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Setting the Rules: The Development of the NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research

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Abstract

From 1986 to 1991 the Australian National Health and Medical Research Council in close consultation with Australian Indigenous organisations embarked on a process of formulating ethical guidelines for the conduct of Aboriginal and Torres Strait Islander health research. These guidelines were drafted under the direction of the National Aboriginal and Islander Health Organisation, reviewed by an NHMRC appointed Aboriginal Working Party, and eventually published – though not formally ratified – as the interim NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research, 1991. This article briefly documents this lengthy and sometimes difficult process, offering an account of the events and actions that led to the release of the 1991 interim guidelines. In doing so, the paper illustrates some of the ways in which the processes and politics of ‘Western’ health research have been debated and confronted within the context of Indigenous/non-Indigenous relations in Australia.

Introduction

In Australia, the National Health and Medical Research Council (NHMRC) has a key, statutory responsibility to oversee the ethical conduct of health and medical research, a task performed through one of its principal committees known as the Australian Health Ethics Committee (AHEC). The NHMRC’s formal attention to ethical issues is, however, comparatively recent and it was not until 1966 that the Committee published its own Statement on Human Experimentation.¹ This statement was, in succeeding years, to be developed through the addition of ‘Supplementary Notes’.²

The Statement on Human Experimentation and Supplementary Notes (as it became known after 1982) was to be quickly adopted as a benchmark set of ‘guidelines’ by existing ethics

committees operating within various institutional contexts. It was also an impetus, particularly during the 1980s and early 1990s, to the formation of new ethics committees given the fact that NHMRC funding was eventually tied to ethics committee review.³

By the mid-1980s, however, the NHMRC was made aware that within certain research contexts ethical issues or, more broadly, issues to do with the process and politics of research practice, were particularly sensitive and were not adequately covered by way of general protocols. Indigenous health research was perhaps the most sensitive of these areas and, as a consequence, separate guidelines were to be developed for Aboriginal and Torres Strait Islander health research.

This specific attention to Indigenous health, however, was by

no means simply NHMRC initiated or lead. On the contrary, the development of specific ethical guidelines for Indigenous health research has been the result of a complex and often difficult consultation and negotiation process. It has also, necessarily, been a highly political process in which the power to address and define issues of research conduct has continually shifted between different 'players' within the Indigenous health field.

This article, drawing on a larger historical study, offers a brief narrative account of the process through which the present NHMRC guidelines on the ethics of Aboriginal and Torres Strait Islander health research were developed (see Humphery, 2002). In outline, this process of guideline development began in the mid-1980s and culminated in the release in 1991 of the interim NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research, hereafter referred to as the Interim Guidelines (NHMRC, 1991).

In exploring this history it is not the intention of this article to suggest that the Interim Guidelines are the only, or indeed the best, example of such rules of research conduct. Over the past decade or so a number of both Indigenous and 'mainstream' organisations in Australia have developed ethical protocols in relation to research practice within Indigenous contexts. Unquestionably, however, the 1991 Interim Guidelines have, over the past decade, proved dominant as an aid to the deliberations of Institutional Ethics Committees throughout Australia – and not only in relation to health research. Indeed, one of the points implicit within this article is that this dominance has, in part, been due to the professional and political influence of the NHMRC and, in part, to the fact that the 1991 Interim Guidelines were developed at a time when few such written protocols existed in Australia.

Background to the Study

During the late 1990s the NHMRC undertook a full review of the Statement on Human Experimentation, and in 1999 the document was superseded by the new *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 1999). In light of this process, and a decade after their release, it was felt that the Interim Guidelines should undergo also a separate but similar review with a view to ultimately producing an updated and officially adopted set of ethical protocols.

In early 2001, AHEC approached the VicHealth Koori Health

Research and Community Development Unit (VKHR&CDU) for the purposes of involving the Unit in this review process. From its establishment in 1999, the VKHR&CDU has been involved in historical and analytical inquiry into the content, ethics and process of Indigenous health research in Australia.⁴ Given this ongoing work, it was agreed that the Unit would undertake a brief historical study of the development of the Interim Guidelines in order to document their development in ways useful to the review process. This study was undertaken between April and December 2001 and involved undertaking both documentary research and a number of detailed oral history interviews with individuals who had been closely involved in the development of the 1991 Interim Guidelines.

The Call for Guidelines: The 1986 Alice Springs Conference

In November 1986, the Araluen Arts Centre in Alice Springs acted as the main venue for a three-day 'workshop' on 'Research Priorities to Improve Aboriginal Health'. This gathering – effectively a full conference – was organised jointly by the Special Purposes Committee of the NHMRC and the Menzies Foundation.

The attendance list and final program indicates that it was a sizeable event, with more than 200 people registered and nearly 100 speakers, many of them (though certainly not a majority) Aboriginal.⁵ This list and program also indicates what a significant conference this was to be, with so many of the key people then (and still now) involved in the field of Indigenous health gathered together.

Although this conference was to lead directly to the development of ethical guidelines, its focus was, in fact, somewhat mixed with most emphasis being placed on papers relating to Aboriginal health and social 'problems', rather than on research ethics. Indeed, in the run-up to the conference the coming event was talked of as a chance to 'examine the health needs of Aborigines in Australia' and identify 'priorities for the provision of health care' (see Seminar to Discuss Aboriginal Health, 1986).

In terms of the conference outcomes, however, the history and process of health research clearly became the central theme as the program progressed. There was recognition by both Aboriginal and non-Aboriginal delegates at the conference of the exploitative history of research within

Indigenous communities and of the distrust that many Indigenous people felt towards researchers and research establishments. Tensions over this history of exploitation were to emerge in full-force in the final 'sessions' of the conference, sessions that were, in fact, to be suspended through the actions of a group of Aboriginal delegates.

There are few written sources available on the events that took place on the final day of the conference, although one newspaper report, perhaps with predictable sensationalism, ran the headline 'Aboriginal Activists Take over Conference'. According to the report this 'take over', on Friday, 28 November, 'launched into a spirited and critical attack on the "insensitivity" of "white middle-class" researchers who were "only interested in the conference as a rubber stamp to improved funding for their research projects" (Aboriginal Activists Take Over Conference, 1986). The report went on to outline how the 'formality of the conference was swept aside' in order to allow Aboriginal people to speak freely and in their own time, and for the drafting of recommendations and resolutions from the conference.

Amongst those interviewed for the study on which this article is based there was general agreement that this 'take over' was indeed just that; it was a purposeful attempt by a number of the Indigenous delegates to substantially redirect the conference proceedings and openly discuss the politics of research. However, as one Indigenous interviewee importantly stated:

It wasn't an 'attack', I think it was an opportunity to very articulately set out our point of view – what was interesting about the '86 meeting as well is that it wasn't just Aboriginal people who were pissed off, it wasn't just Aboriginal people who could see the opportunity, who had experienced the opportunity, for research to be used productively. (Humphery, 2002, p.29)

In all, and as a direct result of the actions of Indigenous delegates, the Alice Springs conference made eighty-seven recommendations, nearly half of which related to the ethics, funding and practice of research within Aboriginal health.⁶ Chief among these recommendations was the call for the development of specific ethical guidelines for health research involving Aboriginal people, and for the formation of a representative Aboriginal forum to establish these guidelines. Also embodied within the final recommendations was a strong

emphasis on issues of community control and on ensuring that research activities resulted in practical outcomes and benefits for the Indigenous communities involved. The recommendations thus highlighted the need both for Indigenous people themselves to be involved in research activities – as researchers rather than research subjects – and for the pursuit of culturally appropriate research methodologies. Emphasis was also given to the necessity of researchers providing community-based skills development and ongoing information or 'feedback' during the progress of research. Importantly, too, the recommendations stressed the need for overall Indigenous control of research development and funding.

Stating the Principles: The Camden Workshop

While only a few of these aims were to be realised, the important call for the development of guidelines would be acted upon within a year of the Alice Springs conference, not least because of the apparent consternation caused within the NHMRC over the strength of Indigenous opinion expressed during the closing sessions. As one interviewee formerly attached to the NHMRC stated:

It [the Alice Springs conference] was a big lesson to us all [in the NHMRC] and we came home thinking 'where are we going now and what are we going to do?' But, boy it gave us the idea that we weren't going to write things like guidelines quickly. We weren't going to write them ourselves, without lots of consultation (Humphery, 2002, p.31)

In August 1987, the 'National Workshop on Ethics of Research in Aboriginal Health' was convened through funding from the NHMRC. This three-day workshop effectively fulfilled the earlier call for a 'forum of Aboriginal people' to establish ethical guidelines.

The only detailed written source on this gathering is the extensive report by Shane Houston – then National Coordinator of the National Aboriginal and Islander Health Organisation – who had previously been nominated to convene the forum (Houston, 1991). His report indicates that the workshop was attended by nearly thirty Aboriginal community representatives, as well as a small number of representatives from the NHMRC's Medical Research Ethics Committee (the forerunner to AHEC) and a handful of 'observers'.

In outline, the principal goals of the workshop were to 'develop a set of ethical guidelines on research into Aboriginal health', and to 'identify the mechanisms necessary to establish a nexus between the guidelines and the funding of research into Aboriginal health'. An important additional goal, however, was the intention to identify 'mechanisms which recognise and respond to the pivotal role of Aboriginal communities in the design, execution and evaluation of research into Aboriginal health' (Houston, 1991, p.9). This latter aim related much more closely to the broader desire of many of the Indigenous representatives at the workshop to increase Indigenous communities' control over the identification of research priorities, the methodological approach of research undertaken, the 'selection' of research projects, and the allocation and on-going supervision of research funds.

Over three days, the forum thus worked through a complex range of issues connected in an immediate sense to the formulation of ethical guidelines, but in a broader one to the politics of 'cross-cultural' research and research funding itself. Significantly, it was not assumed at the 1987 workshop that ethical guidelines were any guarantee to better research practice, nor that they would bring about deeper attitudinal change on the part of non-Indigenous researchers. As such, the term 'guidelines' was dropped in favour of the phrase 'principles, standards and rules', and the formulation and enforcement of these was clearly seen as one step in a broader process of transforming research (Houston, 1991, p.11).

First and foremost, the 'principles, standards and rules' adopted at the workshop emphasised a need for consultation and negotiation by researchers that both recognised the right of Aboriginal communities to self-determination and acknowledged the key co-ordinating role of Aboriginal community-controlled organisations. The workshop thus outlined various protocols to be followed by researchers in obtaining the authority and full involvement of Aboriginal communities in devising and undertaking research. These protocols entailed negotiating not simply with particular individuals but with Aboriginal Medical Services, local community-controlled agencies and/or the national peak body of community-controlled health services (Houston, 1991, pp.11-13).

In formulating such protocols, the Camden workshop insisted that researchers should be obliged to demonstrate *actively* that

consultation and negotiation over proposed research projects had taken place. This was to be done through obtaining the written consent and support of communities, as well as through providing details of how the research directly benefited the community concerned, who was to 'own' the data collected, and how social and cultural 'imperatives' within the community were to be addressed. Moreover, the workshop resolved that this level of project scrutiny should be ongoing, rather than simply 'once-off', and that such scrutiny should be performed by local community-controlled agencies. Indeed, the workshop participants went even further by putting forward a key proposal in which funds for research projects were to be channelled through, and managed by, Aboriginal Medical Services or other community-controlled organisations as a way of 'maintaining appropriate control over the ethical behaviour of researchers' (Houston, 1991, pp.13-14).

Such proposals clearly went strictly beyond the formulation of 'on paper' ethical guidelines. They began to address the history of control of research and its funding by non-Indigenous bodies, and to activate the notion of 'guidelines' as not just a set of written procedures but as potentially facilitating concrete mechanisms for the Indigenous control and possible transformation of health research. In essence, the workshop explicitly recognised the connection between the formulation of 'principles, standards and rules', and the broader task of challenging mainstream institutional control of research funds.

In addition to consultation and negotiation, the 1987 workshop advocated the need for principles of conduct in relation to specific social, cultural and gender issues (Houston, 1991, pp.15-16). Just as importantly, the workshop drew attention to the need for appropriate and ongoing mechanisms for ensuring communication about, and consent to, the research being undertaken (Houston, 1991, pp.17-18). Finally, the 1987 workshop also directly confronted the contentious issue of ownership and publication of materials, resolving that research data should remain the property of the community being researched and that 'the community retains the right to censor research materials of a sensitive nature' (Houston, 1991, p.20).

The NHMRC Response: The Advisory Notes

By mid-1988 the NHMRC Medical Research Ethics Committee had responded to the outcomes and resolutions of the Camden workshop through the release of a document entitled *Some*

Advisory Notes on Ethical Matters in Aboriginal Research (NHMRC, 1988). Incorporating extracts from Shane Houston's report, the notes were issued not as 'official ethical guidelines' but as representing 'the views of a group of Aboriginal people' over which further consultation was to take place. Thus, couched as informal 'source material for research workers, NHMRC committees and other bodies', the 'Advisory Notes' were to be used in conjunction with the NHMRC Statement on Human Experimentation and Supplementary Notes.

The *Advisory Notes* are of value in illustrating both the relative speed with which the NHMRC responded to the 1987 workshop, and the reservations held within the organisation itself about some of the workshop recommendations. Within these notes is an openness to many of the concerns raised within the 1987 workshop, particularly around issues of consultation, socio-cultural sensitivities, communication and consent, community benefit, and the exploitation of community resources. The major identified 'sticking point' is over the ownership of data, an area that the *Advisory Notes* conceded required extensive discussion. Also identified within the *Advisory Notes* is another such 'sticking point'; that of full community control of research and its funding. Both these issues were left pending, as was discussion of the authority of community-based organisations, such as Aboriginal Medical Services or Aboriginal peak bodies, to deliberate on and control research matters.

Here, then, was really the beginning of a 'bargaining process' in which the broader intent of the 1987 workshop to wrest Aboriginal control of research from mainstream bodies was pared back. Cognisant of the challenge that some of the 1987 workshop resolutions posed to NHMRC control of health research and to Western research traditions, and of the sheer difficulty of bringing about broader institutional change, the *Advisory Notes* thus clearly sought to draw some lines in the sand as much as to identify issues for 'further discussion'.

The Final Drafting: The Interim Guidelines

At about the same time as the release of the *Advisory Notes*, the NHMRC Medical Research Ethics Committee (MREC) initiated a program of consultation to 'iron out' some of the more contentious issues involved in the development of the proposed guidelines and an NHMRC appointed Aboriginal working party was formed to develop the guidelines further. The working party members included two Aboriginal

representatives and one non-Indigenous social researcher.

By 1990, and as a result of the activities of the MREC and its working party, the *Advisory Notes* had been superseded by a working document entitled *Guidelines on Ethical Matters in Aboriginal Research*, on which comment was invited. This document went beyond the *Advisory Notes* by recommending twelve possible guidelines in relation to ethical conduct in Aboriginal health research, which covered the 'process of consultation', 'cultural issues', 'communication and consent', 'community benefit and local employment', 'ownership and publication of data', 'exploitation of community resources', and two additional areas, 'mechanisms of ongoing surveillance of research' and 'sanctions'.

Many of these recommended protocols were eventually included within the 1991 Interim Guidelines, although none word for word. The currency of the 1990 document, *Guidelines on Ethical Matters in Aboriginal Research*, was, however, short-lived. Indeed, the document was very quickly replaced by an alternative set of recommended guidelines, which greatly shortened and streamlined the draft code into the three principal areas of 'consultation', 'community involvement', and 'ownership and publication of data'. It was this tripartite version of the guidelines that was eventually released – for the most part unchanged – as the 1991 Interim Guidelines.

This rather rapid shift from a document embodying twelve 'recommendations' to one that offered a draft set of fifteen guidelines (eight of which related to the issue of ownership of data) was, in part, done in the interests of providing a clear and useable set of protocols – and one 'acceptable' to mainstream research establishments. However, it was a product also of the perhaps inevitable manner in which the already *ad hoc* process of developing the guidelines narrowed down to the input of a handful of key people and a rather truncated final move to 'rush something through', particularly in light of the years already taken over drafting the protocols.

Conclusion

In terms of a historical investigation of the development the Interim Guidelines, the 'final mechanics' of the process are of particular interest. It would appear that as the process of developing guidelines haltingly and slowly progressed, fewer and fewer individuals would be directly involved in the final steps of drafting the guidelines themselves. Thus, after almost

five years of negotiation and consultation over the development of ethical guidelines, the documentary evidence suggests that this was a process that 'ended' somewhat problematically.

This was in many respects, however, a reflection of the whole process of guideline development which, with few models of Indigenous/non-Indigenous collaboration on which to draw, was very much a process of invention. As this brief history illustrates, the current guidelines, whatever their merit, are a 'frozen moment' of a partially *ad hoc* process of guideline development, rather than an end outcome of a clearly conceived program of consultation, development, drafting, and ratification. Yet this in no way detracts from the overall importance of the guidelines themselves, nor the relevance of their current revision. On the contrary, the Interim Guidelines have proven highly significant: firstly, as a means of partially transforming research practices within the Indigenous health field in Australia; secondly, as an illustration of collaboration and co-operation between Indigenous and non-Indigenous organisations; and, thirdly, as an assertion of Indigenous authority and control within the broad realm of research.

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Notes

1. The statement was issued in response to a number of international developments, particularly the 'Declaration of Helsinki', adopted at the World Medical Assembly of 1964. For a history of the field of bioethics and of national and international developments in relation to ethical codes and ethics committees see McNeill (1993).
2. For the last published version see NHMRC, 1992.
3. For a summary of these developments see 'Historical context' in NHMRC (1999). See also Section 2 of Commonwealth Department of Health and Family Services (1996) and McNeill, 1993, pp.71-3.
4. For background to this study see Humphery (2000). See also McAullay *et al.* (2002).
5. See 'Workshop: Research Priorities to Improve Aboriginal Health 26-28 November 1986, Final Program' and 'Complete List of Registrations at 12 November 1986'. The only 'conference report' available is a newsletter (Menziess School of Health Research, 1987) which reports that approximately 300 people eventually attended the conference. I am most grateful to Dr Maggie Brady for supplying me with these documents.

6. A copy of the recommendations is included in the Interim Guidelines (NHMRC, 1991)

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