

**National Statement
on Ethical Conduct
in Research
Involving Humans**

The 2007 revised National Statement on Ethical Conduct in Human Research was tabled in Parliament on 28 March 2007

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Letter on Significant national initiative for research in Australia from

Dr Michael Wooldridge, Minister for Health and Aged Care

Dr David Kemp, Minister for Education, Training and Youth Affairs and

Senator Nick Minchin, Minister for Industry, Science and Resources

is not available electronically.

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**NATIONAL STATEMENT
ON ETHICAL CONDUCT
IN RESEARCH
INVOLVING HUMANS**

Issued by the National Health and Medical Research Council (NHMRC) in accordance with the *NHMRC Act, 1992 (Cth)*.

Endorsed by the:

- **Australian Vice-Chancellors' Committee**
- **Australian Research Council**
- **Australian Academy of the Humanities**
- **Australian Academy of Science**
- **Academy of the Social Sciences in Australia**

Supported by the:

- **Academy of Technological Sciences and Engineering**

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PLEASE NOTE

This Statement entitled the ***National Statement on Ethical Conduct in Research Involving Humans*** ('the Statement') consists of a series of Guidelines made in accordance with the *National Health and Medical Research Council Act 1992* ('the Act').

The Statement has revised the guidelines entitled the *NHMRC Statement on Human Experimentation and Supplementary Notes* in accordance with section 90 of the Act, with the exception of Supplementary Notes 5 and 7, which have not yet been revised. This Statement therefore replaces the *NHMRC Statement on Human Experimentation and Supplementary Notes* with the exception of Supplementary Notes 5 and 7 which remain in force from the date they were originally issued in October 1983 and November 1992 respectively.

In addition:

- (1) Despite the changes to the guidelines affecting Institutional Ethics Committees, any committee established under Supplementary Note 1 of the *NHMRC Statement on Human Experimentation and Supplementary Notes 1992* (the previous Statement) and in existence immediately before the commencement of this Statement shall continue in existence as if established under 2. Human Research Ethics Committees of this Statement, and any matter being undertaken by such a committee prior to commencement of this Statement may be continued by that committee.
- (2) Persons who, immediately before commencement of this Statement, had been members of an Institutional Ethics Committee established under the previous Statement are to be taken, with effect from the commencement of this Statement, to have been duly appointed to a Human Research Ethics Committee under this Statement and to be entitled to continue in office as members of that committee until 31 December 1999. From 1 January 2000 all Human Research Ethics Committees must be constituted in accordance with this Statement.

CONTENTS

PREAMBLE	I
Importance of ethics	1
Purpose of this Statement	1
Historical context	1
Statutory considerations	3
The meaning of ethics and of research	3
Structure and interpretation	10
I. PRINCIPLES OF ETHICAL CONDUCT	II
Integrity, respect for persons, beneficence and justice	11
Consent	12
Research merit and safety	13
Ethical review and conduct of research	13
2. HUMAN RESEARCH ETHICS COMMITTEES	15
Composition	15
Appointment of members	16
Procedures	17
Advocates and interpreters	18
Expedited review for minimal risk research	19
Recording of decisions	19
Monitoring	20
Complaints	21
Suspension or discontinuation of research	21
Compliance reports to the National Health and Medical Research Council	21
3. MULTI-CENTRE RESEARCH	23
Review	23
Monitoring	24

CONTENTS

4. RESEARCH INVOLVING CHILDREN AND YOUNG PEOPLE	25
5. RESEARCH INVOLVING PERSONS WITH AN INTELLECTUAL OR MENTAL IMPAIRMENT	26
6. RESEARCH INVOLVING PERSONS HIGHLY DEPENDENT ON MEDICAL CARE	27
Emergency care research	27
Intensive care research	27
Neonatal intensive care research	27
Terminal care research	28
Research involving persons with impaired capacity for communication	28
Research involving unconscious persons	28
Human Research Ethics Committee consideration of research proposals involving persons highly dependent on medical care	28
7. RESEARCH INVOLVING PERSONS IN DEPENDENT OR UNEQUAL RELATIONSHIPS	30
8. RESEARCH INVOLVING COLLECTIVITIES	31
9. RESEARCH INVOLVING ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES	32
10. RESEARCH INVOLVING IONISING RADIATION	33
11. RESEARCH INVOLVING ASSISTED REPRODUCTIVE TECHNOLOGY	34
12. CLINICAL TRIALS	35
13. INNOVATIVE THERAPY OR INTERVENTION	39
14. EPIDEMIOLOGICAL RESEARCH	40

CONTENTS

15. USE OF HUMAN TISSUE SAMPLES	43
Respect for persons	43
Institutional responsibility	44
Where consent would be required	44
Where the requirement for consent could be waived	45
Confidentiality	45
16. HUMAN GENETIC RESEARCH	46
Social significance and consequences of genetic research	46
Privacy and confidentiality	47
Consent	47
Where the requirement for consent could be waived	49
Genetic counselling	50
17. RESEARCH INVOLVING DECEPTION OF PARTICIPANTS, CONCEALMENT OR COVERT OBSERVATION	51
18. PRIVACY OF INFORMATION	52
19. INTELLECTUAL PROPERTY	54
APPENDIX 1 RELEVANT PUBLICATIONS	55
International Declarations and Conventions	55
International Guidelines and Codes	55
National Health and Medical Research Council Publications	56
Other	56
APPENDIX 2 INFORMATION PRIVACY PRINCIPLES	57
APPENDIX 3 GLOSSARY OF DEFINITIONS	62

ABBREVIATIONS

AHEC	Australian Health Ethics Committee
AIATSIS	Australian Institute of Aboriginal and Torres Strait Islander Studies
ARC	Australian Research Council
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
AVCC	Australian Vice-Chancellors' Committee
CTN	Clinical Trial Notification Scheme
CTX	Clinical Trial Exemption Scheme
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
TGA	Therapeutic Goods Administration

PREAMBLE

IMPORTANCE OF ETHICS

Ethics and ethical principles extend to all spheres of human activity. They apply to our dealings with each other, with animals and the environment. They should govern our interactions not only in conducting research but also in commerce, employment and politics. Ethics serve to identify good, desirable or acceptable conduct and provide reasons for those conclusions.

PURPOSE OF THIS STATEMENT

The primary purpose of a statement of ethical principles and associated guidelines for research involving humans is the protection of the welfare and the rights of participants in research.

There is an important secondary purpose of a statement of ethical principles and accompanying guidelines, and that is to facilitate research that is or will be of benefit to the researcher's community or to humankind.

The purpose of this Statement is to provide a national reference point for ethical consideration relevant to all research involving humans. It is the product of wide consultation and builds on the *NHMRC Statement on Human Experimentation and Supplementary Notes (1992)*.

This Statement identifies the ethical principles and values which should govern research involving humans. Throughout this Statement the term "involving" is used to mean not only those who are the principal focus of the research but also those on whom the research impacts. It provides guidance for researchers, ethics committees, institutions, organisations and the public on how such research should be designed and conducted so as to conform to those principles and reflect those values.

This Statement commences with statements of broad ethical principle, followed by short statements of considerations relevant in specific research contexts, arranged according to subject matter. This form offers guidance for rather than prescription of ethically sound research design and practice.

HISTORICAL CONTEXT

The development of modern codes of ethical principles related to all research involving humans is a comparatively recent phenomenon, although codes related to health and health related research commenced in the early part of this century. The awareness of the importance of respect for ethical codes in research involving human participants was accelerated in response to revelations of unethical practices, particularly during the Second World War. The judgement of the Nuremberg military tribunal on war crimes contained a set of principles and standards relating to permissible medical experiments. These have significantly influenced the subsequent development of codes of ethics.

Despite the emergence of these codes, incidents of unethical treatment of people in health research occurred. Most nations have published codes of ethical conduct in health research, often observing the 1964 *Declaration of Helsinki* published by the World Medical Association and a succession of international documents prepared during the last four decades (see [Appendix 1](#)). These documents demonstrate a trend towards making more explicit the ethical standards which must be met if research on human beings is to be ethically acceptable. Continuing revision of standards for and systems of review of research involving humans is necessary.

Australia has followed these trends. The *Statement on Human Experimentation*, a set of applied ethical standards about medical research involving human subjects, closely followed the *Declaration of Helsinki* (which had been ratified by Australia in 1964). The *Statement on Human Experimentation* was first published by the National Health and Medical Research Council (NHMRC) in 1966. In succeeding years, Supplementary Notes were developed providing guidance on ethical issues in relation to distinct kinds of research or categories of research subjects and participants. The *Statement on Human Experimentation* became a widely used standard for the ethical review, by institutional ethics committees, of research involving humans, particularly medical research, but increasingly of social and behavioural research as well. In November 1985, the NHMRC resolved that observance by institutions of the standards and procedures set out in the *Statement on Human Experimentation and Supplementary Notes* for the approval of research would be mandatory for continuing eligibility for NHMRC research funds.

It is now widely accepted that all kinds of research involving or impacting upon humans should conform to the highest standards of academic integrity and ethical practice. The Australian Research Council (ARC), which is the major Australian funding body for research outside the fields of clinical medicine and dentistry, has recently been concerned to develop a code of ethics that will be applicable to all forms of research which either involve humans directly or impact upon them directly or indirectly. The term 'impacting' refers to research which requires interaction with humans with special interests in the research (other than the community of professional colleagues), either as individuals, groups or collectivities, in the course of conducting the research or communicating the results of research.

The original *Statement on Human Experimentation* has undergone several revisions in the light of international ethical and scientific developments. During 1996-98 the ARC also endorsed a code of ethics for human research, parts of which have been incorporated into the present document, after discussions by a Working Party with representation from the NHMRC, ARC, AVCC (Australian Vice-Chancellors' Committee) and the four Learned Academies of Science, Humanities, Social Sciences and Engineering and Technological Sciences. In the report of a review of the system of institutional ethics committees in Australia in 1996,¹

¹ *Report of the Review of the Role and Functioning of Institutional Ethics Committees*, A Report to the Minister for Health and Family Services, March 1996, Commonwealth of Australia, Canberra.

a review of the *Statement on Human Experimentation and Supplementary Notes (1992)* was recommended and has been conducted. This *National Statement on Ethical Conduct in Research Involving Humans* is the outcome of that review and the deliberations of the Working Party.

STATUTORY CONSIDERATIONS

Legislation has been primarily concerned with health and medical research. Since the last review of the *Statement on Human Experimentation*, the Commonwealth Parliament enacted the *National Health and Medical Research Council Act 1992*. The object of that Act is to make provision for a national body to pursue activities designed to foster medical and public health research and the consideration of ethical issues relating to health. The Act establishes the NHMRC as a statutory entity and sets out its functions, powers and obligations. One of the functions of the NHMRC is to inquire into, issue guidelines on and advise the community on ethical issues relating to health. In the exercise of that function, the NHMRC is specifically required to issue guidelines for the conduct of medical research involving humans precisely as developed by the Australian Health Ethics Committee (AHEC). AHEC was established by the *NHMRC Act* as a principal committee of the NHMRC.

In issuing this Statement, the NHMRC fulfils its specific obligation to issue guidelines on medical research as well as its function to provide guidelines on ethical matters relating to health. The NHMRC requires all institutions or organisations that receive NHMRC funding for research to establish a Human Research Ethics Committee (HREC) and to subject all research involving humans, whether relating to health or not and whether funded by the NHMRC or not, to ethical review by that committee. The NHMRC expects this Statement to be used as the standard for that review. It has drawn on internationally accepted principles in developing this Statement by reference to which the ethical acceptability of any research involving humans, whether related to health or not, can be determined. Accordingly, this Statement is recommended for use by any individual, institution or organisation conducting research involving humans as an inclusive, reliable and informative guide to the ethical considerations relevant to the review of that research. This would include any research involving humans undertaken by industry.

THE MEANING OF ETHICS AND OF RESEARCH

These expressions have contested meanings. The following indicates the approach taken to their use in this Statement.

Ethics

Some basic ethical principles

Among the essential values for research is that of the integrity of researchers. This includes the commitment to research questions that are designed to contribute to knowledge, a commitment to the pursuit and protection of truth, a commitment to reliance on research methods appropriate to the discipline and

honesty. A convenient statement of these values is contained in the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997).

In one of the early reflective documents on research ethics, the authors of the Belmont Report² identify three basic ethical principles: those general judgments that serve as a basic justification for particular ethical prescriptions and evaluations of human action. The first of these is *respect for persons*, that is, that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protection. If respect for persons is equivalent to treating others as autonomous agents then we cannot show respect for those whose autonomy we recognise to be diminished. But we clearly can show such respect. That respect is for the inherent dignity and the rights of persons and is, at the same time, a commitment not to use a person only as a means to an end.

The second is *beneficence*, that is, the obligations to maximise possible benefits and minimise possible harms. (The obligation to do no harm is referred to separately as non-maleficence.) Harm, in this context, extends beyond physical harm to a wide range of psychological or emotional distress, discomfort and economic or social disadvantage. Researchers exercise beneficence in assessing the risks of harm and potential benefits to participants, in being sensitive to the rights and interests of people involved in their research and in reflecting on the social and cultural implications of their work.

The third principle is *justice*, addressing the resolution of the question of who ought to receive the benefits of research and bear its burdens. In the early twentieth century, it was recognised as unjust that, while the burdens of serving as medical research subjects fell largely on public patients, the benefits of improved medical care flowed largely to private patients. In contemporary times, researchers and HRECs should recognise the potential for injustice where some groups are regularly selected as research subjects because of convenience and without regard to the frequency of research with those populations or to whom the benefits of the research flow. Questions of justice can also arise in relation to the use of public funds for research.

The detailed and applied provisions of this Statement find their origin and justification in these principles. Other important principles apply to research involving humans. These include the preservation of the integrity of scholarship and research, the integrity of the individual researcher or research team, the promotion of the integrity of institutions and organisations responsible for research, and the accountability of researchers both to the general community and to specific groups or collectivities (see [8. Research Involving Collectivities](#)) who have a defined interest in the research.

² *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, Department of Health, Education and Welfare Publication No (OS) 78-0012, US Government Printing Office, Washington, 1978

Individuals and communities

The basic principles recognised by the authors of the Belmont Report reflect the high value that the dominant Western tradition places on individual autonomy. It is important for researchers to recognise that this is not the only way in which human interaction and responsibilities are conceptualised. In many non-Western societies, and in some communities within Western societies also, the rights and autonomy of the individual are complicated and constrained, to a greater or lesser extent, by those of related individuals and groups with specific authority over that individual. Thus researchers need to be aware of individuals' rights within specific local and national socio-cultural contexts.

It is also the case that non-Western traditions as well as more recent developments in social research practice have often emphasised the importance of community values. Members of societies see value in collective activities well beyond the value of each person's individual share of the benefits. The cultural diversity in Australian society means that there may be a range of views on the relative weight of individual and collective values. A constant awareness of this variety will be necessary to ensure that the application of the ethical values by which research is assessed continues to respect that variety of opinion. Research has a significant value to the community as a whole, and all members of the Australian community share in the responsibility to foster and maintain this valuable social institution.

Ethics and science in research

Ethical considerations are as germane to good research as are scientific considerations. Ethical inadequacies in a research proposal are as significant as scientific inadequacies. But scientific inadequacies also have ethical implications. Projects without scientific merit are wasteful of resources and needlessly subject participants to risks. Accordingly, an essential condition of the ethical acceptability of research is the determination that the scientific quality of a proposal and the skill and experience of the researchers are such that the objectives of the proposal can reasonably be expected to be achieved.

Ethics and law in research.

Research involving human participation is subject to a variety of legal regulation, at Federal, State and Territory levels. Commonwealth laws regulate registration, use of, and certain research on pharmaceutical drugs and medical devices, the protection of privacy and intellectual property. State and Territory laws regulate access to and use of health information held by authorities, consumer protection and professional conduct. Researchers need to conform to relevant legal requirements and HRECs need to be satisfied that the conduct of research that they approve is lawful.

In the event that both a legal requirement and an ethical guideline apply, the legal requirement will prevail (although they will normally be consistent). Ethical guidelines have the objective of defining standards of behaviour to which researchers should adhere. Where the guidelines prescribe a standard that exceeds that required by the law, then researchers should apply this higher standard.

Research

Defining research

The Statement is addressed to research involving or impacting upon humans. Understanding the scope of research involving humans requires knowledge of what research includes and what involving humans includes.

There are many definitions of research. These include systematic investigation to establish facts, principles or knowledge and a study of some matter with the objective of obtaining or confirming knowledge. A defining feature of research is the validity of its results. The knowledge that is generated by research is valid in the sense that what is discovered about the particular facts investigated can be justifiably claimed to be true for all like facts. However, it remains difficult to find an agreed definition of research.

An alternative approach to finding a definition of research is to list examples of what constitutes research, such as:

- systematic prospective collection of information to test an hypothesis;
- a planned study of existing practices with a view to changing/improving practice in light of the study's findings and/or to increase understanding; or
- the administration and analysis of data in response to surveys or questionnaires, interviews or opinion polling.

However, such lists risk including activity that would not normally be included, like quality assurance activities or audits and excluding activity that probably should be included, such as research conducted as part of a course of education. Further, such lists risk omitting newly emerged genres of research, of which various kinds of multi-disciplinary research are examples.

The involvement of humans is no more easily defined. This includes the use and/or collection of personal, collective or cultural data from participants or from their records, which may include their oral testimony or observed cultural activities, the testing of responses to conditions devised by researchers or invasive testing of new therapies.

In some contexts, another way of clarifying the nature of involvement of humans is the distinction between therapeutic and non-therapeutic research. The former is research conducted with the intent of providing a direct benefit to the participants, while the latter is research conducted with the intent to derive knowledge and not to be of direct benefit to participants (although it may be so). The distinction can be used in the ethical assessment of an acceptable balance, for research participants, between the benefits and the risks of research.

A similar distinction used by the Council for International Organisations of Medical Sciences (CIOMS)³ is that between clinical research and non-clinical

³ Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, CIOMS, Geneva, 1993, p.11.

research. The former is defined as that undertaken in combination with patient care with one or more of its components designed to confer diagnostic, prophylactic or therapeutic benefits on the individuals involved in addition to the development of new health knowledge. Non-clinical research is that undertaken on patients or other subjects or with data pertaining to them, with the sole intention of contributing to knowledge. All would be within the meaning of research involving humans as that expression is used in this Statement. However, the Statement is designed to also include research involving humans that may not be categorised as therapeutic, non-therapeutic, clinical or non-clinical.

The ARC distinguishes between “pure” and “applied” research.⁴ Pure research is defined as experimental and theoretical work undertaken to acquire new knowledge without looking for long-term benefits other than the advancement of knowledge. Applied research is defined as original work undertaken primarily to acquire new knowledge with a specific application in view.⁵

It is not possible to define all kinds of research involving humans by using a distinction between therapeutic and non-therapeutic research. Some research, particularly outside the health and medical fields, is not performed directly on human subjects but rather involves their informed cooperation in the researcher’s investigation of some human behaviour or some local knowledge base in, for example, the social, cultural, biological or physical environment. This kind of research involves the exchange of knowledge between the researcher and those with whom he or she interacts.

Defining participants

The definition of participants in this Statement includes not only those humans who are the principal focus of the research endeavour but also those upon whom the research impacts, whether concurrently or retrospectively. Two examples of research that impacts on humans are studies of human remains that are linked to identifiable living humans or fieldwork in which a researcher requires access to community-controlled resources. Research involving (and impacting on) humans may occur in a wide range of disciplinary fields.

What a Human Research Ethics Committee should review

The difficulty faced in providing a suitable definition of research involving humans suggests that a more appropriate focus is to seek to define that which needs to be considered and approved by an HREC. Where activity involves human participation or definable human involvement and has a purpose of establishing facts, principles or knowledge or of obtaining or confirming knowledge, the features of human involvement will be the focus of deciding whether it is research and so subject to review by an HREC.

⁴ Department of Education, Training and Youth Affairs, *Large Research Grants Scheme: Guidelines for Year 2000 Grants*, Australian Research Council, 1999, p.4.

⁵ The Australian Taxation Office also has definitions related to research. See *Income Tax Assessment Act 1936* (Cth) Section 73B (1AB).

Where that involvement has a potential for infringing basic ethical principles, at least respect for humans, beneficence and justice, review by an HREC is warranted. Such a potential arises: where that involvement could cause harm to the well-being of participants, whether physically, psychologically, spiritually or emotionally; or in the exploitation of cultural knowledge and/or property, where their involvement, or the use of their personal or community-based information, has a potential for infringement of their privacy or of the confidentiality or ownership that attaches to that information; or where their involvement imposes burdens with little benefit.

Researchers, regulators, funding bodies, institutions, organisations and HRECs will need to address these issues with deliberate care and caution and arrive at provisional descriptions of what constitutes research that merits ethical review. In this process, a sustained awareness of the characteristics of the evolving research environment and practice will be important.

Institutions and organisations and boundaries between research and practice

The adoption of such an approach to deciding whether an activity ought to be subject to review by an HREC (and be thereby classified as research requiring HREC review) provides guidance rather than prescription to institutions and organisations in which such activities and research are conducted. The range of activities undertaken by and within an institution or organisation will be affected by its capacity, its resources and its mission. It is the responsibility of each institution and organisation to develop criteria to classify which of its activities are reviewable by its HREC and which are not. This Statement should form the basis and source for those criteria. Accordingly, variation in the classification of activities between and among institutions and organisations may occur, so long as it can be justified by reference to this Statement.

The research environment

The experience of humans involved in research ranges from that of passive subject to active co-researcher. Although this Statement tends to use the expression “participants”, mere changes of titles may not reflect the reality of experience. Further, such changes in names may lead to significant changes in expectation among those involved: to be called a participant may lead to expectations to be involved in the design, conduct and reporting of research in ways that may compete with more conventional perceptions of research held by some researchers. Where research moves beyond well established paradigms and contexts, HRECs will need to recognise the tension between, and the ethical implications of, changing perceptions and expectations of those conducting and those involved in research.

The research environment in Australia is marked by an increase in the quantity and diversity of research that is being conducted and in the sources of funding for that research. Not only have there been major developments in traditional research fields during the last century, but new fields are continually opening up in a great many disciplines. Within research related to health, the continuous

advance in knowledge of the predictors of health status increases the avenues of further research. The field of genetics is currently a clear example. In this changing context, the NHMRC regards the development and promulgation of an inclusive, relevant and reliable set of guidelines for the ethical design and conduct of all research involving humans as essential. Such guidelines become more important as the sources of funding and number of researchers multiply. Clarity in published national standards is the basis for consistency in the ethical conduct of research.

Categories of personal information

In this Statement and particularly in [14. Epidemiological Research](#), [15. Use of Human Tissue Samples](#) and [16. Human Genetic Research](#), distinctions are made between three types of personal information or material. Distinctions are made between identified, potentially identifiable (coded or re-identifiable) and de-identified (not re-identifiable, anonymous). There are genuine public concerns about privacy and the storage of information of a personal nature. This Statement distinguishes between the responsibilities of researchers in respect to each category; greater care is required where the research involves identifiable or potentially identifiable information.

The three types of personal data are as follows:

Identified

Data that allow the identification of a specific individual are referred to as “identified data”. Examples of identifiers may include the individual’s name, date of birth or address. In particularly small sets of data even information such as a postcode may be an identifier.

Potentially identifiable (coded, re-identifiable)

Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relate so that the process of de-identification is reversible. In these cases the data are referred to as “potentially identifiable”.

De-identified, (not re-identifiable, anonymous).

The process of de-identification can be irreversible if the identifiers have been removed permanently or if the data have never been identified. These data are referred to as “de-identified”. It should be recognised that the term “de-identified” is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain “potentially identifiable”.

The benefits of research

The conduct and outcomes of research involving humans has had and will continue to have benefits for society. Such research, in seeking new knowledge about the conditions for social wellbeing including the causes of social dysfunction, the origins and progress of disease or the efficacy of treatment or health care, plays an essential part in the beneficial future of Australian society. Further, the opportunity that such research provides for the education of

Australian students and researchers should not be underestimated. In the assessment of the ethical acceptability of any research project, a committee should pay regard to the importance and the benefits of research and assess and balance these against the burdens undertaken by those participating in research.

STRUCTURE AND INTERPRETATION

1. Principles of Ethical Conduct sets out ethical principles and values to which all research that involves humans and to which the Statement applies must conform. 2. Human Research Ethics Committees (HRECs) sets out the procedures for consideration and approval of all such research by an HREC.

In addition, more detailed guidance is provided on how different types of research should be designed and conducted so as to conform to the ethical principles and values in 1. Principles of Ethical Conduct and so as to be suitable for approval by an HREC under 2. Human Research Ethics Committees. Accordingly the general principles in 1. Principles of Ethical Conduct are intended to apply to the interpretation and the use of all subsequent parts of this Statement.

A glossary of terms and expressions used throughout the Statement appears as an appendix to this Statement.

I. 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.

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- 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.

2. HUMAN RESEARCH ETHICS COMMITTEES

Research proposals involving human participants must be reviewed and approved by a Human Research Ethics Committee (HREC) which is established by and advises an institution or organisation regarding ethical approval for research projects. Requirements are set out for:

- institutions or organisations in establishing HRECs;
 - researchers in submitting research proposals to HRECs; and
 - HRECs in considering and reaching decisions regarding those proposals and in monitoring the conduct of approved research.
- 2.1 Institutions and organisations in which research involving humans is undertaken must individually or jointly establish, adequately resource, and maintain an HREC composed and functioning in accordance with this Statement.
 - 2.2 The institution or organisation must, when establishing an HREC, set out its terms of reference including the scope of its responsibilities, relationship to non-affiliated researchers, accountability, mechanisms of reporting, and remuneration, if any, for members.
 - 2.3 The institution or organisation (individually or jointly) must accept legal responsibility for decisions and advice received from the HREC and indemnify its members.
 - 2.4 Researchers without affiliation to an institution or organisation with an HREC must ensure that the project is approved by an established HREC. There should be an agreement between the institution or organisation and researchers that defines the approval, conduct and monitoring of research, and who carries legal responsibility for it.
 - 2.5 The primary role of an HREC is to protect the welfare and the rights of participants in research and the primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC will so protect participants.

COMPOSITION

- 2.6 The minimum membership of an HREC is seven members, being men and women, comprising:
 - (a) a chairperson;
 - (b) at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, are not currently involved in medical, scientific, or legal work, and who are preferably from the community in which the institution or organisation is located;

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- (c) at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (eg. health, medical, social, psychological, epidemiological, as appropriate);
 - (d) at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, social worker, nurse, as appropriate);
 - (e) at least one member who is a minister of religion, or a person who performs a similar role in a community such as an Aboriginal elder; and
 - (f) at least one member who is a lawyer.
- 2.7 The institution or organisation must ensure that the membership will equip the HREC to address all relevant considerations arising from the categories of research likely to be submitted to the HREC. For example, an experienced medical practitioner should be included if the HREC considers research protocols which involve any physically invasive procedures or medical interventions, (eg. surgical, pharmacological, physiological, technological, or nutritional intervention).
- 2.8 An HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific and statistical validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms with this Statement. This may necessitate appointment of additional members with specific expertise.
- 2.9 If an institution or organisation appoints additional members it should ensure that the membership continues to reflect both the diversity of the categories of members listed in paragraph 2.6, including gender, and the relative proportion of institutional to non-institutional members.

APPOINTMENT OF MEMBERS

- 2.10 The institution or organisation may recruit members for an HREC in such a manner and shall appoint them for such a period and on such terms and conditions as it determines.
- 2.11 Members are to be appointed for their expertise and not in a representative capacity.
- 2.12 Members must receive a formal notice of appointment and assurances that the institution or organisation will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as committee members.

PROCEDURES

- 2.13 Institutions and organisations and their HRECs must establish working procedures concerning:
- frequency of meetings;
 - preparation of agendas and minutes;
 - distribution of papers prior to meetings;
 - presentation of research protocols;
 - timely consideration and review of research protocols;
 - methods of decision making;
 - prompt notification of decisions;
 - reporting of adverse occurrences;
 - appropriate monitoring;
 - receiving complaints;
 - advising institution(s) or organisation(s) to discontinue a research project;
 - fees, if any, to be charged; and
 - confidentiality of the content of protocols and of committee proceedings.
- 2.14 An HREC may approve, require amendment of, or reject a research proposal on ethical grounds. The HREC must record decisions in writing and should include reasons for rejection.
- 2.15 Meetings of an HREC must be so arranged as to allow, wherever possible, all members to be fully informed by receipt of all relevant papers and the opportunity to attend.
- 2.16 Where there is less than full attendance at a meeting, the Chairperson must be satisfied, before a decision is reached, that the minimum membership listed in paragraph 2.6 have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- 2.17 An HREC should endeavour to reach decisions by general agreement. This need not involve unanimity, but failure to agree may require an extension of time to reconsider the research protocol and its possible amendment, especially when any member is not satisfied that the welfare and rights of participants are protected.
- 2.18 An HREC may invite the researcher(s) to be present for discussions of the research and may request amendments to the research protocol.
- 2.19 An HREC may seek advice and assistance from experts to assist with consideration of a research protocol, but must be satisfied that such experts have no conflicts of interest in relation to the research project under consideration arising from any personal involvement or participation

in the research, any financial interest in the outcome or any involvement in competing research.

- 2.20 An HREC shall ensure that no member of the committee adjudicates on research in which that member has any conflict of interest including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.
- 2.21 A researcher must disclose to the HREC the amount and sources or potential sources of funding for the research and must declare any affiliation or financial interest when proposing and when reporting the research. The HREC must consider the extent to which it should disclose that information about funding sources.
- 2.22 A researcher must include, in the research proposal, a statement of the ethical considerations involved in the proposed research and an HREC must be satisfied that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and cultural heritage both individual and collective.
- 2.23 An HREC should not communicate directly with a research sponsor on matters relating to the protocol or ethics of a project, but the institution or organisation and the sponsor may have direct communication on matters relating to administration, indemnity and insurance.
- 2.24 All documents and other material used to inform potential research participants should be approved by the HREC including plain language information sheets, consent forms, questionnaires, advertisements and letters of invitation.

ADVOCATES AND INTERPRETERS

Advocates

- 2.25 An HREC must consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision making and understanding by these participants.

Interpreters

- 2.26 Where research involves the participation of persons unfamiliar with the English language (or the language in which the research is to be conducted), an HREC must ensure that:
 - (a) the participant information statement has been translated into the participant's language; and
 - (b) an interpreter is present during discussions with the participants about the project. Normally the interpreter should be independent, but when the research proposed is of minimal risk, an English-speaking relative or friend may be acceptable.

EXPEDITED REVIEW FOR MINIMAL RISK RESEARCH

- 2.27 An HREC may establish procedures for expedited review of research involving minimal risks to participants and in so doing may depart from the requirements of paragraphs 2.15, 2.16 and 2.17 and if so, must determine:
- (a) the class or classes of research to which an expedited review procedure is to apply;
 - (b) the scope of the Chairperson's authority;
 - (c) the delegation of tasks to sub-committees;
 - (d) the relationship between the Chairperson of the full Committee, and the Chairpersons of such sub-committees; and
 - (e) the method of reporting and ratification of decisions by the full Committee.
- 2.28 Research with potential for physical or psychological harm should generally not be considered for expedited review. This includes drug trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.
- 2.29 Where the Chairperson of an HREC considers that research may involve a departure from any of the ethical principles in this Statement, the protocol must be considered by the full Committee and cannot be dealt with by expedited review.

RECORDING OF DECISIONS

- 2.30 An HREC shall maintain a record of all research protocols received and reviewed including:
- name of responsible institution or organisation;
 - project identification number(s);
 - principal researcher(s);
 - title of project;
 - ethical approval or non-approval with date;
 - approval or non-approval of any changes to the protocol;
 - the terms and conditions, if any, of approval of any protocol;
 - whether approval was by expedited review;
 - whether the opinion of another HREC was considered;
 - action taken by the HREC to monitor the conduct of the research; and
 - the relevance, if any, of the *Guidelines for the Protection of Privacy in the Conduct of Medical Research*.⁶

⁶ Included in NMHRC, *Aspects of Privacy in Medical Research*, AGPS, Canberra, 1995 [Under review]

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- 2.31 For multi-centre research proposals the HREC shall also record, from information provided from the researcher (see paragraph 3.7):
- details of other centres involved;
 - the approval status of the study at each centre; and
 - details of any amendments required at other centres.
- 2.32 An HREC shall retain on file a copy of each research protocol and application for HREC approval, including any information sheets, consent forms or relevant correspondence, in the form in which they are approved.

MONITORING

- 2.33 An institution or organisation and its HREC have the responsibility to ensure that the conduct of all research approved by the HREC is monitored by procedures and/or by utilising existing mechanisms within the institution or organisation which will ensure the achievement of the goals for monitoring as determined by the institution or organisation and the HREC.
- 2.34 The frequency and type of monitoring determined by an HREC should reflect the degree of risk to participants in the research project.
- 2.35 As a minimum an HREC must require at regular periods, at least annually, reports from principal researchers on matters including:
- (a) progress to date or outcome in the case of completed research;
 - (b) maintenance and security of records;
 - (c) compliance with the approved protocol; and
 - (d) compliance with any conditions of approval.
- 2.36 An HREC may recommend and/or adopt any additional appropriate mechanism for monitoring including random inspections of research sites, data and signed consent forms, and/or interview, with their prior consent, of research participants.
- 2.37 An HREC shall, as a condition of approval of each protocol, require that researchers immediately report anything which might warrant review of ethical approval of the protocol, including:
- (a) serious or unexpected adverse effects on participants;
 - (b) proposed changes in the protocol; and
 - (c) unforeseen events that might affect continued ethical acceptability of the project.
- 2.38 An HREC shall, as a condition of approval of the research proposal, require researchers to inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion.

COMPLAINTS

- 2.39 An institution or organisation with an HREC shall establish mechanisms for receiving and promptly handling complaints or concerns about the conduct of an approved research project.
- 2.40 An HREC must nominate a person to whom complaints from research participants, researchers, or other interested persons may be made in the first instance. This person or the HREC shall attempt to resolve these complaints.
- 2.41 Where a complaint made under paragraph 2.40 cannot be resolved, the HREC must refer the matter to a person nominated by the institution or organisation to handle and resolve such complaints.
- 2.42 When information on the research is first provided to participants, the name or position and contact details of the person nominated by the HREC to receive complaints must be included together with the procedures for raising concerns or obtaining additional information on the research.
- 2.43 An institution or organisation shall also establish procedures for receiving and promptly handling concerns or complaints from researchers about the consideration of their research protocol by an HREC.

SUSPENSION OR DISCONTINUATION OF RESEARCH

- 2.44 Where an HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the HREC may withdraw approval, inform the researcher(s) and the institution(s) or organisation(s) of such withdrawal, and recommend to the institution(s) or organisation(s) that the research project be discontinued, suspended, or that other necessary steps be taken.
- 2.45 A researcher must not continue the research if ethical approval has been withdrawn and must comply with any special conditions required by the HREC.

COMPLIANCE REPORTS TO THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

- 2.46 The National Health and Medical Research Council (NHMRC), through the Australian Health Ethics Committee (AHEC), will audit the activities of HRECs to ensure compliance with this Statement.
- 2.47 An institution or organisation and its HREC shall provide information from its records to the NHMRC on request.
- 2.48 An institution or organisation and its HREC shall report annually to the NHMRC information relevant to its procedures including:

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- membership/membership changes;
 - number of meetings;
 - confirmation of participation by required categories of members;
 - the number of protocols presented, the number approved, and the number rejected;
 - monitoring procedures in place and any problems encountered; and
 - complaints procedures and number of complaints handled.

3. MULTI-CENTRE RESEARCH

- 3.1 Multi-centre research may include:
- (a) a research project conducted at more than one institution or organisation either by the same or different researchers, eg. a clinical drug trial;
 - (b) a research project conducted jointly by researchers affiliated with different institutions or organisations; and
 - (c) a research project being conducted by a researcher who changes affiliation from one institution or organisation to another.
- 3.2 A research proposal that involves multi-centre research will have additional implications for both review and monitoring by a Human Research Ethics Committee (HREC).

REVIEW

- 3.3 In order to minimise unnecessary duplication in review of multi-centre research, HRECs are encouraged to ascertain whether the same protocol has been reviewed by another HREC, including reviews conducted overseas.
- 3.4 With a view to prompt and efficient consideration of multi-centre research protocols an individual HREC may:
- (a) communicate with, and give advice to or receive advice from, any other HREC;
 - (b) accept a scientific/technical assessment of the research by another institution or organisation;
 - (c) review and, where the same research project is conducted at two or more institutions or organisations, adopt the reasons for ethical approval or disapproval of another HREC in reaching its own decision; or
 - (d) adopt other administrative procedures to accelerate timely consideration and avoid unnecessary duplication.
- 3.5 With a view to prompt and efficient consideration of multi-centre research protocols, the principal researchers may agree that the primary ethical and scientific assessment be made at one agreed institution or organisation, and copies of the approvals be sent with the protocols to the other institutions or organisations involved. Where there is such an agreement, the other HRECs may accept a scientific/technical assessment of the research by another institution, organisation or HREC and adopt the reasons for ethical approval or disapproval of the protocol by the primary HREC.
- 3.6 Where an HREC is satisfied that there has been full and thorough consideration of the protocol (by another HREC under 3.4 or by a primary

HREC under 3.5) the HREC may, after tabling of the protocol, accept the decision of another institution, organisation or HREC in relation to multi-centre research. The HREC may still give further consideration to ethical and administrative aspects of the research which are specific to its own institution or organisation.

3.7 The principal researcher shall:

- (a) inform each HREC of all other Australian sites at which the research is being proposed or conducted, at the time of submission of the research project;
- (b) disclose to each HREC any previous decisions regarding the research made by another HREC; and
- (c) inform each HREC of whether the protocol is presently before another HREC.

MONITORING

3.8 An HREC must determine how the conduct of multi-centre research will be monitored and what roles each of the institutions or organisations and their HRECs will have. Consultation and agreement between and among HRECs and the institutions or organisations involved will be essential to ensure that the research is monitored and that each institution or organisation fulfils its obligations under this Statement.

4. RESEARCH INVOLVING CHILDREN AND YOUNG PEOPLE

- 4.1 Research is essential to advance knowledge about children's and young peoples' well-being but research involving children and young people (see [Appendix 3](#) for definitions) should only be conducted where:
- (a) the research question posed is important to the health and well-being of children or young people;
 - (b) the participation of children or young people is indispensable because information available from research on other individuals cannot answer the question posed in relation to children or young people;
 - (c) the study method is appropriate for children or young people; and
 - (d) the circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person.
- 4.2 Consent to a child's or young person's participation in research must be obtained from:
- (a) the child or young person whenever he or she has sufficient competence to make this decision; and either
 - (b) the parents/guardian in all but exceptional circumstances; or
 - (c) any organisation or person required by law.
- 4.3 An HREC must not approve, and consent cannot be given for, research which is contrary to the child's or young person's best interests.
- 4.4 A child's or young person's refusal to participate in a research project must be respected.

5. RESEARCH INVOLVING PERSONS WITH AN INTELLECTUAL OR MENTAL IMPAIRMENT

- 5.1 When considering approval of research involving persons with an intellectual or mental impairment, an HREC should weigh the potential benefits against risks and undue burden.
- 5.2 Consent to participation in research by a person with an intellectual or mental impairment must be obtained from:
 - (a) the person with the intellectual or mental impairment whenever the person is of sufficient competence and, where the impairment is temporary or recurrent, at a time when the impairment does not prevent the person giving or refusing consent; or, failing that,
 - (b) the person's guardian, or an authority or other organisation or person having that responsibility at law.
- 5.3 A Human Research Ethics Committee (HREC) must not approve, and consent cannot be given for, research which is contrary to the best interests of the person with the intellectual or mental impairment.
- 5.4 Refusal by a person with an intellectual or mental impairment to participate in research must be respected.

6. RESEARCH INVOLVING PERSONS HIGHLY DEPENDENT ON MEDICAL CARE

The involvement in research of people who are highly dependent on medical care raises ethical issues that deserve special attention. The gravity of their medical condition may require more invasive measures carrying increased risk. For those carrying out such research, there is a need to acknowledge that the giving of free and informed consent can be compromised by the effect of the medical condition on the person's capacity to form and express an opinion or to communicate. Additionally, there may be a perception of coercion if a person is reluctant to refuse consent in fear that it may compromise his or her medical treatment. Researchers may also need to consider whether an unfair burden of participation [see paragraph 1.5] is being imposed on such groups as are referred to below.

Each type of research raises significant ethical concerns.

EMERGENCY CARE RESEARCH

- 6.1 The distinguishing feature of emergency care research is that consent for entry into a project usually has to be obtained rapidly, when the vulnerability of patients and families is likely to be greatest. Moreover, the circumstances surrounding emergency care research are such that it may not always be possible to obtain consent for inclusion from either the patient or next of kin without delaying the initiation of treatment, and so risking a reduction of potential benefits.

INTENSIVE CARE RESEARCH

- 6.2 The distinguishing features of intensive care research are the difficulty in communicating with patients receiving ventilatory assistance and the impairment of cognition in heavily sedated individuals.
- 6.3 Whenever possible, information about and consent to intensive care research should be given to and sought from potential participants before admission to that care.

NEONATAL INTENSIVE CARE RESEARCH

- 6.4 Research involving infants receiving neonatal intensive care should only be conducted in accordance with the principles in [4. Research Involving Children and Young People](#). Those principles do not permit research that is contrary to the child's best interests.
- 6.5 The very small size and vulnerability to harm of some infants is a unique feature of this research which renders all but minimal intrusion likely to be contrary to the child's best interests. The collection of even small blood samples additional to those required for diagnostic purposes or handling of a low birth weight infant to make observations will demand careful scrutiny.

TERMINAL CARE RESEARCH

- 6.6 Research in terminal care is distinguished by the short remaining life expectancy of participants and their potential vulnerability to unrealistic expectations of benefits.

Researchers must take care that the prospect of benefit from research participation is neither exaggerated nor used to justify a higher risk than that involved in the patient's current treatment.

Researchers must respect the needs and wishes of participants to spend time as they choose, particularly with family members.

RESEARCH INVOLVING PERSONS WITH IMPAIRED CAPACITY FOR COMMUNICATION

- 6.7 The distinguishing features of research involving persons with impaired capacity for communication include situations where the impairment is an acute state requiring dependence on medical care as well as non-acute states. In the former, the condition and medical care can mask their degree of cognition and require different means to express known wishes. In the latter, the condition may be such as to prevent the person expressing wishes.

RESEARCH INVOLVING UNCONSCIOUS PERSONS

- 6.8 The distinguishing feature of research with unconscious persons is that, due to their incapacity for cognition or communication, it is impossible for them to be informed about the research or to determine their wishes about it. Consent for participation in research by an unconscious person must be given by others, including relevant statutory authorities, on that person's behalf. Because of their extreme vulnerability such persons should be excluded from all but the most minimally invasive observational research.

HUMAN RESEARCH ETHICS COMMITTEE CONSIDERATION OF RESEARCH PROPOSALS INVOLVING PERSONS HIGHLY DEPENDENT ON MEDICAL CARE

- 6.9 When the nature of the research procedure is such that conformity to the principle of consent [see paragraph 1.7] is not feasible, and neither the individual nor the individual's representative can consider the proposal and give consent in advance, a Human Research Ethics Committee (HREC) may approve a research project without prior consent provided it is satisfied that:
- (a) inclusion in the research project is not contrary to the interests of the patient; and
 - (b) the research is intended to be therapeutic and the research intervention poses no more of a risk than that which is inherent in the patient's condition and alternative methods of treatment; and

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- (c) the research is based on valid scientific hypotheses which support a reasonable possibility of benefit over standard care; and
 - (d) as soon as reasonably possible, the patient and/or the patient's relatives or legal representatives will be informed of the patient's inclusion in the research and of the option to withdraw from the research without any reduction in quality of care.

6.10 In the case of research proposals in which it is practicable to approach the patient and/or the patient's relative or legal representative to obtain consent before inclusion in the research, an HREC should also be satisfied that:

- (a) adequate provision will be made for informing patients and their relatives about the research to ensure that stress or other emotional factors do not impair their understanding of it; and
- (b) the dependency of patients and their relatives on the medical personnel providing treatment does not affect any decision to participate.

7. RESEARCH INVOLVING PERSONS IN DEPENDENT OR UNEQUAL RELATIONSHIPS

- 7.1 It is not possible to define exhaustively all types of dependent relationships, but they include situations where unequal power relationships exist between participants and researchers or where participants occupy junior or subordinate positions in hierarchically structured groups. Examples include:
- persons with chronic conditions or disabilities and their carers;
 - patients and health care professionals;
 - students and teachers;
 - prisoners and prison authorities; and
 - employees (including members of the police force, defence forces and hospital and laboratory staff) and their employers or supervisors.
- 7.2 Where it is proposed to involve persons in dependent or unequal relationships in research, the possibility that their relationship may impair their consent requires additional attention from the Human Research Ethics Committee (HREC) in order for the HREC to be satisfied that their consent is both adequately informed and voluntary.
- 7.3 Where research involves persons in dependent or unequal relationships the researcher must give an assurance that refusal to participate in, or a decision to withdraw from, the research will not result in any discrimination, reduction in the level of care or any other penalty.

8. RESEARCH INVOLVING COLLECTIVITIES

Collectivities are distinct human groups with their own social structures that link members with a common identity, with common customs and with designated leaders or other persons who represent collective interests in dealing with researchers. Examples of collectivities may include cultural or ethnic groups, and indigenous communities.

The following is likely to be relevant in relation to some aspects of research involving Aboriginal and Torres Strait Islander peoples. However there are separate guidelines (referred to in [9. Research Involving Aboriginal and Torres Strait Islander Peoples](#)) which deal with these issues specifically when they involve health and medical research or when researchers have applied for funds to specific bodies such as the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS).

8.1 Collectivities are distinguished by:

- (a) recognition of common beliefs, values, social structures or other enduring features that identify them as a separate group;
- (b) customary collective decision making in accordance with tradition and beliefs;
- (c) it being customary for leaders or identified members of the collectivity to express a collective view; and
- (d) members of the collectivity being aware of their common activities and common interests with other members.

8.2 Researchers must seek Human Research Ethics Committee (HREC) approval for research involving a collectivity. Before approving such research, an HREC must be satisfied that the following matters have been addressed in the research protocol:

- (a) whether, in addition to individual consent, collectivity leaders should be consulted for approval;
- (b) whether arrangements to address issues identified in this paragraph have followed a process of negotiation;
- (c) issues of consent, privacy, confidentiality and harms within the collectivity, to either individuals or the collectivity;
- (d) the ownership of data and the manner of dissemination of research findings; and
- (e) the manner in which disagreements between the researcher and the collectivity will be resolved.

9. RESEARCH INVOLVING ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES

Researchers conducting research which involves Aboriginal and Torres Strait Islander individuals, communities or groups and Human Research Ethics Committees assessing research proposals for such research should consult the NHMRC *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (Interim, 1991)*. These guidelines will be revised by a working group which includes indigenous representatives.

Research funded by the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) is required to comply with specific AIATSIS guidelines.

10. RESEARCH INVOLVING IONISING RADIATION

Researchers conducting projects which may involve exposure to ionising radiation and Human Research Ethics Committees (HRECs) assessing research proposals of these projects must follow relevant State and Territory legislation and should consult the *NHMRC Recommendations for Limiting Exposure to Ionising Radiation (1995)*. Advice should be sought from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) regarding legislative requirements, including circumstances in which licensing, notification or approval, in addition to that of an HREC is required.

II. RESEARCH INVOLVING ASSISTED REPRODUCTIVE TECHNOLOGY

Research involving assisted reproductive technology is governed by specific legislation in Victoria, South Australia and Western Australia. In other States and Territories those undertaking such research should consult the *NHMRC Ethical Guidelines on Assisted Reproductive Technology (1996)*.

12. CLINICAL TRIALS

A clinical trial is a study involving humans to find out whether an intervention, including treatments or diagnostic procedures, which it is believed may improve a person's health, actually does so. A clinical trial can involve testing a drug, a surgical or other therapeutic or preventive procedure, or a therapeutic, preventive or diagnostic device or service. Any intervention, including so-called "natural" therapies and other forms of complementary medicine, can be tested in this way. Other related disciplines also conduct research which involves similar ethical considerations to those raised in clinical trials.

In pharmaceutical and medical device trials there are established codes of good clinical research practice which define clearly what is meant by a clinical trial for those purposes. 12. Clinical Trials has principal application in the context of biomedical clinical trials but should also apply to any other intervention claiming therapeutic benefit, wherever provided or conducted.

- 12.1 The aims of every trial must be precisely stated in a protocol presented to and approved by a Human Research Ethics Committee (HREC) and every trial must be conducted by researchers with suitable experience, qualifications and competence and, where applicable, adequate training in relevant procedures including the use of any device being trialed.
- 12.2 An HREC must consider all aspects of the design of a clinical trial and be satisfied that:
 - (a) the trial is directed to answering a specific question or questions;
 - (b) there is a scientifically valid hypothesis being tested which offers a realistic possibility that the interventions being studied will be at least as effective as standard treatment;
 - (c) where the research is therapeutic, and is therefore intended and likely to be of direct benefit to participants, there is an acceptable balance between the risks and benefits of the trial;
 - (d) the methodology provides:
 - (i) a rationale for the selection of appropriate participants;
 - (ii) an appropriate method of recruitment;
 - (iii) adequate, understandable information for the purpose of obtaining participant consent;
 - (iv) a clear description of the intervention and observation to be conducted; and
 - (v) a sample size adequate to demonstrate clinically and statistically significant effects;
 - (e) it has access to adequate expertise or advice to consider the safety of the drugs, medical devices or other intervention under investigation; and

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- (f) it is familiar with the requirements of the Therapeutic Goods Administration (TGA) in relation to unregistered drugs and devices, particularly the Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes, where relevant.
- 12.3 An HREC, before granting approval to a clinical trial, must be satisfied that the protocol conforms to:
- (a) this Statement;
 - (b) the World Medical Association *Declaration of Helsinki*;
 - (c) where relevant, the CPMP/ICH *Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95) and the ISO 14155 *Clinical Investigation of Medical Devices* and the requirements of the TGA; and
 - (d) any requirements of relevant Commonwealth or State/Territory laws.
- 12.4 The use of a placebo alone or the incorporation of a non-treatment control group is ethically unacceptable in a controlled trial where:
- (a) other available treatment has already been clearly shown to be effective; and
 - (b) there is risk of significant harm in the absence of treatment.
- If there is genuine uncertainty about the net clinical benefit of treatment, a placebo controlled trial or a trial with a no-treatment arm may be considered.
- 12.5 A researcher must inform an HREC of any business or other similar association which may exist between a researcher and the supplier of a drug or surgical or other device to be used in the trial.
- 12.6 An HREC must examine those aspects of the budgets of clinical trials which raise ethical issues, including capitation fees, payments to researchers, institutions or organisations involved in the research, current and consequential institutional or organisational costs and costs which may be incurred by participants. It should be satisfied that:
- (a) payment in money or kind would not cause researchers to apply pressure to individuals so as to obtain their consent to participate;
 - (b) payment in money or kind could not influence the findings of the research;
 - (c) there will be disclosure to the research participants of relevant aspects of those budgets; and
 - (d) funding is sufficient to conduct and complete the trial so that participants are not disadvantaged by premature cessation.
- 12.7 An HREC must be satisfied, before approving a clinical trial, that arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of participation in the trial.

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- 12.8 An institution or organisation and its HREC must require the researcher:
- (a) to conduct the trial in compliance with the approved protocol;
 - (b) to provide reports of the progress of the trial to the HREC at a frequency directed by the HREC that is related to the degree of risk to participants, but at least annually;
 - (c) to inform the HREC of, and seek its approval of, amendments to the protocol including any:
 - (i) proposed or undertaken in order to eliminate immediate hazards to participants;
 - (ii) that may increase the risks to participants; or
 - (iii) that significantly affect the conduct of the trial;
 - (d) to inform the HREC and the TGA of all serious or unexpected adverse events that occur during the trial and may affect the conduct of the trial or the safety of the participants or their willingness to continue participation in the trial;
 - (e) to inform the HREC as soon as possible of any new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial or which may indicate the need for amendments to the trial protocol;
 - (f) to inform the HREC, giving reasons, if the trial is discontinued before the expected date of completion; and
 - (g) in relation to trials with implantable medical devices, to confirm the existence of or establish a system for tracking the participant, with consent, for the lifetime of the device, and to report any device incidents to the TGA.
- 12.9 The institution or organisation and its HREC must determine the type and frequency of review appropriate to the drug or device being investigated and to the degree of risk to participants provided that the review occurs at least once a year.
- 12.10 It may be unethical for a researcher to continue a trial if:
- (a) there are or have been substantial deviations from the trial protocol;
 - (b) side effects of unexpected type, severity, or frequency are encountered; or
 - (c) as the trial progresses, one of several treatments or procedures being compared proves to be so much better, or worse, than other(s) that continuation of the trial would disadvantage some of the participants.
- 12.11 In a clinical trial, data must be accurately recorded in a durable and appropriately referenced form and:

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- (a) data management should comply with relevant privacy requirements, including the Standards Australia *Personal Privacy Protection in Health Care Information Systems* (AS4400-1995);
 - (b) if data are of a confidential nature, confidentiality must be observed;
 - (c) data and records must be preserved for such periods and in such manner as prescribed by laws of the Commonwealth, the relevant State or Territory or national policies or guidelines; and
 - (d) where materials of biological origin are being used in a trial, records should be preserved for such periods as will enable participants to be traced in the event that evidence of late or long-term effects emerge.
- 12.12 In trials of therapeutic goods, including pharmaceuticals and biological substances the HREC must follow the requirements of the TGA and the *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95).
- 12.13 In medical device trials, the HREC and the researcher must follow the requirements of the TGA (*Australian Device Requirement Version 4, DR4, May 1998*) and the *ISO 14155 Clinical Investigation of Medical Devices on Human Subjects*.

13. INNOVATIVE THERAPY OR INTERVENTION

Clinical research is defined in the *Declaration of Helsinki* as ‘medical research combined with professional care’. This can occur in a number of settings, including public and private hospitals and clinics, other institutions or organisations, community settings, and in general or specialist medical practices.

Clinical research must conform to the requirements of this Statement.

Innovations in clinical practice include the wide range of new diagnostic or therapeutic methods which are aimed at improving health outcomes beyond those of existing methods, but which have not yet been fully assessed for safety and/or efficacy. The spectrum of innovations ranges widely from minor variations of existing methods, or extension of existing methods to new indications, through to completely novel technologies. Whether a change in an individual’s investigation or treatment represents such an innovation or whether it constitutes clinical research is a matter for the responsible clinician’s judgement.

At the stage at which a specific form of innovative therapy becomes subject to systematic investigation to determine its efficacy and safety in order to decide whether its introduction should be recommended, it should be treated as clinical research requiring formal consideration by a Human Research Ethics Committee.

14. EPIDEMIOLOGICAL RESEARCH

Epidemiological research is concerned with the description of health and welfare in populations through the collection of data related to health and the frequency, distribution and determinants of disease in populations, with the goal of improving health. Some epidemiological research may require whole of population studies and be beyond an individual institution or organisation.

Epidemiological research is part of wider public health and health services research concerned with improvements of health and welfare in human populations and with improving the efficiency and performance of human health services. Public health and health services research are usually or often carried out with human participants, or data or biological samples from them, and provide important new knowledge that is not readily obtainable in other ways.

Public health surveillance should be distinguished from public health and epidemiological research. Its role is to monitor the health status of the community, known risk factors and emerging threats to community health. Its purpose is to facilitate a prompt, effective and corrective response. It may be carried out for reasons of disease surveillance, provision of information to government health services or to inform the development of health policy. Public health agencies generally are required or authorised by law to conduct health surveillance.

In epidemiological research, medically relevant information about individuals and groups is accumulated so those features of groups of persons may be investigated whether the information was or was not originally obtained for research purposes.

CATEGORIES OF PERSONAL INFORMATION

Epidemiological research includes the use of the following types of data:

Identified

Data that allow the identification of a specific individual are referred to as “identified data”. Examples of identifiers may include the individual’s name, date of birth or address. In particularly small sets of data even information such as a postcode may be an identifier.

Potentially identifiable (coded, re-identifiable)

Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relate so that the process of de-identification is reversible. In these cases the data are referred to as “potentially identifiable”.

De-identified, (not re-identifiable, anonymous)

The process of de-identification can be irreversible if the identifiers have been removed permanently or if the data have never been identified. These data are referred to as “de-identified”. It should be recognised that the term “de-identified” is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain “potentially identifiable”.

- 14.1 All epidemiological research must be approved by a Human Research Ethics Committee (HREC) and should be conducted according to written protocols that state the aims of the study, the data needed and the way in which the data will be collected, used and protected.
- 14.2 When an HREC considers a protocol for epidemiological research it must be satisfied that:
 - (a) the research complies with any relevant Commonwealth and State/Territory legislation or policies dealing with the privacy and confidentiality of data held by Government authorities;
 - (b) researchers have the necessary skills in epidemiology and facilities for the research;
 - (c) access to medical or other records for research should be restricted to properly qualified researchers and research associates responsible to them; and
 - (d) there is a scientifically acceptable process for the disclosure of information and communication of research results and, where there is to be selective disclosure of information, that there are scientifically justifiable reasons for so doing.
- 14.3 Consent of participants should generally be obtained for the use of identified or potentially identifiable data for epidemiological research.
- 14.4 An HREC may approve access to identified or potentially identifiable data without consent of those the data identifies where the HREC is satisfied that:
 - (a) either
the procedures required to obtain consent are likely either to cause unnecessary anxiety for those whose consent would be sought or to prejudice the scientific value of the research and there will be no disadvantage to the participants or their relatives or to any collectivity involved

or
it is impossible in practice, due to the quantity, age or accessibility of the records to be studied, to obtain consent;

AND
 - (b) the public interest in the research outweighs to a substantial degree the public interest in privacy.

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- 14.5 Where an HREC approves the use of potentially identifiable data that has been coded, the HREC should decide whether an independent person should hold the code.
 - 14.6 Where the research involves a collectivity, the HREC should be satisfied that the requirements of 8. Research Involving Collectivities have been fulfilled.
 - 14.7 Where identified or potentially identifiable data are used in the research, an HREC must be satisfied that the information:
 - (a) will be collected, dealt with and stored in accordance with the Information Privacy Principles of the *Privacy Act*, 1988 (Cth) (see Appendix 2) and the Standards Australia *Personal Privacy Protection in Health Care Information Systems* (AS4400-1995); and
 - (b) will not be used so as to cause material, emotional or other disadvantage to any participant; and
 - (c) will not be used for any purposes other than those specified in the approved protocol.
 - 14.8 Where research involves linkage of data sets, an HREC may approve the use of identifiers to ensure that the linkage is accurate, but once linkage has been completed the HREC should require that the resulting data be coded or de-identified.
 - 14.9 If identified or potentially identifiable data are to be used for any research purposes or by any persons other than those specified in the approved protocol, a new protocol must be presented to an HREC for approval.
 - 14.10 Information arising from both long and short term epidemiological research must be securely stored.
 - 14.11 When consolidating data for statistical analysis and the preparation of results, researchers must preserve the confidentiality of information about participants.
 - 14.12 Results of research must not be published in a form that permits identification of individual participants and must be published in a form which gives due regard to cultural or other sensitivities.
 - 14.13 If in the course of epidemiological research new knowledge of clinical relevance is obtained, or existing treatment is thought to need alteration, that knowledge should be disclosed to the appropriate health authorities and, wherever possible, participants and their usual medical attendants should be informed.

15. USE OF HUMAN TISSUE SAMPLES

Samples of tissue, including blood and other body fluids, are collected from persons in hospitals and other health care institutions in a variety of circumstances. Samples collected for diagnostic purposes in the course of treatment may also be used for teaching or quality assurance activities and for research. Directors of Pathology have traditionally exercised, and should continue to exercise, discretion in the use of clinical samples in the interpretation and development of laboratory procedures. After the original purpose for which samples were collected has been achieved, the residual tissue may be discarded. Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. Accordingly, most hospitals have collections of stored samples, the use of which in research may lead to important advances in the understanding and treatment of disease.

The principles of ethical conduct and review described in [1. Principles of Ethical Conduct](#) and [2. Human Research Ethics Committees](#) of this Statement should govern all such research.

This Statement refers to such tissue samples as are referred to above but excludes fetal tissue, reproductive tissue and tissue from autopsy to which additional guidelines or legislation may apply.⁷

Where human tissue is to be used in any research, researchers and Human Research Ethics Committees (HRECs) need to be satisfied that the research proposal conforms to the guidelines below. The additional ethical issues that arise in genetic research that uses human tissue need to be addressed in conformity with [16. Human Genetic Research](#).

RESPECT FOR PERSONS

15.1 The fundamental ethical principle to be observed in the use of human tissue samples for research is respect for the person and this is reflected in:

- (a) the provision to the donor of full information about the purposes of the sampling, and/or the plan of the research proposal;
- (b) consent by the donor to the use of the sample;
- (c) the professional removal of samples to be used;
- (d) provision for appropriate and secure storage of tissue samples;
- (e) provision and maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data; and
- (f) accountability in the care and usage of such samples.

⁷ For guidelines on fetal tissue see *Supplementary Note 5 – The human fetus and the use of human fetal tissue (1983)*.

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- 15.2 It is important for institutions or organisations in conjunction with their HRECs to determine when consent should be sought for the use of tissue in research or when a waiver of the requirement for consent may be considered.

INSTITUTIONAL RESPONSIBILITY

- 15.3 Institutions or organisations at which research involving the use of human tissue samples is conducted, should develop policies about the conduct and ethical approval of such research which conform to relevant legislation and are consistent with this Statement. Those policies need to provide guidance to researchers and HRECs in relation to soliciting or accepting voluntary donations of, and specifying conditions for, the use of human tissue samples in research. In their development, relevant considerations include:
- (a) the source, nature and cultural or religious sensitivity of the sample;
 - (b) the original reason for its collection; and
 - (c) the purpose of the research.

WHERE CONSENT WOULD BE REQUIRED

- 15.4 Where human tissue samples are collected for purposes including research, consent for their use in research is generally required.
- 15.5 Consent should:
- (a) be voluntary; and
 - (b) be specific to the purpose for which the tissue is to be used; and
 - (c) follow the provision of full information about the project, including advice as to whether, after completion of the research for which consent is given, tissue samples are to be stored.
- 15.6 Where it is proposed that human tissue samples previously collected and stored with consent for research be used for a research purpose different from that of the previously approved research, consent for the use of the tissue samples in the new research should generally be obtained. An HREC may waive the requirement for consent in conformity with paragraph 15.8.
- 15.7 Where it is proposed to use tissue samples which have been:
- obtained for or held in storage following, or in association with, clinical investigations;
 - held in archives or banks; or

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- removed in the course of a clinical procedure and not required for any clinical purpose,
in research that may be lead to harm, benefit or injustice to a donor of such tissue, consent of those donors should normally be obtained.

WHERE THE REQUIREMENT FOR CONSENT COULD BE WAIVED

- 15.8 An HREC may sometimes waive, with or without conditions, the requirement for consent. In determining whether consent may be waived or waived subject to conditions, an HREC may take into account:
- the nature of any existing consent relating to the collection and storage of the sample;
 - the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
 - the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
 - the extent to which the proposed research poses a risk to the privacy or well being of the individual;
 - whether the research proposal is an extension of, or closely related to, a previously approved research project;
 - the possibility of commercial exploitation of derivatives of the sample; and
 - relevant statutory provisions.

CONFIDENTIALITY

- 15.9 Wherever human tissue samples or related information are gathered in the course of a professional relationship, professional confidentiality must be observed. Identification of samples must be limited to the minimum necessary to achieve the stated objectives of the study. If the study may produce information relevant to the health and well being of the person from which it was derived, the HREC may require procedures to allow participants to be identified to facilitate appropriate follow-up.

16. HUMAN GENETIC RESEARCH

Genetic research enhances our understanding of how genes and environmental factors interact to influence the health of individuals and populations and in doing so, generates knowledge with the potential to improve individual and community health.

Genetic research can reveal information about an individual's susceptibility to disease and hence about the individual's future health. Such information may be of interest and benefit to research participants, especially if preventive strategies exist.

In addition to ethical considerations which apply to all research involving humans there are ethical issues unique to genetic research. These arise from the nature of genes and genetic information which, though personal, are also shared with other family members and with unrelated individuals in the population.

Participation of families rather than individuals is required for many genetic research studies. Research results and genetic material and information collected for research may be of significance to the health of blood relatives, including some who have not participated in the research. These family members may have an interest in their relative's genetic material or in information which the research generates, because testing that material or acquiring that information may create new options for life decisions, including those with potential to improve health. However, some family members may prefer not to be given information which may provide knowledge of future health or health risks. In addition, other family members who are not blood relatives, such as partners and spouses, may have an interest because of concerns about the health of offspring.

There is potential for harm to participants arising from the use of genetic information, including stigmatisation or unfair discrimination, and researchers should recognise that special care must be taken to protect the privacy and confidentiality of this information. The results of genetic tests, particularly those which provide information about future health, could potentially be used by third parties such as insurance companies and employers to assist with decisions concerning research participants and their families. By participating in genetic research people should not be put at risk of being deprived of benefits that are available to other members of the community.

SOCIAL SIGNIFICANCE AND CONSEQUENCES OF GENETIC RESEARCH

- 16.1 Researchers should consider the social and cultural significance of their research, particularly in the areas of complex socially significant characteristics and the genetic characteristics of collectivities. When such characteristics are the subject of research, Human Research Ethics Committees (HRECs) should satisfy themselves that no contestable or dubious ethical values are assumed by the research protocol.
- 16.2 When assessing proposals of this type, HRECs should consider the balance between the contribution to knowledge and the potential for harm to individuals or collectivities.

PRIVACY AND CONFIDENTIALITY

- 16.3 Researchers must ensure the confidentiality and privacy of stored genetic information or research results relating to identified or potentially identifiable participants.
- 16.4 Researchers must keep information provided by participants about family members confidential. Such confidential information must not be revealed either to family members or persons who are not family members.
- 16.5 The research protocol must specify whether genetic information or genetic material, and any information derived from studying the genetic material, will be stored in identified, potentially identifiable (coded) or de-identified (not identifiable, anonymous) form. (See the introduction to [14. Epidemiological Research](#)). Researchers should be aware that the rarity of some genetic disorders might allow certain families to be identified by other researchers, and in some cases by members of the community, even if information is communicated to others in de-identified form.
- 16.6 Researchers should consider carefully the consequences of storing information and material in de-identified form for the proposed research, for future research and for communication of research results to participants.
- 16.7 Identifying genetic information must not be released to others, including family members, without the written consent of the individual to whom the information relates, or a person or institution which may legally provide consent for that person.
- 16.8 A researcher must not transfer genetic material and related information to another research group unless:
 - the researcher and the other research group are collaborating on research which has been approved by an HREC; and
 - the genetic material and information is provided in a form which ensures that participants cannot be identified. However, an HREC may approve transfer of genetic material and information which is identified, or potentially identifiable, in certain circumstances (eg. see paragraph 14.8). If this occurs, the other research group must undertake to hold the material and related information in such a manner that there is no reduction in the protection of the privacy of the participants or of the confidentiality of the information.

CONSENT

- 16.9 Consent from participants (and/or other appropriate person or organisation as specified in guidelines 4, 5, 6, 7 and 8 of this Statement) must be obtained for human genetic research unless an HREC waives the requirement for consent (paragraph 16.13).

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- 16.10 When consent is being sought from individuals for prospective collection of genetic material and information they should be informed:
- (a) that they are free to refuse consent without giving reasons. Researchers should be aware that for some genetic research, an individual's participation may be requested by, and may primarily serve the interests of, other family members and the individual may agree to participate out of a sense of obligation;
 - (b) about arrangements to ensure the privacy and confidentiality of their genetic information both with regard to other family members and persons who are not family members. Participants should be informed whether their genetic material and information will be used in an identified, potentially identifiable, or de-identified form and, if their material or information is to be de-identified, that it will not be possible to provide them with personal research results;
 - (c) if the research may reveal information of potential importance to the future health of an identified or potentially identifiable participant or the participant's offspring;
 - (d) that the researchers will endeavour to provide information about the outcome of the research. Participants should be advised when it is not intended to provide feedback. If relevant, participants should be asked whether they wish to be notified of research results which relate to them as individuals. A decision not to be notified should be respected;
 - (e) that if the research generates information about participants which may be of relevance to the health of other family members, the consent of participants will be sought before offering to disclose such information to the family members concerned;
 - (f) if information about family members, in addition to that provided by participants, is required for the research;
 - (g) if it is proposed to approach relatives, consent to do so will first be obtained from the participant. In coming to a decision to recruit relatives, researchers must consider the privacy and any known sensitivities of the relatives, accepted habits of communication within the family, and the balance of potential benefits and harms which might result from participation in the research;
 - (h) if the research has the potential to detect non-paternity or non-maternity;
 - (i) that genetic material and information may have uses unrelated to HREC approved research. Participants should be advised that their material and information will not be released for other uses without consent, unless required by law;

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- (j) about any intention to store their genetic material and information because it could potentially be useful for as yet unspecified future research conducted in accordance with paragraphs 16.12 and 16.16 below. If consent is given, the duration of storage should be specified. If consent for future research use is refused, the genetic material and information should be disposed of at the end of the research, once the sample storage and record keeping requirements of good research practice have been met;
 - (k) if their genetic material is to be disposed of on completion of the research or after a further period of storage. Some participants or collectivities will have sensitivities regarding disposal of their genetic material. These should be established and recorded at the start of the research and account taken of them at the time of disposal; and
 - (l) that they are free to withdraw from the research at any time. This may involve a request that their genetic material and information be disposed of, provided the samples can be identified. Alternatively samples and information may be retained provided they are de-identified, depending on the wishes of the participants.

16.11 When researchers propose to collect genetic material and information from individuals chosen by virtue of their membership of a particular collectivity, consent should be sought from appropriate collectivity representatives as well as from the individuals concerned, in accordance with 8. Research Involving Collectivities.

WHERE THE REQUIREMENT FOR CONSENT COULD BE WAIVED

- 16.12 As a general principle, where a researcher proposes to conduct research using stored genetic material or genetic information, the consent of the person from whom the material was derived, or to whom the information relates, is required.
- 16.13 An HREC may sometimes waive, with or without conditions, the requirement for consent. In determining whether consent may be waived or waived subject to conditions, an HREC may take into account:
- the nature of any existing consent relating to the collection and storage of the genetic material and genetic information;
 - the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
 - the proposed arrangements to protect privacy, including the extent to which it is possible to de-identify the genetic material and genetic information;

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- the extent to which the proposed research poses a risk to the privacy and well being of the individual;
 - whether the research proposal is an extension of, or closely related to, a previously approved research project;
 - the possibility of commercial exploitation of derivatives of the sample; and
 - relevant statutory provisions.
- 16.14 Institutions or organisations wishing to conduct research on genetic material and information collected for non-research purposes, should develop and disseminate a general policy which informs patients that such material and information may be used for future research following HREC approval, subject to the issues raised in paragraphs 16.12 and 16.13. Patients of such institutions or organisations should be informed that this policy exists, and that their privacy and confidentiality will be protected. They should be given the opportunity to refuse consent to use of their material and information for such research.

GENETIC COUNSELLING

- 16.15 When research may reveal information of potential importance to the future health of an identified or potentially identifiable participant's future health or the participant's offspring, the research protocol must provide for consent procedures, counselling, support, test quality and test result confidentiality as would apply if the participant sought such information in a clinical setting. Otherwise such research may only be performed if the genetic material has been de-identified. Counselling and provision of information arising from the research must be provided by health professionals with appropriate training, skills and experience.
- 16.16 If asked to consent to the use of their genetic material and information for future research, participants should be provided with information and counselling about the possible consequences of doing so. In general, their genetic material and information will be used for future research in de-identified form and feedback will not be possible. However, the HREC may direct the researchers to use the genetic material and information in potentially identifiable (coded) form. In such instances, the views of participants regarding the feedback of information of potential significance to their own or their relatives' future health should be established, recorded and respected. If feedback is requested, the participant should receive information and counselling about the implications of receiving that information; this can be provided at the time of obtaining consent or, in the future, prior to the provision of the feedback.

17. RESEARCH INVOLVING DECEPTION OF PARTICIPANTS, CONCEALMENT OR COVERT OBSERVATION

- 17.1 As a general principle, deception of, concealment of the purposes of a study from, or covert observation of, identifiable participants are not considered ethical because they are contrary to the principle of respect for persons in that free and fully informed consent cannot be given.
- 17.2 In some fields of research, for example the study of human behaviour, there may be exceptional circumstances where studies cannot be conducted without deception, concealment or covert observation of participants. Before approving a research proposal which involves any degree of deception, concealment or covert observation, a Human Research Ethics Committee must be satisfied that:
- (a) the provision of detailed information to prospective participants about the purpose, methods and procedures of the research would compromise the scientific validity of the outcome of that research;
 - (b) the precise extent of deception, concealment or covert observation is defined;
 - (c) there are no suitable alternative methods, not involving deception, concealment or covert observation, by which the desired information can be obtained;
 - (d) participants are not exposed to an increased risk of harm as a result of the deception, concealment or covert observation;
 - (e) adequate and prompt disclosure is made and de-briefing provided to each participant as soon as practicable after the participant's participation is completed;
 - (f) participants will be able to withdraw data obtained from them during the research without their knowledge or consent; and
 - (g) such activities will not corrupt the relationship between researchers and research in general with the community at large.

18. PRIVACY OF INFORMATION

Privacy is a complex concept that stems from a core idea that individuals have a sphere of life from which they should be able to exclude any intrusion. Privacy can refer to the reasons on which individuals rely in reaching decisions about participation in research or in health care, the protection from interventions in the lives of persons who cannot make decisions or the freedom of individuals from observation or surveillance.

A major application of the concept of privacy is information privacy: the interest of a person in controlling access to and use of any information personal to that person. It is this application of privacy that is considered below.

CONFIDENTIALITY AND PRIVACY

Confidentiality refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another. The recipient has an obligation not to use that information for any purpose other than that for which it was given. Traditional examples of relationships in which that obligation arises are those between doctors and patients and priests and penitents. However, the obligation can be created by contract.

Privacy is a broader concept. A person's interest in keeping personal information private relates to anyone who might have access to that information, whether through a relationship or otherwise.

LEGAL REGULATION

At the Commonwealth level, the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the *Privacy Act 1988*. There is regulation at State and Territory level in the form of legislation related to privacy generally or the administration of agencies, or administrative codes of practice. Others have included more limited controls as part of the administrative structure of health departments and agencies.

INFORMATION PRIVACY PRINCIPLES

The *Privacy Act 1988* requires Commonwealth agencies to conform to the Information Privacy Principles (IPPs) in dealing with personal information. These principles, adapted from international standards, form a code of conduct that balances the public need for information with the interests of individuals in their privacy. The IPPs are included in [Appendix 2](#) to this Statement.

INFORMATION PRIVACY PRINCIPLES AND MEDICAL RESEARCH

The use of personal information for research is not exempt from the IPPs. However, a balance between the public interest in medical research and in the protection of privacy is reflected in section 95 of the *Privacy Act*. This provides that a Commonwealth agency may, in relation to medical research, deal with

personal information in ways that may infringe the IPPs if that research conforms with guidelines devised by the National Health and Medical Research Council (NHMRC) and approved by the Privacy Commissioner.⁸

- 18.1 An HREC must be satisfied that a research proposal conforms to all relevant Commonwealth, State or Territory privacy legislation or codes of practice.
- 18.2 An HREC must be satisfied that, where a research proposal involves the collection, storage, disclosure or other use of personal information, the privacy of persons to whom that information relates is protected. In most situations, conformity to the IPPs provides an acceptable standard of protection.
- 18.3 Where a proposal for medical research may involve a breach of the Information Privacy Principles, the HREC must follow the guidelines contained in *Aspects of Privacy in Medical Research* (1995) [Under review].
- 18.4 Generally the consent of participants in research should be obtained for the use of their personal information where:
 - (a) the information is to be held on registers for use by researchers in future research projects; or
 - (b) the information is to be disclosed to other persons for use in future research projects.
- 18.5 In research based on linkages between records, an HREC may permit personal information to be used to enable the record linkage without consent if it is satisfied that:
 - (a) the identity of participants is not disclosed except for the purposes of record linkage and is not retained once record linkage has been completed;
 - (b) identifying information is used with sufficient security; and
 - (c) the research has public benefit.

⁸ Included in NHMRC, *Aspects of Privacy in Medical Research*, AGPS, Canberra, 1995 [Under review].

19. INTELLECTUAL PROPERTY

Some research involving humans may be intended for, or later directed towards, purposes of commercial exploitation. As a general principle disclosure of interests by researchers should be made to the Human Research Ethics Committee (see paragraph 2.21) and the consent of participants obtained (paragraphs 1.2 and 1.7).

The *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997) and the Australian Vice-Chancellors' Committee (AVCC) discussion paper, *Ownership of Intellectual Property in Higher Educational Institutions* (1995), provide useful points of reference for addressing issues of intellectual property, disclosure or commercial-in-confidence undertakings.

APPENDIX I

RELEVANT PUBLICATIONS

International Declarations and Conventions

- UNESCO, *Declaration on Race and Racial Prejudice* (1978)
- UNESCO, *Universal Declaration on the Human Genome and Human Rights* (1997)
- United Nations, *Universal Declaration of Human Rights* (1948)
- United Nations, *International Convention on the Elimination of All Forms of Racial Discrimination* (1965)
- United Nations, *International Covenant on Economic, Social and Cultural Rights and Civil and Political Rights* (1966)
- United Nations, *Declaration on the Rights of Mentally Retarded Persons* (1971)
- United Nations, *Declaration on the Rights of Disabled Persons* (1975)
- United Nations, *Convention on the Elimination of All Forms of Discrimination Against Women* (1979)
- United Nations, *Convention on the Rights of the Child* (1989)
- World Medical Association, *Declaration of Helsinki* (1996)

International Guidelines and Codes

- Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, CIOMS, Geneva, 1993.
- CIOMS, *International Guidelines for Ethical Review of Epidemiological Studies*, CIOMS, Geneva, 1991.
- CPMP/ICH *Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95)
- International Standard ISO-14155 *Clinical Investigation of Medical devices on Human Subjects*.
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APPENDIX 2

INFORMATION PRIVACY PRINCIPLES

[from the *Privacy Act, 1988* (Commonwealth)]

Principle 1

Manner and purpose of collection of personal information

1. Personal information shall not be collected by a collector for inclusion in a record or in a generally available publication unless:
 - (a) the information is collected for a purpose that is a lawful purpose directly related to a function or activity of the collector; and
 - (b) the collection of the information is necessary for or directly related to that purpose.
2. Personal information shall not be collected by a collector by unlawful or unfair means.

Principle 2

Solicitation of personal information from individual concerned

Where:

- (a) a collector collects personal information for inclusion in a record or in a generally available publication; and
 - (b) the information is solicited by the collector from the individual concerned;
- the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, before the information is collected or, if that is not practicable, as soon as practicable after the information is collected, the individual concerned is generally aware of:
- (c) the purpose for which the information is being collected;
 - (d) if the collection of the information is authorised or required by or under law - the fact that the collection of the information is so authorised or required; and
 - (e) any person to whom, or any body or agency to which, it is the collector's usual practice to disclose personal information of the kind so collected, and (if known by the collector) any person to whom, or any body or agency to which, it is the usual practice of that first-mentioned person, body or agency to pass on that information.

Principle 3

Solicitation of personal information generally

Where:

- (a) a collector collects personal information for inclusion in a record or in a generally available publication; and
- (b) the information is solicited by the collector;

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is collected;

- (c) the information collected is relevant to that purpose and is up to date and complete; and
- (d) the collection of the information does not intrude to an unreasonable extent upon the personal affairs of the individual concerned.

Principle 4

Storage and security of personal information

A record-keeper who has possession or control of a record that contains personal information shall ensure:

- (a) that the record is protected, by such security safeguards as it is reasonable in the circumstances to take, against loss, against unauthorised access, use, modification or disclosure, and against other misuse; and
- (b) that if it is necessary for the record to be given to a person in connection with the provision of a service to the record-keeper, everything reasonably within the power of the record-keeper is done to prevent unauthorised use or disclosure of information contained in the record.

Principle 5

Information relating to records kept by record-keeper

1. A record-keeper who has possession or control of records that contain personal information shall, subject to clause 2 of this Principle, take such steps as are, in the circumstances, reasonable to enable any person to ascertain:
 - (a) whether the record-keeper has possession or control of any records that contain personal information; and
 - (b) if the record-keeper has possession or control of a record that contains such information:
 - (i) the nature of that information;
 - (ii) the main purposes for which that information is used; and
 - (iii) the steps that the person should take if the person wishes to obtain access to the record.

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2. A record-keeper is not required under clause 1 of this Principle to give a person information if the record-keeper is required or authorised to refuse to give that information to the person under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.
 3. A record-keeper shall maintain a record setting out:
 - (a) the nature of the records of personal information kept by or on behalf of the record-keeper;
 - (b) the purpose for which each type of record is kept;
 - (c) the classes of individuals about whom records are kept;
 - (d) the period for which each type of record is kept;
 - (e) the persons who are entitled to have access to personal information contained in the records and the conditions under which they are entitled to have that access; and
 - (f) the steps that should be taken by persons wishing to obtain access to that information.
 4. A record-keeper shall:
 - (a) make the record maintained under clause 3 of this Principle available for inspection by members of the public; and
 - (b) give the Commissioner, in the month of June in each year, a copy of the record so maintained.

Principle 6

Access to records containing personal information

Where a record-keeper has possession or control of a record that contains personal information, the individual concerned shall be entitled to have access to that record, except to the extent that the record-keeper is required or authorised to refuse to provide the individual with access to that record under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

Principle 7

Alteration of records containing personal information

1. A record-keeper who has possession or control of a record that contains personal information shall take such steps (if any), by way of making appropriate corrections, deletions and additions as are, in the circumstances, reasonable to ensure that the record:
 - (a) is accurate; and

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- (b) is, having regard to the purpose for which the information was collected or is to be used and to any purpose that is directly related to that purpose, relevant, up to date, complete and not misleading.
 2. The obligation imposed on a record-keeper by clause 1 is subject to any applicable limitation in a law of the Commonwealth that provides a right to require the correction or amendment of documents.
 3. Where:
 - (a) the record-keeper of a record containing personal information is not willing to amend that record, by making a correction, deletion or addition, in accordance with a request by the individual concerned; and
 - (b) no decision or recommendation to the effect that the record should be amended wholly or partly in accordance with that request has been made under the applicable provisions of a law of the Commonwealth;the record-keeper shall, if so requested by the individual concerned, take such steps (if any) as are reasonable in the circumstances to attach to the record any statement provided by that individual of the correction, deletion or addition sought.

Principle 8

Record-keeper to check accuracy etc. of personal information before use

A record-keeper who has possession or control of a record that contains personal information shall not use that information without taking such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is proposed to be used, the information is accurate, up to date and complete.

Principle 9

Personal information to be used only for relevant purposes

A record-keeper who has possession or control of a record that contains personal information shall not use the information except for a purpose to which the information is relevant.

Principle 10

Limits on use of personal information

1. A record-keeper who has possession or control of a record that contains personal information that was obtained for a particular purpose shall not use the information for any other purpose unless:
 - (a) the individual concerned has consented to use of the information for that other purpose;

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- (b) the record-keeper believes on reasonable grounds that use of the information for that other purpose is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or another person;
 - (c) use of the information for that other purpose is required or authorised by or under law;
 - (d) use of the information for that other purpose is reasonably necessary for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue; or
 - (e) the purpose for which the information is used is directly related to the purpose for which the information was obtained.
2. Where personal information is used for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue, the record-keeper shall include in the record containing that information a note of that use.

Principle 11

Limits on disclosure of personal information

1. A record-keeper who has possession or control of a record that contains personal information shall not disclose the information to a person, body or agency (other than the individual concerned) unless:
 - (a) the individual concerned is reasonably likely to have been aware or made aware under Principle 2, that information of that kind is usually passed to that person, body or agency;
 - (b) the individual concerned has consented to the disclosure;
 - (c) the record-keeper believes on reasonable grounds that the disclosure is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or of another person;
 - (d) the disclosure is required or authorised by or under law; or
 - (e) the disclosure is reasonably necessary for the enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue.
2. Where personal information is disclosed for the purposes of enforcement of the criminal law or of a law imposing a pecuniary penalty or for the purpose of the protection of the public revenue, the record-keeper shall include in the record containing that information a note of the disclosure.
3. A person, body or agency to whom personal information is disclosed under clause 1 of this Principle shall not use or disclose the information for a purpose other than the purpose for which the information was given to the person, body or agency.

APPENDIX 3

GLOSSARY OF DEFINITIONS

The definitions provided within this Glossary apply as they are used in the Statement. These are based on the definitions used in the Canadian *Code of Ethical Conduct for Research Involving Humans* (1996).

anonymous samples or data

See De-identified samples or data

benefit

That which positively affects the interests or welfare of an individual or group.

child

Subject to law in the relevant jurisdiction, a minor who lacks the maturity to make a decision whether or not to participate in research.

See also

Young Person

clinical trial

Preplanned, usually controlled, clinical study of the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices or interventions in humans selected according to predetermined criteria of eligibility and observed for predefined evidence of favourable and unfavourable effects.

collectivities

Distinct human groups with their own social structures that link members with a common identity, with common customs and with designated leaders or other persons who represent collective interests in dealing with researchers. Collectivities may include cultural or ethnic groups, and indigenous communities.

competence

The ability of a person or a group to make choices in accord with their own fundamental values.

confidentiality

The obligation of persons to whom private information has been given is not to use the information for any purpose other than that for which it was given.

consent

The voluntary agreement of a person or group, based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of the informed choice process, the other possible result is refusal.

deception

This occurs when research participants have essential information withheld and/or are intentionally misled about procedures and purposes, including studies where participants are deliberately given misleading information about the purpose of a research study.

de-identified (*not re-identifiable, anonymous*) samples or data

The process of de-identification can be irreversible if the identifiers have been removed permanently or the data have never been identified. These data are referred to as “de-identified”. It should be recognised that the term “de-identified” is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain “potentially identifiable.”

See also

Identified samples or data

Potentially identifiable samples or data

ethics

The study of morals and values; that is, the study of right and wrong, justice and injustice, virtue and vice, good and bad, and related concepts and principles.

ethical / unethical

Right or morally acceptable/wrong or morally unacceptable.

families

Individuals forming part of the social construct of the family; families may or may not include biological relatives.

genetic material

Any source of DNA or RNA which can be tested to obtain genetic information. It thus includes cells, whether as single cells or as part of tissues, and extracted DNA and RNA.

harm

That which adversely affects the interests or welfare of an individual or a group;

The amount of harm, conservatively estimated which is, from the research participant’s perspective, an ethically acceptable addition to harm that they would experience were they not part of the research study;

Harm extends to physical harm, discomfort, anxiety, pain, psychological disturbance and includes social disadvantage (eg. ostracism).

human tissue

Includes the substance, structure, and texture of which the human body or any part or organ of it is composed that is removed or separated from living human beings; includes blood, blood components and waste products.

identified samples or data

Data that allow the identification of a specific individual are referred to as “identified data”. Examples of identifiers may include the individual’s name, date of birth or address. In particularly small sets of data even information such as a postcode may be an identifier.

See also

De-identified samples or data

Potentially identifiable samples or data

justice

That which concerns fairness or equity, often divided into three parts: procedural justice, concerned with fair methods of making decisions and settling disputes; distributive justice, concerned with the fair distribution of the benefits and burdens of society; and corrective justice, concerned with correcting wrongs and harms through compensation or retribution.

minimal risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.

monitoring

The review by an HREC of on-going research. Such monitoring can take a variety of forms including review of annual reports, formal review of the informed consent process, establishment of a safety monitoring committee, a periodic review by a third party of the documents generated by the study, a review of the impact of the research on a collectivity, a review of reports of adverse events, or a random audit of the particular processes.

multi-centre research

The conduct of a research project in or by researchers in several autonomous institutions or organisations. This includes multi-centre clinical trials.

non-therapeutic

Interventions not directed towards the benefit of the individual but rather towards improving scientific knowledge or technical application.

personal information

Information by which individuals or collectivities can be identified. This is defined in the *Privacy Act 1988* (Cth) as information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

placebo

A product or substance which excludes the active agent under study to differentiate the effect of the other product influences from the effect of the active agent.

potentially identifiable (coded, re-identifiable) samples or data

Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relate, that is the process of de-identification is reversible. In these cases the data are referred to as "potentially identifiable".

See also

Identified samples or data

De-identified samples or data

privacy

Control over the extent, timing, and circumstances of sharing oneself (physically, behaviourally, or intellectually) with others. Privacy implies a zone of exclusivity where individuals and collectivities are free from the scrutiny of others.

protocol

A document which provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

qualitative research

Any kind of research that produces findings not arrived at by means of statistical procedures or other means of quantification.

research

This involves systematic investigation to establish facts, principles, and knowledge.

research participant

Living individual (or groups of living individuals) about whom a researcher conducting research obtains data through intervention or interaction with the person or identifiable private information.

respect for persons

This has two fundamental aspects: 1) respect for the autonomy of those individuals who are capable of making informed choices and respect for their capacity for self-determination; and 2) protection of persons with impaired or diminished autonomy, that is, those individuals who are incompetent or whose voluntariness is compromised.

risk

The function of the magnitude of a harm and the probability of its occurrence.

See also

Minimal risk

serious adverse effect (event or reaction)

Any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;
- requires in-patient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity; or
- is a congenital anomaly/birth defect.

sponsor

An individual, company or institution or organisation that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Statement

National Statement on Ethical Conduct in Research Involving Humans.

therapeutic

Interventions directed towards the well-being of the individual involved.

unexpected adverse effect (event or reaction)

An adverse reaction, the nature or severity of which is not consistent with the applicable product information.

voluntary

Free of coercion, duress or undue inducement.

young person

Subject to the law in the relevant jurisdiction, a minor who may have the maturity to make a decision whether or not to participate in research.

See also

Child

