PREAMBLE

ETHICAL BACKGROUND

All human interaction, including the interaction involved in human research, has ethical dimensions. However, ‘ethical conduct’ is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one’s fellow creatures. This National Statement on ‘ethical conduct in human research’ is therefore oriented to something more fundamental than ethical ‘do’s’ and ‘don’ts’ – namely, an ethos that should permeate the way those engaged in human research approach all that they do in their research.

Human research is research conducted with or about people, or their data or tissue. It has contributed enormously to human good. Much human research carries little risk and in Australia the vast majority of human research has been carried out in a safe and ethically responsible manner. But human research can involve significant risks and it is possible for things to go wrong. Sometimes risks are realised despite the best of intentions and care in planning and practice. Sometimes they are realised because of technical error or ethical insensitivity, neglect or disregard. On rare occasions the practice of research has even involved the deliberate and appalling violation of human beings – notoriously, the Second World War experiments in detention and concentration camps.

In Australia, the history of the relationship between Aboriginal and Torres Strait Islander people and communities and the conduct of research provides an important context to acknowledge harms done by poor research practices.

From the earliest periods of colonisation, views about Aboriginal and Torres Strait Islander cultures, values and social organisation were based on ill-informed perceptions entrenched in racism and colonialism, and assumptions and comparisons of Aboriginal and Torres Strait Islander worldviews to the perspectives of European colonisers. The substantial errors of judgement and the misconceptions that followed have had significant adverse impacts on Aboriginal and Torres Strait Islander people and communities ever since.

Human research can give rise to important and sometimes difficult ethical questions. Two considerations give further weight to those questions. First, research participants may enter into a relationship with researchers whom they may not know but need to trust. This trust adds to the ethical responsibility borne by those in whom it is placed. Secondly, many who contribute as participants in human research do so altruistically, for the common good, without thought of recompense for their time and effort. This underscores the importance of protecting research participants.

Since earliest times, human societies have pondered the nature of ethics and its requirements and have sought illumination on ethical questions in the writings of philosophers, novelists, poets and sages, in the teaching of religions, and in everyday individual thinking. Reflection on the ethical dimensions of medical research, in particular, has a long history, reaching back to classical Greece and beyond. Practitioners of human research in many other fields have also long reflected upon the ethical questions raised by what they do. There has, however, been increased attention to ethical reflection about human research since the Second World War. The judgment of the Nuremberg military tribunal included ten principles about permissible medical experiments, since referred to as the Nuremberg Code. Discussion of these principles led the World Medical Assembly in 1964 to adopt what came to be known as the Helsinki Declaration, revised several times since then. The various international human rights instruments that have also emerged since the Second World War emphasise the importance of protecting human beings in many spheres of community life. During this period, written ethics guidelines have also been generated in many areas of research practice as an expression of professional responsibility.

But what is the justification for research ethics guidelines as extensive as the National Statement, and for its wide-reaching practical authority?

Research often involves public interaction between people that serves a public good. There is, therefore, a public responsibility to see that these interactions are ethically acceptable to the Australian community. That responsibility is acknowledged and given effect in the wide-reaching authority of the National Statement, which sets out national standards for the ethical design, review and conduct of human research. Its content reflects the outcome of broad consultation with Australian communities who participate in, design, conduct, fund, manage and publish human research.

Research governance

The National Statement should be seen in the broader context of overall governance of research. It not only provides guidelines for researchers, Human Research Ethics Committees (HRECs) and others conducting ethics review of research, but also emphasises institutions' responsibilities for the quality, safety and ethical acceptability of research that 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 ethics review of research; institutions that set up the processes of ethics review, and whose employees, resources and facilities are involved in research; funding organisations; agencies that set standards; and governments. While the processes of ethics review are important in this field, individual researchers and the institutions within which they work hold primary responsibility for seeing that their research is ethically acceptable.

In addition to this National Statement, the *Australian code for the responsible conduct of research, 2018* has an essential role in promoting good research governance. The 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 National Statement

This National Statement has been jointly developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and Universities Australia (UA). This joint undertaking reflects a widely shared conviction that there is a need for ethics guidelines that are genuinely applicable to all human research and it gives expression to the shared responsibility for ethically good research described above.

The *National Health and Medical Research Council Act 1992* (NHMRC Act) establishes NHMRC as a statutory body and sets out its functions, powers and obligations. Section 10(1) of the Act requires the Chief Executive Officer to issue human research guidelines precisely as developed by the Australian Health Ethics Committee (AHEC) and provided to the CEO by the Council. AHEC is established by the NHMRC Act as a Principal Committee of NHMRC. All the guidelines in this National Statement that are applicable to the conduct of medical research involving humans are issued by 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.

Universities Australia (UA) is the peak body representing Australia's universities, both nationally and internationally. Its primary role is to advocate for regulatory, policy and fiscal settings conducive to a world-class university system.

PURPOSE, SCOPE AND LIMITS OF THIS DOCUMENT

The purpose of this National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that benefits the community.

The National Statement is therefore designed to clarify the responsibilities of:

- institutions and researchers for the ethical design, conduct and dissemination of outputs and outcomes of human research; and
- review bodies in the ethics review of research.

The National Statement will help them to meet their responsibilities: to identify ethical issues 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 the National Statement

The National Statement must be used to inform the design, ethics review and conduct of human research that is funded by, or takes place under the auspices of, any of the bodies that have developed the National Statement (NHMRC, ARC, UA).

In addition, the National Statement sets national standards for use by any individual, institution or organisation conducting human research. This includes human research undertaken by governments, industry, private individuals, organisations or networks of organisations.

What is research?

There is no generally agreed definition of research; however, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers. The Australian Research Council's definition of research is somewhat wider:

> Research is the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.[1]

For the purposes of the National Statement, two further questions are more important than any definition of research:

- What is human research?
- When and by what means does human research, or other activities such as quality assurance or improvement, or clinical audit, need ethical review? (See *Ethical Considerations in Quality Assurance and Evaluation Activities, NHMRC 2014*)

What is human research?

Human research is conducted with or about people, or their data or biospecimens. Human participation in research is therefore to be understood broadly to include the involvement of human beings 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 biological material as defined in Chapter 3.2;

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[1] Australian Research Council, Excellence in Research for Australia 2015, https://www.arc.gov.au/sites/default/files/minisite/static/4551/ERA2015/intro-3_define-research.html

- access to their information as part of an existing published or unpublished source or database.

The term ‘participants’ is therefore used very broadly in the National Statement to include those who may not even know they are participating in research for example, where the need for their consent for the use of their biospecimens or data has been waived by an ethics review body.

When is ethics review needed?

Institutions are responsible for establishing procedures for the ethics review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see *Chapter 2.1: Risk and benefit* and *Chapter 5.1: Governance responsibilities of institutions*). Research with a greater than low level of risk (as defined in Chapter 2.1) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.10 to 5.1.14. Institutions may also determine that some human research is exempt from ethics review (see 5.1.15 to 5.1.18).

The involvement of Australian researchers, participants (or their biospecimens or data) and/or research resources, whether in Australia or overseas, raises the question as to whether ethics approval by an Australian review body (HREC or low risk process) is required. This is because an Australian institution may have governance responsibilities arising from the involvement of their employees, affiliated personnel (e.g. contractors, students), patients, clients or the use of their funds in the research.

In these instances, the Australian researchers should notify their institution that the research will be taking place. The Australian institution/HREC must then determine whether its ethics approval is or is not needed. As outlined in Chapters 5.1 and 5.5, institutions may decide to accept an ethics approval from another country or determine that the research is of a sufficiently low risk level that ethics approval from an HREC is not required (noting that, in these circumstances, there may be a lower risk review process that it is necessary to engage with).

A judgement that a human research proposal meets the requirements of the National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released.

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. Contractual arrangements may impose obligations on research funders and institutions.

Some human research is subject to specific statutory regulation, at Commonwealth and State and Territory levels. The National Statement identifies some specific Commonwealth legislation that refers to the National Statement. The National Statement does not identify specific State and Territory laws that may be relevant to human research, such as those relating to use of information held by state or territory authorities, use of human tissues, guardianship, and illegal and unprofessional conduct. It is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant.

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

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, respect, mutual responsibility and equity. 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 *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*. These values include spirit and integrity, cultural continuity, equity, reciprocity, respect and responsibility.

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.

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 below 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.

Human beings should be treated in accordance with both distributive 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. What constitutes potential benefit and whether it justifies research may require consultation with the relevant communities.

Respect for human beings is the common thread through all the discussions of ethical values. Respect involves recognising that each human being has intrinsic worth and that this 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 protecting and helping people wherever it would be wrong not to do so, including those with diminished or no autonomy, as well as empowering them wherever possible.

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 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 (noting that 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;

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

1.2 Where high quality peer review has determined that a project has research merit, this should be factored into any subsequent scientific and ethics review of 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;

(d) disseminating, communicating and translating 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 are fair and are 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;

(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 to participants the potential benefits and risks of the research;

(c) ensuring 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 ethics review body and the institution. The review body must be notified promptly of such suspension and of any decisions following it (see paragraphs 5.5.7 to 5.5.10).

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 ethics review of a research proposal.

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