DRAFT OF THE

NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH

Second consultation

Developed jointly by

National Health and Medical Research Council
Australian Research Council
Australian Vice-Chancellors' Committee

January 2006

An invitation to make a submission

The National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC) are jointly undertaking a revision of the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* 1999 (the *National Statement*). The second stage of public consultation on the revision of the *National Statement* is now underway and you are invited, under paragraph 13 (1) (b) of the *National Health and Medical Research Council Act 1992*, to make a submission about the draft.

The closing date for submissions is Friday 31 March 2006

The substantial changes incorporated into the revised second consultation draft National Statement are described in a separate letter from the Chair of the National Statement Working Party, Dr Chris Cordner.

How to make your submission

Electronic submissions are strongly preferred. If this is not possible please make your submission in writing (preferably typed or word processed) or on audio tape, and submit it by e-mail or mail.

You must complete and provide the following form: *National Statement on Ethical Conduct in Research Involving Humans 2nd Consultation Draft Submission Form'*. This form seeks information on authorship of the submission and other details. Please complete the form and attach to your submission. The form can be accessed electronically from our website at: http://www.nhmrc.gov.au/consult/index.htm. **Submissions that do not have this form attached will not be accepted.**

IMPORTANT POINTS

- **Your comments and suggestions about the draft should be as specific as possible. If you support your point with evidence it should be referenced and/or copies provided with your submission.**
- **The NHMRC, ARC and AVCC also request that, wherever possible, you relate your comments to Section and Chapter titles and to the paragraph numbers that are used in the draft. Using these titles and numbers will greatly help us in our review of the submissions.**
- **A template for comments has been prepared for your guidance and use and can be accessed electronically from our website at: http://www.nhmrc.gov.au/consult/index.htm.**

Please email or post your submission to:

Review of National Statement
NHMRC (MDP 24)
GPO Box 9848
CANBERRA ACT 2601

Ph: (02) 6289 9575
Fax: (02) 6289 9580
E-mail: ahec.nhmrc@nhmrc.gov.au

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PREAMBLE

This Statement sets national standards for the ethical design, review and conduct of human research. It identifies responsibilities of institutions[1], researchers, Human Research Ethics Committees (HRECs) and others conducting ethical review of research. The Statement reflects the outcome of wide consultation with Australian communities who participate in, design, conduct, fund and manage human research.

The responsibilities set out in the Statement are intended to be consistent with the international human rights instruments that Australia has ratified.

Conducting human research is important for Australia and its people. Their willing participation and their justified trust in research are indispensable, and are promoted and maintained only when research meets ethical standards. This Statement will help research to meet such standards.

Historical context

Since earliest times, human societies have reflected on the nature of good behaviour and have sought answers to ethical questions in the writings of philosophers, in the teaching of religions and in everyday individual reflection. The idea that ethical conduct in research might be a distinct sub-field within ethics arose most sharply after the Second World War in the discussion of the role of the so-called 'Nazi doctors' in unethical human experimentation in detention and concentration camps. The judgement recording their conviction included ten principles since referred to as the Nuremberg Code. Discussion of these principles led to the World Medical Assembly in 1964 adopting what came to be known as the Helsinki Declaration. This Declaration, amended most recently in 2004, sets out a number of principles and procedures intended to provide guidance to physicians and others involved in medical research.

Against this background, this Statement contributes to a global effort to develop ethical guidelines for all research. In extending its scope beyond medical research, the Statement has sought to avoid treating medical research as a paradigm for all research. The Statement acknowledges the independent development of ethical codes in other disciplines, especially in the social sciences and humanities. It reflects not only the great diversity of research techniques employed within institutions but also the fact that many of these techniques have closer analogies in everyday life than in medical research practice.

Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. In such circumstances, it is

[1] In this Statement, 'institutions' refers to any institution, organisation or body by which, or in which, human research is carried out.

important that researchers bring a heightened ethical awareness to their decision-making. The Statement is intended to contribute to the development of such awareness. Various codes of conduct developed by research professionals in different fields also have an important role to play in this process.

Research governance

The Statement should be seen in the broader context of overall governance of research. While the Statement provides guidelines for researchers, HRECs and others conducting ethical review of research, it also emphasises the responsibilities of institutions for the quality, safety and ethical acceptability of the research they sponsor or permit to be carried out under their auspices.

Responsibility for the ethical design, review and conduct of human research is in fact exercised at many levels by: researchers (and where relevant their supervisors); HRECs and others conducting ethical review of research; institutions which set up the processes of ethical review, and whose employees, resources and facilities are involved in research; funding organizations; agencies that set standards; and governments. It should be emphasised that while the processes of ethical review are important in this structure, individual researchers and the institutions within which they work have primary responsibility for seeing that the research they conduct and facilitate is ethically acceptable.

In addition to this Statement, the *Australian code for the responsible conduct of research*[2] has an essential role in promoting good research governance. That Code sets down the broad principles of responsible and accountable research practice, and identifies the responsibilities of institutions and researchers in areas such as data and record management, publication of findings, authorship, conflict of interest, supervision of students and research trainees, and the handling of allegations of research misconduct.

Authors of this Statement

This Statement has been jointly developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC).

While the previous (1999) version of this document was endorsed by the Australian Vice Chancellors' Committee, the Australian Research Council, the Australian Academy of the Humanities, the Australian Academy of Sciences and the Academy of Social Sciences in Australia, and was supported by the Academy of Technological Sciences and Engineering, it was issued by the NHMRC. The need for ethical

[2] This is the proposed revision of the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997).

guidelines that are genuinely applicable to all human research is now reflected in the agreement between the NHMRC, the ARC and the AVCC to develop this Statement as an agreed set of guidelines.

The *National Health and Medical Research Council Act* 1992 (NHMRC Act) establishes the NHMRC as a statutory body and sets out its functions, powers and obligations. Section 8(1) of the Act requires the NHMRC to issue guidelines for the conduct of medical research involving humans, and those guidelines are to be issued precisely as developed by the Australian Health Ethics Committee (AHEC). AHEC is established by the NHMRC Act as a Principal Committee of the NHMRC. All the guidelines in this Statement that are applicable to the conduct of medical research involving humans are issued by the NHMRC in fulfilment of this statutory obligation.

The *Australian Research Council Act* 2001 (ARC Act) establishes the ARC to provide the responsible Minister with advice and recommendations about research, including which research programs should receive financial assistance. The functions of the ARC also include administering the regimes of financial assistance for research and providing for the funding of research programs.

The AVCC is the council of Australia's University Vice Chancellors (or Presidents). Its purpose is to advance higher education through voluntary, cooperative and coordinated action, and to serve the best interests of Australia's universities and, through them, the nation. The AVCC acts as a consultative and advisory body for all university affairs, making submissions to public inquiries of interest to the university sector, and preparing statements on major issues.

INTRODUCTION

Purpose

The purpose of this Statement is to promote ethical conduct in all aspects of human research. Fulfilling this purpose involves according participants the respect and protection that is due to them. It also involves the facilitation of research that is of benefit to the community.

In order to achieve its purpose, the Statement is designed to clarify the responsibilities of institutions, researchers, Human Research Ethics Committees (HRECs) and others conducting ethical review of research. The Statement will help them to meet their responsibilities: to identify issues of ethics that arise in the design, review and conduct of human research, to deliberate about those ethical issues and to justify decisions about them.

Use of this Statement

This Statement must be used for all ethical review and conduct of human research that is funded by, or takes place under the auspices of, any of the bodies that have developed this Statement.

In addition, as a reliable and informative guide to the ethical considerations relevant to the design, review and conduct of that research, this Statement sets national standards for use by any individual, institution or organisation conducting human research. This includes human research undertaken by government, industry, private individuals, organisations, or networks of organisations.

Defining research

Research is to be understood as including investigation undertaken in order to gain knowledge and understanding or in order to train researchers, and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes. It does not include routine testing and routine analysis of materials, components and processes as distinct from the development of new analytical techniques. However, some of these activities, such as quality assurance, may sometimes warrant ethical review, even though they are not research (see *When does quality assurance in health care require independent ethical review?* NHMRC 2003).

When is research human research?

Human research is research involving human participants, who may participate through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens);
- their information (in individually identifiable, re-identifiable or non-identifiable form) being accessed as part of an existing published or unpublished source or database.

In addition, often the conduct of human research has an impact on the lives of others who are not participants. Reasonably foreseeable impacts on other human beings can be relevant ethical considerations for researchers and those conducting ethical review.

Ethical conduct and review of human research

The primary responsibilities for the ethical design, conduct and dissemination of results of human research lie with researchers and their institutions.

Institutions also have the responsibility to establish procedures for the ethical review of human research. That review must be based on the values and principles of this Statement, and can be undertaken at various levels and by means of various processes described in Section 5. The differences in these levels and processes of review should reflect the principle that the necessary degree of ethical review is proportional to the risks involved in the research. Research with more than a low level of risk must be reviewed by an HREC.

A determination, after research has been reviewed at the appropriate level, that the research proposal meets the requirements of this Statement and is ethically acceptable must be made before research is commenced and before full funding for the proposal is released.

This Statement does not exhaust the ethical discussion of human research. Provided they are consistent with this Statement, other guidelines and codes of practice pertaining to specific areas of research can be used to supplement it, and should be so used where this is considered necessary for ethical review of research.

Ethics and law in human research

Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers and institutions. Australian common law obligations arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose obligations on research funders and institutions.

This Statement of ethical principles and considerations does not discuss any legal rights or obligations.

Some human research is subject to specific statutory regulation, at Commonwealth and State and Territory levels. For example, Commonwealth laws regulate certain research on pharmaceutical drugs and medical devices, and the protection of privacy and intellectual property in research. Some examples of such specific Commonwealth legislation or regulation are listed in relevant chapters of the Statement. However, examples of State and Territory laws, such as those that regulate access to, and use of, information held by State or Territory authorities, consumer protection and illegal and professional conduct are not listed.

It is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant.

Structure of the Statement

The Statement has five sections. Sections 2 – 5 have multiple chapters. The five sections are:

1. *Values and principles of ethical conduct* sets out values and principles that apply to all human research.

2. *Themes in ethical review: risk and consent* discusses the concept of risk in research and the role of participants' consent.

3. Ethical considerations specific to research methods or fields provides more detailed guidance on ethical considerations specific to different research methods and fields.

4. *Ethical considerations specific to participants* provides more detailed guidance on ethical considerations specific to different categories of participants.

5. *Processes of research governance and ethical review* sets out the requirements on institutions in establishing HRECs and other processes for the ethical review of research; and specifies procedures for the accountability of researchers, those conducting ethical review of research and institutions.

SECTION 1 VALUES AND PRINCIPLES OF ETHICAL CONDUCT

Introduction

The ethical responsibilities of those conducting human research depend on basic values of respect for human beings, research merit and integrity, justice, and beneficence.

While these values have a long history in western culture, they are not the only values that could inform a document of this kind. Others include, for instance, altruism, contributing to societal or community goals, equality, and respect for cultural diversity, along with the values that inform *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).

However, the values of respect, research merit and integrity, justice, and beneficence have become prominent in the ethics of human research in the past six decades, and they provide a substantial and flexible framework for principles to guide the design, review and conduct of such research. This Statement is organised around these values, and the principles set out in paragraphs 1.1 – 1.10 give practical expression to them.

Among those four values, respect is the most fundamental. It centrally involves recognising that each human being has a value in himself or herself, and that this value must govern all interaction between humans. Such respect includes recognising the value of human autonomy — the capacity to determine one's own life and make one's own decisions. But respect goes further than this. It also involves giving particular protection to those with diminished or no autonomy, and protecting and helping people wherever it would be unjust not to do so.

In each section of the statement, however, the values are discussed in the following order: research merit and integrity, justice, beneficence and respect. This order of discussion reflects the order in which ethical considerations commonly arise in human research, and its repetition is a constant reminder of the need for ethical reflection at all stages of human research to be informed by these values.

Research merit and integrity are discussed first. Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable.

Justice is the next consideration. Aspects of justice include distributive justice (the fair distribution of benefits and burdens), and procedural justice ('fair treatment' and accountability in the conduct of research). While benefit to humankind is an important result of research, it is not sufficient in itself. Benefits of research are ethically acceptable only if they have been achieved through just means, are distributed fairly, and involve no unjust burdens.

The third value is beneficence. Researchers exercise beneficence in several ways: in assessing and taking account of the risks of harm and the potential benefits of research to participants and to the wider community; 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 final and most important value is respect for human beings. While specific concerns arise under the heading of respect, this value is also the common thread through all the discussions of ethical values. Turning to it as the final value is a reminder that it draws together all of the ethical deliberation that has preceded it.

The design, review and conduct of research must reflect each of these values.

Research merit and integrity

1.1 Research that has merit is:

(a) justifiable by its potential benefit to humankind, whether through its contribution to knowledge or other benefit. Justification of some research may require consultation with relevant communities;

(b) designed or developed using methods appropriate for the achievement of the aims of the proposal;

(c) based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available;

(d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;

(e) conducted or supervised by persons or teams with experience, qualifications and competence appropriate to the research;

(f) conducted using facilities and resources appropriate to the research.

1.2 Research that is conducted with integrity is carried out by researchers with a commitment to:

(a) searching for knowledge;

(b) following recognised principles of research conduct;

(c) conducting research honestly and ethically;

(d) disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge.

Justice

1.3 In research that is just:

(a) the processes of research are transparent and fair;

(b) the selection, exclusion and inclusion of categories of research participants is — taking into account the scope and objectives of the proposed research — fair, and accurately described in the results of the research;

(c) the process of recruiting participants is fair;

(d) there is no unfair burden of participation in research on particular groups;

(e) there is fair distribution of the benefits of participation in research; and

(f) there is fair access to the benefits of research.

1.4 Research outcomes should be made available to research participants in ways that are accessible, timely and clear.

Beneficence

1.5 The risks of harm or discomfort to participants in research should be minimised.

1.6 Any risks of harm or discomfort must be justified by the likely benefit to be gained. The likely benefit may be either to the participants or to the wider community, or to both. Where there are no likely benefits to participants, possible harm to participants should be less serious and the risk of those harms lower. However, respect for participants requires taking into account their views about what is an acceptable level of risk.

1.7 Where the risks to participants are no longer justified by the potential benefits of the research, the research must be suspended to allow time to consider whether it should be discontinued or proceed in a modified form. In making these decisions the researcher may need to consult with participants, the Human Research Ethics Committee (HREC) or other review body or the institution. The HREC or other review body must be notified promptly of such suspension, and of any decisions following it.

Respect

1.8 The fundamental ethical value of research is respect for human beings. This includes abiding by the preceding values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare,

beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

1.9 Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants, and where relevant of their communities. Any specific agreements made with the participants or the community are to be fulfilled.

1.10 Respect for human beings involves giving due scope to the capacity of human beings to make their own decisions, as well as protecting those who either are unable or have diminished capacity to do so.

Application of these values and principles

Ethical guidelines such as these are not simply a set of rules. The application of the guidelines should not be mechanical. It always requires deliberation on the values and principles, the exercise of judgement, and an appreciation of context.

SECTION 2 THEMES IN ETHICAL REVIEW: RISK AND CONSENT

Chapter 2.1 Risk

Introduction

Application of the values in Section 1, in particular the value of beneficence, requires the assessment of risks to participants, and sometimes to others. This involves assessment of what the risks are, of the extent to which they can be minimised, and of whether they are justified by the potential benefits of the research. This chapter provides information and guidance about this assessment.

A risk is a potential for harm. In some types of medical research, potential harms, which may include permanent disability or even death, are readily perceived and agreed upon. In other fields of human research there is less agreement about what might constitute potential harm, and about the magnitude, significance and likelihood of any risks.

Harm, including discomfort, and some categories of harm

Physical harm and discomfort are familiar concepts in some types of health and medical research. In social, behavioural and humanities research, potential harm or discomfort are commonly of other kinds. They can be more difficult to measure and to predict. Such harms are often, but not always, minor or unlikely.

There are various kinds of potential harm in research. One helpful classification[3] is: physical, psychological, social, economic and legal harms, and devaluation of personal worth. Physical harms include injury, illness, pain, suffering and discomfort. Psychological harms include emotional suffering, negative self-perception or aberrations in thought or behaviour, distress, anger or guilt related to disclosure of sensitive or embarrassing information, and distress or fear at the prospect of research revealing a likelihood of developing an untreatable disease. Social harms include negative effects on one's interactions or relationships with others, examples being discrimination in access to benefits or services, or in employment or insurance, social stigmatization and findings of previously unknown paternity status. Economic harms include imposition of direct or indirect costs on participants; and legal harms include lawsuits or laying of criminal charges if research brings attention to criminal conduct.

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[3] Adapted from National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, Bethesda, 2001 pp.71–72

Devaluation of personal worth includes being humiliated, manipulated or in other ways treated disrespectfully.

There can be harms to people other than participants. Examples include the effects of an unauthorised biography on close friends, the potential emotional distress when a family member is identified with a serious genetic disorder, and infectious disease risks to the community.

A standard dictionary definition of discomfort is 'uneasiness of body or mind'. In some fields of research, discomfort such as the anxiety which may be induced by an interview probing personal beliefs and feelings, fits this definition. In health research, discomforts are commonly physical discomforts, usually temporary and not serious. These include unpleasant accompaniments of invasive procedures, such as the momentary pain of blood-taking, the claustrophobia experienced by some people undergoing scanning, and minor side-effects of medication.

Potential harms involved in research depend not only on the research methods and activities themselves but also on the social and political context of the research and the categories of participants. Research into participants' reading habits or sexual preferences may carry relatively few risks in some contexts but be highly risky for participants in other contexts. Apparently straightforward clinical research may carry social, psychological, economic or legal risks for various categories of participants, including, for example, prisoners or those with genetic abnormalities or intellectual disability.

Risk

Risk, implying the chance or hazard of harm, encompasses two different concepts:

(a) the probability or likelihood that a harm (or discomfort) will occur; and

(b) the magnitude of the harm, including its consequences.

The expression 'low risk' could, logically, therefore refer either to the low probability of a harmful event occurring or to the small size of the harm that will occur, or to a combination of these two features. However, human research with a low probability of serious harm has been regarded, and should continue to be regarded, as not low-risk research. Research of the lowest risk involves a low probability of slight, if any, harm.

Quantifying risk

Individuals' experience of some risks is often very similar. The risk of death or of permanent disability, or the risk of humiliation, will generally be regarded very seriously by people. But people also vary in the significance they attach to different kinds of risk. One person might be greatly distressed by a telephone questionnaire which covers very sensitive topics, but happy to participate in potentially physically

dangerous research, while another person's priorities might be the opposite. Another questionnaire may pose no issue for a younger person but raise issues of self-esteem for older people — or vice versa. Other aspects of circumstance and situation can also come into play. In medical research, for example, side effects of an anti-cancer drug may be intolerable to a relatively well person but may be accepted as of lesser import by a seriously ill patient.

Minimising risk

The value of beneficence includes the obligation on researchers in designing research to minimise the risk to participants. Both researchers and those reviewing research will have regard to the aims of the research, their importance, and the methods by which those aims can be achieved, to whether the participants will be adults with unimpaired capacity to consent, and to the participants' experience and opinions as to the level of risk they are prepared to accept.

In fields other than human research, minimised risk is often understood as risk that is as low as reasonably practicable or achievable. In human research, a useful criterion for the minimisation of risk may be risk as low as ethically achievable, having taken into account the matters identified in the previous paragraph as well as the ways of quantifying risk described above.

Benefits and risks

Benefits of research refer to gains in knowledge, insight and understanding, and to improved social welfare and individual well-being. A further factor to be considered is whether the research carries the prospect of direct benefit to the research participants themselves, their families or their groups. Where this is the case, participants may be ready to assume a higher risk than in research that carries no prospect of such direct benefit.

There are also indirect benefits such as training researchers in research methods. Prospectively, most research design cannot guarantee that there will be actual benefit from research. The benefits to be considered are *potential* benefits. Potential benefits can accrue to those who are not participants — some or all members of their families or communities, or in some instances, the institutions.

Human research depends on the willing support of members of the community. Research that involves higher risks to participants than are acceptable to the general community may risk eroding that support. An assessment of the general community's views as to levels of acceptable risk remains a relevant consideration for researchers and for those reviewing research.

Guidelines for assessing risk

2.1.1 Risks to which participants in research would be exposed are ethically acceptable only if they can be justified by the potential benefits of the research.

2.1.2 Steps to arriving at this judgement should include:

(a) identifying the risks;

(b) establishing the means for minimising the risks;

(c) identifying whom, in addition to the participants, the risks may affect;

(d) identifying the potential benefits; and

(e) identifying to whom benefits are intended, and likely, to accrue.

2.1.3 Researchers and those ethically reviewing research should take care neither to assume nor to over-generalise the existence, likelihood and significance of risks.

2.1.4 In determining the existence, likelihood and significance of risks, those reviewing research should consider seeking advice from those with experience in the conduct of research of the kind to be reviewed.

2.1.5 In judging whether the potential benefits justify the risks of research, those reviewing the research should take account of the participants' perspective on the risks involved and assess the significance of risks in research against the experience and opinions of the participants.

2.1.6 In research with the prospect of direct benefit to participants or to their families or communities, those judging the acceptability of risk should be prepared to give weight to any readiness in participants to assume a higher risk than they would be ready to assume in research lacking the prospect of such direct benefit.

2.1.7 Those reviewing research should be satisfied that risks to participants do not exceed those that are as low as is ethically achievable in each research project, having regard to:

(a) the aims and methods of the research;

(b) the potential benefits of the research;

(c) whether the participants will benefit directly from the research;

(d) whether the benefits will accrue to people other than the participants;

(e) the opinions and experience of the participants; and

(f) the interests of the broader community and their support of human research.

Chapter 2.2 Consent

Introduction

Respect for human beings involves giving due scope to the capacity of human beings to make their own decisions. In the research context, respect for human beings therefore normally requires that participation in research be the result of a choice made by participants. This is commonly known as 'the requirement for consent'. Exceptions to this requirement are set out at paragraphs 2.2.18 – 2.2.23 below. Where there are exceptions, respect for human beings must be shown in the alternative arrangements under which it will be decided whether potential participants may enter the research.

What is needed to satisfy the 'requirement for consent' will vary. It will depend on the nature of the project and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted.

General requirements for consent

2.2.1 The process through which the opportunity for choice about participation is offered, and the choice is made, can vary. The guiding principle for researchers is that a person's decision to participate is to be voluntary, and based on sufficient information and adequate understanding. For exceptions to this principle, see paragraphs 2.2.18 – 2.2.23.

2.2.2 Researchers should seek and verify consent in ways appropriate to the participants' culture and circumstances.

2.2.3 Apart from exceptions set out in paragraphs 2.2.10 and 2.2.19 – 2.2.22, researchers are responsible for communicating to each potential participant the following information, whether orally, in writing, or by some other means, and in ways suitable for that participant:

(a) the purpose of the research;

(b) how it will be conducted;

(c) demands on participants, including any expected costs to participants;

(d) inconveniences and discomforts;

(e) risks and harms;

(f) the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;

(g) financial or other relevant declarations of interests of researchers, sponsors or institutions;

(h) possible outcomes of the research (including the likelihood and form of dissemination, including publication, of research results);

(i) any expected benefits of the research to participants and to the wider community;

(j) how the conduct of the research will be monitored;

(k) the contact details of a person to receive complaints; and

(l) any other relevant information.

2.2.4 The process of communicating such information should not become a matter of merely satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.

2.2.5 Where the research process is dynamic and continuous, consent may need to be renegotiated or confirmed, especially in the case of complex, long-running projects or with participants who are vulnerable. Research participants should be told if there are changes to the terms to which they originally agreed, and given the opportunity to continue their participation or withdraw.

2.2.6 The processes of seeking and obtaining consent will vary in complexity and detail according to the nature and level of risk in the research.

2.2.7 The consent of a person to participate in research should not be subject to coercion or pressure. Researchers should also be aware that a participant's consent might be an expression of deference or compliance in the face of the researcher's actual or perceived position of power.

2.2.8 Payment of research participants in money or kind is not in itself unethical. The decision to participate may be voluntary even if a person would not have participated without a payment. No payment that is likely to encourage participants to take undue risks is acceptable.

2.2.9 In most circumstances, it is appropriate to reimburse the costs to participants of taking part in research. These costs include material costs such as travel, but in some circumstances can also justifiably include the cost of participants' time. Further decisions about payment of research participants or benefit in kind to participants or their community should take into account the customs and practices of the community in which the research is to be conducted.

2.2.10 Where a potential participant lacks the capacity to consent, a person or appropriate statutory body with lawful authority to decide for the participant should be provided with relevant information and may exercise that choice.

2.2.11 The most suitable way for participants to demonstrate their consent will vary according to the nature of the research and the kind and level of risk it involves. Whatever method is chosen, research should be designed so that each participant's voluntary participation is clearly established. Different methods include return of a survey, conduct implying consent, a signed form, or other sufficient means.

2.2.12 In some circumstances and within some communities, participation in research is not only a matter of individual decision, but also involves other properly interested parties, such as formally constituted bodies of various kinds, institutions, families, or community elders. In such cases, researchers need to engage with all properly interested parties before beginning the research.

Consent to future use of data and tissue in research

2.2.13 In many circumstances, consent is limited to the specific project under consideration ('specific consent'). Under certain conditions, however, consent may extend to the use of data in future research projects which are an extension of, or closely related to, the original research project, or even in future projects which are in the same general area of research, for example, genealogical, ethnographical, epidemiological, chronic illness research, etc. ('extended consent'). In some circumstances this 'extended consent' may include permission to enter the original data into a databank. Any restrictions on the use of participants' data should be recorded and the record kept with the collected data so that it is always accessible to researchers who want to access those data for research.

2.2.14 Participants may give their consent for the use of their data in future unspecified research that may not be related to the original project ('unspecified consent'). Information about the nature and extent of this research will inevitably be limited. It is important to ensure at the time of agreement that the terms of the unspecified consent are clearly explained and recorded. Research proposals that rely on unspecified consent to the use of data may still require approval from a Human Research Ethics Committee (HREC), except where alternative processes of approval set out in paragraphs 5.1.7 – 5.1.9 apply to the research. Research proposals should include a record of the unspecified consent given by participants.

2.2.15 Data additional to that covered by the original extended or unspecified consent will sometimes be needed for research. Additional consent for access to such data may need to be sought from potential participants.

Declining to consent and withdrawing consent

2.2.16 People who elect not to participate in a research project need not give any reason for that decision. Researchers should take care to do whatever they can to see that people who decline to participate will suffer no disadvantage as a result of that decision.

2.2.17 Participants are entitled to withdraw from the research at any stage. Before consent to involvement in research is given, participants should be informed about any consequences of such withdrawal (see paragraph 2.2.3).

Qualifying or waiving consent requirements

2.2.18 In some circumstances and in some fields of research, significant qualifications on the obligation to provide information before participation may be justified.

2.2.19 An HREC may approve a research proposal that does not include or alters some or all of the requirements set out in paragraphs 2.2.1 – 2.2.12 or waive the requirement that consent be given for participation.

2.2.20 Before approving the omission or alteration of any of the elements of the consent process, the HREC should be satisfied that:

(a) participation in the research involves no more than low risk to participants;

(b) the omission or alteration is unlikely to adversely affect participants;

(c) the research could not practicably be carried out without the omission or alteration; and

(d) whenever possible and appropriate, after their participation has ended:

(i) participants will be provided with information about the aims of the research and an explanation of why the omission or alteration was necessary, and

(ii) participants will be offered the opportunity to withdraw any data or tissue provided by them.

2.2.21 In thinking about whether to waive the requirement of consent for participation in proposed research, an HREC should consider the following matters:

(a) the scope of any existing consent relating to the collection or storage of data or tissue to be used in the research;

(b) whether there is any reason to think participants would not have consented if they had been asked;

(c) in protecting the privacy of participants, the extent to which it is possible to re-identify or potentially identify the data or tissue or for the identity of the participants to become known;

(d) the extent to which there is an adequate plan to protect the confidentiality of data;

(e) the extent of any interaction between investigators and participants, such as in projects using existing identifiable or re-identifiable data or tissue; and

(f) the possibility of commercial exploitation of derivatives of the data or tissue.

2.2.22 Before taking the decision to waive the requirement that consent be given for participation in proposed research, an HREC must be satisfied that:

(a) participation in the research involves no more than low risk to participants;

(b) it is impracticable to obtain consent;

(c) there is a sufficient justification for the waiver;

(d) the research could not practicably be carried out without the waiver;

(e) any risks to the privacy of participants will be minimised;

(f) there is an adequate plan for contacting participants with information derived from the research, should the need arise;

(g) whenever appropriate, the participants will be provided with additional pertinent information after participating;

(h) the benefits from the knowledge to be gained from the research justify any risks of harm associated with not seeking consent; and that

(i) the waiver is not otherwise prohibited by State, federal, or international law.

2.2.23 When an HREC waives the requirement for consent under paragraph 2.2.22, it should report details of that decision to the institution. The institution should make details of all such decisions publicly accessible.

SECTION 3 ETHICAL CONSIDERATIONS SPECIFIC TO RESEARCH METHODS OR FIELDS

This section discusses various methodologies that may be used in different types of research. The section is a result of the further expansion of the revised National Statement beyond health and medical research. The discussion focuses on general principles and is not intended to be exhaustive. It reflects the interdisciplinary nature of many types of research, and that some researchers might employ a number of research methods.

Human research may be conducted only with ethical approval. Section 5 describes the processes that institutions may use to provide that approval. Those processes include ethical review by Human Research Ethics Committees (HRECs) or other ethical review bodies, according to the risks of the research (see paragraphs 5.1.4, 5.1.7 and 5.1.8).

Research involving more than low risk must be ethically reviewed and approved by an HREC (see paragraph 5.1.15). Research covered by Chapter 3.2 *Limited disclosure,* 3.4 *Therapies and interventions, including clinical and non-clinical trials, and innovations,* 3.5 *Human genetics* and 3.7 *Human stem cells* must also be ethically reviewed and approved by an HREC.

Chapter 3.1 Qualitative methods

Introduction

The information in this introduction is intended for users of the Statement who may not be familiar with the purposes and main methods of qualitative research. It has been included because this is the first time the Statement has dealt explicitly with qualitative research.

Qualitative research involves disciplined inquiry that examines people's lives, experiences and behaviours, and the stories and meanings individuals ascribe to them.[4] Qualitative research can also investigate organisational functioning, relationships between individuals and groups, and social environments.

This approach to research involves the studied use and collection of a variety of empirical materials — such as case studies, personal experience, life stories, interviews, observations, and cultural texts — that describe routine and problematic moments and meanings in the lives of individuals.

Qualitative research can provide in-depth information that may bring new insights into the experiences of individuals or groups, leading to a better understanding of the subject matter that is being investigated.

Qualitative research may also have quantitative elements or aspects.

Qualitative research contributes to the development of new knowledge by:

(a) enabling researchers to better understand complex concepts;

(b) investigating how communities and individuals interpret and make sense of their experiences;

(c) eliciting contextual data in order to improve validity of quantitative tools, such as surveys.

Commonly used approaches to data collection in qualitative research

A number of approaches can be used in qualitative research to collect data. Common approaches to data collection include (but are not limited to) the following methods.

[4] Denzin NK & Lincoln YS (Eds.) 2000 Handbook of Qualitative Research, Sage: California

- **Interviews** involve researchers talking to one or more participants, where the category of responses is focused but not necessarily pre-determined. Interviews are usually recorded by tape, video or notes. These records may be transcribed but are adequate as research data in themselves. Interviews are usually conducted in a location of the participants' choice.

  Interviews can take many forms, including:

  – *structured interviews,* which follow a set list of questions;

  – *semi-structured interviews*, which use an interview guide listing a set of issues to be explored;

  – *unstructured interviews*, which involve spontaneous generation of questions in the natural flow of interaction, and where the interview is driven by the interviewee rather than the interviewer;

  – *key informant interviews*, which are conducted with individuals or groups with special expertise or knowledge about the issue being investigated.

- **Life story or oral history** is based on both structured and semi-structured interviews and is a form of research commonly undertaken in the humanities.

- **Focus groups** of participants draw together a range of responses to a set of research questions. This may entail the researcher acting as a moderator for the discussion**.**

- **Observation** involves the researcher observing participant(s) in their own environment, or in the environment being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment.

- **Archival research** refers to materials that are usually but not necessarily deposited in libraries.

- **On-line research** includes conducting on-line real-time group discussions using web-based chat-room technology (also known as E-groups) through the use of electronic bulletin boards and moderated email groups. On-line recruitment of participants provides the opportunity for extensive global participation in research. Data collection and dissemination can also be utilised on-line.

- **Action research** is often community-based and carried out by a practitioner in the field. This approach involves testing ideas in practice as a means of improving social conditions and increasing knowledge**.** Action research proceeds in a spiral of steps consisting of planning, action, and evaluation. It provides a basis for further planning of critically informed action.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research involving qualitative methods, the following additional matters must be considered.

Research merit and integrity

3.1.1 In their relationships with participants, researchers are expected to maintain their role as researchers and not to engage in activities outside of the research or for which they are not qualified.

3.1.2 Qualitative research emphasises the significance of particular contexts and settings, and aims to provide a sufficiently detailed account and/or analysis to enable others to determine whether the findings are applicable to other circumstances. It is not necessary to be able to apply the results of qualitative research more generally.

3.1.3 The most common sampling strategy is purposeful sampling, which is aimed at the selection of information-rich cases relevant to the research question. While random and representative sampling are not precluded in qualitative studies, most sampling frames are based on other types of logic.

3.1.4 The rigour of a qualitative study should not be judged on sample size. When sampling is appropriate, the objectives and theoretical basis of the research should determine the size of the sample and the sampling strategy. For example, some qualitative methods use a principle of 'saturation', where sampling occurs until no new information is being obtained. This is only one of several criteria for assessing sample size (see paragraph 3.1.7).

3.1.5 Research proposals should clearly describe the recruitment strategy and criteria for selecting participants when sampling is proposed.

3.1.6 The rigour of qualitative research should be assessed primarily by criteria of quality and credibility of data collection and analysis, as well as justice for research participants, and not by matters of validity and reliability as defined in research designs that employ quantitative methods.

Justice

3.1.7 In qualitative research, the criteria for inclusion and exclusion of participants are often complex. For this reason, researchers should state clearly and be able to justify the criteria by which participants are to be included or excluded from a study using qualitative methods (see paragraph 3.1.4).

Beneficence

3.1.8 In qualitative research, participants are often easily identifiable, for example, as members of small communities or groups, or as key informants, and the information they provide may be sensitive. For these reasons, care should be taken that participants are not identified by the information they provide, unless they have consented to be identified. Special care should be taken to protect the identity of participants when disseminating information and storing material.

3.1.9 Participants should be informed about any potential to be identified in the results of research even if identifiers, such as name and address, are removed.

3.1.10 Qualitative research that explores sensitive topics in depth may involve emotional and other risks to both participant and researcher. There should be clear protocols for dealing with distress experienced by participants. Researchers should have sufficient training, and should outline courses of action, such as a referral process, to deal with these effects.

3.1.11 Qualitative research may involve methods of data collection that require the development of personal relationships with participants. Researchers should be aware of the impact that they may have on the participants and vice versa, and as far as possible, describe in the research proposal any anticipated such impact.

Respect

3.1.12 Qualitative research by its nature allows for the interpretive analysis of data. Researchers should try to avoid the risk that their own values will distort their understanding either of the information provided by participants or of its relevance to the research.

3.1.13 While consent is usually expressed in writing in qualitative research, there are justifiable exceptions (see paragraph 2.2.11). Sometimes oral consent is more appropriate, for example, when the research topic is particularly sensitive or the participant feels vulnerable or out of respect for participants' culture or circumstances. In some circumstances, consent may be implied by participation. In other circumstances, for example when observing, photographing or filming people in public places, consent cannot be given by some or all 'participants'.

Chapter 3.2 Limited disclosure

Introduction

Some research involves limited disclosure of the methods or purposes of research, and can be ethically justified where the following requirements are satisfied.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research involving limited disclosure, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

3.2.1 For research that involves limited disclosure, researchers should demonstrate that:

(a) the research is warranted, even though disclosure is limited;

(b) there are no suitable alternatives involving full disclosure by which the aims of the research can be achieved;

(c) the precise extent of the limited disclosure is defined;

(d) participants will eventually be fully informed;

(e) it can reasonably be anticipated that, following debriefing, the research participants will regard the research as justified and acceptable conduct;

(f) the participants are not likely to be harmed by their participation.

Beneficence

3.2.2 Participants must not be exposed to an increased risk of harm as a result of the limited disclosure.

3.2.3 The potential benefits of the research should be sufficient to justify any risk that the research might corrupt the relationship between the community and researchers and research in general.

Respect

3.2.4 An HREC must be satisfied that alterations to the elements for consent meet the requirements set out in paragraph 2.2.20.

Chapter 3.3 Databanks[5]

Introduction

Data are pieces of information. Data may arise through either a specific donation or response by a person, or the actions of others.

Examples of data derived through donations include what people say in interviews, focus groups, questionnaires, personal histories and biographies, and may also arise from the donation of human tissue such as blood, bone, muscle and urine.

Examples of data derived by the actions of others include information or observations about a person, such as those in a photograph, or information or observations made during studies where drugs and/or treatment programs, clinical devices or psychological stimuli are tested.

Data are collected, stored or disclosed, as identifiable data, re-identifiable or potentially identifiable data, or non-identifiable data (which includes a subset, anonymous data). These three categories of data, described below, are mutually exclusive:

(a) individually identifiable: data from which the identity of a specific individual can reasonably be ascertained. Examples of identifiers may include the individual's name, image, date of birth or address;

(b) re-identifiable or potentially re-identifiable: data from which identifiers have been removed and replaced by a code, but from which it remains possible to re-identify a specific individual, for example, by using the code or by linking different data sets;

(c) non-identifiable: data that have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. This includes a subset, anonymous: data which can be linked with other data so it can be known that they are about the same data subject, while the identity of that specific individual remains unknown.

The term 'de-identified data' sometimes refers to a record that cannot be linked to an individual (non-identifiable), and at other times refers to a record in which identifying information has been removed but for which the means exist to re-identify the individual (re-identifiable or potentially re-identifiable). Because of this ambiguity, the terms above are preferred. When the term 'de-identified data' is used, researchers and

[5] In the National Statement, the term 'databank' includes databases.

those reviewing research need to establish precisely which of these possible meanings it has.

It should be noted that with advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples may always be regarded as, in principle, potentially re-identifiable.

This increased ability to link data has greatly enhanced the contribution the accumulation of data can make to research. It allows researchers to match individuals in different data sets without being able to identify the person. Technology has also enabled a wide range of routine data to be employed as research data. For example, in epidemiological research, which is concerned with the study of populations, information about individuals and groups may be collected so that features of groups of people can be investigated. These data may, or may not, have originally been obtained for research purposes.

In the majority of instances, data are collected, aggregated and stored for a single purpose or activity. In some other cases, however, permission may be sought from participants to 'bank' their data for possible use in future research projects.

Data can also be stored in a data warehouse that aggregates data over time, similar to an archive or library. For example, the Australian Social Science Data Archive collects and preserves computer-readable data relating to social, political and economic affairs and makes the data available for further analysis. Data stored in the archives can usually be made available for secondary analysis, depending on whether the depositor(s) imposed restrictions on access to the data.

The values and principles of this Statement apply to data collection not only by researchers but also by others whom they authorise to collect data or to whom they outsource the collection.

These ethical principles for the use of databanks should be reflected and applied in the guidelines and procedures established by institutions for the setting up of data collections.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research involving databanks, the following additional matters must be considered.

Research merit and integrity

3.3.1 When planning a databank, researchers should clearly describe how their research data will be collected, stored, used and disclosed, outlining how that process conforms to this Statement.

Justice

3.3.2 In order to treat participants and their contributions fairly and to promote access to the benefits of research, data should be collected, stored and accessible in such a way that they can be used in future research projects.

Beneficence

3.3.3 Researchers may only use data from databanks as identifiable data, re-identifiable or potentially re-identifiable data, or, characteristically, non-identifiable data, according to the conditions specified by the providers of data (see paragraphs 2.2.13–2.2.15).

3.3.4 Where research involves linkage of data sets, the use of identified data to ensure that the linkage is accurate may be approved even if consent has not been given for the use of identified data in research. Once linkage has been completed, identifiers from the data to be used in the research should be removed.

3.3.5 It is the duty of the custodian to ensure that the data are used responsibly, respectfully, and so as to safeguard the privacy of participants.

3.3.6 Whenever research using re-identifiable data reveals information that, in conformity with paragraph 1.4, ought to be made available to participants, the custodian should be in a position to re-identify the person to whom the original data related.

3.3.7 In most situations, the custodian of data will be the individual researcher or agency who collected the information, or an intermediary such as a data warehouse that manages data coming from a number of sources. In some cases, an independent custodian may be necessary. For example, when coded data are stored in a databank, a custodian who is independent of the collectors of the data and the researchers proposing to use the data may be appointed to enable research participants to access identified results or data.

Respect

3.3.8 When collecting data for deposit in a databank, researchers should provide clear and comprehensive information about the type of data that will be stored, and about the purposes for which the data will be used and/or disclosed. This will include whether specific, extended or unspecified consent for future research will be sought, or whether permission will be sought from an HREC to waive the need for consent (see paragraphs 2.2.21 – 2.2.23).

3.3.9 Identifiable, re-identifiable and potentially re-identifiable data may be included in a repository to which other researchers have access only with the consent of the participant. In preserving and using data, any confidentiality agreement with

the participant should be observed, and the researcher should take every precaution to prevent the data becoming available for uses for which participants did not consent.

3.3.10 When depositing identified research data in a databank or archive, researchers should consider restricting uses of the data that might be detrimental to the welfare of people to whom the data relates. For example, access to the data could be precluded for a period of time, whether before or even after the death of the people to whom the data relates.

Chapter 3.4 Therapies and interventions, including clinical and non-clinical trials, and innovations

Introduction

Clinical research

Clinical research involves the use of clinical procedures and is designed to derive information that can be applied in a clinical setting and to improve the provision of care to individuals. Commonly, this takes the form of a clinical trial (see below), especially of new therapies. It also includes assessment of other interventions in many different fields and may be conducted by a range of different health professionals studying a wide range of matters, including disease prevention and causation, diagnostic methods, treatments, and effects of and responses to illness. Such research can occur in a number of settings, including public and private hospitals and clinics, other institutions or organisations, community settings, and general or specialist medical practices. This chapter focuses especially on randomised clinical trials, but it should be noted that clinical trials are not always randomised. Further, as noted below, randomisation may be used in other areas of human research (for example, education research) and therefore the ethical issues outlined here will be relevant to such research.

At times, it may be difficult to distinguish clinical and related research from quality improvement and clinical audit. In such situations, guidance is available from the NHMRC publication *When does quality assurance need review by a Human Research Ethics Committee?* (NHMRC 2003).

Innovative therapy or intervention

Innovations in clinical practice and complementary medicine include new diagnostic or therapeutic methods which aim at improving health outcomes beyond those of existing methods but which have not yet been fully assessed for safety and/or efficacy. It should always be made clear to potential participants that the proposed intervention is innovative. The spectrum of innovations ranges widely from minor variations of existing methods, or the extension of existing methods, to new indications, through to completely novel technologies.

Whether a change in an individual's investigation or treatment represents an innovation or constitutes clinical research is generally a matter for the responsible clinician's judgement, guided by the relevant institutional policies.

Clinical and other trials

A clinical trial is a form of clinical research designed to find out whether an intervention, including a treatment or diagnostic procedure, which it is believed may improve a person's health, actually does so. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure. Characteristically, such trials seek to test a hypothesis and uses appropriate methods to test it.

Clinical trials of new therapeutic substances are typically categorised into Phase I, II or III trials. Phase I and II studies involve the initial evaluation of a new drug, compound or device for safety, tolerability and suitable dosage in healthy volunteers, while Phase III trials usually involve comparison with existing treatments, using randomisation and 'blinding' or other strategies to ensure freedom from bias. Many disciplines conduct research using similar methodology including randomisation. Such research raises similar ethical considerations to those raised in this chapter.

Clinical research also includes Phase IV studies which most often constitute post-registration surveillance research designed to document safety in a broader and larger population than that involved in Phase III trials. The design, review and conduct of Phase IV trials should satisfy the principles outlined in this chapter.

In pharmaceutical and medical device trials there are established codes of good clinical research practice that define clearly what is meant by a clinical trial for those purposes. This chapter has principal application to biomedical clinical trials but also applies to any other intervention claiming therapeutic benefit, wherever provided or conducted. Trials involving experimentation with therapeutic goods, whether drugs or devices, that are not yet registered or listed on the Australian Therapeutic Goods Register (ATGR) are subject to notification to and oversight by the Therapeutic Goods Administration (TGA).

Application of randomised trial methods to other areas of human research

Research methods intended to avoid or reduce bias include randomisation and 'blinding' participants and researchers to the identity of agents being compared. First applied to the study of new therapies, these research methods are now used in various other fields, including, for example, psychology and education. Researchers in any fields who propose to use such methods should be aware of the ethical issues which may arise in the design and conduct of such research. In particular, paragraphs 3.4.3 and 3.4.6 will apply in all situations, while other paragraphs may be relevant depending on the nature of the research and the relationship between the researcher and potential participants.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent.* When these values, principles and themes are applied to research involving therapies

and interventions, including clinical and non-clinical trials, and innovations, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

3.4.1 Health care and medical institutions should develop and implement policies about the use of innovative interventions and treatments. These policies should include criteria for deciding when innovations should be subjected to systematic investigation to determine their safety and efficacy.

3.4.2 When, in the light of those policies, an innovative diagnostic or therapeutic method should be subject to systematic investigation to determine its efficacy and safety, it **s**hould be treated as clinical research requiring formal consideration by a Human Research Ethics Committee (HREC).

3.4.3 Researchers should show that:

(a) the research 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) the size and profile of the sample to be recruited is adequate to answering the specific research question; and

(d) where relevant, the research meets the requirements of the *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95), ISO 14155 *Clinical Investigation of Medical Devices* and the TGA.

3.4.4 Researchers should inform the HREC of any business, financial or other similar association between a researcher and the supplier of a drug or surgical or other device to be used in the trial, and of any other possible conflicts of interest.

3.4.5 In any clinical research, especially clinical trials, an HREC should be satisfied that:

(a) funding is sufficient to conduct and complete the trial as designed; and

(b) any payment in money or kind, whether to institutions, researchers or participants, will not adversely influence the design, conduct, findings or publication of the research.

Justice

3.4.6 The research methodology should provide a rationale for the selection of appropriate participants and an appropriate method of recruitment (see paragraph 1.3).

Beneficence

3.4.7 The proportion of risks to potential benefits will vary for different research participants. In research without likely benefit to participants, the risks to participants should be low. In clinical research where patient care is combined with intent to contribute to knowledge, any higher risks of participation should be justified by likely benefits for the participants.

3.4.8 The prospect of benefit from research participation should not be exaggerated, either to justify to an HREC a higher risk than that involved in the participant's current treatment or to persuade a participant to accept that higher risk.

3.4.9 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 as to whether currently available treatment has a net clinical benefit, a placebo controlled trial or a trial with a no-treatment arm may be considered.

3.4.10 Data should be accurately recorded in a durable and appropriately referenced form that complies with established legislation, policies and guidelines. Where materials of biological origin, or other materials of which there is limited experience of long-term use, 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 emerges.

Respect

3.4.11 Due to the potential complexity of information to be provided to participants in seeking consent, the requirements of paragraph 2.2.3 should be carefully considered and followed. In particular, in clinical trials, written information should not be unduly long or complex. Adequate time should be allowed for prospective participants to read and take in what is proposed.

3.4.12 Particular care should be taken in clinical trials to make it clear to participants whether there is intended to be any therapeutic benefit to them from the trial.

3.4.13 In clinical research, where patient care is combined with an intent to contribute to knowledge, the following matters should be carefully weighed:

(a) the seriousness of the condition being treated;

(b) the risks involved in the proposed research; and

(c) the possible effects of an unequal or dependent relationship between the treating health professional or researcher and the potential participant.

3.4.14 Where the researcher is also the treating health professional, it may be appropriate for an independent person to seek the consent of potential participants.

3.4.15 An HREC should examine the budgets and other financial aspects of clinical research, especially clinical trials, to be satisfied that:

(a) payment in money or incentives of any kind, whether to researchers or participants, does not result in pressure on individuals to consent to participate;

(b) research participants are informed of the funding arrangements of the research and given the option of knowing the details of any capitation payments to researchers; and

(c) it has been made clear to participants whether they will have continued access after the trial to treatments they have received during the trial and on the same terms.

Monitoring of approved clinical research

3.4.16 The ultimate responsibilities of institutions for monitoring the conduct of approved research are described in Chapter 5.5 *Monitoring approved research.* In clinical research, and especially clinical trials, research sponsors have complementary responsibilities.

3.4.17 Institutions responsible for the conduct of clinical research should require that:

(a) for each project, there are mechanisms by which adverse events will be reported;

(b) for each large multi-centre trial, a Data Safety and Monitoring Board (DSMB) will be used;

(c) there is a mechanism for informing the HREC of any relevant emerging data from the DSMB and from reports of local adverse events; and

(d) for local trials, there is an identified person or committee with responsibility for collecting and storing data on adverse events and for notifying the HREC of adverse events related to research approved by that HREC.

3.4.18 HRECs should consider information provided to them about adverse events and review the project in light of this new information.

3.4.19 In addition to the requirements outlined in Chapter 5.5 *Monitoring approved research*, the granting and continuation of ethical approval of clinical research must be on the condition that the researcher:

(a) conducts the trial in compliance with the approved protocol;

(b) provides 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) informs the HREC, and seeks 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) informs the HREC, the DSMB or person identified by the institution, and the TGA of all adverse events that occur during the trial and may affect the conduct of the trial, the safety of the participants or their willingness to continue participating. This information should be accompanied by an explanation of the significance of these events;

(e) informs 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) informs 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, confirms the existence of or establishes a system for tracking the participant, with consent, for the lifetime of the device, and for reporting any device incidents to the TGA.

3.4.20 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.

3.4.21 Research sponsors and institutions must ensure that arrangements that meet accepted standards are established to provide compensation to participants for harm suffered as a result of their participation in clinical research.

Chapter 3.5 Human genetics

Introduction

Genetic research involves the study of how genes influence the health of individuals and populations with the aim of generating knowledge that has the potential to improve individual and community health. Genes are being studied increasingly in clinical, epidemiological and social research, as well as in basic research.

Genetic research may involve study of:

(a) one or thousands of genes, depending on the research aims and the technology used;

(b) inherited (genomic) gene sequences, both normal and variant;

(c) both inherited (genomic) gene sequences and acquired (somatic) variation in gene sequence at the same time, for example, in cancer tissue;

(d) gene expression, which reflects the activity of inherited genes as well as genes that have been altered by somatic mutation, and also reflects the action of environmental factors on these genes; and

(e) the genes of individuals, families or populations.

When genetic research is conducted using stored data, see also Chapter 3.3 *Databanks* and when conducted using human tissue samples, see also Chapter 3.6 *Human tissue sampl*es.

In addition to ethical considerations which apply to all human research there are ethical issues specific 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. Where research is conducted on inherited (genomic) gene sequences, the familial character of the genetic information involved raises ethical issues of greater consequence for individuals and families than those raised by research on acquired (somatic) variations in gene sequences. Genetic research can reveal information about research participants' predispositions to disease. Although they may neither have nor develop the disease, the information may have implications for their access to employment and education and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have similar implications for relatives.

When identified genetic variation is associated with large increases or decreases in the chance of future disease, such information may be of concern, interest or benefit to research participants, especially if preventive strategies exist for those at increased risk.

When genetic variation is associated with only small increases or decreases in the chance of future disease and the chance can be influenced by the function of other genes and environmental factors, information gained from the research is likely to be of little value to individual research participants.

Research results and genetic material and information collected for genetic research may be significant for close genetic relatives, commonly called 'blood relatives', of research participants. These family members may have an interest in their relatives' 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 such information, or even not to know of its existence. 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. Genetic research can also reveal information about previously unknown paternity or maternity.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to human genetic research, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

3.5.1 Where research may discover or generate information of potential importance to the future health of participants, their offspring or blood relatives, researchers should prepare and follow an ethically defensible plan for handling that information. The plan should include procedures to enable participants or relatives to decide whether or not they wish to receive the information, and to whom the information may be conveyed. Those procedures should take into account the clinical relevance of the information and the quality of the genetic tests in the research and of their results. The procedures should also include measures to protect the degree of confidentiality that participants wish to maintain. Where participants decide to be notified of or given genetic information that is important for their own health, the plan should provide access to clinical advice and counselling from health professionals with appropriate training, qualifications and experience, or make a clear recommendation to participants to seek such services.

Justice

3.5.2 Researchers should consider the potential psychological, social and cultural significance of their research, particularly in the areas of complex socially significant characteristics and the genetic characteristics of communities. When such characteristics are the subject of research, researchers should adopt measures designed to prevent mis-use or misrepresentation of the results of research. These measures are particularly important where results might otherwise lead to prejudice, disrespect or other harm to the participants or communities to which they belong.

3.5.3 Before deciding to store information and material in non-identifiable form, researchers should consider carefully the consequences for future research and for communication of personal research results to participants.

Beneficence

3.5.4 Genetic research may potentially reveal information of importance to the future health of an identified or a re-identifiable participant or of a participant's offspring or blood relatives, although that potential may not be clear until after interim analysis of research information. Both at the commencement of the research and also when the potential is clear, participants should be given the option of whether they wish to be notified of the existence of that information. They should also be given the further option of receiving the information. In accordance with the plan referred to in paragraph 3.5.1, they should be clearly informed of any need for advice or counselling about the implications of these decisions. This advice needs to include a clear explanation of the difference between research and clinical testing, and to clarify any need for clinical testing of research results.

3.5.5 Researchers should not transfer genetic material and related information to a researcher in another research group, unless:

(a) the transferring and receiving researchers are conducting research which has been ethically approved in Australia or through an equivalent process in another country;

(b) either

(i) the genetic material and information provided is in practice non-identifiable (even though, as with all genetic information, it may be in principle re-identifiable),

or

(ii) the transfer is approved by an HREC; and

(c) the other research group undertakes to hold the material and 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.

3.5.6 There is potential for harm to participants arising from the use of genetic information, including stigmatisation or unfair discrimination. Researchers should take special care to protect the privacy and confidentiality of this information. Statutory or contractual duties of disclosure may require participants to disclose the results of genetic tests, particularly those which provide information about future health, to third parties such as insurance companies, employers and financial and educational institutions. As far as possible, participation in genetic research should be designed to minimise any risk, arising from such disclosures, that participants are deprived of benefits that are available to other members of the community.

Respect

3.5.7 Consent from participants should be obtained for human genetic research unless an HREC is satisfied that the research meets the requirements of paragraphs 2.2.21–2.2.23 and waives the requirement for consent.

3.5.8 Stored genetic material or genetic information should be used only for research falling within the scope of the consent originally provided for its use.

3.5.9 In addition to being given information required by paragraph 2.2.3, individuals whose consent is being sought for collection of genetic material and data for use in research should be informed:

(a) that they are free to decline to 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 that 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 with regard both to other family members and to persons who are not family members. Participants should be informed whether their genetic material and data will be used in an identified, re-identifiable or non-identifiable form. If their material or data is to be used in a non-identifiable form, they should also be informed 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 re-identifiable participant or of the participant's offspring and their blood relatives;

(d) that the researchers will endeavour to provide information about the outcome of the research. Participants should be advised whether feedback will relate to individual participants or to participants as a group. If it is not intended to provide feedback, participants should be told why. 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 normally be respected. Participants should be informed, however, that an HREC may consider overriding this decision if research reveals unforseen information with serious implications for their health unless preventive measures that are available are taken;

(e) that if the research generates information about participants which may be of relevance to the health of other family members, the written consent of participants will be sought before offering to disclose such information to the family members concerned. If, however, the research discloses that a family member may be at risk of a life threatening or serious illness for which treatment is available or pending, this information may be given to the family member, even if the research participant does not consent to this;

(f) if information from or about family members, in addition to that provided by participants, is required for the research;

(g) that if it is proposed to approach relatives, consent to do so will first be obtained from the participant;

(h) if the research has the potential to detect non-paternity or non-maternity, or non blood-relationship to siblings;

(i) if the research has potential to generate information that a participant may be legally required to disclose to a third party for the purposes of insurance, employment, finance or education;

(j) that genetic material and data may have uses unrelated to research. Participants should be advised that their material and data will not be released for such uses without their consent, unless required by law;

(k) about any proposal, subject to participants' consent, to store their genetic material and data because it might be useful for as yet unspecified future research conducted in accordance with paragraph 3.5.16 below;

(l) that if consent is not given, the genetic material and data will be disposed of at the end of the research, once the sample storage and record keeping requirements of good research practice have been met;

(m) that any wishes about the method of disposal will be recorded at the start of the research and taken into account at the time of disposal;

(n) that they are free to withdraw from the research at any time. Participants should be informed of any consequences of such withdrawal, including that they may request that their genetic material and data be then disposed of if the samples can be identified. They should also be clearly informed of any practical limitations on the granting of this request; and

(o) that when research involves the study of large numbers of genes simultaneously, it is not necessary for researchers to provide participants with the names of all the individual genes to be studied.

3.5.10 In considering whether to approach relatives, researchers need to 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 the relatives' participation in the research.

3.5.11 Where a participant has given consent to approach relatives, the initial contact should be made by the participant or another relative.

3.5.12 When researchers propose to collect genetic material and information from individuals chosen because of their membership of a particular community, consent should be sought from appropriate community representatives as well as from the individuals concerned (see paragraph 2.2.12).

3.5.13 Researchers should ensure the confidentiality and privacy of stored genetic information or research results relating to identified or re-identifiable participants. Such information or research results should not be added to a participant's clinical record(s).

3.5.14 Researchers should keep information provided by participants about family members confidential. Such confidential information should not be revealed either to family members who are not participants or to anyone else. Identifying genetic information about family members should not be released to anyone, including those family members themselves, without the written consent of the participant who provided the information or of a person or institution legally authorised to consent for that participant.

3.5.15 The research proposal should specify whether genetic information or genetic material, and any information derived from studying the genetic material, will be stored in identified, potentially re-identifiable, or non-identifiable form (see 3.3 Introduction). 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 non-identifiable form. Where genetic data is stored, it might sometimes be appropriate to place an embargo on the release of data (see paragraph 3.3.9).

3.5.16 Institutions wishing to conduct research on genetic material and information collected for non-research purposes, should develop and disseminate a general

policy informing patients of the terms and conditions on which that material and information may be used for future approved research. These policies should reflect the values and principles of this Statement. Patients of such institutions should be informed that this policy exists and be given the opportunity to decline to consent to use of their material and information for future research.

3.5.17 If asked to consent to the use of their genetic material and information for future research, participants should be provided with information about the likely implications of that use. They should also be advised to consider the need for counselling about these implications.

3.5.18 Where genetic material and information will be used for future research in non-identifiable form feedback will not be practically possible. However, researchers may use the genetic material and information in potentially re-identifiable form. In such cases, participants' wishes about 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 be informed, either at the time of consent or prior to the feedback, about the implications of the feedback, and advised to consider the need for counselling about those implications.

Chapter 3.6 Human tissue samples

Introduction

Samples of tissue, including blood and other body fluids, are collected from people in hospitals and other health care institutions. Samples collected for diagnostic purposes in the course of treatment have also traditionally been used for teaching or quality assurance activities and for research. 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 whose use in research may lead to important advances in the understanding and treatment of disease.

Research involving the use of gametes or embryos is governed by *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004).

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research using human tissue samples, the following additional matters must be considered.

Research merit and integrity

3.6.1 Institutions should develop policies to guide researchers and those reviewing research about the conduct and ethical approval of research using human tissue. These policies should conform to relevant legislation and be consistent with this Statement. In the development of policies, relevant considerations include:

(a) the source, nature and cultural or religious sensitivity of the tissue;

(b) the original reason for its collection;

(c) when consent should be sought for the use of tissue in research and when a waiver of the requirement for consent may be considered; and

(d) the purpose of the research.

3.6.2 Where tissue is imported from overseas for use in Australia, researchers should try to establish whether there are ethical and professional policies in that country governing the collection of tissue for use in research.

(a) If there are such policies, researchers should seek assurance that the tissue was collected in accordance with them. Where this assurance is provided, but there is no indication of whether consent was obtained for the use of

the tissue in research, an HREC may decide to waive consent in accordance with paragraphs 2.2.21 – 2.2.23.

(b) Where such policies exist, and reasonable enquiry as to whether the tissue was collected in accordance with them is inconclusive but reveals no positive reason to believe it was not so collected, an HREC may also decide to waive consent.

(c) Where it cannot be established that such policies exist, or where they exist but enquiry reveals reason to believe the tissue was not collected in accordance with them, the tissue should not be used in research in Australia. (For specific conditions on the research use of imported stem cell lines, see paragraph 3.7.4. See also Chapter 4.8 *People in other countries*.)

Justice

3.6.3 Wherever human tissue samples or related information are gathered in the course of a professional relationship, confidentiality must be observed. Identification of samples must be limited to the minimum necessary to achieve the stated objectives of the research. If the research may produce information relevant to the health and well being of the person from whom it was derived, procedures to allow participants to be identified for appropriate follow-up should, wherever possible, be included in the research proposal.

Beneficence

3.6.4 Researchers should demonstrate that:

(a) tissue to be used will be professionally removed;

(b) tissue will be appropriately and securely stored;

(c) data will be recorded, stored and released in ways that ensure confidentiality and privacy; and

(d) tissue will be managed and used in accountable ways.

Respect

3.6.5 Consent for the use of tissue in research should be sought from donors. Consent may be specific, extended or unspecified (see paragraphs 2.2.13-2.2.15).

3.6.6 Where it is proposed to use tissue samples which have been:

(a) collected for, or held in storage following or in association with, clinical investigations;

(b) held in archives or banks; or

(c) removed in the course of a clinical procedure and not required for any clinical purpose,

and the use of these samples may lead to harm, benefit or injustice to the donors, they should be informed of those possibilities and specific consent then sought for use of the samples.

3.6.7 An HREC may sometimes waive, with or without conditions, the need for consent when the requirements of paragraphs 2.2.21 – 2.2.23 are met.

3.6.8 Human tissue samples that have been collected and stored with consent only for use in a specific research project should not be used for a different research project unless further consent for that project is given or an HREC has waived the need for further consent.

3.6.9 Where it is proposed to use tissue from a cadaver, whether removed at autopsy or not, it should first be ascertained whether the deceased person expressed any wish about the issue of his or her post-mortem tissue for research. If so, that wish should be respected. If no such wish is discovered, consent for the use of the tissue should be sought from the senior available next-of-kin.

3.6.10 At the time of seeking consent, it should be agreed with the next of kin how the tissue is to be disposed of when the research has been completed. Researchers should try to accommodate any reasonable wishes of the next of kin about the means of disposal.

Chapter 3.7 Human stem cells

Introduction

Stem cells have the capacity to divide to generate 'progenitor' cells that retain the properties of the stem cell, or to produce 'daughters' that begin to differentiate into a more specialised cell type, or to produce one daughter cell of each type. Stem cells are thus central to normal human growth and development, and are also a potential source of new cells for the regeneration of diseased or damaged tissue. Stem cells are present at all stages of development, and in many (possibly most) tissues of the adult.

At present, there are three recognised classes of stem cells: embryonic stem cells, embryonic germ cells, and somatic stem cells.

Legislation

The *Research Involving Human Embryos Act 2002* (the RIHE Act) and corresponding State and Territory legislation establishes a regulatory framework for the use of these excess assisted reproductive technology (ART) embryos. This legislation does not regulate research activity using stem cells or stem cell lines after they have been derived from an excess ART embryo.

The RIHE Act refers to *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004), known as the 'ART guidelines'. At paragraphs 17.10 – 17.18, these guidelines provide guidance for the design, ethical review and conduct of research involving excess ART embryos.

Stem cell research

Stem cell research involves studies designed to improve biological knowledge of cellular disease processes, such as studies on the pluripotentiality of stem cells, and attempts to improve understanding of specific diseases or studies related to drug metabolism and therapeutics. Research also includes clinical trials and innovative therapy involving stem cells or their products.

The following guidelines[6] relate to research using derived human stem cells or stem cell lines, whether embryonic stem cells or non-embryonic stem cells. For the purpose of these guidelines, these cells are regarded as human tissue, so that Chapter 3.6 *Human tissue samples,* also applies.

[6] The guidelines have been adapted from the Updated Guidelines for Human Pluripotent Stem Cell Research, June 7, 2005, Canadian Institutes of Health Research.

Where research is proposed using stem cells derived from human umbilical cord or placental tissue, Chapter 4.1 *Women who are pregnant and the human fetus*, also applies.

Where clinical research is proposed using stem cells, reference may be needed to the requirements of the Therapeutic Goods Administration (TGA) and the *Australian Code of Good Manufacturing Practice for Medicinal Products.*

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in research: risk and consent.* When these values, principles and themes are applied to research involving human stem cells, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

3.7.1 To inform the ethical review of clinical research involving stem cells, whether embryonic or non-embryonic, researchers and HRECs should seek advice from the NHMRC's Gene and related Therapies Research Advisory Panel (GTRAP).

3.7.2 Research on human embryonic stem cell lines, embryonic germ cell lines or other cell lines of a pluripotent nature created in Australia should only be conducted where those cell lines were derived and made available for research in accordance with this Statement and relevant legislation.

3.7.3 Research is conducted on human embryonic stem cell lines, embryonic germ cell lines or other cell lines of a pluripotent nature, for example, those derived from fetal tissue. Where these cell lines were created in another country, research should only be conducted on them where there is reason to believe that the manner in which the stem cell lines were created and made available for research does not vary significantly from the requirements of Australian legislation, the ART guidelines and this Statement. There must be reason to believe that the stem cell lines were derived and made available for research under laws and policies of that country which require that:

(a) the human embryos from which cell lines were derived were created for reproductive purposes;

(b) embryo donors consented to the use of their embryos for stem cell research;

(c) the human embryos from which the stem cell lines were derived were created by the fertilization of a genetically unaltered ovum by a genetically unaltered sperm;

(d) the pregnant woman from whom fetal tissue was obtained for deriving cell lines made the decision to donate that tissue in a manner similar to that required by Chapter 4.1 *Women who are pregnant and the human fetus*;

(e) the pregnant woman from whom fetal tissue was obtained consented to the use of that tissue for research in the manner similar to that required by Chapter 4.1 *Women who are pregnant and the human fetus*; and

(f) the embryos used to create stem cell lines were not obtained through commercial transactions.

3.7.4 Research involving the grafting of human stem cells or other human cells that are likely to be pluripotent into humans should only be conducted where:

(a) there is overwhelming evidence, from pre-clinical models, of safety and efficacy;

(b) the research is carried out in well-designed clinical trials; and

(c) consent by research participants meets the requirements of this Statement.

3.7.5 Research using human or non-human stem cells that are likely to be pluripotent is ethically unacceptable if those cells are:

(a) combined with a human embryo;

(b) grafted to a human fetus; or

(c) grafted to a non-human fetus.

Justice

3.7.6 Stem cell research should not involve the directed donation of stem cell lines or other human cells or cell lines of a pluripotent nature, to particular individuals, except for autologous donation.

3.7.7 Human stem cell lines, other human cells or cell lines of a pluripotent nature from human embryos, fetuses or adults, should be anonymized for use in research, unless the research involves autologous donation.

Beneficence

3.7.8 Health professionals with clinical care responsibilities for a woman whose consent is to be sought for involvement in research using embryonic stem cells to be derived from her embryo or fetus should not be members of the research team conducting that research (see paragraph 4.1.1 and the ART guidelines).

3.7.9 Human stem cells are human tissue and there should be no element of commerce involved in the transfer of human stem cells, except for the reimbursement of reasonable expenses.

Respect

3.7.10 Research to derive and study human stem cell lines, human embryonic germ cell lines or other cells of a pluripotent nature from the umbilical cord, placenta, human fetal tissue or amniotic fluid should be conducted only where the requirements of Chapter 4.1 *Women who are pregnant and the human fetus* are satisfied.

3.7.11 Research to derive and study human stem cell lines of a pluripotent nature from human somatic tissues should only be conducted where the requirements of Chapter 3.6 *Human tissue samples* are satisfied.

3.7.12 In addition to the information to be given under paragraph 2.2.3, researchers should give to those from whose tissue stem cells will be derived:

(a) an explanation of the research for which the stem cells are to used, and, where extended consent is sought, sufficient information to meet the requirements of paragraphs 2.2.13 and 2.2.14;

(b) an explanation that the cell line(s) will be anonymized unless the research involves autologous donation;

(c) an assurance that research participants are free not to participate and have the right to withdraw at any time before an anonymized cell line is created;

(d) an explanation that the research could result in the production of a stem cell line that could be maintained for many years, distributed to other parts of the world, and used for various research purposes; and

(e) an explanation that the research participants will not benefit financially from any future commercialization of cell lines, and that there will not be any authority over any cell lines created unless the research involves autologous donation.

SECTION 4 ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS

Introduction

In addition to the ethical considerations pertaining to all research participants, specific issues arise in the design, conduct and review of research involving the categories of participants identified in this section.

The Introduction to this Statement contains a definition of participants and notes that the impact of research on wider populations is an important ethical consideration in the design, review and conduct of human research.

Human research may be conducted only with ethical approval. Section 5 describes the processes that institutions may use to provide that approval. Those processes include ethical review by Human Research Ethics Committees (HRECs) or other ethical review bodies, according to the risks of the research (see paragraphs 5.1.4, 5.1.7 and 5.1.8).

Research involving more than low risk must be ethically reviewed and approved by an HREC (see paragraph 5.1.15). Research covered by Chapter 4.1 *Women who are pregnant and the human fetus*, 4.4 *People highly dependent on medical care*, 4.5 *People with a cognitive impairment, an intellectual disability, or a mental illness*, 4.6 *People who may be involved in illegal activities*, 4.7 *Aboriginal and Torres Strait Islander Peoples* and 4.8 *People in other countries* must also be ethically reviewed and approved by an HREC.

Chapter 4.1 Women who are pregnant and the human fetus

Introduction

This chapter provides guidelines for the ethical conduct of research involving women who are pregnant, the human fetus ex utero, and human fetal tissue after the separation of the fetus from the woman.

For the purpose of this chapter, the term *fetus* applies to the whole of the developing human being from implantation to delivery, and whether alive or dead at delivery.

Australian legislation and the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* govern research on embryos created using assisted reproductive technology that have been declared to be excess to the needs of those for whom they were created. For this reason the guidelines in this chapter do not apply to that research.

Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and tissue that contains the genome of a fetus. Fetal tissue is regarded as part of the fetus prior to separation of the fetus from the woman.

After separation, the following chapters of this Statement may also be relevant in designing and conducting research: Chapter 3.4 *Therapies and interventions, including clinical and non-clinical trials, and innovations;* Chapter 3.6 *Human tissue samples;* and Chapter 3.7 *Human stem cells*.

Decisions about the design, conduct and review of human research must clearly reflect the values and principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent.* When these values, principles and themes are applied to research involving women who are pregnant and the human fetus, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Paragraphs 4.1.1 – 4.1.8 should be considered for all research involving women who are pregnant, the human fetus or human fetal tissue. Paragraphs 4.1.9 – 4.1.22 address additional issues specific to some of that research.

Research merit and integrity

4.1.1 Research involving the human fetus ex utero or fetal tissue should be conducted by people with no involvement in the clinical care of the women from whom the fetus or fetal tissue was derived, and no financial or legal relationships with those who are so involved. Such research should be conducted in separate locations from those in which the clinical care of those women is provided.

4.1.2 Researchers should demonstrate that there are no suitable alternatives by which the aims of the research can be achieved.

4.1.3 There should be no commercial element in the transfer of human fetal tissue from the woman who originally gave the tissue except for the reimbursement of reasonable expenses.

Justice

4.1.4 Those who conscientiously object to being engaged in research projects involving fetuses or fetal tissue should not be obliged to participate in those projects, nor should they be put at a disadvantage because of their objection.

Beneficence

4.1.5 Research involving the fetus or fetal tissue, however derived, should include arrangements for access to counselling and support for the woman who consents to the research.

Respect

4.1.6 The well-being and care of the woman who is pregnant and involved in research always takes precedence over research considerations or use of fetal tissue. Her consent should always be obtained for any research involving her fetus or fetal tissue. Where research involves a fetus ex utero or fetal tissue, the interests of others who have parental responsibilities may also be relevant, and seeking their consent may be necessary. Processes for seeking and obtaining consent should also take into account the guidelines in Chapter 2.2 *Consent*.

4.1.7 Proposals for research other than therapeutic innovative therapy should separate the process of providing information and obtaining consent for involvement in the research from clinical care. Information sheets for research projects should be completely separate from, and able to be understood independently of, written information about routine clinical care.

Women who are pregnant

4.1.8 Research involving a woman who is pregnant may affect both the woman and the unborn child. The risks and benefits to each should be carefully considered in every case.

4.1.9 Research of therapeutic benefit to the woman may affect the fetus, and research of therapeutic benefit to the fetus does affect the woman. In both cases the research should:

(a) comply with the standards of disclosure and consent that apply to the woman as a participant; and

(b) involve a second process of disclosure and consent in relation to the effect of the research on the fetus in utero, including consideration of fetal stress, and on the child who may subsequently be born.

4.1.10 It may be ethical to conduct research on the fetus in utero if doing so is consistent with promoting the life and health of the fetus, for example, research aiming to provide the woman with information about the health of the fetus.

4.1.11 Research should be designed so as to minimise pain or distress for the fetus, and should include steps for monitoring for signs of fetal pain or distress and for suspending or ceasing the research if necessary.

4.1.12 The procedures involved in some innovative therapy including fetal surgery, transfusion of cells into the fetal vascular system, gene transfer, and fetal vaccination, should continue to be regarded as innovative treatment to which relevant paragraphs of Chapter 3.4 *Therapies and interventions, including clinical trials and non-clinical trials and innovations* apply.

4.1.13 It is ethically unacceptable to conduct non-therapeutic research that involves administering drugs or carrying out a procedure on the woman or her fetus with the intention of establishing the safety or efficacy of these for the fetus, whether in anticipation of an induced termination or otherwise.

4.1.14 A fetus or fetal tissue may become available for research as the result of induced termination. The process by which the woman is approached, informed about, and her consent sought for research on that fetus should be separate from the process by which she decides whether to terminate her pregnancy and should not begin until that decision has been made. Consenting to the research does not compromise the woman's freedom to change her decision to terminate her pregnancy.

4.1.15 Where it is contemplated that fetal tissues derived after induced termination are to be used for research, the research methods proposed, including the process of seeking the woman's consent for the research, should be designed and

conducted so as not to influence the woman's decision about when to terminate the pregnancy or the method of termination used.

4.1.16 Consideration of a woman's wishes and her physical, psychological and emotional welfare should inform a decision whether to approach her about proposed research involving her, her fetus or fetal tissue. If she is approached, those same considerations should be taken into account in the way information is provided about research on the fetus or fetal tissue, and in the process by which her consent is sought.

4.1.17 In addition to information required to be disclosed under paragraph 2.2.3 of this Statement, the woman should also be informed of:

(a) the need for consent from any other person to the proposed research (see paragraph 4.1.6);

(b) the feasibility of storing the fetus or fetal tissues before commencing research; and

(c) her freedom to withdraw her consent to the research at any time, whether before or after a termination.

Live fetus

4.1.18 A fetus delivered alive should, for all purposes including research, be treated as a child and receive the care that is due to a child, including life-sustaining treatment if the fetus is viable and the prospects for recovery warrant it.

Deceased fetus

4.1.19 Organs and tissues may be removed from a fetus delivered dead and used for research only if:

(a) consent has been given by the woman, and where relevant such others as described in 4.1.6, to the removal and the research;

(b) the fetus is available for research only as a result of separation by natural processes or by lawful means;

(c) death of the fetus has been determined by a registered medical practitioner who has no part in the research; and

(d) research procedures are performed in separate locations from those in which clinical procedures are carried out.

Separated fetal tissue

4.1.20 Those conducting research involving the use of tissue from a fetus should have no part in the management of either the woman or her fetus, nor in deciding whether death of the fetus has occurred.

4.1.21 If, for research purposes, fetal cells are to be derived from the fetal tissue and stored or propagated in tissue culture, or tissues or cells are to be transplanted into a human recipient, consent of the woman, and where practicable such others as are described in paragraph 4.1.6, is required.

4.1.22 Women whose consent is being sought for involvement of their fetus or fetal tissue in research should be given the following information in addition to that required by paragraph 2.2.3:

(a) whether there is potential for commercial application of outcomes of the research, including the development of cell lines;

(b) that they will not be entitled to a share in the profits of any commercial applications; and

(c) whether fetal organs, tissues or stem cells lines developed from them will be exported.

Chapter 4.2 Children and young people

Introduction

Research involving children is essential to advance knowledge about children's and young people's welfare. In such research, ethical considerations arise additional to those in research with only adult participants. These additional considerations include the capacity of a young person to give sufficiently informed consent, the possibility of coercion by parents, peers or researchers to participate in research, and conflicting values and interests of parents and children.

These considerations apply to all research involving children and young people but assume special prominence in educational and health research. In the latter context there are particular tensions between not placing children at risk in studies of new interventions and the need for knowledge about how they are best used for children.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research involving children and young people, the following additional matters must be considered.

Research merit and integrity

4.2.1 The research and its methods should be appropriate for children or young people.

Justice

4.2.2 Involving children and young people in research is justifiable when:

(a) it is likely to advance knowledge about the health or welfare of, or other matters relevant to, children and young people; or

(b) children's or young people's participation is indispensable to the conduct of the research.

Beneficence

4.2.3 The circumstances in which the research is conducted should provide for the physical, emotional and psychological safety of the child or young person.

Respect

4.2.4 Except in circumstances described in paragraphs 4.2.5 – 4.2.9, consent to a child's or young person's participation in research should be obtained from:

(a) the child or young person whenever he or she has the capacity to make this decision; and

(b) either

(i) one parent, except when, in the opinion of the Human Research Ethics Committee (HREC) or others reviewing research, the risks involved in a child's participation require the consent of both parents,

or where applicable,

(ii) the guardian or other primary care giver, or any organisation or person required by law.

4.2.5 An HREC may approve research to which only the child or young person consents when:

(a) the child or young person has the capacity to consent to participation in the specific project; and

(b) (i) the research involves no more than low risk, or

(ii) the child or young person is estranged or separated from his or her parents or guardian, or

(iii) it would be contrary to the best interest of the child or young person to seek consent from the parents.

4.2.6 In any of the circumstances in paragraph 4.2.5, researchers should specify how they will judge the capacity of the child to consent to participation in research, and should demonstrate that the requirements of this chapter will be satisfied.

4.2.7 The justification for a decision that a child or young person does not have the capacity to consent should always be explicitly stated, even if it is as obvious as the fact that the child is an infant.

4.2.8 Schools may arrange for standing parental consent to be given for a child's participation in research that is:

(a) for the benefit of children;

(b) not undertaken for profit; and

(c) comprises no more than overt observation in school classrooms or anonymous or coded (potentially identifiable) questionnaires or surveys on subject matters not involving sensitive personal information or personal or family relationships.

Parental consent for each specific project of this kind is not needed; notification to parents of each project is enough.

4.2.9 A child or young person should not be included as a participant in research where there is reason to believe that such participation is contrary to that child's or young person's best interest.

4.2.10 A child or young person's refusal to participate in research should be respected, except:

(a) where there is standing parental consent for research, refusal to participate should be respected only if there is reason to believe participation in the research is contrary to the child's best interest; or

(b) where in the case of very young children, the child's refusal may be over-ridden by the parents' judgement as to what is in the child's best interest.

Chapter 4.3 People in dependent or unequal relationships

Introduction

In some situations, pre-existing or continuing relationships between researchers and participants competent to make their own decisions may impair the voluntary character of consent. Those relationships typically involve unequal status, in which one party, almost always the researcher, has or had a position of influence or authority.

Examples include relationships where the researcher and potential participants are, or have been:

(a) carers and persons with chronic conditions or disabilities, including long-term hospital patients or residents in nursing homes;

(b) health care professionals and their patients or clients;

(c) teachers and their students;

(d) prison authorities and prisoners;

(e) governmental authorities and refugees;

(f) employers or supervisors and their employees (including members of the police force and Defence forces);

(g) federal, State or local government service-providers and the communities to whom the service is provided.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research involving people in dependent or unequal relationships, the following additional matters must be considered.

Research merit and integrity

4.3.1 The influence of dependent or unequal relationships on the consent process may lead to decisions or responses that participants would not otherwise have made. This does not necessarily invalidate the decision or response. However, it always constitutes a reason to pay particular attention to the process through which consent is negotiated.

Justice

4.3.2 Where the research is designed to improve understanding of dependent or unequal relationships, research proposals involving people in such relationships as participants may be approved.

4.3.3 Where the dependence or unequal nature of the relationship is incidental to the purpose of the research, researchers should make a specific case for including people in dependent or unequal relationships as participants.

Beneficence

4.3.4 Participants in dependent relationships with researchers do not necessarily act under undue influence. However, any potentially detrimental effects of these relationships on research participants should be identified and minimised. Such effects might include the researcher engaging in punitive behaviour in the non-research relationship as a result of what has happened in the research, or participants feeling unable to withdraw consent for fear that doing so will lead to hostility or withdrawal of services.

4.3.5 A person declining to participate in, or deciding to withdraw from, research should not suffer any negative consequences, such as discrimination, reduction in the level of care, or any other disadvantage.

Respect

4.3.6 The design of research involving those in dependent relationships should not compromise respect for them.

4.3.7 Where the researcher is in a pre-existing or continuing relationship with potential participants, it may be appropriate for their consent to be sought by an independent person.

4.3.8 Researchers should take special care to maintain confidentiality of all information they receive, particularly in settings where privacy may be compromised, such as shared work places, rooms in hospitals or nursing homes.

Chapter 4.4 People highly dependent on medical care

Introduction

Medical care increasingly offers interventions or treatment for people at times of serious risk to their lives. These risks may be temporary or permanent. People can become highly dependent on those interventions and treatments and are often incapable of comprehending or communicating about their situation. At the same time, research on the use of those interventions and treatments is necessary to assess and improve their efficacy.

The purpose of this chapter is to describe conditions under which researchers may seek to proceed where participants' dependence on medical care impedes their capacity to give consent. A process is described, under the heading *Respect*, through which a Human Research Ethics Committee (HREC) may authorise participation before consent is possible.

Each of the following types of research raises significant ethical concerns:

(a) emergency care research;

(b) intensive care research;

(c) neonatal intensive care research;

(d) terminal care research; and

(e) research involving unconscious people.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent*. When these values, principles and themes are applied to research involving people highly dependent on medical care, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

4.4.1 Research on the use and efficacy of medical interventions to address, arrest, alleviate or overcome severe threats to the life of humans may be approved where:

(a) it is likely that the research will lead to improvement of those interventions; and

(b) either

(i) in the particular case, the overall level of risk of the participant's present condition combined with the risk of the proposed intervention is justified by the potential benefits of the intervention to this participant,

or

(ii) where participants have capacity to consent, that overall level of risk is acceptable to participants and is justified by the potential benefits of the research.

Justice

4.4.2 People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into research might seem unfair. However, those people are entitled to participate in research; and when the conditions of paragraph 4.4.1 are met, and their participation is indispensable to the conduct of the research, their involvement is not unfair.

Beneficence

4.4.3 The distinguishing features of *neonatal intensive care research* are the small size and unique developmental vulnerability of the participants and the potential for very long-range impact on their growth, development and health. In neonatal intensive care research, risks and potential benefits should be assessed with particular care by individuals or groups with relevant expertise.

4.4.4 The distinguishing features of *terminal care research* are the short remaining life expectancy of participants and their potential vulnerability to unrealistic expectations of benefits. Terminal care research should be designed so that:

(a) the benefits of research to individual participants or groups of participants, or to others in the same circumstances, justify any discomfort or inconvenience to the participants;

(b) the prospect of benefit from research participation is not exaggerated;

(c) the needs and wishes of participants to spend time as they choose, particularly with family members, are respected; and

(d) the entitlement of those receiving palliative care to participate is recognised.

Respect

4.4.5 People involved in research to which this chapter applies may have impaired capacity for verbal or written communication. Provision should be made for them to receive information and to express their wishes in other ways.

4.4.6 In *emergency care research*, recruitment into a project usually has to be achieved rapidly, when participants and their families are likely to be vulnerable. It may not be possible to obtain consent for recruitment from the participants without so delaying the initiation of treatment that there is risk of reducing potential benefits.

4.4.7 In *intensive care research*, communicating with participants receiving ventilatory assistance is difficult and heavy sedation may impair their cognition. Whenever possible, consent to intensive care research, based on adequate information, should be sought from or on behalf of potential participants before admission to that level of treatment.

4.4.8 In *research involving unconscious people*, the participants, because of their incapacity for cognition and communication, cannot be informed about the research and their wishes cannot be determined. Those who are unconscious should be included only in minimally invasive research or in research designed both to be therapeutic for them and to improve the method of treatment for the condition from which they suffer.

Process to be followed

4.4.9 Consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them.

4.4.10 Wherever it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should be sought from the participant's guardian, or organisation or person authorised by law, before inclusion in the research. Such consent needs to be based upon receipt of all the information set out in paragraph 2.2.3.

4.4.11 When consent is to be given, either by the participant or another on his or her behalf, steps should be taken to minimise the likelihood that:

(a) stress or emotional factors impair the understanding of the research or the decision to participate; and

(b) the dependency of participants and their relatives on the medical personnel providing treatment compromises the freedom of a decision to participate.

4.4.12 Where the researcher is also the treating health professional, it may be appropriate for an independent person to obtain consent to participation from potential participants or from others on their behalf.

4.4.13 When neither the participant nor another on his or her behalf can consider the proposal and give consent, an HREC may approve a research project without prior consent provided that:

(a) the research is valid;

(b) there is a reasonable belief that were the participant or the participant's representative to be informed of the proposal, he or she would be willing to consent;

(c) the research is so designed that the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised;

(d) the project is not of a controversial nature and does not involve significant moral or cultural sensitivities in the community;

and, where the research is interventional, also provided that:

(e) the research supports a reasonable possibility of benefit over standard care;

(f) inclusion in the research project is not contrary to the interests of the participant and does not impose an unfair burden of participation on him or her;

(g) the overall level of risk of the participant's present condition combined with the risk of the proposed intervention is justified by the potential benefits of the intervention to this participant.

4.4.14 As soon as reasonably possible, the participant and/or the participant's relatives and authorised representative should be informed of the participant's inclusion in the research and of the option to withdraw from the research without any reduction in quality of care.

Chapter 4.5 People with a cognitive impairment, an intellectual disability, or a mental illness

Introduction

While the three kinds of condition discussed in this chapter are different, the participation in research of people with any of these conditions raises similar ethical issues.

People with a cognitive impairment, intellectual disability or mental illness are entitled to participate in research. While research involving these people need not be limited to their particular impairment or illness, their distinctive vulnerability as research participants should be taken into account.

The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary because of factors such as the person's medication or treatment, or discomfort or distress, and the complexity of the research project. In addition, while intellectual disability is usually permanent, cognitive impairment and mental illness are often temporary or episodic. This is a further cause of variability in the capacity to consent and to participate in research.

Even when capable of giving consent and participating, people with these conditions may be more-than-usually vulnerable to various forms of discomfort and stress.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in ethical review: risk and consent.* When these values, principles and themes are applied to research involving people with a cognitive impairment, an intellectual disability or a mental illness, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

4.5.1 The research design should take into account factors that may affect the capacity to consent to the research and the ability to participate in it. These factors may be permanent or variable.

4.5.2 Special care should be taken to determine whether participants' cognitive impairment, intellectual disability or mental illness makes them more susceptible than other participants to various forms of discomfort or distress. If

so, ways of trying to minimise the effects of this susceptibility should be described in the research proposal.

Justice

4.5.3 People with a cognitive impairment, intellectual disability or mental illness are entitled to participate in research. However, because of their distinctive vulnerability, it should be clearly established that involving people with these conditions in research is justifiable because either:

(a) it is likely to significantly advance knowledge about the health or welfare of, or other matters relevant to, people with these conditions; or

(b) the participation of people with these conditions is indispensable to the conduct of the research.

Beneficence

4.5.4 Because of the distinctive vulnerability of participants with a cognitive impairment, intellectual disability or mental illness, special care should be taken to ensure that the risks and any burden involved in the proposed research are justified by the potential benefits of the research.

4.5.5 A person with a cognitive impairment, intellectual disability or mental illness should not be included as a participant in research where there is reason to believe that such participation is contrary to that person's best interest.

Respect

4.5.6 Consent to participation in research by a person with a cognitive impairment, intellectual disability or mental illness should be sought from either:

(a) the person with the impairment, disability or illness if he or she has the capacity to consent and, where the impairment, disability or illness is temporary or episodic, at a time when the condition does not prevent the person from giving or refusing consent;

or

(b) where at the time consent is initially sought the person lacks the capacity to consent, the person's guardian, or any organisation or person required by law.

4.5.7 The process of seeking consent from a person with a cognitive impairment, intellectual disability or mental illness should include discussion of any possibility that the person's capacity to consent or to participate in the research

may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed.

4.5.8 Where consent has been given under paragraph 4.5.6(b) a researcher should, as far as possible, still explain his or her presence to the participant and explain what participation in the research involves. If at any time the participant recovers the capacity to give or withdraw consent, the researcher should offer him or her the opportunity to decide whether to remain in the research under the terms of paragraph 4.5.7, or to withdraw from the research.

4.5.9 Researchers should inform HRECs how they propose to determine the capacity of a person with a cognitive impairment, intellectual disability or mental illness to consent to the research. This information should include how the decision about the person's capacity will be made, who will make it, the criteria that will be used in making it, and the process for reviewing during the research the participant's capacity to consent and to participate in the research.

4.5.10 Refusal or reluctance to participate in a research project by a person with a cognitive impairment, intellectual disability or mental illness should be respected.

Chapter 4.6 People who may be involved in illegal activities

Introduction

In the conduct of human research, researchers may inadvertently learn of activity that may be illegal, whether of participants in the research or others. Research may also involve gathering information from participants recruited because they are or have been involved in illegal activity, or may aim to discover and expose illegal activity by identifiable individuals. The mere collection of some information may subject a researcher to a statutory obligation to disclose some or all of it while the nature of other information collected may attract legal orders that compel disclosure.

This chapter does not contain information or guidance about legal obligations of researchers arising from their conduct of such research. Further, it is not the role of a Human Research Ethics Committee (HREC) or others conducting ethical review to provide legal advice on the existence or performance of any of those obligations.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes in research: risk and consent*. When these values, principles and themes are applied to research involving illegal activities, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

4.6.1 It should be clearly established that the risks to participants of research that may involve discovery of illegal activity by them are justified by the benefits of the research. This is especially the case in research which aims to discover and expose illegal activity by identifiable people.

4.6.2 The possibility that research designed to expose unlawful conduct may have an adverse impact on those whose conduct is exposed is not a reason for regarding the research as ethically unacceptable.

Justice

4.6.3 Where research may foreseeably discover information about illegal activity by participants or others, researchers and institutions may become subject to orders

to disclose that information to courts or to law enforcement authorities. Institutions should develop policies to inform their and researchers' responses to such orders. Those policies should have regard to values and principles set out in this Statement and to scholarly values of academic freedom and inquiry.

Beneficence

4.6.4 In research that may reveal illegal activity, including research designed to do so, consideration should be given to whether the risks to those whose illegal activity may be revealed can and should be minimised by using pseudonyms, or removing links between names and data.

Respect

4.6.5 Where researchers in research that may reveal illegal activity by participants have contact with those participants in other professional roles, they should ensure that participants understand when a contact or intervention is part of research and when it is not. Researchers who have contact in other roles should ensure that contact in a research role will not compromise contact in those other roles.

4.6.6 Even when research is not intended to reveal illegal activity by participants or others, it nevertheless may foreseeably do so. In such cases researchers should, in addition to the information required by paragraph 2.2.3, provide participants with as clear an explanation as possible of:

(a) the likelihood of such revelation and of any obligation of disclosure they may incur from the revelation; and

(b) the extent to which the researcher will maintain confidentiality of information about illegal activity by participants or others, and the response the researcher will make to a legally enforceable order to disclose such information.

4.6.7 Where research is not intended to reveal illegal activity by participants or others but may foreseeably do so, researchers should take particular care that decisions to participate by those who have been or may be subject to criminal justice processes are voluntary.

Chapter 4.7 Aboriginal and Torres Strait Islander Peoples

Introduction

Research with Aboriginal and Torres Strait Islander Peoples spans many research methodologies and disciplines. It is recognised that the extent to which Aboriginal and Torres Strait Islander individuals, communities or groups are integrated as key players in the research process, varies greatly. Research proposals involving a number of Aboriginal and Torres Strait Islander Peoples as research participants should address appropriate methodological, ethical and cultural issues. Depending on the field and complexity of the research proposal there might be numerous ways that these issues are addressed. A fundamental tenet of research with Aboriginal and Torres Islander Peoples is the development of ethical relationships that respect and value cultural diversity.

Health researchers intending to involve Aboriginal and Torres Strait Islander individuals, communities or groups in proposed research must consult the NHMRC *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003) *(Values and Ethics)* for guidance on ways to develop and adapt their research methods. Human Research Ethics Committees (HRECs) are also required to apply the *Values and Ethics* guidelines as the basis for ethically assessing proposals for health research involving Aboriginal and Torres Strait Islander participation. In applying Section 1 of this Statement, researchers from other disciplines may also find the *Values and Ethics* guidelines informative.

The ethical principles outlined in the *Values and Ethics* guidelines are based on six core values identified as being important to Aboriginal and Torres Strait Islander Peoples and described as:

- Spirit and integrity[7]

  This is an overarching value that binds all others into a coherent whole. It has two components. The first is about the continuity between past, current and future generations. The second is about behaviour which maintains the coherence of Aboriginal and Torres Strait Islander values and cultures. Any behaviour that diminishes any of the following other values could not be described as having integrity.

[7] NHMRC (2003) *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, Commonwealth of Australia, Canberra, page 19.

- Reciprocity[8]

  A mutual obligation exists among members of Aboriginal and Torres Strait Islander families and communities to achieve an equitable distribution of resources, responsibility and capacity and to achieve cohesion and survival of the social order. This mutual obligation extends to the land, animals and other natural elements and features. In contemporary settings the value of reciprocity continues in various forms, and may vary between locations. Examples include the redistribution of income, benefits from the air, land and sea, and the sharing of other resources such as housing.

- Respect[9]

  Respect for human dignity and worth, as a characteristic of relationships between people, and in the way individuals behave, is fundamental to a functioning and moral society. Within Aboriginal and Torres Strait Islander cultures respect is reinforced by and in turn strengthens dignity. A respectful relationship induces trust and co-operation. Strong culture is a personal and collective framework built on respect and trust that promotes dignity and recognition.

- Equality[10]

  One of the values expressed by Aboriginal and Torres Strait Islander Peoples and cultures is the equal value of people. One of the ways this is reflected is a commitment to distributive fairness and justice. Equality affirms Aboriginal and Torres Strait Islander Peoples' right to be different.

- Survival and protection[11]

  Aboriginal and Torres Strait Islander Peoples continue to act to protect their cultures and identity from erosion by colonisation and marginalisation. A particular feature of Aboriginal and Torres Strait Islander cultures and these efforts has been the importance of a collective identity. This collective bond reflects and draws strength from the values-base of Aboriginal and Torres Strait Islander Peoples and cultures.

- Responsibility[12]

  Central to Aboriginal and Torres Strait Islander societies and cultures is the recognition of core responsibilities. These responsibilities include those to country, kinship bonds, caring for others and the maintenance of harmony and balance

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[8] ibid page 10
[9] ibid page 11
[10] ibid page 14
[11] ibid page 18
[12] ibid page 16

within and between the physical and spiritual realms. A key responsibility within this framework is to do no harm, including avoiding impacting adversely on others' abilities to comply with their responsibilities. As well, one person's responsibilities may be shared with others so that they will also be held accountable.

The message for researchers is that there is a great diversity across the many Aboriginal and Torres Strait Islander cultures and societies. Each community has the right to express how these common values and their own unique values should be addressed in research.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Chapter 1. *Values and principles of ethical conduct* and Chapter 2. *Themes of ethical review: risk and consent*. When these values, principles and themes are applied to research involving Aboriginal and Torres Strait Islander Peoples, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) advised by people who have knowledge of research with Aboriginal and Torres Strait Islander peoples and who are familiar with the culture and practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.

Research merit and integrity

4.7.1 The research methodology should provide for mechanisms for such matters as ongoing feedback, agreement about final reporting, appropriate recruitment techniques, and appropriate informed consent processes.

4.7.2 The methodology should be sensitive to the social and cultural protocols and there should be evidence of support for the research project from appropriate Aboriginal and Torres Strait Islander communities or groups involved.

4.7.3 The methodology should respect and acknowledge the cultural distinctiveness of any Aboriginal and Torres Strait Islander community or group involved.

Justice

4.7.4 The research processes should provide opportunities to develop trust and a sense of equal research partnerships.

4.7.5 The research team should recognise any potential consequences from proposed research outcomes and, if negative, provide processes to monitor and take appropriate action to ameliorate any negative impact.

Beneficence

4.7.6 The realisable benefits from the research processes, outcomes and outputs should be reasonably equally proportioned among the research stakeholders.

4.7.7 The described benefits from research should have been discussed with and agreed to by the Aboriginal or Torres Strait Islander research stakeholders.

4.7.8 The benefits should include the enhancement or establishment of capacities, opportunities or outcomes that advance the interests of Aboriginal and Torres Strait Islander Peoples.

Respect

4.7.9 The research proposal should demonstrate evidence of respectful engagement with Aboriginal and Torres Strait Islander Peoples.

4.7.10 The research processes should foster respectful, ethical research relationships that affirm the right of people to have different values, norms and aspirations.

4.7.11 The research methodology should value and create opportunities for Aboriginal and Torres Strait Islander Peoples to provide advice on processes and interpretation of the research data, drawing on their knowledge and wisdom.

Chapter 4.8 People in other countries

Introduction

When a researcher from an Australian institution proposes to conduct research in another country, additional ethical considerations may arise. In some situations, regard for the beliefs, customs and cultural heritage of participants will require recognition of values other than those of this Statement. Sometimes these values will be in tension with one or more of the ethical values of this Statement.

Sometimes the legal, regulatory or ethical review processes of another country may also demand conduct that is in tension with the ethical values of this Statement.

Institutions, Human Research Ethics Committees (HRECs) and researchers may also need to consider whether proposed research that, on its own, may meet relevant ethical standards ought nonetheless be considered against a global background.

Decisions about the design, review and conduct of human research must clearly reflect the values, principles and themes set out in Section 1. *Values and principles of ethical conduct* and Section 2. *Themes of ethical review: risk and consent*. When these values, principles and themes are applied to research involving participants in other countries, the following additional matters must be considered.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8.

Research merit and integrity

4.8.1 Researchers should inform HRECs whether there are ethics approval processes in the overseas country in which they intend to do research, and if so, whether they are mandatory or voluntary in relation to the proposed research, how they function, on what values and principles they rely, and whether they require reporting of the Australian HREC's approval.

4.8.2 While local cultural values should always be acknowledged in the design and conduct of the research, it should also be clearly established that such acknowledgement will result in participants being accorded no less respect and protection than this Statement requires.

4.8.3 Where there are no ethics approval processes in the overseas country, this Statement then provides the only applicable process for ethical approval. In this case, the HREC should take account of the available resources and means to conduct the research and avoid imposing unrealistic requirements, providing

always that research participants are accorded no less respect and protection than this Statement requires.

4.8.4 Some funding or national requirements will mean that researchers and HRECs have to conform to the ethics guidelines of local institutions or to recognised international guidelines or instruments. Research conducted under those guidelines or instruments should be approved only if participants will be accorded no less respect and protection than this Statement requires.

4.8.5 Researchers should have enough experience or access to expertise to enable them to engage with participants in ways that accord them due respect and protection.

4.8.6 When research is to be conducted overseas by a researcher who is subject to academic supervision, researchers should inform an HREC of how that supervision is to be effected so that due respect and protection will be accorded to participants.

4.8.7 When co-researchers are to be recruited in an overseas country, researchers should inform an HREC of how the capacity and expertise to conduct that part of the research assigned to the co-researchers will be established.

Justice

4.8.8 When it is proposed to conduct research in another country, the balance between burdens and benefits of the research, for the participants and in some instances the broader community, should be fair and the research should be neither opportunistic nor exploitative.

4.8.9 The assessment of the fairness of the research should take into account the opinions and expectations of participants and their communities about the effect of any limits of resources on the way the research will be conducted, on the participants' post-research welfare and on the implementation of the results of the research.

4.8.10 Proposed research that on its own may meet ethical standards might, even so, perpetuate injustice, discrimination or economic or social disadvantage. Where there is good reason for believing that a particular research project will have this effect, it should not be approved.

4.8.11 Institutions share with researchers a responsibility for finding out whether what they are planning to do in another country is lawful in that country.

Beneficence

4.8.12 Researchers need to inform HRECs about situations in which participants will be in dependent relationships with researchers, whether through previous or proposed arrangements.

4.8.13 Researchers need to know enough about the communities, and how to engage with them, to be able to assess the burdens and benefits of their research to the communities. Political and social factors that may jeopardise the safety of participants need to be taken into account. Researchers should inform HRECs about these likely burdens and benefits.

4.8.14 Whenever possible, research participants should have a local, readily accessible contact point independent of the researcher for responses, questions or complaints about the research.

4.8.15 In proposing mechanisms for monitoring research, researchers should take account of local circumstances.

4.8.16 Conducting research in other countries can expose researchers to risks of harm. Institutions and researchers should try to identify and evaluate any such risks, and also make provision for dealing with them, for instance by establishing local academic or institutional affiliations.

Respect

4.8.17 The value of respect requires having due regard for the beliefs, customs and cultural heritage of participants in other countries.

4.8.18 Local beliefs and practices regarding recruitment, consent, and remuneration to participants or contributions to communities for participating in research should be taken into account in the ethical review process. It should be clearly established that arrangements about these matters do not compromise the freedom of the participants' choice to participate.

4.8.19 Social or educational factors in the other country that may compromise the freedom or capacity of participants to choose whether to participate should be taken into account in the review process.

4.8.20 It should be clearly established that the processes to be followed in recruiting participants and through which they choose whether to be involved are respectful of their different cultural context and likely to lead to participation that is freely chosen and adequately informed.

SECTION 5 PROCESSES OF RESEARCH GOVERNANCE AND ETHICAL REVIEW

Human research encompasses a wide range of activities with an equally wide range of risks and potential benefits. In some research the apparent risk is negligible, such as research using publicly available material or epidemiological studies using only previously collected non-identifiable data. In other research the risk is widely recognised as high, such as physiological studies involving strenuous exercise activities or studies of treatments for life threatening conditions.

The Statement allows for a range of processes of ethical review of research, reflecting the difference in degree of risk involved in different kinds of research. This Section sets out this range of processes, and among them describes the operations of Human Research Ethics Committees in some detail. Equally important, but described in less detail because more fully set out in the *Australian code for the responsible conduct of research*, are the processes of research governance which must be in place if the ethical review of research is to be undertaken well.

Chapter 5.1 Institutional responsibilities

Research governance

5.1.1 Institutions have responsibilities to ensure that human research that they conduct or for which they are responsible is designed and conducted in accordance with the *Australian code for the responsible conduct of research* and is reviewed and monitored in accordance with this Statement.

5.1.2 Towards meeting these responsibilities, institutions should formulate and implement policies and procedures for:

(a) establishing that human research meets relevant scholarly or scientific standard;

(b) establishing that those conducting human research are:

(i) adequately experienced and qualified, or supervised,

(ii) informed of the need to assess risks to their own safety, and

(iii) free to withdraw from research on conscientious grounds;

(c) ethical review of research (Chapters 5.1, 5.2, 5.3);

(d) managing conflicts of interest (Chapter 5.4);

(e) monitoring research (Chapter 5.5);

(f) handling complaints (Chapter 5.6); and

(g) ensuring accountability (Chapter 5.7).

Processes for ethical review

5.1.3 Institutions must establish and implement processes of ethical review appropriate for the types of human research they conduct and in accordance with this Statement.

5.1.4 Where different processes of ethical review are to be used for different kinds of human research, those processes should be established according to the principle that the level of review of research is proportional to any risks of the kind of research.

5.1.5 Institutions must develop and publish the criteria by which the risks of research are identified and the different processes for peer and ethical review established.

Research that, according to such criteria, involves more than low risk must be reviewed by a Human Research Ethics Committee (HREC).

5.1.6 Institutions should regularly assess all their ethical review processes to ensure that those processes continue to enable the institution to meet its responsibilities under this Statement.

Research involving no more than low risk

5.1.7 Institutions may establish processes for review of research involving no more than low risk to participants in ways that meet institutional responsibilities described in this section. These processes must:

(a) have due regard to Section 1, and to Sections 3 and 4 which relate to different kinds of research and different categories of research participants;

(b) involve peer review;

(c) adequately address the research methodology and the relevant expertise of researcher or supervisor;

(d) allow for interdisciplinary or multi-disciplinary research and make provision for the different scholarly standards of different disciplines;

(e) consider whether the research provides sufficient protection of participants; and

(f) ensure that scholarly standards are not confused with ethical considerations arising from this Statement or other sources (see Introduction, *Ethical conduct and review of human research*).

5.1.8 The processes referred to in paragraph 5.1.7 may include, but need not be limited to:

(a) review or assessment at the departmental level by the head of department;

(b) review or assessment by a departmental committee of peers (with or without external or independent members);

(c) delegated review with reporting to an HREC; or

(d) ethical review by a subcommittee of an HREC.

Research that can be exempted from review

5.1.9 Research in which the only involvement of subjects is in any of the following categories may be exempted by institutions from ethical review because it involves such low levels of risk:

(a) the collection or study of existing data, documents or records, that are all publicly available;

(b) the use of existing collections of data or records that contain only non-identifiable data about human beings;

(c) the observation of public behaviour that involves no interaction with those observed, provided the information obtained is recorded in such a manner that those observed cannot be identified in any way; or

(d) research making use of standard educational practices and conducted in established educational settings, provided there is no interaction with those participating in these activities other than giving and receiving test materials.

Institutions must recognise that in allowing exempt research they are thereby determining that the research meets the requirements of this Statement and is ethically acceptable. If they are not prepared to recognise this, they must subject the research to ethical review.

Continuing oversight of review procedures

5.1.10 Where human research is ethically reviewed and approved by a process other than HREC review, institutions must ensure, as an element of good research governance, that adequate records of the decisions made using any such processes are maintained.

5.1.11 Whatever review processes are established for different kinds of human research, institutions have a responsibility to remain alert to ethical issues in any area of human research which may warrant referral to a different level of review, including referral from exemption to low level review.

5.2.12 The ethical values and principles in this Statement should be the basis on which institutions establish review processes, allocate kinds of research to them and review those allocations.

5.1.13 Institutions must monitor the processes of ethical review of research involving low risk to ensure that they continue to provide sufficient protection for participants.

5.1.14 Institutions must regularly review, and where found necessary revise, the criteria for allocation of kinds of research to the various processes of review. Where possible the review of the criteria should be informed by the documented experience of research participants or by involving participants or the wider community in this review.

Research involving more than low risk

5.1.15 Institutions that conduct human research involving more than low risk have a responsibility to arrange for the review and approval of such research by an HREC constituted and functioning in accordance with this Statement or to establish such an HREC to review and approve that research.

5.1.16 Institutions[13] that establish HRECs have a responsibility to ensure that those HRECs are established and continue to operate in conformity with this Statement.

5.1.17 Institutions which, either individually or jointly, establish HRECs should adequately resource and maintain them. Resourcing should be sufficient to make it possible for HRECs to satisfy the requirements for good ethical review, and for communicating well with researchers, that are set out in this Section.

5.1.18 An institution, when establishing an HREC, should set out its terms of reference including:

(a) the scope of its responsibilities for ethical review;

(b) its relationship to other processes of research review;

(c) its relationship to non-affiliated researchers and external organisations;

(d) its institutional accountability;

(e) its mechanisms of reporting; and

(f) remuneration, if any, for members.

5.1.19 Where an institution has established an HREC, the institution should see that mechanisms have been put in place to ensure that:

(a) members have relevant experience and/or expertise;

(b) members undertake appropriate induction, including mentoring by a current HREC member, and ongoing training;

[13] Where the context is the establishment and maintenance of an HREC, 'institutions' also includes any body or agency that establishes an HREC but does not conduct human research (see Preamble footnote 1).

(c) review of research proposals is thorough;

(d) processes and procedures of review are expeditious;

(e) decisions are transparent and consistent and promptly communicated;

(f) actual and potential conflicts of interest that may affect research are identified and managed;

(g) membership of HRECs is promulgated within institutions who submit research for review and is made public in annual reports or by other routine processes;

(h) good communication between the institution(s), the HREC and researchers is promoted;

(i) the workload of the HREC does not compromise the quality and timeliness of ethical review; and

(j) the institution can be assured that the HREC is operating in conformity with this Statement.

5.1.20 An institution is legally responsible for HREC decisions and approvals in relation to research and should indemnify its HREC members.

Composition of HRECs

5.1.21 The minimum membership of an HREC is eight members. As far as possible there should be equal numbers of men and women on the committee, and at least one third of the members should be from outside the institution for which the HREC is reviewing research. This minimum membership is:

(a) a chairperson;

(b) at least two members who are lay people, one man and one woman, who have no affiliation with the institution and are not currently involved in medical, scientific or legal work;

(c) at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse, or a social worker;

(d) at least one member who performs a pastoral care role in a community, for example, a minister of religion or an Aboriginal elder;

(e) at least one member who is a lawyer, but not a lawyer engaged to advise the institution; and

(f) at least two members with current research experience relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from a pool of further members.

No member may be appointed in more than one of the foregoing categories, but in each category alternating members may be appointed.

5.1.22 The institution should ensure that the membership of the HREC includes a member or members with experience in the application of this Statement.

5.1.23 The institution should establish procedures to ensure that the HREC has access to the expertise necessary to enable it to address the ethical considerations arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.

Appointment of members of HRECs

5.1.24 The chair should be a person with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this Statement.

5.1.25 Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.

5.1.26 Members are to be appointed as individuals for their knowledge, qualities and experience and not as representatives of any organization, community or opinion.

5.1.27 An institution that establishes an HREC should provide each member with a formal notice of appointment and an assurance of legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as HREC members.

Chapter 5.2 Responsibilities of Human Research Ethics Committees

Procedures

5.2.1 An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review, including procedures for:

(a) frequency of meetings;

(b) attendance at meetings;

(c) conduct and structure of meetings and deliberations;

(d) preparation of agendas and minutes;

(e) timely distribution of papers prior to meetings;

(f) presentation of applications for ethical review;

(g) timely consideration and review of applications;

(h) managing conflicts of interest (see paragraphs 5.4.1 – 5.4.6);

(i) communicating with researchers, including face to face, by telephone and in writing (see paragraphs 5.2.40 – 5.2.42);

(j) reporting on its activities to the institution;

(k) methods of decision making;

(l) prompt notification of decisions;

(m) record keeping;

(n) monitoring of approved research (see paragraphs 5.5.1 – 5.5.11);

(o) reporting and handling adverse occurrences;

(p) receiving and handling of complaints (see paragraphs 5.6.1 – 5.6.6);

(q) advising the institution(s) of decisions to withdraw ethical approval of a research project;

(r) accommodating observers at meetings;

(s) fees, if any, to be charged; and

(t) appropriate confidentiality of the content of applications.

Meetings

5.2.2 As far as possible each meeting of an HREC should be arranged to allow relevant members of each category the opportunity to attend and to be fully informed by prior receipt of papers.

5.2.3 Where there is less than full attendance at a meeting, the Chairperson should be satisfied, before a decision is reached, that the minimum membership listed in paragraph 5.1.21 have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.

5.2.4 An HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.

Attendance of researchers or experts

5.2.5 An HREC may invite researcher(s) to be present for discussions of their proposed research and may request amendments to the proposal.

5.2.6 An HREC may seek advice from experts to assist with consideration of a research proposal. Such experts are to be bound by the same confidentiality requirements as the HREC members. Any conflicts of interest that such experts have in relation to the research proposal under consideration should be disclosed and appropriately managed (see paragraphs 5.4.1 – 5.4.6).

Participants' interests

5.2.7 An HREC should consider whether to consult an advocate for any participant or group of participants to inform the HREC about how best to enable informed decision making and understanding by these participants.

5.2.8 Where a significant proportion of potential participants in research are unfamiliar with the language in which the research is to be conducted, an HREC should be satisfied that all information relevant to participation has been reliably translated into the participants' language. This applies whether or not the information is provided in writing.

5.2.9 An HREC should be satisfied that someone able to interpret for participants unfamiliar with the language in which the research is to be conducted, is present during discussions with them about the project.

5.2.10 HRECs should be satisfied that information relevant to participants with a vision or hearing impairment is made available to them in a way that takes their impairment in to account.

5.2.11 An HREC should consider how much of the information provided by the researcher about amounts and sources of funding, financial interests or affiliations, should be disclosed to research participants.

5.2.12 An HREC should not communicate directly with a research sponsor on matters relating to the proposal or to the ethics of a project, but the institution and the sponsor may have direct communication on administrative matters.

Making and communicating decisions

5.2.13 An HREC may approve, request amendment of, or reject a research proposal on ethical grounds.

5.2.14 An HREC should clearly communicate its decisions about a research proposal to the researcher, including its requests for amendments, providing reasons for those decisions and requests. A final decision to approve or reject a proposal should be communicated to the researcher in writing. Where the proposal is approved, approval should state explicitly that the proposal meets the requirements of this Statement. Where the proposal is rejected, reasons linked to this Statement should be provided.

Documents and records

5.2.15 All documents and other material used in recruiting potential research participants should be approved by the HREC, including information sheets, consent forms, advertisements and letters of invitation.

5.2.16 An HREC may approve, request amendment of, or reject a research proposal on ethical grounds.

5.2.17 An HREC should maintain a record of all research proposals received and reviewed including at least the:

(a) name of the institution(s) for which the research approval is being sought;

(b) project identification number(s);

(c) name of principal researcher(s);

(d) title of the project;

(e) correspondence between the HREC and the researcher relating to the review;

(f) acceptance or rejection of any changes to the proposal;

(g) proposed date of completion of the proposal;

(h) formal advice of final ethical approval or non-approval, with date;

(i) terms and conditions, if any, of approval of any proposal;

(j) duration of the approval;

(k) name of any other HREC whose opinion was considered;

(l) mechanisms to be used to monitor the conduct of the research; and

(m) relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

5.2.18 An HREC should record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to this Statement.

5.2.19 For research proposals reviewed by more than one HREC, each HREC undertaking the review should also record, as far as information available allows (see paragraph 5.3.3):

(a) details of other HREC(s) involved;

(b) the decision(s) of each other HREC; and

(c) details of any amendments required by each other HREC.

5.2.20 An HREC should retain on file a copy of each research proposal and application for HREC approval, including any information sheets, consent forms or relevant correspondence, in the form in which they are approved.

HREC member responsibilities

5.2.21 Each member of an HREC has the responsibility to decide whether, in his of her judgement, a proposal submitted to the HREC for review meets the requirements of this Statement and is ethically acceptable.

5.2.22 To fulfil the responsibility in paragraph 5.2.21, each member of an HREC should:

(a) become familiar with this Statement and where relevant other guidelines which the Statement requires to be considered in the review of a research proposal;

(b) prepare for and attend scheduled meetings of the HREC, or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies as to absences; and

(c) attend continuing education or training programs in research ethics at least every two years.

Researcher responsibilities

5.2.23 In each research proposal, researchers should show that the proposal, by meeting paragraph 1.1 of this Statement, has research merit. Researchers should also describe how the proposal reflects the ethical values of justice, beneficence and respect for humans.

5.2.24 Researchers should meet deadlines for the submission of their applications. Applications should contain clear and comprehensive information, in lay language, so that the HREC or other review body (see paragraphs 5.1.7 and 5.1.8) can decide whether the application meets the requirements of this Statement.

5.2.25 A researcher should disclose to the HREC or other review body the amount and sources or potential sources of funding for the research.

Good communication between HRECs and researchers

5.2.26 Without open communication between HRECs and researchers good ethical review is unlikely. The ethical review process should not be adversarial and needs a shared commitment to the process by researchers and HRECs. Institutions should encourage that commitment by promoting awareness of this Statement among researchers, and ready accessibility of HRECs and their staff to researchers.

5.2.27 Misunderstandings often arise when written communication alone is relied upon. From the outset HRECs should encourage informal communication from researchers, and during the review process should consider meeting face to face with researchers to resolve issues about research proposals that have not been resolved by written or telephone communication.

5.2.28 Open communication of these kinds has implications for the resourcing of HRECs (see paragraph 5.1.17).

Chapter 5.3 Minimising duplication of ethical review

Introduction

Research projects which may require multiple ethical review in Australia include:

(a) a research project conducted at more than one institution either by the same or different researchers;

(b) a research project conducted jointly by researchers affiliated with different institutions;

(c) a research project conducted at one institution by a researcher affiliated with another institution, for example, a university-based researcher conducting research at a hospital; and

(d) any other research for which more than one institution has responsibility for ethical review and approval.

This chapter applies both to HRECs and to other ethical review bodies described in paragraphs 5.1.7 and 5.1.8.

Guidelines for minimising duplication of ethical review

5.3.1 Wherever more than one institution has a responsibility to ensure that a human research project is subject to ethical review and approval, whether by an HREC or other review body, they have the further responsibility to reduce or eliminate any duplication of ethical review.

5.3.2 Institutions with responsibilities for the conduct of human research must establish and publish policies for deciding when to accept the outcome of ethical review by other review bodies established at State, regional or institutional level and functioning in compliance with this Statement.

5.3.3 Those institutional policies must:

(a) identify any circumstances local to the institution that are relevant to the ethical review of human research conducted at the institution, and provide both for their disclosure to the review body reviewing that research and for their management;

(b) require communication, and the exchange of information or advice, with any other review body;

(c) permit acceptance of a scientific/technical/methodological assessment of the research by another institution or suitably qualified body, person or persons;

(d) authorise acceptance of a review body's ethical review and approval or disapproval as meeting the institution's responsibility for ethical review of that human research;

(e) specify exceptional circumstances in which the institution may request a review body that it has established to conduct further ethical review, for example, where an institution adopts research begun and ethically approved at another institution;

(f) identify the ways the conduct of the research may be monitored and what roles the institution and the review body will have in the monitoring;

(g) identify mechanisms for informing participants of an early discontinuance of research; and

(h) adopt any other administrative procedures to avoid unnecessary duplication and promote timely ethical review and approval of human research.

5.3.4 A researcher developing or designing a research proposal involving two or more institutions should inform them at an early stage in this process. Those institutions should agree as early as possible about which review body will accept the role of reviewing the proposal.

5.3.5 Where a human research project is to be conducted by different researchers at more than one institution, those researchers should jointly determine, in the light of institutional policies, which institution(s) or suitably qualified other body or bodies should be asked to conduct the ethical and scientific/technical/methodological review of the project.

5.3.6 Researchers involved in human research to which paragraphs 5.3.1 to 5.3.5 apply, should make arrangements to ensure that:

(a) each institution with responsibility for the research is informed of all other Australian sites at which the research is being proposed or conducted, and of the name and location of the body that will conduct the ethical review of the research; and

(b) the review body is informed of any previous decisions made about the research by review bodies in overseas countries.

Chapter 5.4 Conflicts of interest

Introduction

A conflict of interest exists where a divergence between a person's individual interests and institutional role or professional obligation raises the question whether those individual interests influence the person's carrying out of that role or obligation. Similar conflicts can arise where there is a divergence between the interests of an institution and the commitment it has, for example, to doing good research.

A conflict of interest can compromise the validity of the research process by leading to judgements being made on the basis of factors external to the requirements of the research, or can compromise the institutional processes governing research. While financial conflicts of interest are foremost in the public mind, other conflicting interests can include private benefits significantly dependent on research outcomes or significant personal or professional advantage.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about the integrity of individuals or the management practices of an institution.

This chapter applies both to HRECs and to other ethical review bodies described in paragraphs 5.1.7 and 5.1.8.

Guidelines for identifying and managing conflicts of interest

5.4.1 Institutions should establish processes to identify and manage actual or potential conflicts of interest. Where a potential conflict of interest involves an institution, the institution should inform the body reviewing the research to which the conflict relates, of the sources and nature of the conflict.

5.4.2 A researcher should disclose to the review body any actual or potential sources of conflict of interest and, when proposing and reporting the research, any affiliation or financial or other interest in the research and/or its outcomes.

5.4.3 When information provided by a researcher to a review body indicates that there is likely to be a conflict of interest that may affect the ethical conduct of the research, the review body should adopt measures to manage that conflict. These measures may include requiring that the information be disclosed to research participants, that a person other than the researcher negotiate consent with participants or that the information be disclosed in any report of the research.

5.4.4 Where information provided by a researcher indicates to a review body that there may be a conflict of interest involving the institution, the review body should notify the institution.

5.4.5 A review body should require its members to disclose any actual or potential conflict of interest in any research to be reviewed, including any personal involvement or participation in the research, any financial interest in the outcome, or any involvement in competing research. The review body should adopt measures to manage such conflicts of interest. Measures may include either exclusion or absence from some or all of the committee's discussion and/or decision.

5.4.6 A review body may seek advice from experts to assist with consideration of a research proposal. A review body should require those experts to disclose any actual or potential conflicts of interest arising from any personal involvement or participation in the research, and any financial interest in the outcome or any involvement in competing research. The review body should adopt measures to manage such conflicts of interest. Measures may include requiring that expert to provide only written advice, as well as either exclusion or absence from some or all of the committee's discussion and/or decision.

Chapter 5.5 Monitoring approved research

Introduction

Monitoring approved research is the responsibility of the institution in which the research is conducted. Monitoring includes any process or mechanism put in place to check that the conduct of the research conforms to the approved proposal. It contributes to the safety of research participants and the maintenance of community confidence in human research.

Mechanisms of monitoring can include:

(a) reports from researchers;

(b) reports from independent agencies (such as a data and safety monitoring board);

(c) review of adverse event reports;

(d) random inspections of research sites, data or consent documentation; and

(e) interviews with research participants or other forms of feedback from them.

This chapter applies both to HRECs and to other ethical review bodies described in paragraphs 5.1.7 and 5.1.8.

Guidelines for monitoring approved research

5.5.1 Institutions have the ultimate responsibility for ensuring via their research governance arrangements that the conduct of all approved research is monitored.

5.5.2 The frequency and type of monitoring should reflect the degree of risk to participants in that research.

5.5.3 Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes and to take prompt steps to deal with any unexpected risks.

5.5.4 Researcher integrity, as demonstrated by the capacity to self-monitor research in progress, should be emphasised in educating researchers in research ethics.

5.5.5 Researchers are responsible for notifying the review body that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.

5.5.6 At regular periods, at least annually and at the completion of the project, researchers should provide reports to institutions, which include information on at least the following matters:

(a) progress to date, or outcome in the case of completed research;

(b) maintenance and security of records;

(c) compliance with the approved proposal; and

(d) compliance with any conditions of approval.

5.5.7 Researchers should report to the review body events that might affect continued ethical acceptability of the project, including:

(a) serious or unexpected adverse effects on participants; and

(b) proposed significant changes in the conduct, the participant profile or the risks of the proposed research.

Suspension or cessation of research

5.5.8 Researchers should inform the institution, the review body that approved the research and wherever possible research participants, if the research project is to be discontinued before the expected date of completion, and why. In the case of research at more than one site, or research where there has been multiple ethical review, it must be clearly established, before the research begins, how this information will be communicated.

5.5.9 Where an institution or a review body is satisfied that a research project cannot continue to be conducted in accordance with the approved proposal, and that as a result the welfare of participants will not be protected, ethical approval for the research should be withdrawn. The researcher, the institution and where possible the participants should be informed of this withdrawal. The researcher should promptly suspend the research and make arrangements to meet the needs of participants. The research may not be resumed unless it is modified to provide sufficient protection for participants, and the modification is ethically reviewed and the research again approved.

5.5.10 In the light of reports received under paragraph 5.5.7, review bodies may require researchers to amend research procedures to protect participants. Where they are satisfied that such amendments will not achieve that end, review bodies should notify the institution of the report.

Chapter 5.6 Handling complaints

Introduction

Institutions may expect to receive complaints relating to research from:

(a) participants or others about researchers or the conduct of research; and

(b) participants, researchers or others about the conduct of the Human Research Ethics Committee (HREC) or other review body.

Processes of ethical review of research should be transparent and accountable to the research participants they are intended to protect, and to the researchers whose applications are reviewed. Accessible, prompt and effective handling of complaints demonstrates this transparency and accountability. The conclusions of ethical review bodies as to whether applications meet the requirements of this Statement involve substantive ethical judgments on which there can be justifiable differences of opinion. For this reason, this chapter does not provide for appeals to other bodies or authorities by researchers against a final decision to reject a proposal, but deals only with complaints about other decisions or requirements made during the review process.

This chapter applies both to HRECs and to other ethical review bodies described in paragraphs 5.1.7 and 5.1.8.

Guidelines for handling complaints

5.6.1 Where complaints raise the possibility of serious research misconduct the matter should be handled in accordance with other institutional processes established to deal with these issues (see the *Australian code for the responsible conduct of research*).

5.6.2 Procedures referred to in paragraph 5.2.1(p) should include written procedures for receiving and promptly handling complaints or concerns about the conduct of an approved research project and about the review of research proposals.

5.6.3 Complaints handling procedures should provide two paths, corresponding to the two categories of complaints described in the Introduction to this chapter.

5.6.4 Institutions should:

(a) establish procedures for receiving, handling and resolving complaints from research participants and others about researchers or the conduct of research; and

(b) identify a person to receive these complaints.

5.6.5 Institutions should also:

(a) establish procedures for receiving, handling and resolving complaints from

(i) researchers about the conduct of ethical review bodies in reviewing research proposals, and

(ii) participants or others about the conduct of ethical review bodies in handling complaints; and

(b) appoint a person or persons independent of all ethical review bodies to receive, handle and resolve these complaints.

5.6.6 Institutions should identify a person or agency external to the institution to whom a person can take a complaint that has not been resolved by the institution.

5.6.7 Institutions should publicise their complaints handling procedures.

Chapter 5.7 Accountability

Introduction

Responsibility for the ethical design, review and conduct of research involving humans is exercised at all levels, from the detail of research conduct to the more general oversight of review and funding. Accordingly, responsibility is exercised at different levels by: researchers (and where relevant their supervisors); Human Research Ethics Committees (HRECs) and others conducting ethical review of research; institutions whose employees, resources or facilities are involved; funding organisations; agencies that set standards; and governments.

These responsibilities are arranged in a hierarchy from the more detailed to the more general: from researchers to institutions and HRECs or other review bodies, from those bodies and institutions to funders and other agencies, from agencies to government and from government to the Australian public.

In this Statement, accountability means the measures by which any of those involved can demonstrate that their responsibilities have been, or are being, fulfilled. Typical accountability measures involve reporting from one level of the hierarchy to another higher (or more general) level.

This chapter applies both to HRECs and to other ethical review bodies described in paragraphs 5.1.7 and 5.1.8.

Guidelines for accountability

5.7.1 Researchers have responsibilities for the ethical design and conduct of research. The measures of accountability by which researchers demonstrate, to institutions and to ethical review bodies, fulfilment of those responsibilities appear in Chapter 5.1 *Institutional responsibilities* and Chapter 5.5 *Monitoring approved research*.

5.7.2 HRECs have responsibilities for the ethical review of research. The measures of accountability by which HRECs demonstrate, to institutions, fulfilment of those responsibilities appear in Chapter 5.2 *Responsibilities of Human Research Ethics Committees.*

5.7.3 Institutions have responsibilities for the conduct of research and to ensure that ethical review of research occurs. The former responsibilities, that include ensuring that research is both sound and lawful, and is conducted by educated and experienced researchers, are set out in the *Australian code for the responsible conduct of research*. The latter responsibilities are set out in Chapter 5.1 *Institutional* r*esponsibilities*.

5.7.4 In addition to providing information annually, institutions shall provide other information about their ethical review processes to the NHMRC on reasonable request.

5.7.5 Institutions in which health and medical human research is undertaken, and which are in receipt of NHMRC research funding or intend to remain eligible for it, must be registered with the NHMRC. Registration will include information about any HREC(s) or other review bodies which the institution has decided to use, or has established, to provide ethical review of human research.

5.7.6 As provided for in the deed of agreement attached to any NHMRC funding, it will be a requirement that institutions attest annually to the NHMRC in writing that the research governance and ethical oversight processes in place remain compliant with this Statement and with the *Australian code for the responsible conduct of research*.

[From a date to be determined, such attestation must be accompanied by evidence that the research governance processes of the institution have been subjected to external review or accreditation by a relevant agency within the previous four years.]