burdens and benefits. Accordingly, a researcher must:

(a) avoid imposing on particular groups, who are likely to be subject to over researching, an unfair burden of participation in research;

(b) design research so that the selection, recruitment, exclusion and inclusion of research participants is fair; and

(c) not discriminate in the selection and recruitment of actual and future participants by including or excluding them on the grounds of race, age, sex, disability or religious or spiritual beliefs except where the exclusion or inclusion of particular groups is essential to the purpose of the research.

1.6 The proportion of burdens to benefits for any research participant will vary. In clinical research, where patient care is combined with an intent to contribute to knowledge, the risks of participation must be balanced by the possibility of intended benefits for the participants. In other research involving humans that is undertaken solely to contribute to knowledge, the absence of intended benefits to a participant should justly be balanced by the absence of all but minimal risk.

CONSENT

1.7 Before research is undertaken, whether involving individuals or collectivities, the consent of the participants must be obtained, except in specific circumstances defined elsewhere in this Statement [see paragraphs 1.11, 6.9, 14.4, 15.8, 16.13].

The ethical and legal requirements of consent have two aspects: the provision of information and the capacity to make a voluntary choice. So as to conform with ethical and legal requirements, obtaining consent should involve:

(a) provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results); and

(b) the exercise of a voluntary choice to participate.

Where a participant lacks competence to consent, a person with lawful authority to decide for that participant must be provided with that information and exercise that choice.

1.8 A person may refuse to participate in a research project and need give no reasons nor justification for that decision.

1.9 Where consent to participate is required, research must be so designed that each participant's consent is clearly established, whether by a signed form, return of a survey, recorded agreement for interview or other sufficient means.

In some circumstances and some communities, consent is not only a matter of individual agreement, but involves other properly interested parties, such as formally constituted bodies of various kinds, collectivities or community elders. In such cases the researcher needs to obtain the consent of all properly interested parties before beginning the research.

1.10 The consent of a person to participate in research must not be subject to any coercion, or to any inducement or influence which could impair its voluntary character.

1.11 It is ethically acceptable to conduct certain types of research without obtaining consent from participants in some circumstances, for example, the use of de-identified data in epidemiological research, observational research in public places, or the use of anonymous surveys. [See 14. Epidemiological Research and 17. Research Involving Deception of Participants, Concealment or Covert Observation.]

1.12 A participant must be free at any time to withdraw consent to further involvement in the research. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained.

RESEARCH MERIT AND SAFETY

1.13 Every research proposal must demonstrate that the research is justifiable in terms of its potential contribution to knowledge and is based on a thorough study of current literature as well as prior observation, approved previous studies, and where relevant, laboratory and animal studies.

1.14 All research proposals must be so designed as to ensure that any risks of discomfort or harm to participants are balanced by the likely benefit to be gained.

1.15 Research must be conducted or supervised only by persons 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 participants.

ETHICAL REVIEW AND CONDUCT OF RESEARCH

1.16 Research projects involving humans must be reviewed by a Human Research Ethics Committee (HREC) and must not be undertaken or funded unless and until approval has been granted.

1.17 A researcher must suspend or modify any research in which the risks to participants are found to be disproportionate to the benefits and stop any involvement of any participant if continuation of the research may be harmful to that person.

1.18 The results of research (whether publicly or privately funded) and the methods used should normally be published in ways which permit scrutiny and contribute to public knowledge. Normally, research results should be made available to research participants.

1.19 Where personal information about research participants or a collectivity is collected, stored, accessed, used, or disposed of, a researcher must strive to ensure that the privacy, confidentiality and cultural sensitivities of the participants and/or the collectivity are respected. Any specific agreements made with the participants or the collectivity are to be fulfilled.

1.20 Where the records and results of research contain information of clinical significance it is the responsibility of both the researcher and the institution or organisation to maintain the security and storage of records and results so as to enable any necessary follow-up studies to be carried out.

1.21 Where research is conducted in an overseas country under the aegis of an Australian institution or organisation, the research must comply with the requirements of this Statement as well as the laws and guidelines of that country.