

*DISCUSSION PAPER No. 14*  
**ETHICAL ASSESSMENT OF  
INDIGENOUS HEALTH  
RESEARCH:  
A REVIEW OF THE  
LITERATURE**

*Terry Dunbar and Margaret Scrimgeour*

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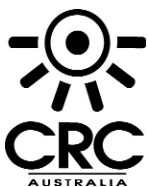
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*Onemda* VicHealth Koori Health Unit

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*Onemda* VicHealth Koori Health Unit  
Centre for Health and Society  
4/207 Bouverie Street  
The University of Melbourne  
Vic. 3010 AUSTRALIA

T: +61 3 8344 0813

F: +61 3 8344 0824

E: [koori@chs.unimelb.edu.au](mailto:koori@chs.unimelb.edu.au)

W: [www.chs.unimelb.edu.au/koori/](http://www.chs.unimelb.edu.au/koori/)

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\* Terry Dunbar is an Indigenous senior researcher in the Faculty of Education, Health and Science at the Charles Darwin University, a member of the NHMRC, Australian Health Ethics Committee and a PhD candidate in the field of public health and ethics.

\*\* Margaret Scrimgeour is a postdoctoral research associate at the Charles Darwin University with a background in Indigenous education, research methodology and research ethics.

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## **Abbreviations**

AHEC	Australian Health Ethics Committee
ARC	Australian Research Council
ATSIC	Aboriginal and Torres Strait Islander Commission
CRCAH	Cooperative Research Centre for Aboriginal Health
CRCATH	Cooperative Research Centre for Aboriginal and Tropical Health
HoRSC	House of Representatives Standing Committee on Family and Community Affairs
HREC	Human Research Ethics Committee
IEC	Institutional Ethics Committee
IPCB	Indigenous Peoples Council on Biocolonialism
IPR	Intellectual Property Rights
IRB	Institutional Review Board
MCR	Multi-Centre Review
NHMRC	National Health and Medical Research Council
RBR	Rights to the Benefits of Research
REC	Research Ethics Committee

# *Onemda* VicHealth Koori Health Unit: Discussion Paper Series

The *Onemda* VicHealth Koori Health Unit (formerly VicHealth Koori Health Research and Community Development Unit), launched in June 1999, has been developed in partnership with Aboriginal communities and organisations, in particular the Victorian Aboriginal Community Controlled Health Organisation. Core funding is provided by the Victorian Health Promotion Foundation, the University of Melbourne through the Centre for Health and Society where the Unit is located, and the Commonwealth Department of Health and Ageing.

At the core of the Unit's work is a commitment to undertaking, collaborating in and supporting research that directly benefits the Koori community. The work of the Unit spans academic and applied research, community development, and medical education. The combination of these activities is a central and innovative aspect of the Unit's function, as is the identification and use of mechanisms to link research with the improvement of health care practices and policy reform. Overall, these tasks are guided both by a Strategic Oversight Committee.

In relation to the research program, five key areas govern the inquiry undertaken within the Unit. These comprise: historical research into Koori health policy and practice; historical and contemporary research into health research practice, ethics and capacity building; applied research on the social and cultural experience of Koori health, well-being and health care delivery; health economics research on the factors and processes that impact on the provision and use of Koori health care; and the evaluation of Koori primary health care and related health promotion programs.

The Discussion Paper Series (DPS) is directly linked to this diverse program of research and provides a forum for the Unit's work. The DPS also includes papers by researchers working outside the Unit or in collaboration with Unit staff. Individual papers aim to summarise current work and debate on key issues in Indigenous health, discuss aspects of Indigenous health research practice and process, or review interim findings of larger research projects. It is assumed that the readership for the series is a broad one, and each paper is closely edited for clarity and accessibility. Additionally, draft papers are 'refereed' so as to ensure a high standard of content.

More information on the series, on the preparation of draft papers, and on the work of the Unit can be obtained by directly contacting the Unit. Copies of all discussion papers are available from the Unit, or can be downloaded as pdfs from the *Onemda* website.

## Discussion Paper Titles

Discussion Paper No. 1: Ian Anderson, Harriet Young, Milica Markovic & Lenore Manderson, *Aboriginal Primary Health Care in Victoria: Issues for Policy and Regional Planning* (December 2000).

Discussion Paper No. 2: Kim Humphery, *Indigenous Health and 'Western Research'* (December 2000).

Discussion Paper No. 3: David Thomas, *The Beginnings of Aboriginal Health Research in Australia* (September 2001).

Discussion Paper No. 4: Michael Otim, *Indigenous Health Economics and Policy Research* (November 2001).

Discussion Paper No. 5: Daniel McAullay, Robert Griew & Ian Anderson, *The Ethics of Aboriginal Health Research: An Annotated Bibliography* (January 2002).

Discussion Paper No. 6: Ian Anderson, *National Strategy in Aboriginal and Torres Strait Islander Health: A Framework for Health Gain?* (March 2002).

Discussion Paper No. 7: Anke van der Sterren & Ian Anderson, *Building Responses to Blood-Borne Virus Infection among Kooris Using Injecting Drugs—Improving the Link between Policy and Service Delivery* (December 2002).

Discussion Paper No. 8: Kim Humphery, *The Development of the National Health and Medical Research Council Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research: A Brief Documentary and Oral History* (December 2002).

Discussion Paper No. 9: Michael Otim, Ian Anderson & Russell Renhard, *Aboriginal and Torres Strait Islander Hospital Accreditation Project: A Literature Review* (November 2002).

Discussion Paper No. 10: Nili Kaplan-Myrth, *Political Visions: Blindness Prevention Policy as a Case Study of Community–Government Relations in Aboriginal Health* (June 2004).

Discussion Paper No. 11: Gregory Phillips & the Project Steering Committee, *Committee of Deans of Australian Medical Schools, CDAMS Indigenous Health Curriculum Development Project: National Audit and Consultations Report* (August 2004).

Discussion Paper No. 12: Ian Anderson, Wendy Brabham, Bill Genat, Helen Keleher, Janice Jessen, Di Fitzgerald & Bernie Marshall, *National Indigenous Public Health Curriculum Audit and Workshop: Project Report* (October 2004).

Discussion Paper No. 13: Katrina Alford, *Comparing Australian with Canadian and New Zealand Primary Care Health Systems in Relation to Indigenous Populations: Literature Review and Analysis* (June 2005).

Onemda VicHealth Koori Health Unit

Centre for Health and Society, Level 4 / 207 Bouverie Street

The University of Melbourne, Vic. 3010 AUSTRALIA

T: +61 3 8344 0813

F: +61 3 8344 0824

E: koori@chs.unimelb.edu.au

W: www.chs.unimelb.edu.au/koori/

# 1. Background

The purpose of this review is to consider issues impacting on the ethical assessment of Indigenous health research in Australia. The review will situate commentary on the ethical review of Indigenous health research in Australia within the context of broader commentaries on systems for ethical review of mainstream health and Indigenous health research in Australia and internationally. A focus will be the identification of unresolved issues associated with processes for ethical review and ‘best practice’ principles for committee-based ethical assessment of Indigenous health research. The review will draw on Australian and International literature in the fields of public health, medical and social science research ethics and research methodologies, Indigenous research ethics and research methodologies.

Search keywords used in locating material include ‘Aboriginal’, ‘Torres Strait Islander’, ‘research’, ‘ethics’, ‘Indigenous’, ‘minority research’, ‘Indigenous research protocols’, ‘cross-cultural research’, ‘Human Research Ethics Committees’, ‘Indigenous Research Ethics Sub-committees’ and ‘Indigenous research ethics’.

Databases searched for this review include Expanded Academic Search Elite, PubMed, Medline, Healthinfonet, Academic Search Premier and the World Wide Web.

In addition to database searches, the ‘grey’ literature (or literature not formally published) was investigated and references from relevant reviews of the literature, annotated bibliographies, reports and journal articles were analysed.

The review initially overviews the development of Indigenous health research guidelines in Australia. Contemporary issues impacting on the ethical assessment of Indigenous health research in Australia are then considered with reference to developments in other countries. A ‘Key Findings’ section summarises the main review findings and unresolved issues are then presented as a series of questions. Following this, some ‘best-practice’ interventions to support the ethical assessment of Indigenous health research are outlined.

The development of a framework for the ethical assessment of Indigenous health research has been the subject of significant commentary in the Australian literature. The following key documents have provided the foundation for identification of key issues within this current review.

Anderson, I., Griew, R. & McAullay, D. 2003, ‘Ethics Guidelines, Health Research and Indigenous Australians’, *New Zealand Bioethics Journal*, vol. 4, no. 1, February, pp. 20–7.

Henry, J., Dunbar, T., Arnott, A., Scrimgeour, M. & Murakami-Gold, L. 2004, *Indigenous Research Reform Agenda—A Review of the Literature*, Links Monograph 5, Cooperative Research Centre for Aboriginal Health, Darwin.

Humphery, K. 2003, 'The Development of the National Health and Medical Research Council Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research: A brief documentary and oral history', *Discussion Paper No. 8*, VicHealth Koori Health Research & Community Development Unit, Melbourne.

Humphery, K. 2000, 'Indigenous Health and Western Research', *Discussion Paper No. 2*, VicHealth Koori Health Research & Community Development Unit, Melbourne.

Humphery, K. 2001, 'Dirty Questions: Indigenous health and Western research', *Australian and New Zealand Journal of Public Health*, vol. 25, no. 3, pp. 197–202.

McAullay, D., Griew, R. & Anderson, I. 2002, 'The Ethics of Aboriginal Health Research: An annotated bibliography', *Discussion Paper No. 5*, VicHealth Koori Health Research & Community Development Unit, Melbourne.



## 2. Introduction

The Australian Health Research Ethics Committee (HREC) system currently operates in a rapidly changing research and policy environment. A rise in the application of multi-disciplinary approaches to health research, advocacy for increasing levels of community input into the ethical assessment process, the increasing volume of research activity (including Indigenous health research) and a tendency toward increasing specialisation of research (particularly in the area of bio-medical and genetic research) has important implications for a system historically guided by a bio-medical approach to the application of ethical research principles. According to some commentators, these pressures are threatening the viability of the HREC system which, they argue, is currently struggling to effectively mediate the interests of those with a stake in the research process, namely the Institutional Ethics Committee (IEC) which reviews proposals, the institution which supports the research, the funding body which requires approval and the potential researchers and participants of research (Albury *et al.* 1996).

Evidence suggests that National Health and Medical Research Council (NHMRC) registered HRECs are responsible for evaluating a significant proportion of Indigenous health research proposals in Australia (CRCATH 2002). It is, however, recognised that ethics committees operating outside this system also evaluate proposals for Indigenous health and mainstream health research (Henry *et al.* 2004, Albury *et al.* 1996). Processes adopted by this second group of committees, including the extent of adherence to national guidelines and processes for inclusion of Indigenous peoples in the ethical assessment of research, are not well documented in the literature: a situation resulting in the exclusion of potentially important perspectives from analysis.

Since 1985, it has been a statutory requirement in Australia that institutions must ensure HREC adherence to NHMRC guidelines for research involving human subjects in order to receive NHMRC funding. The NHMRC *National Statement on the Ethical Conduct of Research Involving Humans and Supplementary Notes* (1999a) (hereafter, the *National Statement*) represents the overarching guide to the conduct of research involving human subjects. Gillam (2000:1) noted that while the *National Statement* is issued by the NHMRC, it is 'endorsed by other academic and research bodies, whose ambit extends far beyond medical research'.

The introduction in 2003 by the NHMRC of new guidelines for the ethical assessment of Indigenous health research in Australia is significant to an appraisal of currently adopted processes for ethical consideration of Indigenous health research proposals. During the 2000–03 triennium, the NHMRC, through its Australian Health Ethics Committee

(AHEC), undertook a revision of the 1991 *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research* (hereafter, the *Interim Guidelines*). This revision resulted in the development of *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003a) (hereafter, the *Values and Ethics Guidelines*). These ethical guidelines were endorsed by the NHMRC in June 2003 and are intended for application in conjunction with the NHMRC *National Statement*. The *Human Research Ethics Handbook* (NHMRC 2001) also contains a commentary paper that provides additional guidance to HRECs in the assessment of Indigenous health research proposals. An addition to the handbook is currently under development, and will provide further practical measures to inform application by HREC members and researchers of the values outlined in the *Values and Ethics Guidelines* (NHMRC 2003a:24).

The effectiveness of the *Values and Ethics Guidelines* as a tool to assist HREC deliberations over proposals for Indigenous health research has not been formally evaluated. Commentaries about the guidelines that are emerging in the literature, however, provide important insights into the changing Indigenous health research and policy environment in Australia and the potential these changes have for influencing HREC procedures for deliberating over Indigenous health research proposals.

Over the past decade in Australia, and before that in New Zealand, the USA and Canada, there has been growing Indigenous community support for reconceptualising the research process. This has involved a retreat from supporting research activity dominated by non-Indigenous ‘experts’, to research framed as a partnership involving high levels of collaboration between Indigenous community members and academic researchers at all stages of the research process (Tuhiwai Smith 1999; Denzin 2003; Humphery 2001). This movement for reform, commonly referred to in Australia as the Indigenous Research Reform Agenda (Henry *et al.* 2002a), has important implications for the way future Indigenous health research will be prioritised, funded, ethically assessed, conducted and monitored. The extent to which this reform agenda is impacting on the practice of key research stakeholders remains unclear. Current commentary, however, indicates that adjustments to existing processes for the ethical assessment and subsequent monitoring of Indigenous health research will be necessary if the broad-based agenda for the reform of Indigenous research activity in Australia is to be realised (Humphery 2001; Henry *et al.* 2002b).

### **3. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research**

The following section will outline three main themes emerging from recent commentaries on the *Values and Ethics Guidelines*, including consideration of the guidelines as an agent of change in the field of Indigenous health research; concerns about the practical application of the guidelines as a tool for the ethical assessment of Indigenous health research; and the tension between the intended application of the guidelines and the capacity of the current ethical governance system to effectively mediate the interests of Indigenous stakeholders in the construction of research. The change from a 'protective' to a 'participatory' focus represented in the framing of the *Values and Ethics Guidelines* was identified as an issue of special concern in the recent literature and will be considered in detail later in this review (Section 5: Comparison of 'Participatory' and 'Protective' Approaches to the Development of Ethical Research Guidelines).

The ethical principles outlined in the *Values and Ethics Guidelines* are based on six core values identified as being relevant to the development of appropriate Aboriginal and Torres Strait Islander health research. These principles include reciprocity, respect, equality, responsibility, survival and protection, and spirit and integrity (NHMRC 2003a). The background section of the guidelines articulates the reasoning behind the choice of these fundamental principles as the basis for ethical assessment. Each of the six core values are then discussed within the context of Aboriginal and Torres Strait Islander culture and each nominated value is supported by a series of 'Points to Consider'. It is intended that these points will provide a reference for researchers and HREC members when framing and ethically assessing research. The document also includes a list of related prescriptions for the ethical assessment of research that are drawn from the NHMRC *National Statement*.

The *Values and Ethics Guidelines* mark a significant shift in approach to guideline development and application in the Indigenous research field in Australia (Gillam & Pyett 2003). Unlike its precursor, the NHMRC 1991 *Interim Guidelines*, the overarching NHMRC *National Statement* and other institutional Indigenous research guidelines and protocols, the framework adopted in the *Values and Ethics Guidelines* articulates core Indigenous values but is less prescriptive about 'process'. The current National Statement provides the broader prescription of core ethical processes, while the *Human Research Ethics Handbook* (NHMRC 2001) is intended to provide the 'how' to the application of the *Values and Ethics Guidelines*.

A rationale for the adoption of an approach to guideline development that is underpinned by the articulation of core Indigenous values is provided by the principal authors of the *Values and Ethics Guidelines*:

It is our contention that specific guidelines on key issues are limited to the extent to which they can anticipate all possible research contexts. In order to address this problem, and guide researchers, guidelines should also explicitly outline the values, from an Aboriginal and Torres Strait Islander perspective that are foundational to an ethical research process. (Anderson, Griew & McAullay 2003:20)

A similar position is held by the American Indian Law Center (1999) in relation to the application of guiding principles for research involving First Nations tribes. The American Indian Law Center provides an overarching set of guiding principles (Model Tribal Research Code) for ethical assessment of research, which include a 'Checklist for Indian Health Boards: Support or approval of research proposals'. In the preamble to the checklist, the American Indian Law Center suggests that:

These materials are intended to help Indian tribes provide both a framework within which the tribes' expectations will be clearly articulated to would-be researchers, governments and other funding agencies, and a clear process for compliance. (1999:6)

Humphery (2001) criticised previous approaches to the ethical assessment of Indigenous health research that were reliant on the 'procedural observance of rules'. He suggested that an over-emphasis on the nature of guidelines for the ethical assessment of research may have the effect of masking other more pressing issues that pose potential barriers to more broad-based reform of Indigenous health research practice. According to Humphery,

over emphasis on guidelines tends to encourage the procedural observance of rules rather than a more dynamic movement towards fully reconceptualising research practice. (2001:200)

The shift away from detailing specific processes for governing Aboriginal and Torres Strait Islander health research to the development of an overarching ethics and values framework to complement the *National Statement* may partly satisfy Humphery's call for a broad-based move to 'reconceptualise' Indigenous health research practice. According to Gillam and Pyett, the differences in format and content between the 1991 *Interim Guidelines* and the *Values and Ethics Guidelines* are not incidental:

Rather, the changes in the new document represent a fundamental shift in philosophy. In the 'Background' section, the Working Party focuses on the notion of an ethical relationship as the foundation for ethical research. Further, it argues that the construction of ethical relationships between Aboriginal and Torres Strait Islander peoples and the research community 'must take into account the principles and values of Aboriginal and Torres Strait Islander cultures'. This is the reason that the new draft guidelines are cast around Aboriginal and Torres Strait Islander values. (2003:11)

McAullay, Griew and Anderson (2002) anticipated that effective uptake of the *Values and Ethics Guidelines* would depend on some key factors. They suggested that AHEC-sponsored ethics committees would require training in order to give proper consideration to the issues raised in the document and that a realignment of NHMRC funding to support the uptake of these guidelines would be necessary. In addition, the authors suggested that mechanisms to support compliance with the new guidelines required further development.

McKendrick and Bennett (2003) were critical of the *Values and Ethics Guidelines* on the grounds that the document would not result in radical changes to the way research is conducted with Aboriginal and Torres Strait Islander communities. They also argued that the guidelines avoid the questions of ‘who should initiate research in Aboriginal and Torres Strait Islander communities?’ and ‘who should have overall control of the research and who owns the research findings?’ (2003:22).

Gillam and Pyett (2003) speculated that HRECs might encounter difficulties if they applied the *Values and Ethics Guidelines* as a direct basis for deliberations over proposals for Indigenous health research. They nominated specific interventions that might make best use of the document in the current climate of ‘high workload and under-resourcing of HRECs’ and recommended the development of (a) three specially targeted documents from the original framework document to meet the particular needs of HRECs, Indigenous people and researchers, and (b) a system of Indigenous ethics advisers to implement the central ideas of the new draft guidelines, without falling into the legalism and rule-following that these guidelines explicitly aim to avoid.

Cunningham suggested that the *Values and Ethics Guidelines* contain ‘well-meant, mixed messages’ (2003:30) and expressed concern that the distinction in the *Values and Ethics Guidelines* between ‘ethical review’ and ‘review of responsiveness’ is unclear. He nominated these dual processes as ‘separate yet inter-related’ (2003:26) and described them in terms of (a) the assessment of research proposals, and (b) opportunities for researchers to respond to the issues raised (2003:26). Cunningham proposed the New Zealand approach to reconciling these dual processes as a possible model for future application in Australia (detailed in Section 7 of this review, Ethical Governance of Indigenous Health Research: Structures and Processes).

Analysis of the literature in the preceding section is complicated by an apparent lack of agreement between commentators about the purpose of ethical research guidelines and a tendency to conflate structural issues (for example, institutional arrangements for representation of community interests) with process issues (for example, application of research guidelines as tools for ethical assessment). For this reason, following sections of this review will separately consider the role of guidelines in the ethical review of research and compare ‘participatory’ and ‘protective’ approaches to guideline development. Consideration will also be given to the literature detailing common applications of governance terminology within the Indigenous sector in Australia. Structural and process aspects of ethical governance in the research domain will also be separately discussed.

## **Summary**

The *Values and Ethics Guidelines* document marks a significant shift in approach to research guideline development in the Indigenous research field in Australia. The document articulates core Indigenous values and has an explicit ‘participatory’ orientation. Some commentators have expressed concern that the guidelines will not adequately ‘protect’ Indigenous interests and that negative outcomes will result from their application. This position is countered by the argument that guidelines which are ‘rules-based’ cannot

anticipate all possible research contexts and so the research community can be more effectively instructed by guidelines which detail key Aboriginal and Torres Strait Islander values (Anderson, Griew & McAullay 2003).

## 4. The Role of Guidelines in the Ethical Review of Research

The literature indicates generalised concern about the effectiveness of an approach to the ethical assessment of research that is based primarily on the application of externally developed guidelines. Identified concerns include the static nature of guidelines, difficulties in interpreting guidelines, lack of uniformity in the application of guidelines, the prescriptive nature of guidelines, the difficulties in adapting guidelines to local conditions, researcher resistance, and the inadequacy of processes for monitoring both researcher and institutional adherence to existing research guidelines.

The static nature of guidelines emerges as a general issue of concern across the research spectrum. In a commentary on the NHMRC *Values and Ethics Guidelines*, Sporle (2003) noted that research guidelines in general, and guidelines for Indigenous health research in Australia and New Zealand Maori health research in particular, are infrequently reviewed and updated. He nominated this as a problem because

guidelines that seek to specify and/or prescribe specific health research practices can become rapidly out of date, overtaken by the evolution of novel and or sustained research relationships between communities and researchers. (2003:29)

Bouma and Diemer (1996) identified the problem of developing research guidelines suitable for application across traditionally recognised disciplinary boundaries. In particular, the authors pointed to the impossibility of devising a small set of easily followed rules, categories and exclusions to guide research in the social sciences and the humanities, at a time when these fields are expanding in scope. This problem is especially relevant to the development of research guidelines for application in the field of public health research where the trend in Australia and other countries has been toward the adoption of multi-disciplinary and multi-method research approaches (Baum 1998).

The combined application of bio-medical and social science research methodologies is an identified problem for those charged with responsibility for the ethical assessment of proposals for research (Kaufert & Lavoie 2003; Bouma 2001). Bouma (2001) argued that HRECs in Australia take inadequate account of the diversity of potential outcomes deriving from a range of methodological approaches adopted within the social sciences and the humanities. He suggested that the social sciences and humanities have their own research cultures and that: 'These differences are reflected in the fact that the HSSs [Humanities and Social Sciences] conduct research using a wider range of methodologies—quantitative, qualitative, action and evaluation' (2001:1). According to Bouma, this apparent difference in research culture leads many in the field of social science and the humanities to resist the application of ethical insight drawn from the bio-medical sciences.

Bouma noted that some members of HRECs have been reported as declaring, 'If it is not quantitative and experimental, it is not research' (2001:1).

Interpreting official guidelines has been nominated as a problem for some Australian HREC members. In a report of a workshop set up to investigate issues of concern to IECs, Albury *et al.* (1996) noted that committee members expressed concern about the ambiguity of ethical guidelines available to IECs. Workshop participants suggested that:

The framework proposed by the NHMRC is inadequate particularly for the many IECs being called on to assess social and behavioural research which frequently requires a quite different approach to assessment of medical research involving drug trials and new medical treatments. (Albury *et al.* 1996:14)

Albury *et al.* reported a range of HREC experiences with research ethics guidelines and noted diverse approaches to approval processes within and between IECs. According to their findings, some committees applied *ad hoc* mechanisms for decision-making, while others demonstrated well-developed internal review processes. Albury *et al.* also suggested that the imposition of guidelines by an external body (such as the NHMRC) is problematic because IECs do not have ownership of the benchmarks and policies these guidelines might contain (1996:16). On this basis, the authors supported the call for increased levels of local input into guideline development and proposed that:

The local re-evaluation of guidelines would also contribute to the sense of transparency of committee operation that many workshop participants hoped for. While external guidelines such as those developed by the NHMRC and AHEC may provide a useful starting point, they need to be supplemented by the development of more detailed internal guidelines by each IEC suited to local research needs. (Albury *et al.* 1996:17)

According to Albury *et al.*, the application of uniform ethical principles or guidelines should ideally be supplemented by internally developed committee guidelines that become 'local expressions' of those principles (1996:17). The authors, however, recognised that resolving the tension between procedures that are applicable at local levels as well as sharing broadly uniform procedures with other IECs is a difficult undertaking. Models for internal committee processes of this nature have been developed in the USA by the American Indian Law Center (1999) and by the World Health Organization (WHO 2004). These models include templates for Indigenous research ethics guidelines, locally negotiated research agreements and research checklists to be used as a guide by representative Indigenous bodies. These initiatives represent concrete examples of interventions designed specifically to ensure that the local values and priorities of Indigenous communities influence processes for the ethical evaluation, monitoring and conduct of research.

While supporting the incorporation of 'local expressions' of guiding principles for research, Sporle (2003) pointed to the practical difficulty of consulting nationally with different communities represented by diverse experiences and needs. He suggested that institutionally developed guidelines could prescribe clear expectations of processes and collaborative structures that research institutions implement in working with Indigenous peoples. The role of national guidelines in this model would be to inform the development



of institutional processes without specifying the detail, which Sporle argues should be ‘worked out locally in collaboration and cooperation with local people’ (2003:30). Sporle concluded by suggesting that:

The national funding body would then accredit institutional processes that would inform and monitor individual research projects—much as institutional research ethics committees do now. In this way national policies could remain informed by consultation, but research practice involving indigenous peoples would be informed by a local indigenous voice operating at a local level. (2003:30)

According to some commentators, health research guidelines have historically privileged Western researcher interests over Indigenous community interests (Dodson 2000; McKendrick & Bennett 2003; Johnstone 1991; Scrimgeour 1993). In a commentary on the NHMRC *Statement on Human Experimentation and Supplementary Notes* (1992:vii), Johnstone (1991) argued that although the statement appeared committed to protecting the interests of research participants it is the researcher who ultimately retains the power and the recognised authority.

Proposals for redressing the identified power imbalance between non-Indigenous and Indigenous participants in research activity include the adoption of processes to facilitate the interpretation of national guidelines by Indigenous peoples at either the level of local communities (Eades, Read & Bibbulung Gnarneep team 1999; Henderson *et al.* 2002) or at the State or regional level (Johnstone 1991). Eades, Read & Bibbulung Gnarneep team (1999:433) reported that, in their experience, the 1991 *Interim Guidelines* were useful as a broad guide to the negotiation of ethical issues, but that the guidelines required specific application in the unique circumstances of each Indigenous community. Johnstone’s proposal called for the development of guidelines for Aboriginal health and related research that did not merely follow or adopt a modified version of mainstream research ethics guidelines. According to Johnstone:

This would help to provide a mechanism for rejecting or denying approval of any research proposal which does not comply with Aboriginal values as expressed through Guidelines developed from an Aboriginal cultural perspective. (1991:11)

As a way of dealing with what Johnstone refers to as ‘loose’ Aboriginal health research guidelines, she argued that it was important for Aboriginal people to

identify and clearly state what their primary ethical values and views are with regard to research. They could demand that these—plus their Aboriginal interpretation—be given at least equal weighting to the ethical values and views that are expressed (although, it should be noted, not necessarily interpreted) in mainstream Australian research ethics guidelines and policies. (1991:11)

Achieving consensus between local Indigenous community members over fundamental ethical issues is nominated as a potentially problematic undertaking. Describing the implementation of a locally developed Koorie health research framework in Victoria, Henderson *et al.* (2002) emphasised the limitations imposed by issues of local significance.

[D]espite inclusive processes and openness of information, local political and family histories still raise issues. The partnership team, Koorie Team and researchers can find themselves between conflicting family groups or perceived to favour some families or organisations over others. The challenge for outsiders to understand and address this, and for insiders to work between them while living in communities, remains. (2002:485)

Anderson, Griew and McAullay (2003) also suggested that within the construction of Indigenous health research it is not feasible to develop guidelines on community consultation that set clear and unambiguous defined endpoints. The trend involving development of research partnerships between researchers and Indigenous community members means that guidelines need to

both allow for flexibility in the process of consultation and consent, whilst at the same time setting a framework through which such processes should occur, leading either to a formal partnership or agreement. (Anderson, Griew & McAullay 2003:26)

The authors argued that guidelines for Aboriginal and Torres Strait Islander health research, which address ethical concerns only through 'specific rules and minimum standards', are problematic on two grounds. First, making an ethical assessment of research practice not clearly articulated in guidelines requires IECs to make a judgment. Given that these committees are still dominated by non-Indigenous interests, it is possible that such a judgment is likely to reflect the values of the ethics committee members as opposed to those of the Indigenous community. Second, the authors argued that most non-Indigenous researchers have a poor understanding of Aboriginal and Torres Strait Islander cultures and that historically 'Indigenous cultures and values have been explicitly undermined and disregarded through the process of colonisation in Australia' (2003:23). The authors concluded by stating that:

In order to establish the foundations for ethical research in Aboriginal and Torres Strait Islander health it is critical that guidelines provide a more explicit framework for incorporating the key values that, from an Indigenous perspective, are foundational to an ethical relationship. (Anderson, Griew & McAullay 2003:26)

In a consideration of the role of researchers in upholding ethical research standards, Chalmers (2002) argued that HRECs do not carry sole responsibility for the ethical testimony of the Australian research effort and that, in the end, 'HRECs can never police the system' (2002:55). According to Chalmers:

The *National Statement* recognises that prime responsibilities for the ethical health of the system rests with the integrity of the researchers themselves which is expressed in the design of the research and respect for participants. (2002:52; see *National Statement* principals 1.1, 1.2, 1.3 and 1.4)

While Chalmers (2002) positions researcher integrity as central to the maintenance of ethical research standards, other commentators nominate researcher resistance to change (involving increased levels of community control over research) as a possible reason for poor compliance with Indigenous research guidelines across a range of disciplines (Maddocks 1992; Dunbar *et al.* 2004; Scrimgeour 2002; ARC 1999).

Concern over the restrictive consequences of ethical guidelines and their potential harm to academic freedom is represented in the literature. For example, in a commentary on the 1991 *Interim Guidelines*, Maddocks (1992) reported that Aboriginal research guidelines are

worrying to many scientists because they are seen to have the potential to prevent the pursuit of important scientific questions arising in the course of research, and to stop publication of research findings; cutting across the free exchange of information which is the very life-blood of science. (1992:554)

In response to a description by Eades, Read and Bibbulung Gnarneep team (1999) of a locally developed Indigenous research protocol involving a high level of community control, Kamien (1999) provides an example of the identified tension between the quest for scientific 'truth' and the project to increase the level of community control over the research process. Kamien argued that there was a fundamental contradiction between guidelines that privileged 'community ownership' and the power of veto over publication, and the culture of research that is to report the 'truth' (1999:23). Similar concerns about the potentially restrictive consequences of research guidelines are raised in the international literature. In the context of a discussion about the implementation of research guidelines by Institutional Review Boards (IRBs) in the USA, Denzin (2003) reported that institutional protection of human subjects has expanded to the extent that many fear that there may be a 'growing harm to academic freedom and scholars' First Amendment rights if the authority of IRB's is interpreted too broadly or becomes too intrusive' (Gunsalus 2002 cited in Denzin 2003:6).

## **Summary**

The literature indicates concern about the effectiveness of an approach to ethical decision-making that is based primarily on the application of externally developed research guidelines. Identified concerns include the static nature of guidelines, difficulties in interpreting guidelines, lack of uniformity in the application of guidelines by HRECs, the prescriptive nature of guidelines, the difficulties in adapting guidelines to local conditions, researcher resistance, differing requirements for assessing bio-medical and behavioural research, and the inadequacy of processes for monitoring both researcher and institutional adherence to existing research guidelines. The blurring of disciplinary boundaries is particularly evident in the Indigenous health research field where concentration on the social determinants of health requires the application of multi-disciplinary research approaches. In this situation, an approach to guideline development that is framed around core Indigenous values holds the promise of providing the necessary flexibility to take account of varying disciplinary approaches to research.

## 5. Comparison of ‘Participatory’ and ‘Protective’ Approaches to the Development of Ethical Research Guidelines

In 1991, the NHMRC developed *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research*. The 1991 *Interim Guidelines* provided the first formal guidance on issues relating specifically to the conduct of Indigenous health research in Australia (McAullay, Griew & Anderson 2002) and ‘proved dominant as an aid to the deliberations of Institutional Ethics Committees throughout Australia—and not only in relation to health research’ (Humphery 2003a:15). McAullay, Griew and Anderson summarised the background to the development of the *Interim Guidelines* as follows:

These guidelines were developed through a public conference in 1986 on ‘Research Priorities in Aboriginal Health’ and a ‘National Workshop on Ethics of Research in Aboriginal Health’ in 1987. The National Workshop was convened with the specific purpose of developing principles for the ethical regulation of research involving Aboriginal and Torres Strait Islander people. Subsequent to these meetings, the NH&MRC and Aboriginal representatives pursued a lengthy process of negotiation over the wording of the guidelines that were eventually released. (2002:4)

According to Humphery (2001), some key issues concerning advocates for the development of specific Indigenous health research guidelines in the 1980s in Australia included concern over the poor status of Indigenous health, the lack of useful research, the cultural insensitivity of some researchers conducting Indigenous research, and the lack of ethical appreciation of specific issues relevant to Indigenous research (2001:14). Scrimgeour (1993) noted that the main concerns of the 1991 *Interim Guidelines* were issues of proper consultation, community involvement, and ownership of data; ‘issues which have not always been adequately addressed in the past, contributing to a deep suspicion of research among many Aboriginal people’ (1993:958).

The *Interim Guidelines* were also viewed as an important step toward reducing the previously fragmented and inappropriate nature of Indigenous health research in Australia (Lake 1992). Commenting on the development of the *Interim Guidelines*, Anderson, Griew and McAullay suggested that:

These Guidelines, as they have remained, were developed in response to political activists in the Aboriginal health movement who, in alliance with a number of sympathetic non-Aboriginal researchers, pressed for protection from exploitative research practices and greater Aboriginal and Torres Strait Islander control of the research process. (2003:21)

Since the publication of the 1991 NHMRC *Interim Guidelines*, various academic, health and government agencies have developed institutionally based guiding principles for research involving Aboriginal and Torres Strait Islander peoples across a range of research

disciplines. McAullay, Griew and Anderson noted that, in general, these guiding principles cover the same areas as those contained within the 1991 *Interim Guidelines*, namely consultation, collaboration, consent, involvement, and feedback (2002:10).

McAullay, Griew and Anderson (2002) contrasted two fundamental approaches to the development of Indigenous health research guidelines in international contexts. These approaches are broadly distinguished by their 'protective' or 'participatory' orientation. According to the authors, the approach traditionally adopted in Australia has involved the development of protective research guidelines that provide a framework for protecting Indigenous peoples from exploitation. In contrast, the National Institutes for Health in North America has adopted an approach aimed at ensuring that research guidelines primarily redress the past history of exclusion of Indigenous peoples from research that might ultimately benefit their communities. This 'participatory' focus is concerned with changing the way Western researchers engage with Indigenous peoples through the research process. Commenting on these contrasting approaches to guideline development, McAullay, Griew and Anderson suggest that:

it is interesting, therefore, that such a significant divergence exists in the approach taken to research ethics. The difference between protective and participatory emphases in ethical guidelines is an issue for further consideration in the process of reviewing the *Interim Guidelines* in Australia. (2002:8)

Within the Australian context, Humphery (2003b) suggested that ongoing tension about the fundamental purpose of Indigenous health research guidelines centres around the question of whether guidelines should aim to 'facilitate' or 'prevent' research. (This reflects the 'participatory' or 'protective' distinction outlined by McAullay, Griew and Anderson (2002). Humphery predicted that such tensions will most likely continue to inform the development of revised guidelines for Indigenous health research in Australia and that these tensions 'can only be dealt with effectively in process, in applying the letter and the spirit of *Interim Guidelines* to specific instances of research' (Humphery 2003b:40). He also asserted that 'Guidelines do not work "on paper" but only through their actual use, through making interpretations and judgements based on the protocols outlined' (Humphery 2003b:40).

The agency of research guidelines in the overall project to position Indigenous peoples as central to the construction and conduct of research is emphasised by Pickering (2003). In an editorial commentary on 'Indigenous Peoples and Medical Research', he suggested that in addition to acting as a vehicle for protecting Indigenous peoples against racist attitudes, guidelines might

also be a vehicle for a more active involvement of Indigenous peoples in research design and planning, thereby minimising risks of harms and maximising opportunities for benefits. In this way, the guidelines may influence the development of a collaborative model of medical (and scientific) research generally. (2003:2)

A participatory approach to guideline development was advocated by Tuhiwai Smith (1999), a Maori academic, who promoted a framework for considering alternative research processes with a capacity for privileging Indigenous Maori voices (including decolonisation, healing, transformation and mobilisation). In a commentary on Tuhiwai Smith's position, Denzin pointed out that

these four complex, interdependent processes address issues of cultural survival, and collective self-determination. In each instance they work to de-colonize Western methods and forms of inquiry to empower Indigenous peoples. (2003:5)

Denzin also argued that the successful application of principles specific to the conduct of Indigenous research is dependent on the establishment of an appropriate set of moral and ethical research protocols. 'A code embodying these principles interrupts the practice of research, resists the idea of research being something that white men do to Indigenous peoples' (Denzin 2003:5).

In a review of the literature detailing the development of ethical guidelines for the conduct of Indigenous health research in Australia, Henry *et al.* (2004) noted that commentary on the 1991 *Interim Guidelines* has focused mainly on their effectiveness as a vehicle for promoting and supporting fundamental changes to the way Indigenous health research is conducted in Australia. According to the authors, many commentators have argued that, despite the introduction of guidelines specific to the conduct of Indigenous health research in Australia, non-Indigenous approaches to research and persistent non-Indigenous control over the research agenda still characterise Indigenous health research activity (ARC 1999; Humphery 2001, 2003a; Dunbar *et al.* 2004; Dodson 2000). Some commentators attribute this situation to the fact that very little research funding is channelled through Indigenous community-controlled organisations, thus perpetuating the dominance of non-Indigenous approaches to research and non-Indigenous control over the research agenda (Anderson 1996, Anderson *et al.* 2001; Houston & Legge 1992). These commentaries imply that without a prescription for more direct control of funding by Indigenous community organisations, it is unlikely that the main aims of ethical guidelines for the conduct of Indigenous health research will be achieved (Henry *et al.* 2004).

Humphery (2001) took up the argument that research guidelines developed in isolation from local Indigenous community concerns represent a potential for the perpetuation of mainstream dominance over the research process. In an analysis of the impact of the 1991 *Interim Guidelines*, he argued that although a sense of struggle over the formulation of research guidelines continued during the 1990s, current NHMRC ethical guidelines 'preserve a white institutional dominance over health and medical research funding' (2001:22).

## **Summary**

Recognising the distinction between ‘participatory’ and ‘protective’ approaches to the development of ethical research guidelines is important to understanding the intention of the *Values and Ethics Guidelines*. While the NHMRC 1991 *Interim Guidelines* maintained a focus on ‘protection’ of the interests of Indigenous peoples, the *Values and Ethics Guidelines* aim to extend the boundaries of ethical assessment to promote ‘inclusiveness’ as a way of ensuring that the previous history of marginalisation of Indigenous interests within the construction of research is redressed. According to commentators, the success of such an intervention will rely on the application of research guidelines in close consultation with Indigenous peoples at the grassroots level (Anderson, Griew & McAullay 2003; Gillam & Pyett 2003).

## 6. The Current Status of the Australian HREC System

The HREC system represents the principal site for ethical review of research proposals in Australia and, according to the *National Statement*, the primary role of an HREC is to

protect the welfare and the rights of participants in research and the primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC will so protect participants. (NHMRC 1999a:15)

A secondary role is to 'facilitate research that is or will be of benefit to the researcher's community or to humankind' (NHMRC 1999a:1).

There are approximately 217 NHMRC-registered HRECs currently operating in Australia. These committees function in hospitals, universities, research institutions, government departments and community-controlled organisations. Approximately 2200 members of HRECs consider in excess of 15,000 research proposals each year (NHMRC 2003b:115). The Australian Health Ministers' Advisory Council, State/Commonwealth Research Issues Forum surveyed 228 HRECs registered with the NHMRC in 2002. From a survey response rate of 74 per cent, the following statistics were collated: in 2002, 13,913 proposals underwent ethical review in the 168 respondent HRECs and 49.5 per cent of these were dealt with by HRECs in Victoria and New South Wales (NHMRC 2003b).

The minimum membership of an HREC is seven men and women, comprising:

- a. A chairperson.
- b. At least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, are not currently involved in medical, scientific, or legal work, and who are preferably from the community in which the institution or organisation is located.
- c. At least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (e.g. health, medical, social, psychological, epidemiological, as appropriate).
- d. At least one member with knowledge of, and current experience in, the professional care, counseling or treatment of people (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate).
- e. At least one member who is a minister of religion, or a person who performs a similar role in a community such as an Aboriginal elder.
- f. At least one member who is a lawyer. (NHMRC 1999a:15)



The sustainability of the HREC system is currently the focus of extensive debate in the Australian literature. In an article entitled 'Is the Australian HREC system sustainable?', Dodds (2002a) raised a number of concerns about the current operation of the HREC system. She nominated burgeoning workloads, insufficient processes for training of HREC members and underdeveloped compliance mechanisms as some problematic areas requiring attention. Dodds viewed the 'crisis' facing HRECs as 'the expectation gap between what the HRECs are asked to do by regulators and legislators and what they can practically accomplish, given the capacities of the current system' and argued that it is vital that the 'expectation gap' is narrowed (2002b:78). Dodds encouraged steps to protect the system before it 'disintegrates or is found inadequate' and argued for a system-wide review of the needs and sustainability of HRECs to assess the effects of the implementation of the 1999 *National Statement*.

The NHMRC will not grant funding to institutions that do not have HRECs duly constituted through the Australian Health Ethics Committee (AHEC)... Nonetheless, the vast majority of HRECs in hospitals, universities and other organisations rely heavily on voluntary labour to conduct those reviews... These committees are provided with modest resources to support the work of the HREC, including limited funds for training, workshop attendance and publication budgets. (Dodds 2002a:43)

Dodds posed some key questions aimed at promoting discussion about HREC workloads and institutional support:

- Should there be a centralised review of multi-centre research?
- Should there be a national body that reviews research being conducted through the Clinical Trial Notification or the Clinical Trial Exemption schemes of the Therapeutic Goods Act?
- Should institutions be encouraged or discouraged from having multiple HRECs covering different types of research?
- Should institutions supporting HRECs be required to make specific funding support available?

Dodds proposed three key areas within the current HREC system that need addressing:

- HREC workloads and institutional support.
- Training and guidance for HRECs through individual review of HRECs.
- A system of compliance auditing which is not entirely based on self reporting and written compliance reviews. (Dodds 2002a:47)

In response to the criticism of the HREC system posed by Dodds and others, Kerry Breen (2001), the chairperson of AHEC, proposed that it was too early to assess the full impact of the *National Statement*, or to call for a major review of the current HREC system. While agreeing that some HRECs are 'overstretched', he argued that the system is not on the verge of collapse and outlined the various interventions currently employed by the NHMRC to address identified problems (Breen 2001:58). Millar (2002) also responded to

the problems identified by Dodds by arguing that it is an exaggeration to claim that the current HREC system is in danger of collapse but agreed that it was timely to reassess current directions.

Under-resourcing of HRECs is nominated as a general problem affecting the capacity of Australian health ethics committees to effectively discharge their duties (Millar 2002; Dodds 2002a; Savulescu 2002). Savulescu advanced the argument that 'ethics review is at a fork in the road' (2002:74), and suggested that under the current system the protection of research participants cannot be guaranteed. In addition to the problem of under-resourcing, he suggested that ethics review is becoming too technical for the people currently asked to perform it and proposed that:

Either we significantly increase the resources we provide to support institutional research ethics committees. Or we abandon the institutional base of human research ethics review and move to a model of expert 'suprainstitutional' ethics committees. (2002:74)

A similar proposal for centralisation of processes for ethical review was advanced by Frew (2003). On the basis of investigations into ethical review processes implemented by HRECs and their secretariats in the Netherlands, United Kingdom, the USA and France, he suggested that problems associated with increasing HREC workloads in Australia might be addressed through the implementation of a system for multi-centre review (MCR) and monitoring. Frew provided a detailed proposal for MCR development (2003:73) and within this context proposed that each State and Territory in Australia could be classified as a 'region' for the purpose of achieving a co-ordinated approach to ethical review.

Since the mid-1980s, the scope of institutional ethics committees in Australia has broadened to include most of the research conducted in the social sciences and humanities (Bouma & Diemer 1996). Chalmers (2002) predicted that the demands and expectations of the HREC system would increase as research activity intensifies (especially in the field of biotechnology) and that this will in turn place additional burdens on the HREC system. Commenting on the particular problem of reviewing bioethics research by methods involving traditionally constituted committees, expert boards and commissions, Crotty (1995) suggested that committees should advise governments on policy and legislation rather than concern themselves with individual morality. In the current research environment, Crotty argued that much of what passes for codes of ethical conduct is just 'professional etiquette' and that to attempt to derive a code of ethics which is absolute is outmoded.

The adequacy of research monitoring mechanisms is identified as an issue of concern across the spectrum of health research activity in Australia (McNeill, Berglund & Webster 1990, 1992; Humphery 2001; Johnstone 1991; Dodds 2002a; ARC 1999; Frew 2003). There is concern over the adequacy of existing NHMRC processes for monitoring HREC adherence to official guidelines and questions about the adequacy of internal processes employed by HRECs to monitor research activity once committee approval has been granted.

According to McNeill, Berglund and Webster (1992), an investigation into the operation of mainstream institutional research ethics committees (RECs) in Australia revealed evidence that a significant number of researchers deviated from approved research proposals without seeking consent for those deviations from an REC. In addition, they found that monitoring of research by RECs relied on self-reporting by researchers on the ethical conduct of their research and that overall the active monitoring of research by RECs was minimal (McNeill, Berglund & Webster 1992:318). McNeill, Berglund and Webster (1990) also reported that less than half the committees surveyed actively monitored research projects in progress. McNeill, Berglund and Webster (1992) concluded that although monitoring, frequency of meetings, selection of committee members, member involvement in the review of their own protocols, and provisions for expedited review gave cause for concern, most committees were found to follow national health research guidelines.

Spriggs (2002) supported the proposition that there are problems with compliance monitoring at the HREC and research project level in Australia, and suggested that there is a need for a system of compliance auditing which is not entirely based on self-reporting and written compliance reviews. Frew (2003) linked poor rates of HREC conformity with monitoring requirements to the more general problem of significantly increased HREC workloads and the problem of under-resourcing.

Insufficient resourcing reportedly extends to the capacity of AHEC to effectively monitor HREC activity. Dodds (2002a) suggested that while AHEC has traditionally provided support for HRECs, its own members are also straining under increased workload and suffering the effects of limited resources. Dodds also claimed that there is still no effective mechanism for reviewing individual HREC processes and that, in order to fulfil NHMRC monitoring requirements, AHEC relies mainly on HREC self-reporting through the annual review report process.

Van Essen *et al.* (2004) considered the extent to which HREC members apply the principles of natural justice to the ethical assessment of research in Australia. The authors contended that while there is currently no statutory requirement for HRECs to apply the principles of natural justice (the *hearing rule*, requiring a decision-maker to allow a person affected by a decision to present his or her case; the *rule against bias*, requiring a decision-maker to be unbiased in the matter to be decided; and the *evidence rule*, requiring that a decision be based on the evidence provided, and not irrelevant issues), the principles are obviously relevant to the ethical assessment of research. Van Essen *et al.* (2004) concluded that the degree of familiarity with the principles of natural justice varied widely between committees. Thirty-three per cent of respondents stated that they were very familiar with the principles, while 25 per cent were completely unfamiliar with the principles. These findings raise questions about the extent to which the HREC system is effectively arbitrating the application of natural justice principles within the ethical assessment process.

## Summary

The sustainability of the Australian HREC system is currently the focus of extensive interest in the literature. Under-resourcing of HRECs is nominated as a general problem affecting the capacity of Australian health ethics committees to effectively discharge their duties (Millar 2002; Dodds 2002a; Savalescu 2002). Several commentators have expressed concern that the increasing workload of HRECs is problematic (Dodds 2002a, 2002b; Frew 2003; Savalescu 2002). Frew (2003), for example, suggested that it is now questionable whether HRECs can adequately conform to the review and monitoring requirements of the *National Statement* given the degree to which workloads have increased. This situation is reportedly being driven by current trends including the increasing volume of research applications, the complexity of proposed specialist research interventions in the biological sciences (particularly gene therapy), increased requirements for monitoring researcher and institutional compliance with existing guidelines and approved protocols, advocacy for recognition of special group interests, the increasing complexity of assessing large, multi-site research projects, and the increasing application of complex legalistic frameworks for assessment of research proposals (frequently driven by large company interests).

A special case for the provision of additional resources to promote and protect the interests of Indigenous and other minority groups within the current system for ethical review of research in Australia generally relies on the argument that their minority profile, social disadvantage, ongoing poor health status, and historic marginalisation of cultural and material interests warrants a different or 'special' approach. Proposals requiring additional funding are problematic when considered within the context of commentary detailing the current widespread under-resourcing of HRECs in Australia (Savalescu 2002; Dodds 2002a, 2002b).

## 7. Ethical Governance of Indigenous Health Research: Structures and Processes

Commentaries on the ethical governance of Indigenous research in the Australian and international health research literature typically include reference to structural issues, including the need for broad-based reorganisation of existing ethical governance systems—and more practical issues associated with implementing effective processes for committee-based ethical review of research. The following section of this review will consider both structural and process elements of ethical governance as these relate to the assessment of proposals for Indigenous health research. Within this context, barriers to achieving proposed reform initiatives will also be considered.

### a) Proposals for broad-based reform of Indigenous research activity

The literature maps the development of a sustained international movement by Indigenous peoples to take inquiry into their own hands, and to develop their own conceptions of human subject, researcher, research, ethics, harm and community review apparatuses (Denzin 2003). In Australia, issues of power and control over the research process are regularly identified as central tensions between Indigenous peoples and the broader research community (Henry *et al.* 2004).

According to Henry *et al.* (2004), promoting Indigenous participation in all aspects of research (including participation in ethical deliberations) has been a cornerstone of the movement to reform Indigenous health research activity in Australia over the past three decades. Maori representatives in New Zealand have also advocated for substantial changes to the way research is conducted. According to Tuhiwai Smith, an outcome of this advocacy has been a move toward research that is

more ethical, and concerned with outcomes as well as processes. It has also meant that those who choose to research with Maori people have more opportunities to think more carefully about what this undertaking may mean. (1999:177)

Anderson, Griew and McAullay (2003) argued that social connections between research institutions and Aboriginal and Torres Strait Islander peoples must undergo change if researchers are to develop ethical research relationships with Indigenous communities in Australia. The authors suggested that the fundamental challenge currently confronting the research community is to

simultaneously change the social dynamics of research to enable Indigenous Australians to show leadership in research; actively participate in the development of research projects (as researchers and not research assistants) and to develop collaborative models for research

and partnership structures between research institutions and Aboriginal and Torres Strait Islander community structures. (2003:26)

The role of researchers in assisting this change process has emerged as an issue of interest in the literature. Dunbar *et al.* (2004) suggested that although researchers are framed as key agents of change within proposals to reform the way Indigenous research is initiated, conducted and its findings disseminated, the question of how to engage individual researchers in this reform process remains unresolved. Within this context, institutional support for researchers was nominated as important.

McAullay, Griew and Anderson (2002) noted that since the publication of the NHMRC 1991 *Interim Guidelines*, Aboriginal and Torres Strait Islander researchers have assumed an increasingly important role in research activity and that there has been significant increase in the development of collaborative research models (2002:17). Despite these gains, the literature reflects persistent concern that the broad-based Indigenous research reform agenda is apparently stalled over a range of unresolved issues. In his analysis of the movement to reform Indigenous health research activity in Australia, Humphery (2000, 2001) nominated the following key issues as requiring ongoing attention:

- involvement by Aboriginal communities in the design, execution and evaluation of research;
- defining the co-ordinating role of Aboriginal community-controlled organisations;
- consultation and negotiation defined in practice as ongoing and open to scrutiny;
- mechanisms for Indigenous control and transformation of research;
- mechanisms for ongoing surveillance of research projects;
- processes to determine research priorities and benefit;
- determination of ethical processes for the conduct of research in terms of consultation and negotiation;
- transformation of research practices from ‘investigator-driven’ to a re-assertion of control by Indigenous community-controlled organisations over the research project and an adoption of a needs-based approach to research;
- linkage between research and community development and social change;
- the training of Indigenous researchers;
- the adoption of effective mechanisms for the dissemination and transfer of research findings; and
- ownership and control of research findings by Aboriginal communities.

There is agreement between many of the issues identified by Humphery (2000, 2001) and those identified by a House of Representatives Standing Committee on Family and Community Affairs, the *Health Is Life—Report on the Inquiry into Indigenous Health* (HoRSC 2000). The report proposed radical restructuring in the management of Indigenous health research and recommended that research in the Indigenous health area should:

- be developed in conjunction with communities to reflect community priorities;
- be focused on achieving benefit to the community and on achieving health outcomes;
- provide mechanisms for the involvement of Indigenous people;
- provide mechanisms for the transfer of research findings into practice; and
- provide information that is useful in developing policies and programs. (HoRSC 2000:119)

There is evidence that increasing levels of cooperation between Indigenous peoples is leading to the development of a unified international approach to the conduct and ethical assessment of Indigenous research. For example, formalisation of cooperation between Indigenous peoples in Australia, Canada and New Zealand was marked by the signing of a tripartite memorandum of understanding on Indigenous health research in 2002. According to Cunningham, Reading and Eades (2003) these countries share in common:

- the central funding of research through contestable grant rounds; and
- the existence of considerable Indigenous populations whose health outcomes are poorer than those in non-Indigenous populations and developing sectors of Indigenous researchers alongside Western oriented researchers.

The aim of the alliance is to develop a co-ordinated approach to the conduct of research involving issues of interest to Indigenous peoples. Key initiatives involve sharing of expertise and developing a policy for collaborative research between the countries. According to the authors, the purpose of the formal tripartite agreement is to share expertise on the 'purchase' (funding) of health research and to develop policy for collaborative research between the three countries, including sponsoring placements of individuals, funding international research projects, and supporting other collaborative research relationships.

Alignment between adopted approaches to achieving reform of research involving Indigenous participation is also indicated by the emergence of a significant body of detailed discussion and draft pro formas published on the World Wide Web. This source records alternative approaches to establishing Indigenous research ethics protocols, guidelines, and codes of conduct and research agreements. A representative sample of these documents includes Kahnawake Schools Diabetes Prevention Project, *Code of Research Ethics* (1995); American Indian Law Center, *Model Tribal Research Code* (1999); World Health Organization (2004); Indigenous Peoples Council on Biocolonialism (IPCB), Canada (2000); and NHMRC, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003a). There is evidence of significant cross-referencing between these documents and indications of agreement over fundamental issues including support for the establishment of collaborative research partnerships between researchers and Indigenous peoples and improving research processes. These processes comprise monitoring of research, achieving individual and collective community consent for research, assessing the risks and benefits of research, achieving increased levels of community control over research findings, and providing access to training for Indigenous

researchers. Underlying emerging initiatives in this field is the importance of promoting the authority of Indigenous people over the research process and protecting Indigenous cultural interests.

## **Summary**

A developing international movement for the reform of Indigenous research activity includes significant alignment between the positioning of Indigenous advocates over proposals to reform processes for the ethical assessment of research. There is broad agreement between these advocates over issues including:

- the need to reconceptualise intellectual property rights to take adequate account of communal rights associated with Indigenous knowledge generation and transmission;
- the need to increase the level of Indigenous community input into the assessment of the ‘risks and benefits’ of research;
- the adoption of research guidelines that extend beyond ‘protection’ of Indigenous interests to include processes that ‘enable’ the agenda for reform of research activity;
- the need for development of regional and local frameworks for the ethical governance of Indigenous research; and
- the value of developing formal research agreements between professional researchers and Indigenous peoples (based on nationally constructed guidelines).

Although researchers are framed as key agents of change within proposals to reform the way Indigenous research is initiated, conducted and its findings disseminated, the question of how to engage individual researchers in this reform process remains unresolved. Changes to the way proposals for research are ethically assessed is positioned as one way of engaging researchers in a consideration of fundamental Indigenous values at the outset.

## **b) Representation of Indigenous community interests**

Commentary about the representation of Indigenous community interests in the construction and governance of health research in Australia includes reference to national and regional arrangements for incorporation of Indigenous perspectives. The literature also reports international initiatives aimed at increasing the level of representation of Indigenous interests in research and the emergence of formal links between Indigenous peoples in Australia and other countries, aimed at promoting a co-ordinated approach to the construction and governance of Indigenous research activity (Cunningham, Reading & Eades 2003).

Cunningham, Reading and Eades (2003) reported that the NHMRC in Australia has agreed to allocate at least five per cent of research funding to the area of Indigenous health for the next triennium and that the level of Indigenous representation on the council and its principal committees has increased substantially in recent years.



The Cooperative Research Centre for Aboriginal and Tropical Health (CRCATH) *Survey of Australian Human Research Ethics Committees* (2002) provided preliminary indication that HREC processes for achieving Indigenous community input into deliberations over research proposals vary significantly between the States and Territories in Australia. Some commonly adopted interventions include referral of proposals for Indigenous research to permanent Indigenous committee members, to an all-Indigenous ethics committee or sub-committee and/or to a specified Indigenous person outside the committee process. Reference by HRECs to national Indigenous health research guidelines and institutionally based protocols is another commonly adopted process (CRCATH 2002).

Other procedural interventions implemented in Australia to ensure the representation of Indigenous community interests in research include the adoption of specialised Indigenous health research proposal pro formas (Aboriginal Health Council of South Australia 2003) and the implementation of negotiated research agreements between researchers and Indigenous community members (Henderson *et al.* 2002). The Aboriginal HREC of South Australia requires intending researchers to complete an application form with emphasis on consultative processes with Aboriginal communities, the proposed need for the research, the proposed benefits of the research to Aboriginal people and the nomination of methods for reporting back to Aboriginal community members. The Cooperative Research Centre for Aboriginal Health (CRCAH) (Darwin) requires that researchers sign a Memorandum of Understanding (MOU) before research funding is released. This internally generated document includes a detailed outline of key aspects of the proposed research including adopted approaches for ensuring appropriate processes for Aboriginal community consultation and consent, processes for dissemination of findings, processes for ensuring Indigenous community input into the research process and training opportunities for Indigenous peoples. It is important to note that MOUs, negotiated research agreements and specially designed research application pro formas are not legally binding documents. They usually demonstrate good will, respect and good intent. More importantly, these types of documents establish the strength of the working relationship between the Aboriginal community and researchers.

The background section of the *Values and Ethics Guidelines* notes that, historically, most HRECs in Australia had few Aboriginal and Torres Strait Islander members and that this situation 'unfortunately led to instances where clearance or monitoring of research failed to consider Aboriginal and Torres Strait Islander perspectives' (NHMRC 2003a:27). This situation reportedly led Aboriginal and Torres Strait Islander peoples to seek greater representation on HRECs and eventually to the development of specialist Indigenous health ethics committees and sub-committees. An advantage of the sub-committee structure was identified by Scrimgeour (1993) as being the opportunity to consider research proposals in the light of both Indigenous and Western ethical systems. According to the *Values and Ethics Guidelines*, Indigenous ethics committees and sub-committees have a specific brief to review the ethical viability of research proposals in Aboriginal health.

The Aboriginal HRECs proceed uniquely from an Aboriginal and Torres Strait Islander value base and perspective. However, there are not yet sufficient committees with this

composition to review all health research involving Aboriginal and Torres Strait Islander peoples. (NHMRC 2003a:24)

Gillam and Pyett (2003) proposed that significant Indigenous community participation will be required if research proposals are to be ethically assessed in the way envisaged within the draft *Values and Ethics Guidelines*. To facilitate this required level of involvement, the authors suggested that HRECs be required to formally involve Aboriginal and Torres Strait Islander people in the ethical review process, rather than simply trying to use the new draft guidelines on their own.

Indigenous people will be best placed not only to provide the knowledge of communities and their processes that is needed, but also to interpret whatever set of guidelines is used from an Indigenous perspective—which surely must be a key feature of a successful process. (Gillam & Pyett 2003:16)

Gillam and Pyett (2003) also pointed out that HRECs are empowered under the *National Statement* to consult external experts. The authors proposed that when Indigenous ethics committees or sub-committees are not available to provide input into the ethical assessment of research proposals, consultation with local Aboriginal ‘experts’ becomes a mandatory practice. The authors specified that:

The Indigenous Ethics Advisers would need to be appropriately paid for this process of consultation, and recompensed for any costs incurred. Arrangements for this would need to be made in some way—through project budgets, through HRECs, or perhaps directly from the NHMRC. The Indigenous Ethics Adviser would:

- Consider and advise the HREC whether they are the most appropriate adviser and, if not, refer the HREC to another adviser;
- Assess the proposal against the approved guidelines for Aboriginal and Torres Strait Islander Health Research;
- Consult and involve the appropriate communities in the review and assessment of proposals and in monitoring the implementation of the research;
- Advise the HREC of the ethical assessment of the proposal from an Indigenous perspective. (Gillam & Pyett 2003)

In a discussion of processes for ethically assessing Koorie health research in Victoria, Henderson *et al.* (2002) recommended that in the absence of a dedicated Koorie ethics committee, the adoption of one of the following approaches is an important way of preventing problems arising between researchers and participating communities:

- (1) The ethics committee reviewing the research proposal should include two Koorie people (to avoid tokenism and intimidation) to assess the need for referral to a Koorie community group.
- (2) A local Koorie community group with cross-community representation should be convened to assess any additional local Koorie community issues (history, social context, etc) in relation to any proposal. This group is likely to include greater representation than the initial group consulted. (2002:483)

In international contexts, permanent Indigenous membership on ethics committees is a recognised avenue for ensuring representation of Indigenous interests in the ethical review of research. In New Zealand, for example, accredited ethics committees are required to include two Maori members (Cunningham 2003). Currently in Australia, there is a requirement for two layperson positions on HRECs, and it is under this classification that an Indigenous community member is sometimes engaged. According to the NHMRC, the qualifications for lay members are 'their independence from the institution and their non-involvement in medical, scientific or legal work' (NHMRC 1999a). The NHMRC *National Statement* proposes that

those recruited from the community in which the institution is located are more likely to understand that community and how its members would view involvement in research. And those who have no experience in professions associated with research on human beings are more likely to bring a truly lay perspective. (NHMRC 1999a)

According to Spriggs (2002), non-institutional members of ethics committees represent a capacity for taking the perspective of research subjects (2002:41). As a way of achieving a higher level of community input into mainstream HREC decision-making in Australia, Spriggs suggested that increasing the number of lay or unaffiliated members deserves consideration. This recommended innovation represents a potential for providing additional opportunity for increasing Indigenous representation on HRECs, although there is no indication that the NHMRC is currently considering altering the membership formula for HRECs in Australia.

The trend toward progressive centralisation of the HREC system is identified as a problem by Millar (2002), who argued that this trend compromises the aim of increasing the level of local community input into the assessment of research proposals. Devolution and not centralisation of decision-making processes is apparently the trend favoured by commentators who promote the development of locally constituted Indigenous community panels or 'ethics advisors' to provide advice to HRECs on issues relating to proposals for Indigenous health research (Maddocks 1992; Gillam & Pyett 2003).

The negotiation of research agreements between Indigenous peoples and professional researchers is a process actively promoted by the American Indian Law Center and by WHO as a way of ensuring that special issues of concern to local Indigenous community members are not overlooked in the ethical review process. Key elements of proposals for the application of negotiated research agreements centre on issues of respect for Indigenous knowledge, maintenance of cultural integrity, nomination of expected research benefits and risks, ownership and control of data, processes for community participation, employment opportunities for local community members, nomination of appropriate processes for dissemination of research findings, and ensuring ongoing surveillance of research activity (WHO 2004; American Indian Law Center 1999).

Within the Indigenous health research field in Australia, research agreements have not been widely implemented. An approach based on the establishment of a framework for conducting participatory research with members of the Koorie community in Victoria,

however, has something in common with the approach put forward by WHO (2004) and the American Indian Law Center (1999). The framework (developed by the Department of Rural Health at The University of Melbourne) incorporates cultural understandings and outlines culturally appropriate protocols. The four parts of the framework include a committee to initiate, direct, and oversee all research projects; a Koorie team to guide research; a set of research guidelines; and a policy for the department (Henderson *et al.* 2002). Henderson *et al.* explained that the research guidelines and departmental policy contain the specific details on which a ‘research agreement’ would be based.

The WHO (2004) provide a ‘research agreement’ pro forma for application by Indigenous peoples and professional researchers. According to the WHO:

While research agreements of the kind proposed in this document are not legally binding, they do represent formal signed agreements between the parties. As such, they provide an opportunity for full discussion, exploration, and clarification of all aspects of the proposed research, from both the researchers’ and the population’s perspective. This process facilitates mutual understanding, trust, and the acceptance by all parties of their duties and responsibilities. It also helps to develop a sense of joint ownership of the research process, leading to more mutually satisfactory outcomes. (2004:2)

The WHO suggests that research agreements alert researchers to some of the specificities of research with Indigenous peoples and inform Indigenous peoples about what they can legitimately expect and require in the context of collaborative research. The WHO points out that a research agreement

is not intended to replace obligatory national or institutional procedures for reviewing and authorizing health research, nor is it intended as an ethics guideline. Rather, the establishment of research agreements constitutes a prior and additional measure to be taken where all parties concerned feel it is in their interests. (2004:2)

The issues of self-determination, capacity building and community ownership of the research process underpin much of the commentary surrounding recent developments in the Indigenous health research field in Australia and internationally. In particular, the importance of engendering Indigenous community ownership of the research process is identified as being important to the achievement of more useful research outcomes. The link between community ownership and successful capacity building initiatives was made by Taylor (2003), who pointed out that when researchers and others enter into any collective initiatives involving community capacity building, ‘there needs to be a fundamental collective understanding, recognition and commitment to the legitimacy and primacy of community ownership, decision-making and action, i.e. self-determination’ (2003:4).

### **c) Institutional involvement in the ethical assessment of Indigenous research**

According to the NHMRC *National Statement*, ‘Institutions and organisations in which research involving humans is undertaken must individually or jointly establish, adequately

resource, and maintain an HREC composed and functioning in accordance with this Statement' (NHMRC 1999a:15).

Concern about institutional liability has apparently encouraged institutional research ethics committees to evolve (Savalescu 2002). The literature, however, indicates that the level of institutional commitment to ensuring adequate resourcing of research ethics committees is inadequate and varies across the States and Territories in Australia (Savalescu 2002; Dodds 2002a).

Commentators on issues specific to Indigenous research activity have suggested that insubstantial institutional support, especially from within the university sector, is hindering the progress of Indigenous research reform initiatives, especially those centring around the requirement for Indigenous community control over key aspects of research and the importance of establishing research partnerships as a way of promoting inclusivity (Kelly & O'Faircheallaigh 2001; Scrimgeour 2002; ARC 1999; Melville & Rankin 2000; Rawsthorne 2003; Hart & Whatman 1998). Commentaries in the literature relate primarily to social science research where it is commonly argued that material institutional support is fundamental to the achievement of improved processes for ethical review of Indigenous research activity. Rawsthorne (2003), from the Social Policy Research Centre at the University of New South Wales, suggested that there is generalised concern by Indigenous researchers about the inappropriate processes employed by most academic institutions in relation to Indigenous research activity.

Commenting on developments in the field of Indigenous education research in Australia, Scrimgeour (2002) argued that although the changed rights and responsibilities of researchers in relation to research activity have been outlined within higher education institution-sponsored Indigenous research guidelines in recent years, researchers and research participants are struggling to come to terms with the implications of these sometimes significant changes.

The project to re-educate Indigenous research stakeholders is under way in a range of forums, but the reform process is in danger of stalling if the impetus for this project is not maintained and materially supported by all higher education institutions that sponsor Indigenous research activity. (Scrimgeour 2002:179)

Similarly, Hart and Whatman (1998) linked the success of the project to 'decolonise' Western research practices with the achievement of fundamental changes to the way universities manage and support Indigenous research activity. They argued that:

If researchers are representing the institutions that are supporting their studies, it seems practical if not clearly ethical that institutions embark on negotiating research agreements that set out the principles by which 'knowledge' is extracted. (1998:1)

In a study entitled *Indigenous Participation in Managing University Research*, Kelly and O'Faircheallaigh (2001) were critical of the level of institutional commitment to ensuring Indigenous community input into ethical deliberations and noted that only eleven universities in Australia had instituted formal arrangements for the inclusion of Indigenous staff on HRECs (2001:13). The authors concluded that

a large majority of Australian Universities, and especially the long-established institutions which play a critical role in university research, have failed to create even the most basic institutional arrangements for ensuring that proposals for the conduct of Indigenous research are assessed in an appropriate manner. (2001:21)

Insufficient documentation of good practice in the field of Indigenous education research is also identified as problematic in the Australian context. In a study confined to Indigenous education research activity in Australia, Melville and Rankin suggested that although there is evidence that Indigenous education units within Australian universities are apparently satisfied with their level of influence over the management of Indigenous research, 'documentation of good practice in the form of policies or procedures is conspicuously lacking' (2000:67).

## **Summary**

It has been argued that although Australian institutions benefit from involvement in Indigenous research activity, institutional commitment to the implementation of processes to support appropriate approaches to research remains inadequate (Kelly & O'Faircheallaigh 2001; Scrimgeour 2002; ARC 1999; Melville & Rankin 2000; Rawsthorne 2003; Hart & Whatman 1998). The development of appropriate processes for research priority setting, evaluation and monitoring of Indigenous research activity, and Indigenous participation in the ethical assessment of research are regarded as key areas requiring institutional attention in Australia.

## **d) Compliance and monitoring**

The Indigenous research literature contains significant commentary about the problem of effectively monitoring research activity once ethics approval has been granted. This problem is aligned with identified concerns in the mainstream research literature, namely inadequate institutional mechanisms for monitoring research activity, inadequate ethics committee processes for ensuring researcher compliance with agreed protocols and inadequate mechanisms for monitoring HREC compliance with national guidelines.

In a review of the literature tracking the development of the Indigenous research reform agenda in Australia, Henry *et al.* (2004) indicated that Indigenous research guidelines do not mandate for substantial changes to the way researchers operate and that, currently, inadequate institutional mechanisms are in place to monitor the activity of researchers once formal ethics committee approval has been granted. The authors cited research conducted by the Australian Research Council (ARC 1999) which provided evidence of a substantial mismatch between the current nature of research being conducted in a number of social science disciplines in Australia and the ethical and protocol guidelines that have been developed to guide researchers involved in 'research of interest' to Indigenous peoples. On this basis Henry *et al.* adopted the position that:

These research findings represent important evidence that there has not been much movement on the ground in terms of changed researcher practices and that there are

implementation problems associated with ethical and protocol guidelines for researchers involved in research activity involving Indigenous participation. (2004:11)

In an annotated bibliography of Indigenous health research ethics, McAullay, Griew and Anderson (2002) reported that poor rates of adherence by HRECs to national guidelines and poor compliance by researchers with agreed research protocols were identified issues of concern in the literature.

There is, however, apparent confusion over the division of responsibility for implementing monitoring arrangements. Humphery argued that the absence within previous Indigenous health research guidelines of mechanisms to ensure ongoing surveillance of research projects has led to the situation where the guidelines 'have developed primarily as a gateway process for obtaining ethical approval' (2001:200). On this basis he argued for the development of institutional processes to facilitate the ongoing surveillance of research projects once they are 'inside the perimeter of ethical approval' (2001:200). This position ignores the existence within the NHMRC *National Statement* of the prescribed role for the research institution and the HREC to effectively monitor ongoing research projects that have previously gained ethical endorsement. According to the NHMRC, responsibility for the monitoring of research activity lies with both the institution and the administering HREC:

An institution or organisation and its HREC have the responsibility to ensure that the conduct of all research approved by the HREC is monitored by procedures and/or by utilising existing mechanisms within the institution or organisation which will ensure the achievement of the goals for monitoring as determined by the institution or organisation and the HREC. (1999a:20)

Henry *et al.* (2004) noted that although the 2000 NHMRC Health and Medical Research Strategic Review included a plan to revise the 1999 *Interim Guidelines*, the review did not include specific reference to the need for investigating ways of improving the monitoring of research once it has gained ethical approval. The ARC (1999) noted an overall paucity of surveillance or monitoring in social science research 'of interest' to Aboriginal and Torres Strait Islander peoples. In a review of the Menzies School of Health Research in Darwin, Baume concluded that the 'monitoring of researcher adherence to conditions agreed between them and the Ethics Committee at the time approval is given' should be an important function of ethics committees (1992:330).

The significant shift in focus represented by the revised format of the *Values and Ethics Guidelines* is identified as problematic by commentators who are concerned that the 'enabling' or 'participatory' objectives will perpetuate unethical research behaviour. McKendrick and Bennett (2003), for example, argued that the move away from a 'protective' or 'rules based' approach to an approach primarily aimed at 'enabling' effective research partnerships between professional researchers and Indigenous peoples relies too heavily on voluntary researcher compliance. The authors expressed the view that the 'trust' afforded researchers within the *Values and Ethics Guidelines* is misplaced, and they predicted a resultant rolling back of Indigenous research reform gains of the past two decades. The

historic dominance of Western researchers and the violation of trust associated with previous Indigenous research activity in both Australia and New Zealand are provided as evidence for this claim: ‘Our experience has been that trust has been forever violated by past research in Indigenous communities which has seen the researched merely as objects’ (McKendrick & Bennett 2003:22).

The ineffectiveness of sanctions against researchers is identified as a possible reason for reportedly low rates of researcher compliance with agreed research protocols in the Indigenous health research field. Atkinson (1999), for example, argued that the issue of the 1999 *Interim Guidelines* being overdue for revision was less important than the level of adherence by researchers to existing guidelines. Atkinson proposed an approach where those with responsibility for publishing Indigenous health research findings are charged with responsibility for checking researcher compliance with the relevant guidelines. McAullay, Griew and Anderson (2002) cited commentary in a submission by the National Aboriginal Community Controlled Health Organisation to the AHEC to demonstrate concerns about researcher compliance. This submission argued that the only threat to researchers who fail to adhere to the *Interim Guidelines* was the withdrawal of NHMRC funding.

## **Summary**

The problem of how to effectively monitor Indigenous health research activity once ethics approval has been granted aligns with identified concerns in the mainstream health research field, namely inadequate institutional mechanisms for monitoring research activity, inadequate ethics committee processes for ensuring researcher compliance with agreed protocols and inadequate mechanisms for monitoring HREC compliance with national guidelines. Sanctions against researchers for non-compliance with agreed protocols are reportedly inadequate and some commentators argue that this requires a strengthening as opposed to a loosening of guidelines in some areas. In commenting on the *Values and Ethics Guidelines*, McKendrick and Bennett (2003), for example, argued that the move away from a ‘protective’ or ‘rules based’ approach to an approach primarily aimed at ‘enabling’ effective research partnerships between professional researchers and Indigenous peoples relies too heavily on voluntary researcher compliance.

### **e) The assessment of ‘benefit’**

Commentaries relating to the assessment of risks and benefit in Indigenous research canvass four main themes, including alternative constructions of the notion of benefit, proposed timeframes for the achievement of nominated benefits, proposals for ensuring that nominated benefits accrue to Indigenous peoples who are the ‘subjects’ of research, and suggested markers for the assessment of research ‘benefit’. Commentaries are generally underpinned by reference to the past history of exploitative research practices across a range of disciplines and the delivery of insubstantial benefit to Indigenous peoples. A recurrent perspective in the Australian and international literature is that the notion of benefit or beneficence remains poorly defined with respect to Indigenous research activity (McAullay, Griew & Anderson 2002; Sharp & Foster 2002; Anderson 1996).



Sharp and Foster (2002) linked the process of community consent with the identification of ‘community benefit or risk’ and argued that community members are best placed to assess potential risks and benefits of proposed research. They also proposed that processes for community decision-making involving approval or rejection of proposals for research may be guided through a process involving collective assessment of risk and benefit.

The literature also represents emergent argument for the development of a process for assessing potential research ‘benefit’ in Indigenous community contexts that is not reliant on the more traditional ‘cost-benefit’ analysis associated with the assessment of mainstream research (Denzin 2003; Sharp & Foster 2002). According to McAullay, Griew and Anderson (2002) many commentators take the concept of ‘benefit’ from research as self-evident. In a commentary on Alaskan and native Canadian Indian research, Sharp and Foster pointed out that

little is known about how members of various underserved or marginalized communities weigh individual research risks against group risks, how salient collective risks are in relation to other risks encountered in daily life, or how individuals attempt to reconcile potential conflicts that may exist between personal interests in research participation and collective opposition to proposed research. Because not all collective harms carry the same weight—that is, some group harms are more significant than others—it is important to assess how members of historically underserved communities evaluate collective research-related harms. Moreover, without such information it will be difficult, if not impossible, to tailor oversight processes to specific communities. (2002:145)

Anderson (1996) provided an analysis that referred to the problem of assessing benefit and risk in research as ‘the ethics of benefit’. He suggested that the issue of how this may be assessed with respect to particular Indigenous health research projects has not been clearly defined and argued that this is a moral problem for two reasons:

First, in the distribution of research resources questions about benefit cannot be resolved unless differences between alternative value systems are reconciled. Second, Aboriginal communities have such poor health status and poor access to health system resources that it is essential to maximize the potential of all resources. Here, the ethical issues confronted by Aboriginal people are similar to those faced by others who engage with the research establishment from a position of marginalisation and disadvantage. (1996:156)

Denzin (2003) was critical of the way the notion of beneficence has been traditionally applied and assessed with respect to research involving Indigenous peoples. He argued that beneficence, including risks and benefits, cannot be quantified and that a clear meaning of acceptable risk is unavailable. Denzin considered the commonly accepted notion of beneficence from an Indigenous perspective and noted that

the principal of beneficence asks that research maximize benefits to the person and the collectivity while minimizing harm. Typically, harm has been determined through the application of the Common Rule, which asks if harm or risk does not exceed what is ordinarily encountered in daily life. (2003:9)

Anderson (1996) suggested that timeframes for the assessment of benefit (or risk) from research could be measured in terms of being short, medium or long term. In a commentary on variously presented timeframes for the achievement of benefit, Torzillo (1997) warned against over-emphasis on the achievement of identified short-term benefits and suggested that, sometimes, longer-term benefits need to be enabled. These benefits, he argued, will result from the advance of knowledge and not just immediate material gain. The WHO (2004) proforma *Research Agreement between Indigenous Peoples and Professional Researchers* requires researchers to nominate anticipated short- and long-term benefits to the community in terms of education, information gained, health gains and economic benefits. The WHO (2004) also suggests that agreements between Indigenous peoples and research institutions should be made in the context of a commitment to a long-term relationship.

A report commissioned by the CRCATH, *The Yarning Report* (Franks *et al.* 2001), considered the nature of the relationship between Indigenous and non-Indigenous research stakeholders. The authors referred to the development of a long-term research relationship as being central to the development of 'equivalent relationships' between professional researchers and Indigenous community members. Within this report it is argued that, once established, these relationships represent a potential for developing a level of ongoing 'ethical accountability' over activities between the parties and an avenue for the delivery of ongoing benefits from research.

In a commentary on the assessment of benefit associated with Indigenous research, Denzin cited Indigenous commentators Tuhiwai Smith (1999) and Bishop (1998a), who argued that that in Indigenous community contexts 'the collectivity must determine collectively what are the costs and benefits for participating in research' (Denzin 2003:110). Denzin also suggested that a cost-benefit model of society and inquiry does injustice to the empowering, participatory model of research that many Fourth World peoples are now advocating.

Glasziou and Chalmers (2004) pointed out that the balance of risks and consequences would clearly be different for different types of research. They pointed out that 'some questionnaires, clinical audits, or comparisons of standard treatments are associated with low risks, while comparisons of known treatments against placebo and studies of new, potentially dangerous interventions carry higher risks' (2004:121). Variations in approach to risk assessment, they argue, are inadequately considered within the mainstream model of ethical review currently operating in Britain and many European countries.

In an analysis of Indigenous research activity in Australia, Hart and Whatman (1998) argued that the most important question when determining how beneficial proposed research would be to any community is 'What will be left behind after you have completed your research?' (1998:18). According to Hart and Whatman, 'ideally, tangible outcomes such as procedures, changes in practice, ongoing community empowerment (through the sharing of *knowledge* and training), and workable infrastructure would exist' (1998:8). In a case study of a health education research project in the Torres Strait outlined by Hart and Whatman, the creation of new community decision-making structures, modified

curriculum development approaches and the training of Indigenous researchers based in the community were some of the outcomes negotiated between relevant sections of the community and the researcher (1998:8). A related conception of 'benefit' relates to the provision of 'service'. Miller and Rainow (1997), for example, argued that research activity should always be associated with 'service' to participating Indigenous communities.

The IPCB in Canada (2000) urged Indigenous peoples to consider the possibility of rejecting proposals for genomic research that do not represent a potential for directly benefiting their communities. The Council suggested that tribal leaders should demand that federal spending priorities be shifted away from genomic research in favour of funding programs and services that provide 'real outcomes and benefits for the community'.

For instance, instead of allocating federal funding for non-beneficial research such as the search for the 'binge-drinking' gene, funding should be spent on proven strategies, such as treatment programs. Instead of diverting precious resources to a search for 'the diabetes gene(s),' funding should be allocated to programs that provide direct benefits in improving diets, exercise, and lifestyles. (IPCB 2000:33)

The IPCB also noted that in the identification of potential research benefits, Indigenous communities are often disadvantaged by being dependent solely on the researcher for information explaining the benefits and risks of the proposed research (2000:19).

Processes for monitoring the achievement of nominated 'benefits' from research are also identified by some commentators as being historically inadequate in the Indigenous health research field in Australia. Commenting on previous Indigenous health research guidelines in Australia, McAullay, Griew and Anderson (2002) pointed out that although the 1991 *Interim Guidelines* suggested that proposed research should be useful to Aboriginal and Torres Strait Islander communities, the reality was that the guidelines did not provide criteria against which this could be assessed. In recent years, the NHMRC has called for the nomination of proposed benefits from research. McAullay, Griew and Anderson (2002) noted that in the 2000 and 2001 NHMRC funding cycles, for example, researchers were asked to articulate how their proposed research would lead to sustainable, transferable solutions and how the research process would enable community participation. What is apparently lacking, however, is a prescription for monitoring the achievement of nominated benefits from NHMRC-funded research.

McAullay, Griew and Anderson (2002) noted a proposal put forward by Kothari (1997) involving application of the notion of the 'Rights to the Benefits of Research' (RBR) in non-commercial research, and as a complement to Intellectual Property Rights (IPR). Kothari's RBR proposal involved a strategy to

enable Indigenous peoples to have access to monetary and non-monetary benefits from research, access and control of the findings, acknowledgment as being the rightful owners of the knowledge, and the opportunity to participate in the research process. (Kothari 1997 cited in McAullay, Griew & Anderson 2002:14)

According to McAullay, Griew and Anderson, the RBR proposal

may provide a pragmatic focus for discussion about future publication rights by addressing for the community the question, 'What are we going to get out of this?' An RBR complements rather than replaces IPR but can provide a focus for discussion that is more tangible and may lead more easily to meaningful agreements. (2002:14)

The WHO nominated two main ways of framing 'benefit' from research involving Indigenous community participation, and suggested the following considerations as a guide to community-based assessment of proposals:

- improved health status or services for the research population, or prospects of such improvement within a defined period of time through interventions discussed and agreed with the IP. The benefits, and the timeframes involved, will depend on the type and scale of the planned research;
- resources and funding for the training, employment (where appropriate capacities exist), and general capacity-building of community members in all aspects of the research process. In the past, community members have generally been employed in a token way, or in areas such as translation and data collection. This does not allow them to obtain a full understanding of the research process. (2004:7)

Compatibility between proposals for research and the identified needs and priorities of Indigenous peoples is noted by the WHO (2004) as an important marker for the assessment of research 'benefit'. This issue is reflected in the Australian health research literature where dissatisfaction with the overall level of Indigenous involvement in research priority setting is indicated. According to Henry *et al.* (2004), Indigenous research reform proponents have argued persistently that the establishment of Indigenous health research priorities should be located within the control of the community-based Indigenous health sector on the basis that 'a closer alignment between the interests of researchers and the interests of Indigenous peoples may be achieved' (Henry *et al.* 2004:52).

Recent Australian initiatives to ensure that community-identified Indigenous health research priorities are addressed have relied on processes for broad-based community consultation. This form of consultation has led to the nomination of key research priority areas in the draft *National Aboriginal and Torres Strait Islander Health Council Health Strategy* (NATSIHC 2002) and to the development of *The NHMRC Road Map: A Strategic Framework for Improving Aboriginal and Torres Strait Islander Health through Research* (NHMRC 2002). An objective of the *Road Map* is to

support the NHMRC to advise Aboriginal and Torres Strait Islander communities throughout Australia, on the achievement and maintenance of the highest practicable standards of individual and public health, and to foster research in the interests of improving those standards. (2002:3)

The draft NATSIHC Health Strategy (2002) identified important 'next steps' in the implementation of key research directions suggested in the 1989 *National Aboriginal Health Strategy* (NAHS 1989).

## Summary

Commentaries relating to the assessment of risks and benefit in Indigenous research canvass four main themes, including alternative constructions of the notion of benefit, proposed timeframes for the achievement of nominated benefits, proposals for ensuring that nominated benefits accrue to Indigenous peoples who are the 'subjects' of research, and suggested markers for the assessment of research 'benefit'. The application of locally negotiated research agreements is one identified way of achieving increased levels of Indigenous community input into the assessment of risks and benefits associated with research (WHO 2004).

### f) Consultation and consent

The literature relating to the establishment of effective processes for consultation and the achievement of collective and individual consent within the construction of Indigenous research is dominated by three main issues: contended notions of 'community' within the construction of research, the distinction between the application of community consent and individual consent, and the associated tension between 'group rights' and 'individual rights'.

According to McAullay, Griew and Anderson (2002), the Australian and international literature stresses that consultation needs to produce consent at both the community and the individual level if research in Indigenous communities is to be supported, and that a significant focus within the Indigenous health research literature centres on the problem of implementing effective community consultation and consent strategies. The authors suggested that the consent of individual research subjects is one of the bedrock principles of research ethics and identified an important distinction between community consent (which implies social collectivity) and the application of individual consent. Indigenous commentators generally agree that when the community interest is involved, community consent for the conduct of research is required. According to Bishop (a Maori researcher):

Knowledge is powerful and is to be treasured and protected for the benefit of the group, not for the individual... Rather, the gaining of new knowledge in a Maori context is to enhance the lives of all the participants involved. (1998b:428)

It is argued that Indigenous community consent for the conduct of research can most effectively be negotiated within the context of collaborative research partnerships (Sharp & Foster 2002; Bishop 1998b; WHO 2004). The difficulty in establishing a shared definition of 'community' for the purpose of consultation and the enactment of research involving Indigenous peoples is, however, a recognised barrier to achieving effective collaborative arrangements (Anderson, Griew & McAullay 2003; Dunbar *et al.* 2004; WHO 2004).

According to Zion (2003), examining the ethics of Indigenous research focuses us to explore what a community really is. Zion pointed out that although the notion of community is represented as a

warmly persuasive word, often denoting support, unity and friendship, many groups that are known as communities are in fact composed of diverse groups and individuals with different beliefs and values. (2003:2)

The WHO (2004) proposed that, depending on the structure of the Indigenous community concerned, it may be necessary to obtain three levels of consent for research: from individuals, from the community, and from an umbrella organisation. In addition to the informed consent of individuals, the consent of recognised representatives of Indigenous peoples should be required. According to the WHO, this is commonly achieved at a community leadership level through the Indigenous community's own internal procedures. The WHO proposed formal research agreements as the most effective mechanism for negotiating community consent. The third identified level of consent requires the involvement of a wider Indigenous organisation (umbrella organisation). The WHO proposed that as well as providing additional collective consent, this measure ensures that a larger collective is informed about, and consents to, the research. The WHO also warned that obtaining consent from community leaders or an umbrella organisation should not be considered a substitute for securing the consent of individual participants. Also, consent from an umbrella organisation should not be considered a substitute for consent from the community leadership.

Insufficient distinction between institutional and community approval for research is identified by Rawsthorne (2003) as a problematic issue in Australia. Rawsthorne suggested that there is concern from within the Indigenous community that current processes for gaining institutional ethical approval (involving HREC requirements for proof of individual informed consent) may hide the need for community ethical approval. The Indigenous Peoples Council on Biocolonialism (IPCB) is organised to assist Indigenous peoples in the protection of their genetic resources, Indigenous knowledge, and cultural and human rights from the negative effects of biotechnology. The IPCB refers to the tension between 'group rights' and 'individual rights' as follows:

Current bioethical protocols fail to address the unique conditions raised by population-based research, in particular with respect to processes for group decision-making and incorporation of cultural world-views. Genetic variation research is population-based research, but most ethical guidelines do not address group rights. In this context, one of the challenges of ethical research is to include respect for collective review and decision making, while also upholding the traditional model of individual rights. (2000:19)

## **Summary**

There is concern from within the Indigenous community that current processes for gaining institutional ethical approval (involving HREC requirements for proof of individual informed consent) may hide the need for community ethical approval. The IPCB (2000) refers to this problem in terms of the tension between 'group rights' and 'individual rights'. Others refer to the importance of gaining community support for research instead of community consent as a way of reinforcing the notion of 'in principle' support which is reliant on the researcher continuing to deliver on agreed processes. The WHO (2004) proposes that, depending on the structure of the Indigenous community concerned, it may be necessary to obtain three levels of consent: from individuals, from the community, and from an umbrella organisation.

## **g) Ethical governance systems**

The Australian and international health research literature details a range of proposals for the reform of systems for the ethical governance of human research. Commentaries typically include reference to structural issues including the need for broad-based reorganisation of existing ethical governance systems and more practical issues associated with implementing effective processes for committee-based ethical review of research. In the following section, commentary on the ethical governance of Indigenous and mainstream health research will be considered. The linkage between developments in the broader Indigenous policy domain in Australia and proposals for change involving the ethical governance of Indigenous research will then be discussed.

Representatives of Indigenous interests in Canada, USA, New Zealand and Europe have detailed problems associated with developing effective processes for the representation of diverse community interests within overarching ethical governance systems. In Canada for example, the Canadian Interagency Advisory Panel on Research Ethics was established to review the Canadian ethical governance system. This panel was mandated to represent the interests of a broad range of research stakeholders and major Aboriginal stakeholder organisations have since advised the panel on processes for addressing Aboriginal values through a separate Aboriginal research ethics framework (Kaufert & Lavoie 2003). While the panel mandate did not include a special focus on Indigenous community interests, it stated significant commitment to a broad consultation process leading up to recommendations for change to the Canadian ethical governance system. The panel identified poor co-ordination between organisations actively engaged in research activity as especially problematic.

In a commentary on the broad-based project to decolonise Indigenous research activity in the USA, Denzin (2003) argued that under the current system for ethical review of research involving Institutional Review Boards in America, the interests of Indigenous peoples are not adequately represented. He proposed change involving the implementation of a two-track system, one model for the bio-medical sciences and another model for the human sciences and the humanities as a possible way forward. More radically, Denzin proposed another option involving the dismantling of the IRB system altogether and rejection of the bio-medical model (Belmont model) as the main tool for assessment of research proposals. In his view, this would involve the replacement of the current 'top-down', State-sponsored model to the local level entirely. Under this proposed system, 'inquiry would be collaborative, done through the kind of moral give and take outlined by Indigenous and First Nation Scholars' (Denzin 2003:15).

Commenting on the British system for ethical review of human research, Glasziou and Chalmers (2004) were critical of a 'pan' approach to the application of ethical standards to all types of research. The authors questioned the merit of maintaining an ethical governance system that takes inadequate account of the overlap between the spheres of responsibility of research governance and clinical governance. They argued that it is time that a more concerted effort is made to assess the likelihood of benefits, harms, and costs

of different approaches to ethics review for different types of evaluation and that although ethical standards are clearly essential for all types of evaluation, the notion that 'one size of ethics review fits all types of evaluation, should be rejected' (Chalmers 2004:121).

Within the WHO (2004) model, formal research agreements are proposed as the most effective mechanism for negotiating consent at the community level. In summary, the WHO approach relies on recognition of the rights of individuals, of the local community and of umbrella organisations in the ethical assessment of proposed research. Indigenous research agreements are proposed as a practical way of achieving this goal within existing international mainstream ethical governance systems. It is interesting to note that the success of this approach is reliant on participation by local Indigenous leadership structures and umbrella Indigenous organisations. In the Australian context, some questions remain: How well equipped are HRECs within the existing ethical governance system to mediate the requirement for gaining three levels of Indigenous community consent for research? Are the structures in place in local communities to provide the level of Indigenous participation required? The WHO provides some direction in this regard by pointing to the potential role of Indigenous community-controlled organisations in the ethical assessment of research:

In some developed countries, ethics committees have been established by within indigenous-controlled organizations to represent the Indigenous participants in the proposed research. Where they exist, such committees must have a say on any ethical issues and approval procedures pertaining to the proposed research. (2004:5)

Mainstream commentaries on the ethical review of health research in Australia focus mainly on practical problems associated with the conduct of committee-based review. The literature (outlined in more detail in Section 6 of this review, 'The Current Status of the Australian HREC System'), identifies problems including:

- rapid pace of change associated with interventions in the bio-medical research field;
- burgeoning workloads of HREC members;
- reportedly insufficient level of HREC resourcing;
- intervention of varied methodological approaches to research; and
- tension between demands for increased levels of community input into research activity (including input into the ethical assessment of research) and industry pressure to centralise arrangements for the ethical review of research.

Identified issues of relevance to the Indigenous health research sector include the reportedly inadequate level of resourcing of mainstream HRECs and the relatively small number of specialist Indigenous health research committees and sub-committees, and the tension between the recognised need for increased levels of Indigenous community input into the ethical assessment of research and proposals recommending increased centralisation of processes for ethical review of mainstream research.

The current agenda for reform of Indigenous research activity aims to ensure increased levels of Indigenous involvement in all stages of research activity; a process demanding



additional (and not reduced) opportunities for direct community involvement in decision-making at key points in the research process. Commenting on mainstream health research, Millar (2002) argued that the centralisation trend might impact negatively on achieving requisite levels of local community input into the ethical assessment of proposed research.

Ethical review of Indigenous health research in Australia is carried out substantially within the mainstream HREC system. Within this system there is provision for special consideration of Indigenous interests through the intervention of a small number of specialist Indigenous committees and sub-committees, Indigenous membership on mainstream committees, selective reference to expert Indigenous advice outside the committee process and national guidelines for the conduct of Aboriginal and Torres Strait Islander health research (CRCATH 2002). The CRCATH *Survey of Australian Human Research Ethics Committees* (2002) provided preliminary evidence that only a select number of HRECs regularly deliberate over Indigenous health research proposals in Australia. The survey identified six Aboriginal and Torres Strait Islander ethics committees or sub-committees registered with the NHMRC. These committees were reportedly operational in Queensland, New South Wales, Northern Territory, South Australia and Western Australia. The *Onemda* VicHealth Koori Health Unit (formerly VicHealth Koori Health Research and Community Development Unit) initiated research in partnership with the Victorian Aboriginal Community Controlled Health Organisation that reviewed a range of processes for improving Aboriginal Community input into the ethical assessment of proposals for Aboriginal health research. The research findings outline some appropriate models for the ethical review of Aboriginal health research in Australia (Stewart & Pyett 2005).

Commentaries on the implementation phase of the *Values and Ethics Guidelines* in Australia emphasise the importance of ensuring adequate opportunity for local Indigenous community values and interests to be represented within the construction and ethical assessment of research (Anderson, Griew & McAullay 2003; Gillam & Pyett 2003). While the development of an alternative governance system to guide the ethical assessment of Indigenous research has not been recommended, the imperative to develop more appropriate mechanisms for ensuring adequate representation of Indigenous community values and interests is implied.

Consideration of various models for Indigenous representation features strongly in the literature relating to the development of Indigenous systems of governance in the broader political sphere in Australia. Particular emphasis is placed on opportunities for representation of Indigenous interests through the network of Indigenous organisations which developed during the period broadly defined in policy terms as 'self-determination'. Rowse pointed out that

one of the outstanding results of the policy of self-determination in Australia has been the rise of the Indigenous sector and the institutions of this sector now form part of the apparatus by which Australians (especially Indigenous Australians) are governed.  
(2002:2)

In an analysis of the history of the Aboriginal and Torres Strait Islander Commission (ATSIC), Palmer (2003) noted recent changes in political rhetoric in Australia away from terms like 'self-determination' and 'self-management' to the application of terms such as 'empowerment' and 'outcomes for Indigenous Australians'. Despite indications of waning support for the goal of self-determination for Indigenous peoples across a range of government program areas, Palmer argued that the essentials have been put in place with the establishment of Indigenous representative organisations. Palmer noted evidence of generalised government support for decentralisation of Indigenous governance and service delivery structures, and suggested that devolution of responsibility for decision-making to local Indigenous organisations can be supported on the grounds that it facilitates representation of diversity and ownership of decisions that affect people at local levels (2003:12).

'Good governance', according to Dodson and Smith (2003), provides the foundation for sustainable community development. The authors also suggested that Indigenous communities and their representative organisations have potentially significant control over the development of future governance arrangements. Within the context of considering the future of ATSIC, Palmer pointed out that representation of diversity, localism and the desire for people to own the decisions that affect them most, all support the ideal that greater decision-making and responsibility be devolved to local organisations (2003:216).

## **Summary**

Commentaries on the implementation phase of the *Values and Ethics Guidelines* in Australia emphasise the importance of ensuring adequate opportunity for local Indigenous community values and interests to be represented within the construction and ethical assessment of research (Anderson, Griew & McAullay 2003; Gillam & Pyett 2003). The extent to which the current Australian HREC system can accommodate proposals for localised and community-based interpretations of research guidelines remains unclear. It is, however, strongly argued that full benefit from the *Values and Ethics Guidelines* will only be realised if there are some changes to current governance structures and processes (Anderson, Griew & McAullay 2003; Gillam & Pyett 2003; Sporle 2003; Cunningham 2003).

While the development of an alternative governance system to guide the ethical assessment of Indigenous research is not directly recommended by Australian commentators, the imperative to develop more appropriate mechanisms for ensuring adequate representation of Indigenous community values and interests in the ethical assessment process implies the need for change. An ethical governance structure with a capacity for linking with existing structures of Indigenous representation throughout Australia seems an obvious way forward. Representation of diversity, localism and the desire for people to own the decisions that affect them most, all support the ideal that greater decision-making and responsibility should be devolved to local organisations (Palmer 2003:216).

## 8. Key Findings

The history of engagement between Indigenous peoples and the broader health research community in Australia is well documented in the literature. Commentaries trace the development of guidelines for the construction and ethical assessment of Indigenous health research since the 1970s (Humphery 2003a, 2003b; Anderson, Griew & McAullay 2003) and provide a rationale for the reform of frameworks for ethical assessment.

The literature indicates generalised concern about the effectiveness of an approach to ethical decision-making that is based primarily on the application of externally developed research guidelines. Identified concerns include the static nature of guidelines, difficulties in interpreting guidelines, lack of uniformity in the application of guidelines by HRECs, the prescriptive nature of guidelines, the difficulties in adapting guidelines to local conditions, researcher resistance, differing requirements for assessing bio-medical and behavioural research, and the inadequacy of processes for monitoring both researcher and institutional adherence to existing research guidelines.

The sustainability of the Australian HREC system is currently the focus of extensive interest in the literature. Several commentators have expressed concern that the increasing workload of HRECs is problematic (Dodds 2002a, 2002b; Frew 2003; Savalescu 2002). This situation is reportedly being driven by current trends including the increasing volume of research applications; the complexity of proposed specialist research interventions in the biological sciences (particularly gene therapy); increased requirements for monitoring researcher and institutional compliance with existing guidelines and approved protocols; advocacy for recognition of special group interests; the increasing complexity of assessing large, multi-site research projects; and the increasing application of complex legalistic frameworks for assessment of research proposals (frequently driven by large company interests).

The literature includes proposals for change aimed at redressing the problem of burgeoning HREC workloads. Some commentators are pointing to the inevitability of an increasingly centralised approach to ethical assessment involving, among other things, the development of specialist and nationally based ethics committees (expert 'suprainstitutional' ethics committees) and the implementation of standardised application forms and committee deliberation processes. These proposals contrast with the suggestion that uniform ethical principles or guidelines should ideally be supplemented by internally developed committee guidelines that become 'local expressions' of those principles (Albury *et al.* 1996:17).

Proposals for reform of the current system for ethical governance of Indigenous and mainstream health research share a common requirement for additional resources and

substantial structural reform. This presents as a problematic option when considered within the context of commentary detailing the current widespread under-resourcing of HRECs in Australia (Savalescu 2002; Dodds 2002a, 2002b). A special case for the provision of additional resources to promote and protect the interests of Indigenous and other minority groups within the current system for ethical review of research in Australia generally relies on the argument that their minority profile, social disadvantage, ongoing poor health status and historic marginalisation of their cultural and material interests warrants a different or 'special' approach.

Recognising the distinction between 'participatory' and 'protective' approaches to the development of ethical research guidelines is important to understanding the intention of the NHMRC *Values and Ethics Guidelines* (2003a). While the NHMRC 1991 *Interim Guidelines* maintained a focus on 'protection' of the interests of Indigenous peoples, the *Values and Ethics Guidelines* aim to extend the boundaries of ethical assessment to promote 'inclusiveness' as a way of ensuring that the previous history of marginalisation of Indigenous interests within the construction of research is redressed. According to commentators, the success of such an intervention will rely on the application of research guidelines in close consultation with Indigenous peoples at the grassroots level (Anderson, Griew & McAullay 2003; Gillam & Pyett 2003).

There is apparent tension between the trend toward the centralisation of processes for the ethical assessment of health research and the project to ensure that local community interests inform the ethical assessment process. The extent to which the current HREC system is capable of accommodating localised interpretation and application of the *Values and Ethics Guidelines* remains a matter for speculation. It is, however, argued that full benefit from the guidelines will only be realised if there are some changes to current practice (particularly at the level of involvement by locally-based Indigenous community representatives in the ethical assessment process) (Anderson, Griew & McAullay 2003) and additional clarification of the rights and responsibilities of stakeholders with an interest in Indigenous research (namely, HREC members, institutions, researchers and Indigenous community members). The development of appropriate processes for priority setting, evaluation and monitoring of Indigenous research activity and Indigenous participation in ethical assessment of research are regarded as key areas requiring institutional attention in Australia.

It has been argued that although Australian institutions have historically benefited from involvement in Indigenous research activity, institutional commitment to the implementation of processes to support appropriate approaches to research has been inadequate (Kelly & O'Faircheallaigh 2001; Scrimgeour 2002; ARC 1999; Melville & Rankin 2000; Rawsthorne 2003; Hart & Whatman 1998). The development of appropriate processes for research priority setting, evaluation and monitoring of Indigenous research activity, and Indigenous participation in the ethical assessment of research are regarded as key areas requiring institutional attention in Australia.

A developing international movement for the reform of Indigenous research activity includes significant alignment between the positioning of Indigenous advocates over

proposals to reform processes for the ethical assessment of research. There is broad agreement over issues including:

- The need to reconceptualise IPR to take adequate account of communal rights associated with Indigenous knowledge generation and transmission.
- The need to increase the level of Indigenous community input into the identification and assessment of the 'risks and benefits' of research.
- The adoption of research guidelines that extend beyond 'protection' of Indigenous interests to include processes that 'enable' the agenda for reform of research activity.
- The need for development of regional and local frameworks for the ethical governance of Indigenous research.
- The value of developing formal research agreements between professional researchers and Indigenous peoples (based on nationally constructed guidelines).

The application of locally negotiated research agreements is one of the identified ways to achieve increased levels of Indigenous community input into the assessment of risks and benefits associated with research (WHO 2004).

While the development of an alternative governance system to guide the ethical assessment of Indigenous research is not directly recommended by Australian commentators, the imperative to develop more appropriate mechanisms for ensuring adequate representation of Indigenous community values and interests in the ethical assessment process implies the need for change. An ethical governance structure with a capacity for linking with existing structures of Indigenous representation throughout Australia seems an obvious way forward. Representation of diversity, localism and the desire for people to own the decisions that affect them most, all support the ideal that greater decision-making and responsibility should be devolved to local organisations (Palmer 2003:216).

### **a) Questions arising from this review**

- Is there potential for arguing that there are links (through cultural principles) between proposals to reform both the ethical assessment of research proposals and the application of appropriate research methodologies in the Indigenous research field?
- Is there sufficient capacity within the current system for ethical assessment of research in Australia for properly considering the particular circumstances of Indigenous peoples?
- What are the most effective processes for achieving optimal levels of Indigenous community input into the ethical assessment of research and does devolution of responsibility to local Indigenous community-controlled organisations represent a viable option?
- What is the current status of the Indigenous ethics committee and sub-committee network in Australia, and how effectively is this network integrated into the mainstream HREC system?

- How will proposals for change to the current system of ethical governance for Indigenous research in Australia impact on the broad-based project to reform Indigenous research activity?
- What can Australia learn from international initiatives to improve processes for the ethical governance of Indigenous health research? In particular, what specific proposals for change emanate from the current review being undertaken by the Canadian interagency advisory panel on research ethics, what is the evaluation of the recently reformed New Zealand system of ethical governance for Maori research (involving mandatory membership of two Maori representatives on all HRECs), and what further steps are being taken by the WHO to promote Indigenous participation in the ethical governance of research worldwide?
- What is the extent of alignment between the expressed concerns of Indigenous peoples and other minority or marginalised groups (both in Australia and internationally) about the need for changed approaches to the ethical assessment of research?
- Responsibility for research ethics education and research monitoring is poorly defined in the NHMRC 1999 *National Statement*. Does this ambiguity lead to the perception that responsibility for these functions rest with HRECs and not Institutions?

## **b) Identified ‘best practice’ interventions to support the ethical assessment of Indigenous health research (Australia and international)**

The following ‘best practice’ interventions (designed to assist in the ethical assessment and conduct of Indigenous research) have been identified from the Australian and international research literature. It is considered that further investigation and adaptation of these interventions will potentially inform the development of processes to improve the ethical assessment and conduct of Indigenous health research in Australia.

- 1) Implementation of special purpose sections in ethics application forms for Indigenous health research proposals and the development of national electronic ethics application forms that are applicable across disciplines.
- 2) Implementation of Memorandums of Understanding between Aboriginal or Torres Strait Islander health research organisations and research project teams
- 3) Formalisation of research agreements between Aboriginal and Torres Strait Islander representatives (for example, Indigenous community-controlled organisations) and intending researchers (WHO 2004; Henderson *et al.* 2002).
- 4) The development of a regional network of Aboriginal and Torres Strait Islander ethics committees and sub-committees to operate in conjunction with existing Indigenous community-controlled organisations.
- 5) Increased Aboriginal and Torres Strait Islander membership on mainstream HRECs.

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