Supplement 1:

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National Statement on Ethical Conduct in Human Research

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SECTION 1: VALUES AND PRINCIPLES OF ETHICAL CONDUCT

INTRODUCTION

The relationship between researchers and research participants is the ground on which human research is conducted. The values set out in this section – respect for human beings, research merit and integrity, justice, and beneficence – help to shape that relationship as one of trust, mutual responsibility and ethical equality. For this reason, the National Statement speaks of research 'participants' rather than 'subjects'.

While these values have a long history, they are not the only values that could inform a document of this kind. Others include altruism, contributing to societal or community goals, 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 National Statement is organised around these values, and the principles set out in paragraphs 1.1 to 1.13 give them practical expression.

Among these values, respect is central. It involves recognising that each human being has value in himself or herself, and that this value must inform all interaction between people. 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 providing for the protection of those with diminished or no autonomy, as well as empowering them where possible and protecting and helping people wherever it would be wrong not to do so.

Reference to these values throughout the National Statement serves as a constant reminder that, at all stages, human research requires ethical reflection that is informed by them. The order in which they are considered reflects the order in which ethical considerations commonly arise in human research.

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.

At a profound level, justice involves a regard for the human sameness that each person shares with every other. Human beings have a deep need to be treated in accordance with such justice, which includes distributive justice and procedural justice. In the research context, distributive justice will be expressed in the fair distribution of the benefits and burdens of research, and procedural justice in 'fair treatment' in the recruitment of participants and the review of research. While benefit to humankind is an important result of research, it also matters that benefits of research are achieved through just means, are distributed fairly, and involve no unjust burdens.

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 welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of their work.

Respect for human beings is 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.

GUIDELINES

Research merit and integrity

1.1 Research that has merit is:

(a) justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;

(b) designed or developed using methods appropriate for achieving 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, or research requiring a quick response to an unforeseen situation;

(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 that are appropriate for the research; and

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

1.2 Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.

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

(a) searching for knowledge and understanding;

(b) following recognised principles of research conduct;

(c) conducting research honestly; and

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

Justice

1.4 In research that is just:

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

(b) the process of recruiting participants is fair;

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

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

(e) there is no exploitation of participants in the conduct of research; and

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

1.5 Research outcomes should be made accessible to research participants in a way that is timely and clear.

Beneficence

1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

1.7 Researchers are responsible for:

(a) designing the research to minimise the risks of harm or discomfort to participants;

(b) clarifying for participants the potential benefits and risks of the research; and

(c) the welfare of the participants in the research context.

1.8 Where there are no likely benefits to participants, the risk to participants should be lower than would be ethically acceptable where there are such likely benefits.

1.9 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 at least modified. This decision may require consultation between researchers, participants, the relevant ethical review body, and the institution. The review body must be notified promptly of such suspension, and of any decisions following it (see paragraphs 5.5.6 to 5.5.9, page 91–92).

Respect

1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the 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.

1.11 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 should be fulfilled.

1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

1.13 Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

Application of these values and principles

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 important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making. The National Statement is intended to contribute to the development of such awareness.

This National Statement does not exhaust the ethical discussion of human research. There are, for example, many other specialised ethical guidelines and codes of practice for specific areas of research. Where these are consistent with this National Statement, they should be used to supplement it when this is necessary for the ethical review of a research proposal.

These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.

SECTION 2: THEMES IN RESEARCH ETHICS: RISK AND BENEFIT, CONSENT

Two themes must always be considered in human research: the risks and benefits of research, and participants' consent. For this reason, the two themes are brought together in this section, before discussion in the following sections of ethical considerations specific to different research methods and categories of participants.

CHAPTER 2.1: RISK AND BENEFIT

INTRODUCTION

The conduct of research in Australia is characterised by high ethical and scientific standards, and the dangers to participants have been few. The continued promotion of ethically good human research – the purpose of this National Statement – will help to maintain these standards.

Application of the values in Section 1, in particular the value of beneficence, requires that risks of harm to research participants, and to others, be assessed. Research will be ethically acceptable only if its potential benefits justify those risks.

While this chapter provides guidance on the assessment of risk, such assessment inevitably involves the exercise of judgment.

What is risk?

A risk is a potential for harm, discomfort or inconvenience (discussed below). It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur; and
- the severity of the harm, including its consequences.

Assessment of risk

Assessment of risks involves:

- identifying any risks;
- gauging their probability and severity;
- assessing the extent to which they can be minimised;
- determining whether they are justified by the potential benefits of the research; and
- determining how they can be managed.

Assessment of risks engages:

- researchers, who need to identify, gauge, minimise and manage any risks involved in their project;
- institutions, in deciding the appropriate level of ethical review for research projects;
- Human Research Ethics Committees (HRECs) and other ethical review bodies (see paragraph 5.1.7, page 78), in reviewing research proposals and making judgements on whether risks are justified by potential benefits; and
- participants' perceptions of risks and benefits. These perceptions are a factor to be considered by review bodies in deciding whether the risks are justified by the benefits.

Harm, discomfort and inconvenience

Research may lead to harms, discomforts and/or inconveniences for participants and/or others.

No list of harms can be exhaustive, but one helpful classification identifies the following kinds of potential harms in research[3]:

- physical harms: including injury, illness, pain;
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- economic harms: including the imposition of direct or indirect costs on participants;
- legal harms: including discovery and prosecution of criminal conduct.

Less serious than harm is discomfort, which can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.

Less serious again is inconvenience. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

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

Examples of risks to non-participants include the risk of distress for a participant's family member identified with a serious genetic disorder, the possible effects of a biography on family or friends, or infectious disease risks to the community. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.

Harms that may arise from research misconduct or fraud, and harms to members of research teams from other forms of misconduct (for example, harassment or bullying) are addressed primarily in the *Australian code for the responsible conduct of research*. These forms of misconduct may, of course, also lead to potential harms to participants.

Low risk and negligible risk research

The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

Requirements for the ethical review of low risk research and negligible risk research are set out in paragraphs 5.1.18 to 5.1.23, page 79.

Gauging risk

Gauging risk involves taking into account:

- the kinds of harm, discomfort or inconvenience that may occur;
- the likelihood of these occurring; and
- the severity of any harm that may occur.

These judgements should be based on the available evidence. The evidence may be quantitative or qualitative. In either case, the process needs to be transparent and defensible.

For those gauging the severity of the harm, the choices, experience, perceptions, values and vulnerabilities of different populations of participants will be relevant.

Minimising risk

In designing a research project, researchers have an obligation to minimise the risks to participants. Minimising risk involves an assessment of the research aims, their importance, and the methods by which they can be achieved.

Where a researcher or review body judges that the level of risk in a research proposal is not justified by the benefits, either the research aims or the methods by which they are to be achieved, or both, will need to be reconsidered if the research is to proceed.

Do the benefits justify the risks?

Research is ethically acceptable only when its potential benefits justify any risks involved in the research.

Benefits of research may include, for example, gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions.

Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to well people. Those ethically reviewing research should take such willingness into account in deciding whether the potential benefits of the research justify the risks involved.

For ethical review bodies, there can be a profound tension between the obligation on the one hand to give maximum scope to participants' freedom to accept risk, and on the other to see that research is conducted in a way that is beneficent and minimises harm.

Managing risks

When risks have been identified, gauged and minimised, and the research has been approved, the risks must then be managed. This requires that:

- researchers include, in their research design, mechanisms to deal adequately with any harms that occur; and
- a monitoring process is in place and carried out (see *Chapter 5.5: Monitoring approved research*, page 91–92).

The greater the risk to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

GUIDELINES

2.1.1 Institutions that choose to establish levels of ethical review other than by HREC for research that carries low or negligible risk (see paragraphs 5.1.18 to 5.1.23, page 79) should use this chapter (i.e. Chapter 2.1) to inform their identification of the level of risk.

2.1.2 Risks to research participants are ethically acceptable only if they are justified by the potential benefits of the research.

2.1.3 Steps to arriving at a judgement on the ethical acceptability of risks should include:

(a) identifying the risks, if any;

(b) assessing the likelihood and severity of the risks;

(c) identifying whom (participants and/or others) the risks may affect;

(d) establishing the means for minimising the risks;

(e) identifying the potential benefits; and

(f) identifying to whom benefits are likely to accrue.

2.1.4 In determining the existence, likelihood and severity of risks, researchers and those reviewing the research should base their assessments on the available evidence, whether qualitative or quantitative. They should consider whether to seek advice from others who have experience with the same methodology, population and research domain.

2.1.5 In considering whether the potential benefits of the research justify the risks involved, those reviewing research should take into account any willingness by participant populations to assume greater risks because of the potential benefits to them, their families, or groups to which they belong.

2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

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

2.1.8 The greater the risks to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

CHAPTER 2.2: GENERAL REQUIREMENTS FOR CONSENT

INTRODUCTION

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

What is needed to satisfy these conditions depends 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.

Variations of these conditions may be ethically justified for some research. Respect for human beings must, however, always be shown in any alternative arrangements for deciding whether potential participants are to enter the research.

It should be noted that a person's consent to participate in research may not be sufficient to justify his or her participation.

This chapter provides guidelines on the requirement for consent. *Chapter 2.3: Qualifying or waiving conditions for consent* then discusses and provides guidelines on conditions under which the requirement may be qualified or waived.

GUIDELINES

2.2.1 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. For qualifications of this principle, see *Chapter 2.3: Qualifying or waiving conditions for consent,* page 23.

2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.

2.2.3 This information must be presented in ways suitable to each participant (see paragraph 5.2.16, page 84).

2.2.4 The process of communicating information to participants and seeking their consent should not be merely a matter of 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 Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:

(a) the nature, complexity and level of risk of the research; and

(b) the participant's personal and cultural circumstances.

2.2.6 Information on the following matters should also be communicated to participants. Except where the information in specific sub-paragraphs below is also deemed necessary for a person's voluntary decision to participate,

it should be kept distinct from the information described in paragraphs 2.2.1 and 2.2.2:

(a) any alternatives to participation;

(b) how the research will be monitored;

(c) provision of services to participants adversely affected by the research;

(d) contact details of a person to receive complaints;

(e) contact details of the researchers;

(f) how privacy and confidentiality will be protected;

(g) 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;

(h) the amounts and sources of funding for the research;

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

(j) any payments to participants;

(k) the likelihood and form of dissemination of the research results, including publication;

(l) any expected benefits to the wider community;

(m) any other relevant information, including research-specific information required under other chapters of this National Statement.

2.2.7 Whether or not participants will be identified, research should be designed so that each participant's voluntary decision to participate will be clearly established.

Renegotiating consent

2.2.8 In some research, consent may need to be renegotiated or confirmed from time to time, especially where projects are complex or long-running, or participants 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 (see paragraphs 5.2.16 and 5.2.17, page 84).

Coercion and pressure

2.2.9 No person should be subject to coercion or pressure in deciding whether to participate. Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes. Here as always, a person should be included as a participant only if his or her consent is voluntary.

Reimbursing participants

2.2.10 It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.

2.2.11 Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted.

Where others need to be involved in participation decisions

2.2.12 Where a potential participant lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the person's best interests. Researchers should bear

in mind that the capacity to consent may fluctuate, and even without that capacity people may have some understanding of the research and the benefits and burdens of their participation. For implications of these factors, see *Chapter 4.2: Children and young people*, *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*, and *Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness*.

2.2.13 Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research.

Consent to future use of data and tissue in research

2.2.14 Consent may be:

(a) 'specific': limited to the specific project under consideration;

(b) 'extended': given for the use of data or tissue in future research projects that are:

(i) an extension of, or closely related to, the original project; or

(ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);

(c) 'unspecified': given for the use of data or tissue in any future research.

The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent (see paragraph 2.2.2).

2.2.15 Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank (see paragraph 3.2.9, page 31).

2.2.16 When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.

2.2.17 Subsequent reliance, in a research proposal, on existing unspecified consent should describe the terms of that unspecified consent.

2.2.18 Data or tissue additional to those covered by the original extended or unspecified consent will sometimes be needed for research. Consent for access to such additional data or tissue must be sought from potential participants unless the need for this consent is waived by an ethical review body.

Declining to consent and withdrawing consent

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

2.2.20 Participants are entitled to withdraw from the research at any stage. Before consenting to involvement in the research, participants should be informed about any consequences of such withdrawal.