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GUIDELINES FOR RESEARCH INTO ABORIGINAL
HEALTH

(Including appendices)

AH&MRC Ethics Committee's Submissions to the NHMRC

**The Aboriginal Health & Medical Research Council
of New South Wales**

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Produced by the Aboriginal Health & Medical Research Council of NSW.

Foreword

The history of Aboriginal health research reflects a persistent reluctance to take seriously the need to consult with and receive consent from the Aboriginal communities that are the subject of research. On occasion there has even been blatant circumvention of cultural mores and processes. The issues of relevance; duplication; necessity; cultural appropriateness; standards of excellence; timely consideration; individual and community consent; transference of skills; positive and tangible Community benefits and outcomes; and employment opportunities have been conspicuously absent, or belatedly sought.

Regrettably, this aloofness and polarised positioning has had counterproductive implications for research into Aboriginal health. Conversely, the unique conventions, familial structures, mores, wisdom, learning, cultural imperatives and protocols of Aboriginal society are often unknown, or else ignored, breached or mistaken.

The NAIHO Ethical Guidelines developed by Aboriginal scholars during the 1980's and the subsequent NH&MRC Ethical Guidelines into Aboriginal Health, developed in the 1991, provided yardsticks by which research was considered to be appropriate. Nonetheless, ill-considered research continued unabated, particularly where Community ethical consent was assumed to have been granted or where certain elements within academia persisted undaunted oblivious of Aboriginal community protocol and conventions.

To combat this tendency, the Aboriginal community has provided more recent definitive documentation such as the *NACCHO Data Protocols for the Routine Collection of Aboriginal Health Data (1997)*. Parallel to this process was the emergence of Aboriginal Health Ethics Committees at the State and Territory level throughout the country. This opportunity for scrutiny of research into Aboriginal health from an Aboriginal perspective has sharpened the focus on ethical propriety and scientific rigour when researching in Aboriginal health. This national Aboriginal ethical perspective will be formalised by the establishment of the *Coalition of Aboriginal Health Ethics Committees (CAHEC)* with representation from most States and Territories.

From these experiences, and those of an Aboriginal Health Ethics Committee routinely evaluating ethical and cultural compliance in health research, the AH&MRC Monograph, *Guidelines for Research into Aboriginal Health*, has been developed. It seeks to provide scholars, data custodians and academic institutions with helpful suggestions for researching into Aboriginal health and comments on processes that facilitate meaningful and constructive relationships with Aboriginal communities where the amelioration of ill health and lack of well being is sought.

The Editorial Committee

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Guidelines for Research into Aboriginal Health

by the

AH&MRC Ethics Committee

of the

Aboriginal Health & Medical Research Council
of New South Wales

1. BRIEF HISTORY OF THE AH&MRC ETHICS COMMITTEE

In 1996 the Executive Committee of the precursor organisation to the AH&MRC, the former NSW Aboriginal Health Resources Co-operative Ltd. (AHRC), being the peak Aboriginal health body in NSW, resolved to establish an ethics committee to specifically evaluate research projects which relate to the health of Aboriginal people.

The need for an Aboriginal ethical perspective and analysis of research and data surveys into Aboriginal health arose following sustained practice over decades which enabled inappropriate, unnecessary or duplicated research being undertaken without Aboriginal community consultation or approval.

It was further observed that many research applicants were oblivious of the acknowledged definitive documents outlining necessary ethical standards when researching into Aboriginal health. Even when a superficial familiarity of these sources was indicated, inadequate examination for compliance with the criteria was being carried out by non-Aboriginal committees unaware of Aboriginal cultural and spiritual values nor conversant with important Aboriginal societal mores and protocol.

Since its inception the AH&MRC Ethics Committee has met regularly, evaluating applications for research into Aboriginal health upon criteria enunciated within the numerous documents outlined in the following historical summary. It has tendered numerous submissions on Aboriginal health related matters and provided a comprehensive submission to the Australian Health Ethics Committee on the proposed revision of both the *Statement on Ethical Conduct in Research Involving Humans* and the *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research 1991*.¹

¹ The printing of this *Volume* in the *Monograph Series* has been postponed since 1999 pending the publication of the replacement NHMRC document for the *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research (1991)*. This occurred with the NHMRC publication *Values and Ethics: Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research* in 2003. The AH&MRC has attempted to negotiate ethical guidelines that embody the principles of the original document and in this context copies of both AH&MRC submissions to the NHMRC, alluded to here, together with the AH&MRC response to NACCHO concerning the final version of the NHMRC document, are attached as additional appendices for perusal and objective evaluation. [Editorial Committee 2004]

This document is an attempt to bring together the diverse threads from within various position statements, documents, reports, guidelines and conferences which refer to ethical conduct when researching the health of Aboriginal people and to provide a helpful and useful tool to assist both members of Aboriginal ethical committees in their deliberations and evaluations as well provide a helpful guide to applicants seeking to carry out culturally appropriate and necessary research into Aboriginal health.

2. HISTORICAL CONTEXT FOR THE DEVELOPMENT OF ETHICAL STANDARDS FOR RESEARCH IN ABORIGINAL HEALTH

A) National Conference on Research Priorities into Aboriginal Health

At Alice Springs in December 1986 a national conference entitled '*Research Priorities into Aboriginal Health*' was held under the auspices of the National Health and Medical Research Council (NHMRC) and the Menzies Foundation. The conference concluded that special consideration was well overdue to Aboriginal and Torres Strait Islander peoples in the area of research into their health carried out with the highest standards for scientific method and ethical conduct. The singling out of the Aboriginal community for special consideration was due to the following conference conclusions:

- a) The conspicuous level of poor health stemming from social, historical and cultural factors.
- b) Past research into Aboriginal health had failed to address this poor level of health adequately and was primarily concerned with non-Aboriginal or scientific matters.
- c) Insensitivity amongst researchers to the values, needs and customs of Aboriginal and Torres Strait Islander communities.
- d) A lack of appreciation of ethical issues relevant to research involving Aboriginal and Torres Strait islander peoples, which led to, *inter alia*,
 - advice and approval of Aboriginal or Torres Strait Islander individuals in Government departments being accepted as a substitute for proper community consultations and negotiations;
 - lesser standards for obtaining consent among disadvantaged Aboriginal and Torres Strait Islander Communities;
 - conflict between activities thought to be ethically proper and scientifically sound research and Aboriginal and Torres Strait Islander views on moral, social and cultural correctness;
 - Aboriginal and Torres Strait Islander groups being more vulnerable than other sections of the Australia community to exploitation by persons conducting research.

B) 'National Workshop of Ethics in Aboriginal Health'

The subsequent 'National Workshop of Ethics in Aboriginal Health' was convened in 1987 near Camden, funded by the NHMRC, to address the "contentious" issue of ethics as it relates to research into Aboriginal health. Accordingly, it developed a set of ethical guidelines into research into Aboriginal health and developed mechanisms

necessary to establish a nexus between the guidelines and Aboriginal health research funding.

The conference formulated clarifying statements, among which were that:

- Aboriginal communities be given a greater say in the distribution of funds, allocation of priorities, the methodologies of research and the implementation and evaluation of research proposals
- Aboriginal communities be central to the development and execution of research
- Aboriginal communities receive financial support for research and development training
- priority be given to the collective nature and needs of Aboriginal communities over that which is individualistically oriented
- priority be given to issues for research that are identified by Aboriginal communities

C) Report of the National Workshop on Ethics of Research in Aboriginal Health, (NAIHO)

The subsequent NAIHO² *Report of the National Workshop on Ethics of Research in Aboriginal Health* is a definitive document on ethics into Aboriginal health research to which applicants are referred as it represents criteria by which the AH&MRC Ethics Committee bases its assessment of research applications.

This scientific and ethical conference witnessed proactive, positive and culturally appropriate initiatives for ethical conduct when researching into Aboriginal health. It recommended that the initial stages of research and data collection have to conform to stringent guidelines that meet Aboriginal community approval.

Obtaining ethical approval from the Community controlled sector is spelt out with clear expectations for what constitutes proper consultation.³ The process of “consultation/negotiation” has to be clearly identified, ensuring that proper discussion occurs and that the control of these is vested in the Communities.

Provision must be made to also ensure that appropriate cultural protocols and procedures are in place. It is clearly stated that approval of Aboriginal people in government departments is no substitute for proper community consultation/negotiations.⁴

The *Report* mentions the importance of Community involvement at each stage of research and the related data collection process. It covers topics on such subjects as:

² NAIHO being the precursor organisation to NACCHO

³ *National Aboriginal & Islander Health Organisation (NAIHO), Report on the National Workshop on Ethics of Research in Aboriginal Health, 1 & 2*

⁴ *ibid.*

- The Process of Consultation
- Social and Gender Issues
- Community Benefit
- Communication and Consent

“Communities must be provided with all the relevant information and explanations on the intent, process and methodology, evaluation and potential use of any research proposal.

Researchers must comply with any request for further information from relevant community controlled agencies associated with the research proposal.

Community process of decision making will reflect varying social and cultural values. In obtaining the consent of communities to research, researchers must respect the Aboriginal community’s process of decision making.”⁵

- Employment of Local Aboriginal People

The recommendation for employment of Aboriginal people in research projects is also within the context of ethical matters associated with researching in Aboriginal and Torres Strait Islander health.

“In many circumstances the employment of community members will aid the Researcher and improve the quality of communication and ultimately strengthen the initiative.”

“Researchers, where local community controlled agencies believe it necessary, must provide for the employment of local Aboriginal co-investigators.”⁶

Accordingly, where Aboriginal people are locally employed in health research projects as mentioned above, where possible, the process of recruitment, selection and employment should be undertaken in association with Aboriginal Community Controlled Health Services.

- Ownership and Publication of Materials

The *Report* also covers publication and ownership of material and the on-going role in monitoring the implementation of research, all of which are considered of vital importance to local Aboriginal communities. This report reflects the current position of NACCHO and its state affiliates. Some of the recommendations within this area are:

“Research material and data shall remain the property of the Community. The Community retains the right to censor research of a sensitive nature. Prior to publication or other use of research materials or Reports, the approval of the relevant controlled agency is required.”

“In preparing acknowledgement of research, the proper accreditation of participation and assistance of Aboriginal individuals, communities and their agencies should be noted.”⁷

⁵ *ibid. Part 5*

⁶ *ibid. Part 6*

⁷ *ibid. Part 7*

- Exploitation of Aboriginal Community Resources

As other primary documents have recognised, there should be no imposition upon the Aboriginal community controlled health sector to be involved in processes that are not adequately funded or resourced.

Associated costs incurred by Aboriginal communities and Aboriginal community controlled organisations should be fully reimbursed. The role of the department in this respect would be considered the body responsible for meeting these costs.

“In seeking the co-operation of Aboriginal communities and local community controlled agencies, [researchers] must provide reimbursement of any cost incurred which relates, directly or indirectly, to programs of research. Such costs could include telephones, transport, freight, gas and water, accommodation, supervision costs and wages of assistants and interpreters.”⁸

- Ongoing Review of Ethical Standards

The *NAIHO Report* realistically appraises ethical standards in Aboriginal health and recommends

“Ethics Committees and the relevant community controlled agencies have an ongoing responsibility to ensure compliance with appropriate ethical standards.”⁹

The thrust of the remainder of this section of the *Report* specifically relates to procedures for research projects and practical recommendations for administering of related funds. This document is very relevant to research and the collection and use of Aboriginal health information. The *Report* is definitive in any consideration of ethical standards in consideration of proposals for research into Aboriginal health.

D) Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research, 1991 (NH&MRC)

A later NHMRC document, *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research* was published in 1991 and also provides helpful procedural material to which research applicants are directed. The *Guidelines* are also used as a definitive source upon which research proposals are evaluated by the AH&MRC Ethics Committee.

E) National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health, 1997 (OATSIHS/NACCHO)

[A summary of these Protocols is attached in Appendix 4, page 10]

A further ethical publication was developed in October 1997 entitled *National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health (1997) (OATSIHS)*, and was endorsed by the NACCHO and the then AHRC Executive Committees in 1998.

⁸ *ibid.* Parts 8

⁹ *ibid.* Part 3

The establishment of these “culturally sensitive and ethically sound privacy and confidentiality protocols” was a provision within the *Commonwealth/State Framework Agreements*, which clearly acknowledged Aboriginal and Torres Strait Islander ownership of health data.

“These protocols are to recognise Aboriginal and Torres Strait Islander ownership of the data including clarity about the collection and use of data. Any change in the use of the data will require agreement from the owners of the data;”¹⁰

This document, specifically designed for the collection and use of data from Aboriginal Community Controlled Health Services, has clearly demonstrated the necessity for separate ethical guidelines for the gathering of research data in Aboriginal health.

Whilst it is not entirely applicable for all types of research it will indicate the extent and complexity of the ethical dimension when researching the health of Aboriginal people, requiring onerous and rigorous evaluation from a cultural perspective. An adaptation of these ethical provisions for routine data collection on Aboriginal health has been provided later in this document which would be considered by the Ethics Committee when undertaking evaluation of research projects into Aboriginal health.

F) Recommendations of the Royal Commission into Aboriginal Deaths in Custody

The *Recommendations of the Royal Commission into Aboriginal Deaths in Custody* also specifically address the area of statistical data and health information on Aboriginal health. (see *Recommendations* 250, 260 & 270)

Of particular importance are the following:

Recommendation 260 (b)

That representatives of the Aboriginal community should be invited to participate in the control of the evaluation and research activity;

Recommendation 270 (a)

That Aboriginal people be involved in each stage of development of Aboriginal health statistics;

G) National Aboriginal Health Strategy (NAHS)

The National Aboriginal Health Strategy contains an entire chapter on the specific issues of data systems, evaluation and monitoring the prevailing condition of Aboriginal health, all of which require the need to ensure compliance with ethical standards.

¹⁰ *Agreement on Aboriginal and Torres Strait Islander Health between the [relevant State or Territory Minister for Health]; the Commonwealth Minister of State for Health and Family Services; the [Relevant State or Territory peak bodies affiliated with NACCHO]; and the Aboriginal and Torres Strait Islander Commission, 3.12*

Throughout the *Strategy* the place of Aboriginal community is central. Monitoring and evaluation by the community "serve a useful purpose in promoting greater participation in the provision of Primary Health Care."¹¹

"Communities have often had good reason to see the process of monitoring and evaluation as a means by which government might gather information about a community without that community's consent and/or the means by which government might coerce a community into adopting standards it might otherwise wish to reject."¹²

The centrality of the Aboriginal Community in all matters relating to its own health is paramount throughout the Strategy and involvement of Aboriginal communities in the process itself is seen as "integral" in making an objective analysis of progress in Aboriginal health. This includes the evaluation of research and the collection of data.¹³

The *Strategy* considers that the essential attributes to the collection of data on the health of Aboriginal people are:

"Relevance, adequacy, progress, efficiency, effectiveness quality and impact."¹⁴

and considers it

"is also necessary to have a clear picture of how and by whom the information is to be used."¹⁵

These are particular matters against which research proposals are assessed.

H) Aboriginal and Torres Strait Islander Health, Goals and Targets

Another document which address the ethical values necessary for research into Aboriginal health is *Aboriginal and Torres Strait Islander Health, Goals and Targets*, an interim document developed in March 1992 under the oversight of a committee which comprised the Department of Health, Housing and Community Services, ATSIC, Department of Education and DEET with Community input, in particular, the Kimberley Aboriginal Medical Service and the North Queensland Aboriginal and Torres Strait Islander Child Care.

The document specifically address health information and health research in Aboriginal health, and aligning with the NAHS and NAIHO positions, it recommends:

- Ensure research in Aboriginal and Torres Strait Islander communities appropriately and adequately addresses the issues of:
- Community consultation in proposal preparation with indication of its usefulness to the community and a demonstrable process for obtaining informed consent;
- Community rights to seek an independent opinion on the research proposal;
- Community involvement in the research project;

¹¹ NAHS, 12.1.2

¹² *ibid.* 12.1.2

¹³ *ibid.* 12.1.4

¹⁴ *ibid.* 12.1.3

¹⁵ *ibid.* 12.1.2

- Community ownership of blood or tissues samples gathered during the project;
- negotiation over the disposal or storage of raw data;
- publication and appropriate acknowledgement;
- training and development of indigenous research workers wherever possible;
- media arrangement; and
- requirement of future consent for use of information or biological materials for ‘piggy back’ or other research not explicitly covered by initial arrangements.”¹⁶

I) NSW Aboriginal Health Information Guidelines (NSW Aboriginal Health Partnership)

In August 1998 the NSW Aboriginal Health Partnership, a formal co-operative working relationship between the NSW Health Department and the AH&MRC, known then as the AHRC, developed guidelines covering ethical responsibilities in Aboriginal health information which form the basis for a *Memorandum of Understanding* between the Minister for Health in NSW, the NSW Health Department and the Aboriginal Health & Medical Research Council of New South Wales.

The purpose of these *Guidelines* is to ensure consistency and good practice in the management of health and health related information about Aboriginal and Torres Strait Islander peoples in NSW. The document also addresses such subjects as “the collection, ownership, storage, security, access, release, usage, reporting and interpretation of information as well as issues of confidentiality and privacy.”

The AH&MRC Ethics Committee would expect adherence to the *NSW Aboriginal Health Information Guidelines* by all prospective researchers.

The document specifically clarifies where Aboriginal community consent is considered necessary for the collection and use of health and health-related community information. Aboriginal community consent is required if one or more of the following factors apply:

- Aboriginality is a key determinant;
- data collection is explicitly directed at Aboriginal peoples;
- Aboriginal peoples, as a group, are to be examined in the results;
- the information has an impact on one or more Aboriginal communities; and
- Aboriginal health funds are a source of funding.¹⁷

¹⁶ *National Aboriginal and Torres Strait Islander Health Goals and Targets, (Interim) 1992*, Department of Health Housing and Community Services, Goal 44. p. 70

¹⁷ *NSW Aboriginal Health Information Guidelines*, NSW Department of Health and the NSW Aboriginal Health Resources Co-operative, 1998, 6.1. p.4. The importance of this document and its intrinsic cultural imperatives should not be underestimated as there is a provision in the NHMRC publication *Values and Ethics: Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research* (2003) that enables adherence to Aboriginal cultural ethical processes in NSW, namely, “In some jurisdictions, review or approval procedures may have been given regulatory status by government legislation or published policy. These will vary between jurisdictions, however, these procedures should be followed.” p. 23. Whilst this welcome caveat still presupposes government interpretation and control over Aboriginal cultural matters the astute initiative of the government within this jurisdiction should be acknowledged as it has enabled an Aboriginal conscience to prevail

Tangible assistance is provided for inclusions to a consent agreement which would complement similar recommendations in the *National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health*.¹⁸ These inclusions are as follows:

- an explanation of why the information is being collected and how it will be used;
- assurances that additional consent will be sought if there are any changes in the specified use of the information
- identification of who will, or is likely to, have access to the information; and
- advice regarding the right to withdraw consent.¹⁹

3. ETHICAL CONSIDERATION AND THE ROLE OF THE ABORIGINAL COMMUNITY

The above-cited documents provide clear indication of the role of the Local Aboriginal Community for research into Aboriginal health and their right to ensure ethical standards are maintained.

The NAIHO report, specifically writing to address ethical issues for research into Aboriginal health, advocates Community involvement at each stage of the research and data collecting process. Stringent and appropriate guidelines for Aboriginal community involvement have to be met with the actual control over the consultancy and negotiation process vested in the Communities themselves.

“Communities must be provided with all the relevant information and explanations on the intent, process and methodology, evaluation and potential use of any research proposal.

“Researchers must comply with any request for further information from relevant community controlled agencies associated with the research proposal.

“Community process of decision making will reflect varying social and cultural values. In obtaining the consent of communities to research, researchers must respect the Aboriginal community’s process of decision making.”²⁰

It is also incumbent upon researchers and data requesting bodies to acknowledge the necessity to seek the consent of each participating Aboriginal community rather than utilise an overriding, all inclusive authorisation from a state or federal body. The following model Consent Agreements, are provided as guides as to what ethical matters should be addressed by prospective researchers in any research into the health of Aboriginal peoples.

and allowed genuine Community involvement in the vital cultural area of ethics. [Editorial Committee 2005]

¹⁸ The Australian Health Ethics Committee (AHEC) within the NHMRC is currently finalising this national document which should be available for AHMAC consideration in 2005. The Aboriginal community controlled health sector is represented on the writing group through its national peak body, the National Aboriginal Community Controlled Health Organisation (NACCHO). [Editorial Committee 2005]

¹⁹ loc. cit.

²⁰ *Ibid. Part 5*

- Individual Aboriginal Consent Forms for research associated with an Aboriginal ACCHS
- ACCHS Organisation Consent Forms for research within the Aboriginal community
- Individual Aboriginal Consent Forms for research into Aboriginal health to be undertaken separate from the clientele of an ACCHS but providing an assurance to participants and the nearest ACCHS of compliance with ethical standards enunciated by the Aboriginal community controlled health sector

MODEL ABORIGINAL MEDICAL SERVICE

INDIVIDUAL CLIENT CONSENT FORM

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Name of Research Project	<p>.....</p> <p>.....</p> <p>.....</p>
<p>Detailed brief on the project addressing:</p> <ul style="list-style-type: none"> * Purpose of the project * Why information is being collected * How information will be used * Any necessary definition of terms * Timeframe for data use * How data will be disposed 	<p>Is a brief of the research attached? YesNo ...</p> <p>Number of pages of the brief? pages.</p>
Name, address and telephone number of principal researcher, for the purposes of this document, unless otherwise stated, also called the Data Custodian	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
Name, address and telephone number of institution, for the purposes of this document, unless otherwise stated, also called the Data Repository	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
Right to Withdraw	I understand that I have the right to withdraw my consent and cease any further involvement in the research project at any time and without any penalty, either financial or personal.
Purpose of Research	The purpose of the research, as outlined in the attached brief numbered pages ...to ... , has been explained to me and I have had the opportunity to ask questions about the project.
Confidentiality and Anonymity	I am assured that any information provided by me or relating to me or any personal details obtained in the course of this research are confidential and that my name or any identifiable information will neither be used nor published without my written permission.

Aboriginal Community Consent	I am assured that any information provided in the course of this research that identifies the Aboriginal community to which I belong, including de-identified data, will not be used nor published without the expressed written permission of the Community through the identified Aboriginal Community Controlled Health Service.
Timeframe	I am assured that the Aboriginal community has agreed that an adequate time-frame to consider the appropriateness of this project has been provided.
Community Consultation	I am assured that the Aboriginal community, through the representative members of the identified Aboriginal Community Controlled Health Service has been duly consulted and that any required negotiation has occurred
Data Security	I am assured that the information in the brief indicates: Those responsible for the security of data; Those who will have access to the data Any intended third party to whom the data will be disclosed; Details for data storage and destruction; A requirement for additional consent for any change in use Provisions to preclude derived information being linked to multiple or other data banks.
Ethical Provisions	I am assured that the ethical provisions relating to the health of Aboriginal people, as enunciated in NACCHO, NH&MRC and AH&MRC publications, have been complied with and that there are terms of reference for any variation from these protocols.
Free and Informed Consent	I freely give my consent in the above-mentioned research project
Contacts	I understand that if I have any complaints or questions concerning this research project that I can contact the principal researcher mentioned above; the Chairperson of the Model Aboriginal Medical Service; or the The Chairperson AH&MRC Ethics Committee P.O. Box 1565 Strawberry Hills NSW 2012 Telephone: 02 9698 1099

I [print name]..... hereby authorise the Model Aboriginal Medical Service to participate in the research/survey and agree to the identified tests and to release any required information for the purposes of this research project.

Signed

Date

Witnessed by

Position of the witness at the Model Aboriginal Medical Service

.....

MODEL ABORIGINAL MEDICAL SERVICE

ORGANISATION CONSENT FORM

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Name of Research Project	<p>.....</p> <p>.....</p> <p>.....</p>
Detailed brief on the project addressing: * Purpose of the project * Why information is being collected * How information will be used * Any necessary definition of terms * Timeframe for data use * How data will be disposed	Is a brief of the research attached? YesNo ... Are the pages of the brief numbered? YesNo ... Number of Pages
Name, address and telephone number of principal researcher, for the purposes of this document, unless otherwise stated, also called the Data Custodian	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
Name, address and telephone number of institution, for the purposes of this document, unless otherwise stated, also called the Data Repository	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
ACCHS Right to Withdraw	It is acknowledged that the Model AMS, also known as an Aboriginal Community Controlled Health Service (ACCHS), has the right to withdraw its consent and cease any further involvement in the research project at any time and without any penalty, either financial or personal, and without any reasons being given.
Purpose for the Research	The purpose of the research, as outlined in the attached brief (numbered pages ...to ...) has been explained and the ACCHS has had the opportunity to ask questions about the project.
Client Confidentiality and Anonymity	The ACCHS is assured that any information it provides or any personal details of its clients obtained in the course of this research, are confidential and that clients identity or any identifiable information will neither be used nor published.
Aboriginal Community and ACCHS Confidentiality and Anonymity	The ACCHS has been assured that, unless otherwise specifically stated and agreed upon, any information provided in the course of this research that identifies the ACCHS or the Aboriginal community which it serves, including de-identified data, will not be used nor published without the written permission of this ACCHS.
Adequate Timeframe	The ACCHS has been provided an adequate timeframe to consider the appropriateness of this project.
	The ACCHS has been assured that the schedule for the proposed research includes

Community Consultation	provision for Aboriginal community consultation and negotiation and that the project will not proceed until any required negotiation has occurred to the satisfaction of this ACCHS, or, if applicable, the AH&MRC Regional Director, and/or the AH&MRC Ethics Committee.
Data Security	The ACCHS has been assured that the information in the brief indicates: Those responsible for the security of data; Those who will have access to the data Any intended third party to whom the data will be disclosed; Details for data storage and destruction; A requirement for additional consent for any change in use or purpose. Provisions to preclude derived information being linked to multiple or other data banks.
Ethical Provisions	The ACCHS has been assured that the ethical provisions relating to the health of Aboriginal people, as enunciated in NACCHO, AH&MRC and NHMRC publications, have been complied with and that there are terms of reference for any variation from these protocols and that the AH&MRC Ethics Committee has endorsed the project.
Free and Informed Consent	This ACCHS freely gives its consent to the above-mentioned research project, subject to compliance with the conditions contained within this Consent Agreement
Contacts	The ACCHS understands that if it has any complaints or questions concerning this research project that it can contact the principal researcher mentioned above; the Chairperson of the Model AMS; or the AH&MRC Ethics Committee as follows: The Chairperson AH&MRC Ethics Committee PO Box 1565 Strawberry Hills NSW 2012 Telephone: 9698 1099

The Model Aboriginal Medical Service Ltd hereby authorises the above identified research person/organisation to participate in the identified research/survey and agree, subject to the individual consent of its clients, to the identified tests and to release any relevant and required information for the purposes of this research project.

Signed by or on behalf of

.....
(Name of Researcher/Research organisation)

Signature..... Date

Position held

Signed on behalf of the Model AMS.

Signature Date

Position held at the Model AMS

Witnessed by Date

Position held at the Model AMS

INDIVIDUAL ABORIGINAL CONSENT FORM

© AH&MRC 1999

For researchers undertaking projects into Aboriginal health separate from the clientele of an Aboriginal Community Controlled Health Service (ACCHS) but assuring participants and the nearest ACCHS of compliance with ethical standards enunciated by the Aboriginal community controlled health sector

Name of Research Project	<p>.....</p> <p>.....</p> <p>.....</p>
<p>Detailed brief on the project addressing:</p> <ul style="list-style-type: none"> * Purpose of the project * Why information is being collected * How information will be used * Any necessary definition of terms * Timeframe for data use * How data will be disposed 	<p>Is a brief of the research attached? Yes ...No ...</p> <p>Number of pages of the brief? pages.</p>
Name, address and telephone number of principal researcher, for the purposes of this document, unless otherwise stated, also called the Data Custodian	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
Name, address and telephone number of institution, for the purposes of this document, unless otherwise stated, also called the Data Repository	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
Right to Withdraw	I understand that I have the right to withdraw my consent and cease any further involvement in the research project at any time and without any penalty, either financial or personal.
Purpose of Research	The purpose of the research, as outlined in the attached brief & the numbered pages identified above, has been explained to me and I have had the opportunity to ask questions about the project.
Confidentiality and Anonymity	I am assured that any information provided by me or relating to me or any personal details obtained in the course of this research are confidential and that my name or any identifiable information will neither be used nor published without my written permission.

Aboriginal Community Consent	I am assured that any information provided in the course of this research that identifies the Aboriginal community to which I belong, including de-identified data, will not be used nor published without the expressed written permission of the Community from the identified Aboriginal Community Controlled Health Service in association with the AH&MRC Ethics Committee.
Timeframe	I am assured that the Aboriginal community, through the local ACCHS, or the AH&MRC Regional Director where no ACCHS exists, has been provided a timeframe for the research and that it has been agreed to as appropriate for this project.
Community Consultation	I am assured that the Aboriginal community, through the representative members of the identified Aboriginal Community Controlled Health Service, or AH&MRC Regional Director where no ACCHS exists, has been duly consulted and any required negotiation has occurred and there is agreement for the commencement of the research.
Data Security	I am assured that the information in the brief indicates: Those responsible for the security of data; Those who will have access to the data Any intended third party to whom the data will be disclosed; Details for data storage and destruction; A requirement for additional consent for any change in use Provisions to preclude derived information being linked to multiple or other data banks.
Ethical Provisions	I am assured that the ethical provisions relating to the health of Aboriginal people, as enunciated in NACCHO, NH&MRC and AH&MRC publications, have been complied with; that there are terms of reference for any variation from these protocols; and that the research project has received ethical approval by the AH&MRC Ethics Committee
Free and Informed Consent	I freely give my consent in the above-mentioned research project
Contacts	I understand that if I have any complaints or questions concerning this research project that I can contact the principal researcher mentioned above; the Chairperson of the Aboriginal Medical Service or Regional Director of the AH&MRC witnessing the signing of this document; or the The Chairperson AH&MRC Ethics Committee PO. Box 1565 Strawberry Hills NSW 2012 Telephone: 02 9698 1099

I [print name]..... hereby authorise the researcher identified above to participate in the research/survey and agree to the required tests, examinations or questionnaires identified in the brief subject to the provisions for the use, dissemination and publication of health information and compliance with ethical standards implicit within this document.

Signed *Date*

Witnessed by

.....
[Position of the witness at the Model Aboriginal Medical Service or the name of the Regional Director of the AH&MRC]

4. THE ABORIGINAL COMMUNITY AS THE ULTIMATE DETERMINING BODY IN ETHICAL MATTERS

The provisions within the *Australian Standard AS4400-1995, 'Personal Privacy Protection in Health Care Information Systems'* and the eleven Information Privacy Principles (IPP's) within the *Commonwealth Privacy Act (1988)* preclude the use of any personal information which has been collected within a health information data system for any other purpose than that for which explicit informed consent has been obtained²¹

There are provisions under section 95 of the Privacy Act (1988) which provide bases for the IPP's to be breached, where it is considered that the public interests of privacy are substantially outweighed by the public interest of medical research.

The Act provides for the NH&MRC to develop guidelines for the protection of privacy, which require the approval of the Privacy Commissioner. These 'Guidelines' make provision for a Commonwealth organisation to disclose information for medical research purposes following consideration being given by an ethics committee which concludes that the public interests of medical research substantially outweighs the public interests of privacy.

Of particular importance, the *NH&MRC Supplementary Note 6, Report on Ethics in Epidemiological Research (1985)* advocates an unacceptable position from an Aboriginal community perspective. It actually justifies the use of health information for purposes other than that for which it was collected on the grounds that priorities in epidemiology can seldom be accurately predicted.²²

Accordingly, from an Aboriginal community position those responsible for obtaining, collating, researching, analysing and reporting data on Aboriginal health information must clearly state their specific purpose and identify appropriate personnel responsible to ensure that consent agreements are complied with.

Furthermore, it has been mooted that the Australian legal system does not legally recognise the concept of Community owned information.²³ However, while the High Court application by *Mabo et al* concerned matters of real property only and therefore, no findings were extended either in the affirmative or negative to notions of property in general, Aboriginal peoples have always applied the same principles to whatever they own. According to Aboriginal societal constructs, Aboriginal people must exert exclusive ownership rights over all aspects of their secular and spiritual existences (noting that Aboriginal peoples do not accept that a dichotomy obtains between secularity and spirituality).

²¹ *Privacy Act (1988) 'Information Privacy Principles'*; *Australian Standard AS4400-1995, 'Personal Privacy Protection in Health Care Information Systems'*. The provisions for privacy of personal health information have been incorporated into the *Privacy Protocol for the use of Personal Information in the Co-ordinated Care Trails, Commonwealth Department of Health and Family Services, 2.1.*

²² *NH&MRC Report on Ethics in Epidemiological Research, (1985) p. 17 #7.*

²³ *Information Privacy Code of Conduct, Territory Health Services, (Draft) p53. 7.2*

Therefore, in order to conform to culturally sensitive modes of practice in relation to any matters regarding the ownership, custodianship and use of any information, including health information, as it concerns Aboriginal peoples, non-Aboriginal persons or organisations will need to develop and subsequently implement information agreements which accord with Aboriginal cultural principles.

In addition to concerns about the use of personal information provided for research and data systems there is also the need for provisions to protect the Aboriginal community where anonymity is considered necessary and to ensure correct use of cultural information provided to researchers or data repository bodies.

Accordingly, in light of more recent legislative developments and the pre-eminence of Ethics Committees for determining where consent agreements can be overruled or negated, the deliberations of Ethics Committees should not be seen as a substitute for the Aboriginal community decision making process and ideally should work in association with Aboriginal community health organisations.

It is for this reason that the Community itself is considered the determining body in matters relating to Aboriginal health information rather than any regional, national, State or Territory Ethics Committee solely determining matters concerning Aboriginal health. State and Territory affiliate bodies of NACCHO do have valuable ethics committees but the underlying principle upon which the AH&MRC Ethics Committee operates is the inviolate and unfettered nature of the Aboriginal community itself to ultimately consider the appropriateness and relevance of research into Aboriginal health.

The majority of the research proposals forwarded to the AH&MRC for ethical evaluation are proposals forwarded on behalf of the Aboriginal community through local Aboriginal Community Controlled Health Services. The need for this separate state wide ethical body is self-evident in light of the demanding workload and intricate and specialist nature of most medical research proposals. However, whilst the AH&MRC Ethics Committee accepts responsibility for providing advice and evaluating ethical matters related to specific research projects it is a task carried out in association with each Aboriginal community.

5. THE AH&MRC STATEMENT OF ETHICAL COMMITMENT

The AH&MRC Ethics Committee is committed to encouraging professional proposals in epidemiological and specific medical research which increase scientific knowledge, demonstrate benefit to Aboriginal communities and provide transfer of skills to Aboriginal medical workforces.

The Committee is answerable to the AH&MRC Board of Directors to ensure that in all its deliberations the highest standard of professionalism is always maintained and that in all its actions, neutrality and objectivity are routinely demonstrated to encourage scientific and ethical excellence in research into Aboriginal health.

The Ethics Committee is committed to adhere to its onerous task of ensuring conformity with ethical standards which reflects Aboriginal cultural, spiritual and

societal values as well as Community mores and protocols in all research proposals for which it has responsibility to evaluate.

6. COMPOSITION OF THE AH&MRC ETHICS COMMITTEE

Committee Members

The composition of the AH&MRC Ethics Committee adheres to the Australian Health Ethics Council (AHEC) requirements for specific representatives of the community and professional groups. All members are appointed Aboriginal personnel from the Aboriginal community controlled health sector, appointed by the Board of Directors of the AH&MRC. However, the Ethics Committee may also from time to time include appointed members from the non-Aboriginal community as specialists in required disciplines.

The AH&MRC Ethics Committee also has provision to seek additional specialist advice and reports and to accept scientific analyses and written opinions from other ethics committees, both within and without Australia.

The Committee meets on the second Wednesday of alternate months, commencing in February of each year or more frequently where necessary.

Secretary

Secretariat services will be provided or arranged by the AH&MRC Secretariat. The appointed Secretary may participate in every aspect of the Committee's deliberations but cannot be considered as representing one of the essential categories of membership for the purposes of decision making unless eligible and appointed in one of those categories.

7. SUMMARY OF ETHICAL MATTERS TO BE ADDRESSED IN APPLICATIONS FOR RESEARCH OR THE COLLECTION AND USE OF DATA ON ABORIGINAL HEALTH

Applicants would need to ensure appropriate compliance with the following relevant matters summarised from documentation cited earlier.

- Aboriginal community control
- free and informed written consent
- provision for withdrawal of consent
- appropriate forms for consent
- need for written objectives for research and purposes for data
- culturally appropriate questionnaires
- provisions for modification to research
- adequate time frames
- employment of Aboriginal people in research
- Aboriginal ownership
- publication procedures and protocol
- confidentiality
- storage and archiving
- access to data and security

8. EVALUATION PROCEDURE

The Ethics Committee is also mindful that the Aboriginal community controlled health sector must be ever vigilant in monitoring acceptable current opinion of ethical standards to ensure that these comply with the ethical standards within the Aboriginal community.

In addition to standard scientific and ethical criteria for research and procedural requirements as enunciated by the Australian Health Ethics Council (AHEC) and the National Health & Medical Research Council (NH&MRC), together with the ethical matters already cited within this document, criteria for evaluation of research proposals include that:

- (i) in accordance with the priorities set out in the *National Aboriginal Health Strategy* and the *Report of the National Workshop on Ethics of Research in Aboriginal Health*, research proposals must be both scientific and ethical and advance scientific knowledge so as to result in demonstrated additional benefit to the health of Aboriginal communities.
- (ii) there be Aboriginal community control over all aspects of the proposed research including research design, ownership of data, data interpretation and publication of research findings
- (iii) the research to be conducted in a manner sensitive to the cultural principles of Aboriginal society.
- (iv) Aboriginal communities and organisations be reimbursed for all costs arising from their participation in the research process.
- (v) Aboriginal communities and organisations should be able to benefit, where appropriate, from the transfer of skills and knowledge arising from the research project.

9. APPLICATIONS

The original letter and application should be submitted together with additional 8 copies of all documentation.

To expedite the evaluation process the format for applications is elastic in light of the diverse and varied types of research proposals, reports, analyses studies and projects submitted to the Committee. To avoid duplicative effort applicants can use discretion on application format and can submit the same application provided to other ethics committees or research funding providers.

To ensure consideration of applications at a given Ethics Committee meeting, documentation should be provided to the Committee secretariat a week prior to the meeting date.

Address for all Correspondence and Research Proposals:

The Chairperson
The AH&MRC Ethics Committee
PO Box 1565
Strawberry Hills NSW 2012

10. COMPLAINTS MECHANISM

A process for addressing complaints about ethical matters in current research, health projects, data collection and related reporting, as well as complaints about procedural matters for given applications has been provided for.

All correspondence in this regard should be marked and addressed as follows:

“Confidential”
Attention: Ethics Complaints Process

The Chairperson
Aboriginal Health & Medical Research Council of NSW
PO Box 1565
Strawberry Hills NSW 2012

11. APPENDIX 1

A Brief History of the AH&MRC

The Aboriginal Health & Medical Research Council of New South Wales (AH&MRC), formerly the AHRC, was established in 1985 following a recommendation of the *NSW Aboriginal Task Force on Aboriginal Health* in 1982-83. The *Report* recognised Aboriginal community control as crucial in laying the foundation for a better standard of health care for Aboriginal people. One role recommended for the AH&MRC was to advise Ministers for Health & Aboriginal Affairs at State and Federal levels on Aboriginal health policy, programs and needs. The *Report* sought an increased measure of control by the Aboriginal community over health service delivery and resources and acknowledged that the Aboriginal community controlled health sector is the most appropriate means by which this outcome can be achieved at both policy and service levels.

In June 1995, the membership endorsed the *NSW Aboriginal Health Partnership Agreement* with the NSW Health Department. This *Partnership* acknowledges Aboriginal self-determination, a partnership approach and intersectoral collaboration as its guiding principles. Its primary function is to provide the NSW Minister for Health with “agreed positions” with regard to Aboriginal health policy, strategic planning and broad resource allocation issues. Numerous policies and strategies, specifically relating to Aboriginal health issues, have been developed within this collaborative relationship. This constructive Partnership approach will be effected at every level of the NSW public health system and will be implemented at the local level through *Local/Area Aboriginal Health Partnerships* where the parties are Chairpersons and CEO’s of Aboriginal Community Controlled Health Services (ACCHS) and the executive of Area Health Services.

At the Commonwealth level, each State and Territory has negotiated Framework Agreements between Commonwealth and State Ministers for Health and affiliates of NACCHO. In this NSW the document is called the *NSW Framework Agreement*, to which the AH&MRC is a co-signatory together with the NSW and Federal Ministers for Health. The Agreement establishes a joint planning approach through the *NSW Aboriginal Health Forum* that has oversight of joint planning processes in Aboriginal health which have developed Aboriginal Health Plans at Local, Regional and State levels.

Members of the AH&MRC meet annually when Directors are elected from each of the 12 AH&MRC Regions by delegates of member organisations. Policy matters and membership are determined at general meetings by the membership. As the peak body for Aboriginal health in NSW, the Council also plays a role directly assisting ACCHS; supporting community controlled health initiatives; liaising with non-Aboriginal agencies and evaluating, developing and advising on the wide range of health programs, policies, strategies and appropriate educational courses in Aboriginal health. AH&MRC representatives also represent the Aboriginal community in health matters on numerous health committees. The Council, through its Ethics Committee, plays an important role in the ethical evaluation of research proposals and appropriate delivery of health services to Aboriginal people.

The Council has a state-wide representative role on behalf of its constituent members as well as responsibility for the planned expansion of its benevolent services that will be channelled directly into Aboriginal communities. Membership is open to Aboriginal Community Controlled Health Services (ACCHS); Aboriginal Community Controlled Health Committees (ACCHC) in the process of establishing an ACCHS; and Aboriginal community controlled Health Related Services (ACCHRS) which are organisations that provide specialist primary health-related services and work closely with ACCHSs. The Council also established the Aboriginal Health College in 2003 whose new premises will be located at Little Bay in Sydney. A Comprehensive range of courses covering all aspects of Aboriginal primary health care is being developed. The AH&MRC embraces the Aboriginal values of trust, integrity, consensus and local Aboriginal community control.

(Current at date of printing)

12. APPENDIX 2



AH&MRC ETHICS COMMITTEE

Submission to the Australian Health Ethics Committee

24th August 1998

Commenting upon the 4th August 1998 *Draft Statement on Ethical Conduct in Research Involving Humans* as the proposed replacement of the *NHMRC Statement on Human Experimentation and Supplementary Notes 1992**

In response to a letter dated 2nd July 1998 from Dr Cindy Wong, Secretary of the Australian Health Ethics Committee, the AHRC wishes to provide a submission on the proposed *Draft Statement on Ethical Conduct in Research Involving Humans* responding as to whether it adequately addresses issues relating to research into the health of Aboriginal and Torres Strait Islander peoples.

The answer in short is that it is rather optimistic, in spite of the potential for brevity within the English language, to condense the 7 page comprehensive NHMRC document *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research* to a mere one page summary in an altogether different context under the topic "Research involving collectivities."

The Committee would also be conversant with the NAIHO (precursor organisation to NACCHO) supplement in the said NHMRC document entitled "*Report of the National Workshop on Ethics of Research in Aboriginal Health*" which is a 26 page definitive ethical statement about Aboriginal and Torres Strait Islander research. There is no similarity between the proposed truncated ethical statement for research on "collectivities" and these documents.

A further 52 page statement *National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health (1997)*, endorsed by NACCHO but awaiting summarisation by OATSIHS, has clearly demonstrated the necessity for separate ethical guidelines for the gathering of research data into Aboriginal health.

* The *National Statement on Ethical Conduct in Research Involving Humans (1999)* is currently under review to develop replacement guidelines. The closing date for submissions is 16th March 2005. [Editorial Committee 2005]

Noneclature “collectivities”

Whilst aware of the Canadian document that has been adopted to accommodate the indigenous peoples of this country within the proposed *Statement* it would be less than courteous to convey the impact such a designation would have upon the original owners of this country.

It is quite an inappropriate and unacceptable to have Aboriginal and Torres Strait Islander peoples referred to in this manner and to have them merely incorporated within a plethora of diverse “collectivities” in this immigrant country.

Aboriginal and Torres Strait Islander peoples should be correctly referred to in any NHMRC documentation as well as being acknowledged as the host peoples of this country rather than be relegated to a collective multi-cultural smorgasbord of unique immigrant traditions, important as multiculturalism has been in enriching this nation’s societal mores and culture.

It is apparent here that even ethicists are needing cultural awareness training and to continue on this rather myopic route of insensitivity would probably precipitate an inevitable severance of indigenous academia in health from established structures to a parallel ethical process for the evaluation and monitoring of research into the health of their Communities.

It is rather incongruous that the proactive, positive and culturally appropriate initiatives into ethical conduct for research into Aboriginal health which resulted from the NHMRC and the Menzies Foundation national conference in 1986 are about to be now relegated to the obscurity to an A4 page statement of “collectivity”. Rather less generous critics might infer that this is the ultimate sanction of assimilationist policies that have caused the suffering and disparity in health and which still plague our communities’ well being.

There are crucial reasons for ethically assessing research into Aboriginal health from an Aboriginal viewpoint and perspective. These indispensable criteria have already been spelt out in NHMRC documents as well as numerous other Reports, Commissions, Acts and Memoranda of Understanding between governments and the Aboriginal community.

In fact the experience of the AHRC Ethics Committee is that the naiveté and harm which have been perpetrated upon Aboriginal people in the name of research have not yet evaporated and numerous research topics still reflect an absolute indifference to the needs of the Aboriginal Community and betray that certain applicants are oblivious of indispensable ethical requirements so necessary for positive outcomes in research into Aboriginal health.

To assist the Committee in considering the complexities of the matter before us we have enclosed an adaptation of a summary of definitive documents of ethical provisions for data collection on Aboriginal health. Whilst it is not entirely applicable it will indicate the extent and complexity of the ethical dimension in research into Aboriginal and Torres Strait Islander peoples requiring onerous and rigorous evaluation from a

cultural perspective which cannot be relegated to a mere parenthesis. This documentation covers areas such as

- Aboriginal community control
- free and informed written consent
- provision for withdrawal of consent
- appropriate forms for consent
- need for written objectives for research and purposes for data
- questionnaires
- provisions for modification to research
- adequate time frames
- employment of aboriginal people in research
- Aboriginal ownership
- Confidentiality
- publication matters
- complaint mechanisms
- storage and archiving
- access to data and security

Whilst most of the above have been allowed for in the *Statement* they have been adapted to the unique Aboriginal situation ensuring Community sensitivity. For research to proceed in a constructive and appropriate manner the cultural needs of the Aboriginal community cannot be accommodated within your current proposed *Statement*.

We concur with the submission provided to your committee by NACCHO which has addressed similar issues. However there are three additional points we would like to make:

1. Whilst we agree in principle with the purpose for NACCHO's suggestion to obtain a MOU for each research project we do not feel that a MOU is the appropriate document to document informed Aboriginal community consent. Such documentation is more applicable for agreements between agencies and departments. Written consent in the manner alluded to in the above-attached documentation is considered more suitable and practicable.

2. The proposed *Statement* has much merit and will be a helpful and practical amendment. The following may require attention.

(i) Under 14.3 an REC is to report annually upon certain matters which includes "the number of rejections and reasons for rejections.". It would seem intrusive for an indigenous ethics committee to provide reasons why it has culturally rejected certain applications. Although every attempt would be made to have an acceptable amendment to some offensive or inappropriate matter some projects are simply not in the best interest of the Aboriginal community. Criteria for culturally appropriate research are provided but it is a very delicate matter to communicate non-compliance and fraught with litigation possibilities.

3. Chapter 5. 5(iii) states that

“...personal information ...will not be used for any purposes other than those specified in the approved protocol.”

With regard to this matter please note the following:

Consent to use personal and Aboriginal community health information

The provisions within the *Australian Standard AS4400-1995, 'Personal Privacy Protection in Health Care Information Systems'* and the eleven Information Privacy Principles (IPP's) within the Commonwealth *Privacy Act (1988)* preclude the use of any personal information which has been collected within a health information data system for any other purpose than that for which explicit informed consent has been obtained²⁴

It must be clearly understood that the provision for specific and restricted use of information within these above-mentioned documents apply only to those data systems which refer to and contain **personal** information. However, some data may have Community significance and while they not contain personal information there are other Community and cultural factors which may necessitate provisions for similar safeguards necessary to protect the information supplied to the repository body.

Yet, in spite of this laudable ethical maxim there are provisions under section 95 of the Privacy Act (1988) which provide bases for the IPP's to be breached where it is considered that the public interests of privacy are substantially outweighed by the public interest of medical research.

The Act provides for the NH&MRC to develop guidelines for the protection of privacy which require the approval of the Privacy Commissioner. These 'Guidelines' make provision for a Commonwealth organisation to disclose information for medical research purposes following consideration being given by an ethics committee which concludes that the public interests of medical research substantially outweighs the public interests of privacy.

It is for this reason that the Aboriginal community itself is considered the determining body in matter relating to Aboriginal health information rather than any national, State or Territory, regional or institutional ethics committee considering matters concerning Aboriginal health. Some State and Territory affiliated bodies of NACCHO do have ethics committees with much of their material for consideration having been forwarded by local Aboriginal health services, but the underlying principle upon which they operate is the inviolate and unfettered nature of the Aboriginal community itself to ultimately consider research into Aboriginal health.

More poignantly in this regard, in light of the proposed amended *Statement*, the *NH&MRC Supplementary Note 6, Report on Ethics in Epidemiological Research*

²⁴ *Privacy Act (1988) 'Information Privacy Principles'*; *Australian Standard AS4400-1995, 'Personal Privacy Protection in Health Care Information Systems'*. The provisions for privacy of personal health information have been incorporated into the *Privacy Protocol for the use of Personal Information in the Coordinated Care Trails, Commonwealth Department of Health and Family Services, 2.1.*

(1985) advocates a diametrically opposite viewpoint which would be untenable from an Aboriginal community position. It actually justifies the use of information for purposes other than that for which it was collected on the grounds that priorities in epidemiology can seldom be accurately predicted.²⁵

From an Aboriginal community position those responsible for obtaining, collating, analysing and reporting data on Aboriginal health information, either personal information on its peoples or community material considered having a cultural sensitive significance, appropriate provisions to safeguard such data should be available.

In light of this factor, together with the compounding difficulties which arise from possible complications in the differences between the Australian legal system and traditional Aboriginal legal systems, legally binding provision must be made in any Consent Agreement to ensure that the interests of the Communities are protected.

It has been mooted that the Australian legal system does not legally recognise the concept of Community owned information.²⁶ However, while the High Court application by *Mabo et al* concerned matters of real property only and therefore, no findings were extended either in the affirmative or negative to notions of property in general, Aboriginal peoples have always applied the same principles to whatever they own. According to Aboriginal societal constructs, Aboriginal people must exert exclusive ownership rights over all aspects of their secular and spiritual existences (noting that Aboriginal peoples do not accept that a dichotomy obtains between secularity and spirituality).

Accordingly, in order to conform to culturally sensitive modes of practice in relation to any matters regarding the ownership, custodianship and use of any information, including health information, as it concerns Aboriginal peoples, non-Aboriginal persons or organisations will need to develop and subsequently implement information agreements which accord with Aboriginal cultural principles.

Furthermore, the *National Aboriginal Health Strategy* states that there are good reasons, from past experiences of negative stereotyping, why certain geographically distinct Aboriginal and Torres Strait Islander communities are sensitive about disclosing data on their community's health.²⁷

Subject to the provision for statutory mandatory reporting requirements, the right for these Communities to exercise their prerogative to maintain privacy and effect the non-identification of the their communities for certain culturally sensitive matters should be provided for within Ethical Protocols for the collection of data.

It is reassuring that the *Commonwealth/State Aboriginal Health Framework Agreements*, signed by State and Commonwealth Ministers for health, ATSIC and the respective peak State and Territory affiliated bodies of NACCHO, have clearly

²⁵ NH&MRC Report on Ethics in Epidemiological Research, (1985) p. 17 #7.

²⁶ *Information Privacy Code of Conduct*, Territory Health Services, (Draft) p53. 7.2

²⁷ *ibid.*, See also the NAHS, 12.1.2

enunciated guidelines which leave no misunderstanding as to the role that the Aboriginal communities play in both the collection and use of data.

“These protocols are to recognise Aboriginal and Torres Strait Islander ownership of the data including clarity about the collection and use of data. Any change in the use of the data will require agreement from the owners of the data;”²⁸

Apart from the inevitable dismay within the community at large which would result from knowledge about apparent impotence of prevailing scientific procedures to monitor adherence to accepted norms of ethical conduct, and to ensure compliance with signed consent agreements with regard to the restricted use of personal information, these deficiencies have an additional relevance to the Aboriginal community. It is significant that from a Community context NACCHO has resolved:

Limitations on Usage of Data

- All data supplied as part of the collection of information on Aboriginal community health shall only be used for the purposes for which it was collected as indicated within a free and informed consent agreement. Any intention to vary this condition requires the additional consent of the Aboriginal Community health service concerned and failure to obtain new consent obligates the Repository Body to either return the information or destroy the information as initially agreed.
- Due to the NH&MRC provisions for Ethics Committees to overrule consent agreements, with regard to the use of collected data on Aboriginal community health, the determinative body for ethical evaluation of data on Aboriginal community health is the local Aboriginal community controlled health service or, in areas where no such body currently operates, then the relevant peak State or Territory health body affiliated with NACCHO in association with the local Community concerned.

Aboriginal Community Ownership of Data

- All data on Aboriginal community health and related research material are owned by and shall remain the property of the Aboriginal community.

Publication of Data on Aboriginal Community Health

- The Aboriginal Community retains the right to censor research of a cultural or community sensitive nature related to the provision of data on Aboriginal community health and that prior to any publication, reports or other use of research materials the approval of the Aboriginal community controlled health service, or when appropriate, the approval of the appropriate level of Aboriginal community controlled health, is required.

Anonymity

²⁸ *Agreement on Aboriginal and Torres Strait Islander Health between the [relevant State or Territory Minister for Health]; the Commonwealth Minister of State for Health and Family Services; the [Relevant State or Territory peak bodies affiliated with NACCHO]; and the Aboriginal and Torres Strait Islander Commission, 3.12*

- With regard to the collection of data on Aboriginal health, confidentiality is considered the characteristic of data, with information being disclosed only to authorised persons, entities and processes at authorised times and in the authorised manner agreed upon at the time free and informed consent was obtained.
- Within the process of data collection on Aboriginal health a “duty of confidence” relationship is considered to exist between the Repository Body and the participating local Aboriginal community controlled health service or other levels at which information has been provided by the Aboriginal community controlled health sector.
- This “duty of confidence” relationship is considered to exist with regard to the provision of both identifiable personal health information, which may have been inadvertently provided to the department or Repository Body, as well as to any information considered confidential by those Communities requesting the de-identification of their communities.

Destruction of Records

- All records of data on Aboriginal health provided by a participating Aboriginal community shall upon the completion of their agreed use be either destroyed by the Repository Body, upon notifying the Community concerned, or returned to that participating Community as directed by the terms of the consent agreement.
- Disposal and destruction of records should be done in such a manner as to render them unreadable and left in a form from which they cannot be reconstructed in whole or part
- the Repository Body shall provide a statutory statement indicating the date and place of destruction of records; the officer responsible for certifying this action and confirmation that no reproduced part or copy of the data is still stored in any retrieval system or data base.

4. Chapter 2:4.10 makes practical provisions for ‘Multi-Centre Research’ enabling the acceptance of other REC’s scientific reviews. It would seem a very practical and time saving procedure to have the same provisions extended to the discretion of REC’s for projects in general, or certain aspects of particular projects, which already have been assessed by other REC’s. A case in point would be complex research projects that have already undergone extensive scientific analysis by reputable REC’s yet applicants are required, or responsibly choose to seek, specific ethical approval for the application of the project, or aspects of the project, which relate to the Aboriginal or Torres strait Islander communities.

5. The *Statement* provides for the composition of a REC:

- (iii) at least one member who is a minister or a person who performs a similar role in the community.

The particular role of elders in the Aboriginal community is not always defined in a structured manner comparable to non-Aboriginal religious institutions, nor necessarily do they reflect similar roles to those within European religious orders. Nonetheless, they perform vital roles in the spiritual understanding within a Community and

provisions for such persons to be included on an REC should be available which would be at the discretion of an Aboriginal Ethics committee.

6. It is both opportune and ironic that today witnessed the launching of the *NSW Aboriginal Health Information Guidelines* which is a co-operative effort by the NSW Health Department and the NSW Aboriginal Health Resource Co-operative Ltd. Any attempt to dispense with separate ethical protocol for research into Aboriginal health, in addition to responding to criticism raised in this submission, would need to respond to this document which is a definitive ethical statement developed jointly by mainstream and Aboriginal community controlled health sectors. Both this new publication and the *Commonwealth/State Framework Agreements*, incongruously sight the *NHMRC Ethical Guidelines in Aboriginal and Torres Strait Islander Research (1991)* as an important reference document.

In closing may we thank you for this opportunity to respond to what has obviously been a demanding task. If it is considered helpful that the Ethics Committee of the AHRC meets with you or your committee members to discuss some of the above matters raised, we would be only too pleased to do so.

On behalf of the AHRC Ethics Committee

Yours sincerely

Sandra Bailey
Chief Executive Officer

24th August 1998

Attachments: Appendix A: *Summary of Definitive Documents for Ethical Provisions in the Collection and Use of Data on Aboriginal Health*
Appendix B: *Summary - National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal & Torres Strait Islander Health*
Appendix C: *NSW Aboriginal Health Information Guidelines (1998)*

APPENDICES

APPENDIX A

Summary of Definitive Documents for Ethical Provisions in the Collection and Use of Data on Aboriginal Health

Documents

- NH&MRC Statement on Scientific Practice
- NH&MRC Statement on Human Experimentation
- National Health & Medical Research Council (NH&MRC), Health Australia Project Discussion Paper, August 1996
- National Aboriginal Health Strategy (NAHS)
- National Aboriginal & Islander Health Organisation (NAIHO), Report on the National Workshop on Ethics of Research in Aboriginal Health
- Recommendations of the Royal Commission into Aboriginal Deaths in Custody
- Memorandum of Understanding between ATSIC and the Commonwealth Minister for Health and Family Services
- Framework Agreement

1. NH&MRC Statement on Scientific Practice

Ethical Commitment:

“Research workers should only participate in work which conforms to accepted ethical standards and which they are competent to perform...”²⁹

Confidentiality

“If data of a confidential nature are obtained, for example, from individual patient records or from certain questionnaires, confidentiality must be observed and research workers must not use such information for their own personal advantage or that of a third party....”³⁰

As in general medical research recommended by the NH&MRC *Statement* it is also essential to establish appropriate confidential protocols for receiving complaints of the health data information process as well as timely informative reports on the matters raised.³¹

Staff engaged in collecting data must observe that the data is only used for the purpose agreed upon and no other application for the data is permissible or transfer to a third party is permitted without the expressed consent of the contributors.

²⁹ NH&MRC *Statement on Scientific Practice*, General Consideration (b)

³⁰ NH&MRC *Statement on Scientific Practice*, General Consideration (d)

³¹ NH&MRC *Statement on Scientific Practice*, Specific Matters 5.1

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Secrecy

“Secrecy may also be necessary for a limited period in the case of contracted research.”³²

Data Gathering, Storage and Retention

The NH&MRC recommends that data should be retained within the department or research unit within which they were generated. From a practical basis, some information flow may be necessary, however, this does not negate the need to trace and monitor information flow of data and for the providers, at the appropriate level, to be kept informed at all times.³³ The document makes recommendations for appropriate storage and recording.³⁴

Disclosure of potential conflicts of interests

To ensure that confidence is given to the data assembled on Aboriginal health it is imperative that any conflict of interest be declared and acknowledged, no matter how minimal.

Concerning the above sighted emphasis for complete disclosure of any conflict of interest in the general field of medical research it is considered prudent and necessary that from an Aboriginal community perspective these principles should also be incumbent upon contributing parties to health data information mechanisms.

2. NH&MRC Statement on Human Experimentation

(To be read in conjunction with the *Supplementary Notes*, especially *Supplementary Note 6 - Epidemiological Research*)

Researchers have ethical and legal responsibilities towards those they are researching and should carefully follow clear guide-lines. Several of these apply with regard to the collection of data in Aboriginal health.

Informed consent

NH&MRC *Statement on Human Experimentation* provides that consent must be in writing unless there are good reasons to the contrary and in the case of the latter, documents of the circumstances should be recorded. For the collecting of data verbal authorisation is inappropriate.³⁵

Provision to Withdraw Consent

It is also recommended in this NH&MRC *Statement* that informed consent for medical research is always qualified by the right to withdraw and no longer participate.³⁶ Accordingly, the collection of raw data for epidemiological analysis in Aboriginal health should be viewed accordingly with similar provisions and participants should be free of duress and mandatory reporting requirements.

³² NH&MRC *Statement on Scientific Practice*, General Consideration (e)

³³ NH&MRC *Statement on Scientific Practice*, Specific Matters, 1,(iii)

³⁴ NH&MRC *Statement on Scientific Practice*, Specific Matters, 1(i)

³⁵ NH&MRC *Statement on Human Experimentation*, (8)

³⁶ NH&MRC *Statement on Human Experimentation*, (9)

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Ethics Committees

In medical research in general it is recommended by the NH&MRC for institutions to introduce ethic committees. Whilst similar bodies could be developed for epidemiology and data collection, from an Aboriginal community viewpoint, the definitive words on ethical matters would be the Aboriginal community at each level - local, state and national. Some State bodies affiliated with NACCHO have their own ethics committees which are used by their constituent member organisations. Such bodies would naturally be part of any analysis or review of ethical and cultural matters related to data collection and its use.³⁷

3. National Health & Medical Research Council (NH&MRC), Health Australia Project Discussion Paper, August 1996

Relevant recommendations within this publication by the NH&MRC under the topic “Monitoring and Surveillance” are as follows:

- “designated funding be provided to enable the Australian Bureau of Statistics to continue to conduct regular national health and risk factor surveys for Aboriginal and Torres Strait Islander peoples.”
- “... the Australian Institute of Health and Welfare work with Aboriginal and Torres Strait Islander communities to develop a plan to improve all aspects of information about their health and access to health services.”³⁸

4. NH&MRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research

Whilst requiring further refinement from an Aboriginal community perspective the document breaks new ground in the field and provides specific details for appropriate standards to be in place before any research can be considered.

Consultation.

The importance of community consultation is acknowledged by the Medical Research Ethics Committee of the NH&MRC which recognised that there was:

“... a lack of appreciation of ethical issues relevant to research involving Aboriginal and Torres Strait Islander people, which led to:

- advice and approval of Aboriginal or Torres Strait Islander individuals in Government departments being accepted as a substitute for proper community consultations and negotiations;
- lesser standards for obtaining consent among disadvantaged Aboriginal and Torres Strait Islander communities;³⁹

³⁷ *NH&MRC Statement on Human Experimentation*, (1)

³⁸ *National Health & Medical Research Council (NH&MRC), The Health Australia Project - A review of infrastructure supports for Aboriginal and Torres Strait Islander health advancement, Discussion Paper, August 1996, 11.4*

³⁹ *NH&MRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research*, Preamble, (d)

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Among its salient points the *Guidelines* document provides content for its expressed concern for Aboriginal community involvement and participation and includes recommendations which are also considered having direct relevance in the collection of Aboriginal health information data for epidemiological and bio-statistical purposes.

“1 In the preparation of the research proposal, the researcher has sought advice not only from State, Territory and Federal Aboriginal and Torres Strait Islander Health agencies, but also from local community-controlled Aboriginal and Torres Strait Islander health services and agencies.

2 The Aboriginal and Torres Strait Islander community, or appropriate community controlled agency able to represent the Aboriginal and Torres Strait Islander Group which is the focus or context of research, has indicated that the research being proposed will be potentially useful to the community in particular or Aboriginal and Torres Strait Islanders in general, and will be conducted in a way that is sensitive to the cultural and political situation of the that community.

3 The researcher has obtained written documentation of consent from the communities in which it is proposed to conduct research and where this has not been possible, the reasons should be obtained.”⁴⁰

There follows specific tangible provisions which ensure informed consent from the Aboriginal communities.

Adequate Time-frame

One such provision is to remedy the perennial difficulty Aboriginal communities have experienced across the whole country in being given sufficient time to adequately respond to given requests. This has direct application for data collection with its required documentation, questionnaires and responses. Informed consent is described within the document to include documented evidence which demonstrates that involvement has taken place which enables

“the allowance of sufficient time for the community and the individuals concerned to assimilate and respond to the information offered.”⁴¹

Community Involvement

The document provides a very positive and workable basis for ensuring informed consent from the Aboriginal community, stressing the indispensable requirement for genuine Community involvement. The NAHS has documented former procedures which reduced community consultation to mere information sessions. In essence, appropriate Community consultation incorporates ‘negotiation’ which implies mutual agreement and informed discussion.

The researcher recognises the right of the community to request further information about aspects of ongoing research, and accepts that changes in research protocols, procedures or methodologies will require further negotiations with the community and consent for that change by the community or an agency nominated by the community.

⁴⁰ *ibid*, Consultation, 1,2,3

⁴¹ *ibid*, Consultation, 3 (c)

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The Institutional Ethics Committee (IEC) must also be notified and be given the opportunity to approve changes to the research protocol.⁴²

Local Community Ownership and Consent.

It is also incumbent upon the data requesting body to acknowledge the necessity to seek the consent of each participating Aboriginal community .

Ownership & Publication of Data

The *NH&MRC Guidelines* on 'Ownership and Publication of Data' moves the debate a long way towards the Community position. One of its recommendations for the ownership of data is as follows:

"If there is any reason to expect that there may be a misunderstanding between researchers and Aboriginal and Torres Strait Islander research subjects over the conduct of research, the ownership of raw data or the rights to publication of research findings, these matters should be discussed and negotiated and preferably agreed upon by both parties before the research begins."⁴³

From an Aboriginal community perspective it is considered deficient that provision for negotiation is merely "preferable" and not mandatory. Failure to secure an agreement for the collection of data precludes any use or publication of related research and is inconsistent with recommendations made and assurances agreed between interested parties.

It is also recommended within this NH&MRC document that any publication following analysis of data is also to be reported to the "community as a whole" with details of an individual nature being confidentially conveyed to the participants.

From an Aboriginal cultural perspective the publication of findings would need to be reported to the body providing the information, local, state or national, rather than an all inclusive statement which does not constitute informed consent.

5. National Aboriginal Health Strategy (NAHS)

The National Aboriginal Health Strategy contains an entire chapter on the specific issues of data systems, evaluation and monitoring the prevailing condition of Aboriginal health.

Throughout the whole document the place of the Aboriginal community is central in working through both its own health services and in co-operation with Commonwealth and State mainstream health programs.

Monitoring and Evaluation

Monitoring and evaluation by the community "serve a useful purpose in promoting greater participation in the provision of Primary Health Care."⁴⁴

Unrealistic and Onerous Demands

Performance Indicators should not make "unrealistic demands" upon an organisation which provide "little information useful in improving services delivered".

⁴² *ibid*, *Community Involvement*, 6

⁴³ *ibid* p.8

⁴⁴ *NAHS*, 12.1.2

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Cause for Concern

Similar to the acknowledgement in the *NH&MRC Guidelines* reference is made to past practices which have given rise for concern.

“Communities have often had good reason to see the process of monitoring and evaluation as a means by which government might gather information about a community without that community’s consent and/or the means by which government might coerce a community into adopting standards it might otherwise wish to reject.”⁴⁵

Centrality of the Aboriginal Community

The centrality of the Aboriginal Community in all matters relating to its own health is paramount throughout the *Strategy* and involvement of Aboriginal communities in the process itself is seen as “integral” in making an objective analysis of progress in Aboriginal health and to identify new goals and any necessary policy adaptation and revision. It is also the basis for providing an informed position in the assessment role it shares with the Commission and the Department of Health for “the establishment of new services and facilities in response to changing needs.”

Collection of Data

The *Strategy* recognised the role for:

“National, State and Territory agencies’ involvement in the collection of data information on Aboriginal health and their need for a more adequate monitoring of mainstream services and improvement in the provision and quality of data collection information systems.”⁴⁶

The NAHS Working Party Report recommended:

“That an appropriate level of resources be made available to the Australian Institute of Health to enable comprehensive Aboriginal health statistics data collection, analysis and reporting.”⁴⁷

Aboriginal community involvement in monitoring and evaluating

The *Strategy* recognises the Aboriginal community’s involvement in monitoring and evaluating Primary Health Care and stresses the need to have data collections and analyses at the service delivery level and that sufficient resources be provided to Community Health Services to develop and operate the detailed monitoring and evaluation identified in the *Strategy*.

The *Strategy* acknowledges the progress in data systems within certain Aboriginal community controlled health services and considers that:

"Responsibility for monitoring and evaluation falls on those individuals or groups most closely concerned with the delivery of service. This requires that at each level of care... mechanisms should be developed ...within each level of the health

⁴⁵ *ibid*, 12.1.2

⁴⁶ *ibid*, (12.1.4)

⁴⁷ Within the list of recommendations in the *Aboriginal Health Development Group Report*, December 1989. See also the *NAHS An Evaluation* December 1994, p. 69. #9.4

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system. It also applies to the evaluation and monitoring of the policy function and to primary, secondary and tertiary levels of care."⁴⁸

Information Collection

The *Strategy* considers that the essential attributes to the process are:

“Relevance, adequacy, progress, efficiency, effectiveness quality and impact.”⁴⁹

However, it considers that:

"It is also necessary to have a clear picture of how and by whom the information is to be used."⁵⁰

... the strengthening of the information capacities of primary health care providers is fundamental to improved monitoring and evaluation. The enhancing of such capacities at the community level will assist in terms of program budgeting and the development of valid and relevant performance indicators ... Aboriginal health services should be encouraged individually and collectively to develop and prepare information and other evaluative reports as part of their management system.⁵¹

6. National Aboriginal & Islander Health Organisation (NAIHO), Report on the National Workshop on Ethics of Research in Aboriginal Health

The *Report* mentions the importance of Community involvement at each stage of research and related data collection process.

The initial stages of research and data collection have to conform to stringent guidelines that meet Aboriginal community approval. Obtaining ethical approval from the Community controlled sector is spelt out with clear expectations for what constitutes proper consultation.⁵² The process of “consultation/negotiation” has to be clearly identified and ensure that proper discussion occurs and that the control of these are vested in the Communities. Provision must be made to also ensure that appropriate cultural protocols and procedures are in place. It is clearly stated that approval of Aboriginal people in government departments is no substitute for proper community consultation/negotiations.⁵³

Communication and Consent

The following definition was given as the accepted text from the workshop which developed the *Report*.

“Communities must be provided with all the relevant information and explanations on the intent, process and methodology, evaluation and potential use of any research proposal.

Researchers must comply with any request for further information from relevant community controlled agencies associated with the research proposal.

⁴⁸ *ibid*, 12.1.2

⁴⁹ *ibid*, 12.1.3

⁵⁰ *ibid*, 12.1.2

⁵¹ *ibid*, 12.1.4.

⁵² *National Aboriginal & Islander Health Organisation (NAIHO), Report on the National Workshop on Ethics of Research in Aboriginal Health, 1 & 2*

⁵³ *ibid*

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Community process of decision making will reflect varying social and cultural values. In obtaining the consent of communities to research, researchers must respect the Aboriginal community's process of decision making."⁵⁴

Other relevant matters with regard to the collection of data information for research purposes would be that sufficient time is provided for adequate examination of all proposals by the Community.

Ownership and Publication of Materials

The *Report* also covers publication and ownership of material and the on-going role in monitoring the implementation of research, all of which are considered of vital importance to local Aboriginal communities. This reflects the current position of NACCHO with the document being attached to the NH&MRC Guide-lines. Some of the recommendations within this area are:

“Research material and data shall remain the property of the Community. The Community retains the right to censor research of a sensitive nature. Prior to publication or other use of research materials or Reports, the approval of the relevant controlled agency is required.”

“In preparing acknowledgement of research, the proper accreditation of participation and assistance of Aboriginal individuals, communities and their agencies should be noted.”⁵⁵

Other recommendations cover the assurances for privacy and non-identification in research which are equally binding in any collection of data on Aboriginal health or epidemiological study.

Exploitation of Community Resources

As other primary documents have recognised, there should be no imposition upon the Aboriginal community controlled health sector to be involved in processes that are not adequately funded or resourced.

Associated costs incurred by Aboriginal communities and Aboriginal community controlled organisations should be fully reimbursed. The role of departments or agencies in this respect would be considered the bodies responsible for meeting these costs.

“In seeking the co-operation of Aboriginal communities and local community controlled agencies, [researchers] must provide reimbursement of any cost incurred which relates, directly or indirectly, to programs of research. Such costs could include telephones, transport, freight, gas and water, accommodation, supervision costs and wages of assistants and interpreters.”⁵⁶

Employment of Aboriginal people in research projects

The recommendation for employment of Aboriginal people in research projects is also within the context of ethical matters associated with researching in Aboriginal and Torres Strait Islander health.

⁵⁴ *ibid*, Part 5

⁵⁵ *ibid*, Part 7

⁵⁶ *ibid*, Parts 8

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“In many circumstances the employment of community members will aid the Researcher and improve the quality of communication and ultimately strengthen the initiative.”

“Researchers, where local community controlled agencies believe it necessary, must provide for the employment of local Aboriginal co-investigators.”⁵⁷

Ongoing Review of Ethical Standards

The *NAIHO Report* realistically appraises ethical standards in Aboriginal health and recommends

“Ethics Committees and the relevant community controlled agencies have an ongoing responsibility to ensure compliance with appropriate ethical standards.”⁵⁸

The thrust of the remainder of this section of the *Report* relates to procedures for research projects and practical recommendations for administering of related funds, but the introductory comment, sighted above, is very relevant to the Aboriginal health information process and requires specific inclusion in any Protocols for ethical standards.

In light of more recent legislative developments caution should be given to the role of Ethics Committees which can, under certain conditions, negate the Information Privacy Provisions within the Privacy Act. Whilst they make an important contribution in the field Ethics Committee should not be seen as a substitute for the Aboriginal community decision making process and ideally should work in association with Aboriginal community health organisations.

It is for this reason that the Community itself is considered the determining body in matters relating to Aboriginal health information rather than any national, State or Territory Ethics Committee solely determining matters concerning Aboriginal health. State and Territory affiliate bodies of NACCHO do have valuable ethics committees but the underlying principle upon which they operate is the inviolate and undisputed nature of the Aboriginal community itself to alone consider research into Aboriginal health.

7. Recommendations of the Royal Commission into Aboriginal Deaths in Custody

Recommendation 270

“That:

- a) Aboriginal people be involved in **each stage of development** of Aboriginal health statistics; and
- b) appropriate Aboriginal health advisory bodies (such as the Council of Aboriginal Health) consider developing an expanded role in this area, perhaps in an advisory capacity to the Australian Institute of Health and Welfare, and that the aim of this involvement should be to ensure that priority is given to the collection, analysis, dissemination and use of

⁵⁷ *ibid*, Part 6

⁵⁸ *ibid*, Part 3

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Aboriginal Health Statistics most relevant to Aboriginal health development.”

8. Memorandum of Understanding between ATSIC and the Commonwealth Minister for Health and Family Services

A definitive document which underpins the implementation and procedures for the collection of statistical data for health information on Aboriginal health is the *Memorandum of Understanding between ATSIC and the Commonwealth Minister for Health and Family Services*. (MoU) This document, which is the instrument which facilitated the transition between the Department and the Commission for carriage of the Aboriginal health portfolio, is valid until the 30th June 1999. It also incorporates an important ongoing role for the Commission in the collection of data on Aboriginal health.

Germane to the process of collecting and assessing statistical data on information on Aboriginal health the following provisions appear relevant from an Aboriginal community perspective.

- 3.1.1** The Commission has statutory responsibilities to:
 - (i) monitor the effectiveness of programs for Aboriginal and Torres Strait Islanders, including those programs to be conducted through the Department;
- 3.1.5** The Commission will assist the Department by providing access to any data collected on the impact of the activities undertaken by the Commission which may have relevance to health outcomes or to the planning and delivery of primary health care services.
- 3.3.3** The Department will be responsible, in consultation with NACCHO, ATSIC, the National Health and Medical Research Council and other health professional organisations for the development of appropriate standards for the delivery of health services, as well as mechanisms which meet the needs of both the Commonwealth and the Services for monitoring the effectiveness of health services;
- 3.3.5** To ensure effective coordination in the delivery of services, the Department will develop mechanisms to involve the Commission in the planning and priority setting for health services at the National and Regional level. Local Community controlled services and NACCHO will also be invited to participate in such consultative mechanisms as appropriate.
- 3.3.8** The Department will consult with the Commission on the development of any data collections on primary health services and will provide the Commission with access to the aggregated data, as it relates to the delivery of environmental health programs provided by the Commission.

9. Commonwealth/State/ACCHS Framework Agreement

“The parties to the Framework Agreement, being the Commonwealth of Australia and the respective States and Territories agree, in partnership with ATSIC, NACCHO and the relevant State and Territory peak bodies affiliated with NACCHO, to:

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establish culturally sensitive and ethically sound, privacy and confidentiality protocols for the routine collection of standardised data of Aboriginal and Torres Strait Islander health. These protocols are to recognise Aboriginal and Torres Strait Islander ownership of the data including clarity about the collection and use of data. Any change in the use of the data will require agreement from the owners of the data;
(Framework Agreement 3.12)⁵⁹

improve the quality of relevant data available on the provision of mainstream health services to, and utilisation of mainstream health services by, Aboriginal and Torres Strait Islander peoples; and
(Framework Agreement 3.13)⁶⁰

to:

develop appropriate health outcome indicators to measure progress in improving the health of Aboriginal and Torres Strait Islander peoples; and
develop a mechanism to report specifically on health outcome indicators in (a) above.
(Framework Agreement 3.14)⁶¹

⁵⁹ *Agreement on Aboriginal and Torres Strait Islander Health between the NSW Minister for Health; the Commonwealth Minister of State for Health and Family Services; the [Relevant State or Territory peak bodies affiliated with NACCHO]; and the Aboriginal and Torres Strait Islander Commission (ATSIC), 3.12*

⁶⁰ *ibid, 3.13*

⁶¹ *ibid, 3.14*

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APPENDIX B

Summary

NATIONAL ABORIGINAL & TORRES STRAIT ISLANDER HEALTH DATA PROTOCOLS

for the

ROUTINE COLLECTION OF STANDARDISED DATA ON ABORIGINAL & TORRES STRAIT ISLANDER HEALTH

NACCHO

October 1997

(Developed by NACCHO for the collection and use of data from Aboriginal
Community Controlled Health Services)

4.3 Statement of Ethical Commitment in Aboriginal Health Information

- All participants in the Aboriginal health information processes should only be involved in activities which conform to accepted ethical standards reflected in this document.
- An ethical commitment to confidentiality is incumbent on all participants collecting data on Aboriginal health information.
- All participants in Aboriginal health information processes should acknowledge and respect the ultimacy of the Aboriginal community's discretion.

4.4 Aboriginal Community Control - Definition

- Community control is a process which allows the local Aboriginal community to be involved in its affairs in accordance with whatever protocols or procedures are determined by the Community.
- The term Aboriginal Community Control has its genesis in Aboriginal peoples' right to self-determination.

4.5 Levels of Aboriginal Community Control

4.5.1 Local

- The pivotal tenet of Aboriginal community control in health is the indisputable and definitive role of the local Aboriginal community concerned. All other levels of representation, whether regional, state or territory and national, revolve around this essential component.
- In all matters relating to Aboriginal health information provision must be made for each individual Aboriginal Community to determine the process and content related to its own well-being.
- Aboriginal people must be involved in each stage of development of Aboriginal statistics. (RCIADIC Recommendation 270)

4.5.2 Regional

- That health services in the public sector and Aboriginal community controlled health services work closely together to maximise procedures for improving information on

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Aboriginal health within their regions and that there be reciprocal sharing of information and data on Aboriginal health at this level to enable immediate response to local health priorities.

- That Memoranda of Understanding or Partnerships be effected at the regional level between health services within the public sector and the Aboriginal Community controlled health sector which incorporate procedures for improving information on Aboriginal health to ensure that this process has immediate and direct application within the region for improving Aboriginal health; to enable prioritising of health programs; to increase access and equity in health service and to allow more appropriate resource allocation.

4.5.3 State/Territory

- That State and Territory Health Departments and peak State and Territory health bodies affiliated with NACCHO work closely together to maximise procedures for improving information on Aboriginal health within their States or Territories and that there be reciprocal sharing of information and data on Aboriginal health at this level to enable immediate response to health priorities.
- That Memoranda of Understanding or Partnerships be effected at State and Territory levels which incorporate procedures for improving information on Aboriginal health to ensure that this process has immediate and direct application within the State or Territory for improving Aboriginal health; to enable prioritising of health programs; to increase access and equity in health service and to allow more appropriate resource allocation.

4.5.4 National

- That the Department of Health & Family Services and NACCHO work closely together to maximise procedures for improving information on Aboriginal health and that there be reciprocal sharing of information and data on Aboriginal health at this level to enable immediate national response to health priorities.
- That Memoranda of Understanding or Partnership Agreements be effected at national level with the Department of Health and Family Services; the Australian Institute of Health and Welfare; ATSIC and the Australian Bureau of Statistics which incorporate procedures for improving data systems to ensure that this process has immediate and direct application for improving Aboriginal health; to enable prioritising of health programs; to increase access and equity in health service and to allow more appropriate resource allocation.

4.6 Aboriginal Cultural Appropriateness

- The best possible practice for gathering, analysing, using and disseminating information on Aboriginal community health is an unquestioned acceptance of Aboriginal communities' prerogative to use their own discretionary judgement in the decision making process and to acknowledge the need for Aboriginal communities to have unfettered control over determining what is culturally appropriate for their community's health and what is culturally relevant in the provision of health data.

4.7 Aboriginal Community Consent

4.7.1 Free and Informed Consent

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- Before any collection of data on Aboriginal health, or before any research on data is undertaken, the free and informed consent of each Community concerned must be obtained in writing.
- The collection of data on Aboriginal health, and any research on such data, are subject to the free and informed consent by the Aboriginal community concerned and, in the interest of professional recognition of the data for epidemiological analyses, must be free of any form of duress or any mandatory reporting requirement.

4.7.2 Provision to Withdraw Consent

- It is a condition of any free and informed Consent Agreement relating to the collection of information on Aboriginal health that the participating party has the right to withdraw consent upon experiencing concern or dissatisfaction with the process or procedures.

4.7.3 Appropriate Forms for Consent

- That appropriate Consent Agreements forms be developed in association with Aboriginal community health services, peak State and Territory health bodies affiliated with NACCHO and NACCHO with the following factors incorporated into the instrument:
 - written information why the information is collected
 - Statement on ‘confidentiality’
 - definition of terms
 - details for the Data Custodian
 - Assurances for de-identified data
 - Statement precluding derived information for multiple data banks
 - Details of the repository body
 - Details on who will have access to the information
 - any intended disclosure to third parties
 - the name of the Data Custodian for computerised filing
 - details on how the information will be used
 - the non-mandatory nature for the collection of the information
 - the anticipated time-frame for the use of the data
 - details on the storage of data
 - adequate time-frame-for Community consideration
 - confirmation of due consultation or any required negotiation with the Community health service or Community
 - provision for the right to withdraw consent
 - assurances that in any change of use or linking of data additional consent is obligatory
 - terms of reference for any variation to the ethical standards espoused within these protocols
 - terms of reference for the destruction or return of data
 - provision of materials which demonstrate that the question of ownership of data has been addressed.
 - terms of reference for approving any publishable material

4.7.4 Partnership Agreements or Memorandum of Understandings

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- That State and Territory health departments and peak State and Territory health bodies affiliated with NACCHO enter into Agreements between themselves, either through Partnership Agreements or Memoranda of Understanding, making provisions for the collection and analysis of data on Aboriginal health which comply with the NAHS and other recommendations cited within this document. Furthermore, that provisions be made which ensure the right of Aboriginal communities and peak Aboriginal health bodies to exercise their prerogative in deciding what is culturally and socially appropriate to provide in the collection of Aboriginal community health data.
- That Health Services in the public sector and ACCHS's in each State and Territory enter into Agreements between themselves, either through Partnership Agreements or Memoranda of Understanding, making provisions for the collection and analysis of data on Aboriginal health which comply with the NAHS and other recommendations cited within this document. Furthermore, that provisions be made which ensure the right of Aboriginal communities to exercise their prerogative in deciding what is culturally and socially appropriate to provide in Aboriginal community health data.

4.7.5 Community Involvement, Consultation and /or Negotiation

- That at each stage of development of Aboriginal health statistics the Aboriginal community:
 - (i) at the local and regional level through the Aboriginal community controlled health service;
 - (ii) at the State level through its peak State or Territory health body affiliated with NACCHO; and
 - (iii) at the national level through NACCHO is vitally involved and as integral part of the process, ensuring:
 - (a) free and informed consent has been effected
 - (b) collection of data is culturally and socially appropriate
 - (c) terms of use are clear and responsible
 - (d) analyses and applications are valid and scholarly
 - (e) publication of material is approved and culturally appropriate
 - (f) that reporting mechanisms back to the Community are complied with
 - (g) that any time-frame for use is adhered to
 - (h) that terms of reference for destruction or return of documents are administered

4.7.6 Written Objectives and Stated Purpose for the Data

- All requests and procedures for collection information on Aboriginal health must be accompanied by written protocols outlining the reason for the required data; the way in which data will be collected, used, stored, reported and protected and the anticipated time-frame related to the specific purpose for the data.

4.8 Mechanisms for Aboriginal Health Information Data Collection

4.8.1 Collection

- No personal information to be collected as part of this process

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- No identifiable personal information on any individual client should be collected and provided to the repository body.
- Personal files within Aboriginal community controlled health services are sacrosanct and information cannot be disclosed to any third party without the expressed written consent of the client concerned.
- No identifiable information on any individual client can be collected or included for storage in any manual filing system, retrievable data system or linking facility other than that for facilitating an individual medical file within the Aboriginal community controlled health service concerned.

4.8.2 Purpose and Manner of Collection

- No information can be provided to the Repository Body outside of the stated purpose within a Consent Agreement or the terms of reference of that consent.
- The only information to be collected is for a lawful purpose that is directly related to the stated function or activity of the repository body.
- the collection of information is necessary for and directly related to the stated purpose for which consent had been given.
- data on Aboriginal community health shall not be collected by unlawful or unfair means nor as a result of any action of duress.
- no soliciting for health information shall take place by the Repository Body or collector of health information outside of these protocols or any agreement based upon these protocols

4.8.3 Questionnaires

- Questionnaires which are part of documentation for any collection of data on Aboriginal community health should be:
 - available prior to any consent being requested by the Repository Body or provided by the participating Community health service
 - be given adequate time for evaluation and response from a scientific, ethical and Community viewpoint
 - any revision or amendment precludes the questionnaire being the basis for any previously provided consent
 - Confidentiality shall apply to all information collected and any Community's request for being de-identified should be respected.
 - Questionnaires should be subject to any independent scientific assessment, ethical evaluation and consideration by the participating Community or if requested, the peak State or Territory health body affiliated with NACCHO or NACCHO to ensure cultural appropriateness and professional standards; and
 - should not be part of any mandatory reporting system or action of duress.

4.8.4 Modification and Cessation of Projects

- Any modification, alteration, amendment or change in the use of the data and its period of use; the storage and security of the data and its return or destruction date shall be the basis for a new or amended Consent Agreement.
- Failure to comply with this understanding renders the basis for participation null and void.

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- Non-compliance by the Repository Body following notification by the participating Community health service renders the Repository Body liable to the provision of common law.

4.8.5 Adequate Time-frame

- That in all matters related to the collection and use of data on Aboriginal community health adequate time be provided for Community health services to comprehensively assess all relevant issues. This includes the provision for realistic time-frames at each stage of the development of data information processes and that in any consent agreement, written evidence be included to indicate that appropriate consultations, negotiations or communications have taken place.

4.8.6 Interpreters

- That the Repository Body ensure that all communication is written in appropriate and comprehensible language and that in those Communities in which interpretation is required, where possible trained and qualified interpreters be utilised to minimise the risk of personal privacy and community confidentiality being breached.

4.9 Monitoring and Evaluation

- That monitoring and evaluation are acknowledged as vital roles at each level of the Aboriginal community's involvement in the collection, use, reporting and publication of data on Aboriginal health. The various levels of involvement are: local ACCHS's; peak State & Territory health bodies affiliated with NACCHO; and at the national level, NACCHO.
- That monitoring and evaluation by the Repository Body be carried out consistent with the recommendations of this document, and that frequent reporting be provided to the Aboriginal community at the local ACCHS level; at the level of peak State & Territory health bodies affiliated with NACCHO and at the national level with NACCHO.

4.10 Analysis, Interpretation, Research and Use of Data

4.10.1 Analysis, Interpretation, Research and Use of Data

- That following the recommendations cited within this document that ATSIC, the Australian Institute of Health & Welfare and the Department of Health and Family Services negotiate with NACCHO and enter into Memoranda of Understanding which enable the Aboriginal Community's endorsement for appropriate analysing and evaluation of data supplied to the Repository Body by participating Aboriginal community controlled health services.

4.10.2 Limitations on Usage of Data

- All data supplied as part of the collection of information on Aboriginal community health shall only be used for the purposes for which it was collected as indicated within a free and informed consent agreement. Any intention to vary this condition requires the additional consent of the Aboriginal Community health service concerned and failure to obtain new consent obligates the Repository Body to either return the information or destroy the information as initially agreed.
- Due to the NH&MRC provisions for Ethics Committees to overrule consent agreements, with regard to the use of collected data on Aboriginal community health,

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the determinative body for ethical evaluation of data on Aboriginal community health is the local Aboriginal community controlled health service or, in areas where no such body currently operates, then the relevant peak State or Territory health body affiliated with NACCHO in association with the local Community concerned.

4.11 Aboriginal Community Ownership of Data

- All data on Aboriginal community health and related research material are owned by and shall remain the property of the Aboriginal community.

4.12 Publication of Data on Aboriginal Community Health

- The Aboriginal Community retains the right to censor research of a cultural or community sensitive nature related to the provision of data on Aboriginal community health and that prior to any publication, reports or other use of research materials the approval of the Aboriginal community controlled health service, or when appropriate, the approval of the appropriate level of Aboriginal community controlled health, is required.

4.13 Employment of Aboriginal People

- That in the collection, monitoring, analysis, research, storage, dissemination and publication of data on Aboriginal community health, attention be given to opportunities for the employment of Aboriginal and Torres Strait Islander peoples at each stage of the process and at each level within the Aboriginal community controlled health sector - local, regional, State & Territory and National.

4.14 Exploitation of Community Resources

- In the collection and evaluation of data on Aboriginal community health, and in the monitoring of the process, there should be no imposition placed upon the Aboriginal community controlled health sector and no expectation for involvement in processes that are not adequately funded or resourced.

4.15 Provision of Community Resources

- That involvement of each level of the Aboriginal community controlled health sector in the collection and use of data on Aboriginal Community health be adequately resourced to cover all direct and indirect additional expenses, wages, administrative costs and any necessary computerisation be provided to ensure the efficiency of the process.

4.16 Ongoing Participation of the Aboriginal Community

- that the Aboriginal community controlled health sector have an active ongoing involvement at each stage of the process for the collecting and utilising of data on Aboriginal community health with a continuing liaison with the Repository Body, routinely responding to its reports on both the findings of the data and also reports concerning the monitoring of the process itself. The process will also incorporate interaction at the various levels of the Aboriginal community controlled sector, at the local and regional level with Health Services within the public sector, at the State and Territory level with State and Territory health departments and at the national level, interaction between NACCHO and the various agencies involved in the analysing of statistical health data.

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4.17 Ongoing Review of Ethical Standards

- That the Aboriginal community controlled health sector have an ongoing role in assessing the ethical standards related to the collection and use of data on Aboriginal community health as well as monitoring relevant ethics committees to ensure that where matters directly or indirectly affect data on Aboriginal community health they comply with the ethical standards within the Aboriginal community.
- Furthermore, that at each level of the Community controlled health sector the role and functions of ethics committees with regard to overriding of agreed use of collected data be closely examined and that free and informed consent agreements contain clauses defining expected ethical conduct of the Repository Body and provisions be included for the prohibition of any variations of such expected ethical conduct.

4.18 Confidentiality

4.18.1 Disclosure of Personal and Community health information,

- The restriction of access to personal information to authorised persons is understood to be currently automatically applicable in all activities within ACCHS's and Commonwealth and State health departments. Specifically, within the process of collecting and using data on Aboriginal community health, the conveyance of personal information could only arise inadvertently.

4.18.2 Anonymity

- With regard to the collection of data on Aboriginal health, confidentiality is considered the characteristic of data, with information being disclosed only to authorised persons, entities and processes at authorised times and in the authorised manner agreed upon at the time free and informed consent was obtained.
- Within the process of data collection on Aboriginal health a “duty of confidence” relationship is considered to exist between the Repository Body and the participating local Aboriginal community controlled health service or other levels at which information has been provided by the Aboriginal community controlled health sector.
- This “duty of confidence” relationship is considered to exist with regard to the provision of both identifiable personal health information, which may have been inadvertently provided to the department or Repository Body, as well as to any information considered confidential by those Communities requesting the de-identification of their communities.

4.18.3 De-identification of Data

- With regard to Communities requesting their collected data to be de-identified, all Community identifiers are to be stripped or altered in such a manner to render the identification of the Community concerned improbable.

4.19 Complaint Mechanisms

- That is incumbent upon the Repository Body to establish and provide confidential mechanisms for receiving complaints or reports on the conduct of the process of collecting and using information on Aboriginal community health.

4.20 Storage and Databank Register

4.20.1 Storage

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- All data on Aboriginal health that are stored by the Repository Body shall be protected from loss, misuse, unauthorised access or alteration by the utilisation of appropriate security services and functions.

4.20.2 Databank Register

- A current register shall be kept at the administrative office of the Repository Body where the information is stored and that such a register shall contain as a minimum the entries as listed within these Protocols.

4.21 Archiving

- All data on Aboriginal health that are stored by the Repository Body shall be protected from loss, misuse, unauthorised access or alteration by the utilisation of appropriate security services and functions. A current register shall be kept at the administrative office of the Repository Body where the information is stored.
- Upon receipt of collected data from Aboriginal Community controlled health services the Repository Body shall identify and provide in writing the name of the Data Custodian.

4.22 Access

4.22.1 Levels of Accessibility

4.22.2 Internal Requests for Access to Data

4.22.3 External Requests for Access to Data

- That provision should be made in the collection and analysing of data on Aboriginal community health for internal and external levels of access to the databank. The Data Custodian Officer shall be responsible to ensure that access is permitted to appropriate internal personal and trusted third parties consistent with the original consent agreement or any amended consent agreement and shall ensure that data will only be used for the purposes for which it was provided.
- Any requests which indicate a purpose other than that for which the data was originally provided shall be submitted to the participating Aboriginal community health service for their consideration and consent with full written documentation provided to justify consideration to vary agreed disclosure.
- Any variation in the original purpose of and access to the data shall also be referred to the respective peak State or Territory health body affiliated with NACCHO and, if relevant, NACCHO itself.

4.23 Safeguards for Protection

4.23.1 Mail and Courier items

- Packaging of mailing and courier material should be secure with appropriate care taken to avoid incorrect labelling or addressing.

4.23.2 List of Codes

- That master lists of codes assigned to Communities and details of internal coding stems should securely stored separate from the data to which they refer.
- Master lists of codes should be secured in computerised systems by means of appropriate safety measures

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- Upon completion of work all files held on hard copy are to be either destroyed or if retained under a consent agreement securely stored with the participating Aboriginal community health service informed of this process.
- Upon completion of work all files held on hard discs are to be deleted or if retained under a consent agreement copied to floppy files which are to be securely stored with the participating Aboriginal community health service being informed of this process.

4.23.3 Data Sponsor

- That the Data Sponsor be responsible on behalf of the Repository Body for the ownership of data collected from Aboriginal community controlled health services and his duties, amongst others, are as delineated in these Protocols.

4.23.4 Data Custodian

- The Data Custodian is responsible for the observation and compliance of all relevant protocol within this document, in particular the listed duties, and for the safety and confidentiality of the Aboriginal community health data.

The duties of the Data Custodian include:

- Ensuring the overall security of Community information on the databank
- Ensuring that the databank and related information systems are professionally designed, operated and maintained in accordance with appropriate professional standards
- Enforcement of necessary rules and conditions to access the databank
- Ensuring authorised databank users have entered into an access agreement and are conversant with related rules of access.
- Ensuring that the appropriate levels for access and restrictions of access are complied with
- Developing necessary codes, passwords and related security measures.
- Ensuring databank users undertake their duties in accordance with appropriate Rules.
- Ensure that at all times privacy to Community information is protected
- Responsible for the observation and compliance of all relevant protocol within this document, in particular the safety and confidentiality of the Aboriginal community health data.
- Ensure that use of the data is consistent with the original purpose for which the data was provided.
- Ensure that all internal and external requests for data comply with the original consent agreement.
- Ensure that timely reports on system security, access, transference, data analysis, data reports, requests to vary use and access, destruction and return of data are provided to the local Aboriginal community controlled health service and the appropriate levels of the Aboriginal Community controlled health sector.
- Ensure that any internal or external linkage of data collections is consistent with the original purpose for which data has been provided.

4.24 Reporting Mechanisms for Data Security

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- That Data Custodian shall routinely report to ACCHS's and, where applicable, the appropriate level of the Aboriginal community controlled health sector, at least annually, or at each stage of the process, concerning the following items:

- Relevant information concerning the security of the data within the Repository Body databank
- Compliance with approved consent procedures
- Compliance with any special conditions
- Current location of the data at each stage of the process
- Confirmation by a trusted third party for responsibility of disclosed data
- Changes which might affect the ethical standards consented to
- Adverse effects upon participating Community health services
- Proposed changes to objectives for and uses of data consented to
- Unforeseen events which might affect continued ethical acceptance of the process

4.25 Reporting Mechanisms for Data Transmission

- It is incumbent upon the Data Repository Body to provide timely reports, not less than annually, or at each stage of the process, with specific reference to stages in the process requiring any transfer of data and the following items:

- collation, analysis and reporting
- internal disclosures as part of staged progression
- disclosures to trusted third parties, including agencies and contractors
- any proposed printed report, analysis or publication.

4.26 Evaluation of Mechanisms and Application

- That a mechanism be developed enabling all participating parties to periodically evaluate the current mechanisms which direct each stage of the process of collecting and evaluating data on Aboriginal community health.

4.27 Education of Staff

- All staff working with data on Aboriginal community health should be conversant with the provisions of these Protocols and be routinely informed of related guidelines and legislated provisions and have training in confidentiality and privacy of information, particularly as it relates to Aboriginal community data, and undertake cross cultural awareness courses in Aboriginal culture and community life.

4.28 Destruction of Records

- All records of data on Aboriginal health provided by a participating Aboriginal community shall upon the completion of their agreed use be either destroyed by the Repository Body, upon notifying the Community concerned, or returned to that participating Community as directed by the terms of the consent agreement.

- Disposal and destruction of records should be done in such a manner as to render them unreadable and left in a form from which they cannot be reconstructed in whole or part

- the Repository Body shall provide a statutory statement indicating the date and place of destruction of records; the officer responsible for certifying this action and confirmation that no reproduced part or copy of the data is still stored in any retrieval system or data base.

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4.29 Disclosure of Potential Conflict of Interest

That to ensure perceptions of sound scientific practice in the collection of data on Aboriginal community health there should be a complete severance of scientific medical data from the Service Reporting process and the acquittal processes of financial grants which have been provided for the management of participating Aboriginal community controlled health services.

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13. APPENDIX 3



AH&MRC SUBMISSION TO THE NHMRC (AHEC)

on the

DRAFT GUIDELINES FOR ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH RESEARCH

Values and Ethics in Aboriginal and Torres Strait Islander Research

from the

ABORIGINAL HEALTH & MEDICAL RESEARCH COUNCIL OF NSW

Following advice from the AH&MRC Ethics Committee

December 2002

A revision of the *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research (1991)* was first mooted, to the knowledge of the AH&MRC, during the public forums associated with the review and revision of the *NHMRC Statement on Human Experimentation and Supplementary Notes (1992)* which led to the current *National Statement on Ethical Conduct in Research Involving Humans*.

To assist the Committee in its onerous task the following comments are provided so that the revised *Guidelines* can be reflective of and embraced by all sectors involved in ethical research into Aboriginal and Torres Strait Islander health, whilst at the same time not diminishing the Aboriginal and Torres Strait Islander communities' rightful place to be in control of a process that enables culturally appropriate research into their health and well-being.

The AH&MRC Understanding of the Context for the Review

At the respective NHMRC public consultation in Sydney which considered the draft *National Statement*, representatives from the AH&MRC raised concerns about the possibility of condensing extant NHMRC documentation on ethical matters pertaining to Aboriginal and Torres Strait Islander health within the planned synopsis entitled *Research Involving Collectivities*. A case against this proposal was formalised by the AH&MRC as part of its 33 page submission forwarded to the Australian Ethics Committee commenting on the *Draft National Statement*. It was stated in the forwarding letter from the Council that:

Aboriginal and Torres Strait Islander peoples should be correctly referred to in any NHMRC documentation as well as being acknowledged as the host peoples of this country

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rather than be relegated to a collective multi-cultural smorgasbord of unique immigrant traditions, important as multiculturalism has been in enriching this nation's societal mores and culture.

It is apparent here that even ethicists are needing cultural awareness training and to continue on this rather myopic route of insensitivity would probably precipitate an inevitable severance of indigenous academia in health from established structures to a parallel ethical process for the evaluation and monitoring of research into the health of their Communities.

It is rather incongruous that the pro-active, positive and culturally appropriate initiatives into ethical conduct for research into Aboriginal health which resulted from the NHMRC and the Menzies Foundation national conference in 1986 are about to be now relegated to the obscurity of an A4 page statement of "collectivity". Rather less generous critics might infer that this is the ultimate sanction of assimilationist policies that have caused the suffering and disparity in health and which still plague our communities' well being.

It was in this context that the AH&MRC was assured that separate *Guidelines* would remain together with a one page chapter in the *National Statement*, Chapter 9, entitled *Research Involving Aboriginal and Torres Strait Islander Peoples*, which would make reference to complementary *Guidelines*. This is indeed the current situation with mention in the *National Statement* that the *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research (1991)* are to be revised.

Consistency in Titles of Relevant Documentation

Notwithstanding the comment in the *National Statement* alluding to inevitable and routine refinement of the *Guidelines* it would appear that the additional qualification in chapter 9 of the *National Statement*, namely, "(Interim 1991)", is somewhat unfortunate and possibly misleading.

To revise or amend the Australian *Constitution* does not render the instrument 'Interim', implying its precepts and imperatives are transient. The cover of the document actually states:

"Approved by the 111th Session of the National Health and Medical Research Council, Brisbane, June 1991 and produced in this interim format pending publication."

What is referred to here, as 'interim' is the format, not the contents. This is no mere matter of pedantry as the *Guidelines* that underpin several instruments, reports and ethical agreements in Aboriginal and Torres Strait Islander health at State and National levels, are now being referred to by some scholars as interim and, accordingly, the proposed departure from prescriptive standards to interpretive contemplation and reciprocal trust between academics and the Community could jeopardise and undermine the confidence in and definitiveness of these instruments. For example, in one of the associated documents alluded to in the revision process it states:

"In 1991 the National Health and Medical Research Council (NHMRC) [sic] officially adopted the Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research.

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In this otherwise insightful and informative publication the *Guidelines* are throughout “referred to as the Interim Guidelines.”⁶² The matter is compounded when each of the three authors is a member of the relevant working party of the Australian Health Ethics Committee, a principal committee of the NHMRC, responsible for the drafting of the proposed *Draft Guidelines for Aboriginal and Torres Strait Islander Health Research (1991)* and their cited annotated bibliography is one of the adopted strategies by AHEC “to pursue this revision.”

There is no question as to the objectivity and integrity of the scholars concerned but as this nomenclature also permeates the ‘Consultation paper for the revision of the *Guidelines (1991)*’ it may have innocently influenced attitudes about the permanent value and relevance of the precepts underlying the recommendations of that document, both in form and content.

The NAIHO Report and NH&MRC Guidelines

The concern expressed above is exacerbated when it is recalled that the bound document that included the *Guidelines* circulated by the NHMRC always included a copy of the NAIHO Report, namely, the *Report of the National Workshop on Ethics of Research in Aboriginal Health (1987)* which, by association, could be inferred to be also interim and dispensable.⁶³

As scholars have described the *Guidelines* as being a “watered down” version of the NAIHO Report⁶⁴ and its perceived safeguards for ensuring Community control within research, it is open to serious question whether the current revision may depart even further from that document’s cultural and Community perspective, in spite of its ostensible emphasis upon Aboriginal core values. It may also be fair to speculate whether the NAIHO Report will continue to be circulated by the NH&MRC together with the Revised *Guidelines* as a historical yardstick of the Aboriginal communities’ aspirations for ethical standards in research.

The importance of the NAIHO Report from the Aboriginal Community Controlled perspective can be seen in the embracing of that document by the National Aboriginal

⁶² Daniel McAullay, Robert Griew and Ian Anderson, *The Ethics of Aboriginal Health Research: An Annotated Bibliography*. VicHealth Koori Health Research & Community Development Unit, Discussion Paper No. 5, January 2002. p. 6.

⁶³ In both the journal article ‘Dirty questions: Indigenous health and ‘Western research’, *Australian and New Zealand Journal of Public Health*, Vol 25, No. 3 footnote 23, and in the commendable publication *Indigenous Health & ‘Western Research*, VicHealth Koori Health Research & Community Development Unit, Discussion Paper No. 2, December 2000. pp. 16 & 30, Kim Humphrey cites Shane Houston as the author of the NAIHO *Report of the National Workshop on Ethics of Research in Aboriginal Health (1987)*. Mr Houston, as correctly stated, was the convenor of the ‘Workshop’ and was the National Coordinator of NAIHO at that time, however, correct citing of the document should be the NAIHO Report, similar to the corporate reference on page 31 to the NH&MRC Guidelines. NAIHO is now known as the National Aboriginal Community Controlled Health Organisation (NACCHO).

⁶⁴ Biggins, Davis, R., ‘Research in Aboriginal Health: Priorities, Ethics and Philosophy’, *New Doctor*, 1999, pp. 28-30. For a detailed analysis see Kim Humphrey, ‘Western research’, *Australian and New Zealand Journal of Public Health*, Vol 25, No. 3, p. 18.

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Health Strategy (NAHS),⁶⁵ specifically endorsing its 'Principles' as the basis upon which Aboriginal health research proposals were considered.⁶⁶

It may need reminding scholars that the tenuous basis of Community control in health was no more evident than in the recent abortive attempt by the Department of Health to amend the NAHS (1989) without the endorsement of NACCHO, one of the parties to the document. Any momentum for change that has not been carefully considered by the Communities is vulnerable to being perceived with suspicion, regardless of any admirable motivation by the proponents for change.

Whilst not all the recommendations in the NAIHO Report were incorporated into the NHMRC *Guidelines* - even those that were discretely avoided contentious matters like the ownership of data - nevertheless, the pro-active stance of the NHMRC in this matter provided an opportunity for ensuring acceptable standards and cultural respect when dealing with Aboriginal communities in health research. Several of the deficiencies noted by critics have been remedied in the provisions of the current *National Statement*.

Accordingly, instruments that have been acknowledged by the Community as protecting its cultural requirements need very careful scrutiny before amendment and revision. The old maxim that you don't discard proven policy until the ones that replace are demonstrably assured to be superior, should caution too radical a divergence from the status quo.

The importance with which the *NAIHO Report* is viewed by the AH&MRC was evident in its criticism of NH&MRC Supplementary Papers in the previous submission. It is ironic that the issue of an AHEC overriding the informed written consent of a participant has been abandoned and now the *National Statement* more closely complies with the ethical imperative as enunciated in the NAIHO Report - a matter that illustrates the wisdom of the members of 1986 Workshop and explains the document's use by the AH&MRC Ethics Committee as a defining instrument when assessing the Community's interests in given applications.

The proposed *Draft Guidelines* are seen by the AH&MRC as helpful guides to those researching in Aboriginal health, or ethically evaluating appropriateness of given research projects. They are not seen as synonymous with Aboriginal culture nor a written substitute, which if perused and its core principles and values meditated upon by non-Aboriginal participants, would enable researchers and ethics committees to pre-emptively know the mind of the Aboriginal community - a perceived potential danger in the proposed draft.

⁶⁵ National Aboriginal Health Strategy 1989, p. 212

⁶⁶ The position for Aboriginal community involvement and control in the health research process was ably defended by Ken Wyatt, 'The Rights of Aboriginal Communities: The Obligations of Health Researchers', *Aboriginal and Islander Health Worker Journal*, Vol 15, No.2, 1999, pp. 7-8.

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The AH&MRC is yet to be convinced that the *Draft Guidelines*, in their departure from the *Guidelines* authoritative and prescriptive format, are not a further aberration from the *NAIHO Report* that gave its genesis.

The importance of the underlying nature of the *NAIHO Report* can be seen in the AH&MRC's comment to the AHEC in its previous submission, which while relating to the resolved issue of 'Collectivities' appears relevant:

The Committee would also be conversant with the NAIHO (precursor organisation to NACCHO) supplement in the said NHMRC document entitled "*Report of the National Workshop on Ethics of Research in Aboriginal Health*" which is a 26 page definitive ethical statement about Aboriginal and Torres Strait Islander research. There is no similarity between the proposed truncated ethical statement for research on "collectivities" and these documents.

By way of historical comment, the earlier work by Central Australian Aboriginal Congress based in Alice Springs⁶⁷, paved the way for the acknowledgment of Aboriginal control within and respect for culturally sensitive and ethical processes when researching into Aboriginal health.

The Stated Purpose of the Revision

The covering letter from the AHEC Chairperson that solicited submissions, correct in its use of nomenclature, indicates that the *Draft Guidelines*

"... are different in their approach to the current NHMRC *Guidelines* ... [and] ... explicitly written around Aboriginal and Torres Strait Islander values."

This begs the converse question whether the more prescriptive *Guidelines* weren't also written around explicit cultural values.

The earlier letter inviting the AH&MRC to participate at the Ballarat Workshop mentioned that the admirable aims of the workshop were:

- to articulate the core values and principles that Aboriginal and Torres Strait Islander peoples value in research
- to exchange ideas with researchers; and
- the development of these core values and exchange of ideas to inform the drafting for the revision of the *Guidelines*.

The attached program also included examination of 'contentious issues' and the process of 'ethical scrutiny' with reference to 'areas of possible improvement in the *Guidelines*'.

There would appear to be an additional aim retrospectively inserted into the *Draft Guidelines*

- get beyond the superficial compliance mentality identified in consultation⁶⁸

⁶⁷ Central Australian Aboriginal Congress, 'Some Research Guidelines' 1982.

⁶⁸ *Draft Guidelines* p. 9

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From the verbal report of AH&MRC delegates attending the workshop they had no recollection of this concept being mentioned as an actual aim but confirmation of this matter must be sought from the minutes. At least it was not a matter discussed in correspondence from the NHMRC to the Council.

Core Aboriginal and Torres Strait Islander values relevant to health research ethics.

The following relevant values were suggested at the workshop.

Reciprocity
Respect
Equality
Survival & protection
Responsibility

These values are entwined with ‘Spirit’ and ‘Integrity’ and are all admirable precepts but wouldn’t these values be held in common in any society, indigenous and non-indigenous, and equally relevant in deliberations within all AHECs.

Whilst valuable, these do not exhaust Aboriginal culture nor do they reflect the essential Community values and process by which Aboriginal Ethics Committees assess research, nor it is necessarily the case that the Indigenous Working Group at Ballarat considered the provision of this helpful summary and process would replace prescriptive provisions in the *Guidelines*, and certainly would not have seen it as any substitute for the Community’s voice in any evaluation of a given research project related to Aboriginal health.

As a didactic tool for researchers the *Draft Guidelines* is an excellent attempt to elucidate non-Aboriginal researchers in cultural awareness, academic integrity and sensitivity in scholarship as well as providing a kaleidoscope of selective ethical and social matters for Ethics Committees to introspectively grapple with. In this endeavour the working group should be commended. As a complementary tool to current prescriptive provisions it could assist Aboriginal Health Ethics Committees and would benefit those unfamiliar with health and research issues within Aboriginal and Torres Strait Islander communities.

When assessed as a substitute for prevailing prescriptive provisions that have enabled genuine Aboriginal control over endemic inappropriate academic intrusions into Community culture and societal mores and providing opportunities for positive reciprocal trust relationships between academia and Aboriginal communities, it is but a pale reflection of the former instrument at best and, potentially, a further distancing from the Community position as reflected in the *NAIHO Report*, and accordingly, is hardly a workable instrument to ensure conformity in ethical practice.

Ethics Committees

There is no attempt to minimise the thoroughness of the *Draft Guidelines* in postulating scenarios for ethical examination. However, the nebulous nature of the format eludes the ability and capacity for definitive resolution and introduces additional interpretative

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subjectivism at the discretion of academics and university or departmental institutional ethics committees, albeit with potential for token Aboriginal representation.

From the experience of the AH&MRC Ethics Committee the academic community by and large is appreciative of the cultural perspective brought to bear by an Aboriginal ethics committee and it is an exception when an application, even those referred by other ethics committees, doesn't require helpful recommendations to ensure appropriate processes and standards are in place. These responses not only enhance the quality of the research itself but cement trusted reassuring relationships with Communities for future research in health.

This positive attitude and experience of Aboriginal ethics committees is not shared by all academics working in Aboriginal health. Another member of the AHEC Working Party has stated:

In the past, Indigenous people have had bad experiences with research which has all too often identified problems but seldom proposed workable solutions. This has made them very wary of the whole enterprise. Some Indigenous individuals and groups have responded by trying to control flows of information about Indigenous people living in their regions. This is stopping important research and evaluation, including work by Indigenous people. The kinds of controls being sought by such individuals and groups are not sought and are not available to any other sector of the community.⁶⁹

In fairness, due to the absence of the causative factors that have initiated this response, comment should be qualified but suffice it to say that in general, attempts to erode controls within the Community in their assessment of what is considered appropriate research and identifiable data are fraught with the serious danger of jeopardising the whole process itself and only buttresses the case for ensuring that prescriptive provisions continue. Unless serious ethical compromise is detected by a given Community, surely there are other constructive opportunities to resolve impasses rather than in effect disempower Aboriginal communities by dismantling a proven structure that has been, and has the potential to be, a useful and constructive tool in genuine collaborative academic endeavour.

To eliminate the prescriptive parameters for ethical conduct in academic research into Aboriginal health by virtually introducing nebulous situation ethics renders the process at the mercy of the integrity and subjectivity of one party to the exercise. The history of scholarship, whilst epitomising the benefits of Hegelian debate, also indicates the potential for subjectivism in genuine disagreement and, accordingly, it is this subjectivism, in light of negative experience cited by the NAHS, that is too high a price to pay in this exercise of revision.

To eliminate within formal Aboriginal ethical guidelines any prescriptive provision that is standard prudent precaution in both the *National Statement* and the NHMRC model funding application requires logical justification and ethical explanation as it could be

⁶⁹ Sibthorpe, Beverly, *Inquiry into Indigenous Health*, House of Representatives Standing Committee on Family and Community Affairs, Submissions Authorised for Publication, Volume 2, December 1997. Submission Number 50 pp. 530-531 from the National Centre for Epidemiology and Population Health, The Australian National University, Canberra.

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seen to be as rendering the *Guidelines* contributive to a double standard at the expense of the Community itself.

In the context of ethical relationships the *Draft Guidelines*' authors quote from their own Report to AHEC and, whilst making important findings that there was an apparent ignorance of the application of the *National Statement* for Aboriginal people in health research and "a continual level of support and ownership of the *Interim Guidelines*" they also ascertained "a sense that more was needed to move beyond a kind of superficial compliance mentality". Whilst criticism of the Aboriginal community control in health and health ethics committees labours the point of 'radical rhetoric' and 'over reliance on written prescriptive guidelines' within the Aboriginal community controlled health sector, this last deduction - "to move beyond a kind of superficial compliance mentality" - is subject to the criticism of emotive hyperbole. Whilst open to correction and criticism of this analysis, in light of the serious concerns raised above, their call falls on sceptical ears.

The fallacy of this logic is the assumption that over reliance on written prescriptive guidelines and positive rhetoric, *vis a vis* changing of research practices and positive involvement of researchers in Aboriginal communities, are mutually exclusive.

The authors of the *Draft Guidelines* are correct when they state that:

The responsibility for maintaining trust and ethical standards does not therefore depend upon solely on rules or standards. Trustworthiness of research and of researchers is a product of engagement between peoples. It involves transparent and honest dealing with values and principles, the elimination of 'difference blindness' and the subtlety of judgement required to eliminate prejudice, to maintain respect and human dignity.⁷⁰

However, it is not clear how the subsequent conclusion necessarily follows:

For these reasons this Consultative Paper is based on the importance of trust, recognition and values. It seeks to move away from a sole reliance on the quasi-legal consideration of compliance with rules. It seeks a more flexible approach that encourages research to reposition itself to incorporate alternative perspectives, and exercise nuanced judgment as to ethical implications.⁷¹

The basis of any instrument or document that encapsulates the importance of trust, recognition and values is commendable. However, it is not a matter of "moving away from a sole reliance on the quasi-legal consideration of compliance with rules." but, rather, the actual dispensing of them altogether.

To mix metaphors, if we compare driving on the roads with an ethical understanding of the principles that bind all drivers together, in spite of good intentions of citizens, without heavy fines for not wearing seat belts most drivers would fail to comply - a non-prescriptive disaster.

The authors then comment on the difficulties that some scholars would have in meeting 'rule-based requirements' compared to those who can and, furthermore, to those who do meet requirements but do not engage honestly in the complexities of their research as it impinges upon Aboriginal communities. The question should be asked how do

⁷⁰ *Draft Guidelines* pp. 6-7

⁷¹ *ibid.* p.7

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such researchers meet the prescriptive requirements of the *National Statement* and the NHMRC Funding Submission for research in general and still maintain meaningful relationship of trust in honestly engaging with differences as they impinge upon any researched group or project and/or the respective ethics committee.

It is the contention of the AH&MRC that this is an erroneous issue and that honest engagement between scholars in relation to the complexities of their research; their relationship with the researched; liaison with a given ethics committee; and ongoing involvement of Aboriginal people and communities is not in principle affected by prescriptive requirements that, in effect, are not dissimilar to those within the wider ethical arena.

It is ironic that prescriptive provisions within the *National Statement* protecting “Collectivities” are conspicuously absent for Aboriginal and Torres Strait Islanders in the proposed *Draft Guidelines*. It is mandatory for Ethics committees assessing research applications from Collectivities that they are satisfied that compliance has occurred with regard to individual consent; collective consent; negotiation; privacy; confidentiality; potential harming factors to individuals and the collectivity; ownership of data; the manner of dissemination of research findings; and the manner in which disagreements between researchers and collectivities will be resolved.⁷²

The AH&MRC Ethics Committee

Prior to 1996 the Aboriginal Medical Service in Redfern provided ethical evaluation of research projects on behalf of the AH&MRC. Due to the increasing number of applications a separate Ethics Committee was established in 1996 and has assessed some 400 applications.

In all matters requiring ethical evaluation the Ethics Committee is committed to professional projects in essential epidemiological and medical research that increase scientific knowledge, demonstrate benefit to our communities and provide transfer of skills to our medical workforce.

Included in the criteria used by the Committee to evaluate applications for proposed research and publications of statistical data on Aboriginal health are the following principles which are contained within the AH&MRC publication *Guidelines for Research into Aboriginal Health*.

- (i) that in accordance with the priorities set out in the *National Aboriginal Health Strategy* and the *Report of the National Workshop on Ethics of Research in Aboriginal Health*, research proposals must advance scientific knowledge to result in demonstrated additional benefit to Aboriginal communities.
- (ii) that there be Aboriginal community control over all aspects of the proposed research including research design, ownership of data, data interpretation and publication of research findings
- (iii) that the research to be conducted in a manner sensitive to the cultural principles of Aboriginal society.

⁷² NHMRC, ‘National Statement on ethical Conduct in Research Involving Humans.’ 1999, p. 31

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- (iv) that Aboriginal communities and organisations be reimbursed for all costs arising from their participation in the research process.
- (v) that Aboriginal communities and organisations should be able to benefit from the transfer of skills and knowledge arising from the research project.

Furthermore, the Committee assumes that applicants of research proposals and epidemiological publications of Aboriginal health are conversant with relevant provisions within the following documents.

1. *Report of the National Workshop on Ethics of Research in Aboriginal Health* (NAIHO) [1987]
2. *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health research* (NH&MRC) [1991]
3. *National Statement on Ethical Conduct in Research Concerning Humans*, (NH&MRC) [2000]
4. *NSW Aboriginal Health – Information Guidelines* (NSW Aboriginal Health Partnership, NSW Health Department/AH&MRC) [1998]
5. *Guidelines for Research into Aboriginal Health* (AH&MRC Ethics Committee) [1999]

The Committee has laboured to ensure that research applications are encouraged and are sensitive and appropriate. There have only been a handful of rejected applications. These occurred following abortive attempts to assist in making the research relevant and appropriate. Deliberate attempts by a few scholars to circumvent acceptable ethical practice have resulted in unfortunate experiences in certain Aboriginal communities, which has undermined confidence for future research.

The Ethics Committee works closely with the NSW Department of Health, its Chief Epidemiologist and Chief Medical Officer. Numerous other departments like Corrections Health and Juvenile Justice present all research that involves Aboriginal people to the Committee for evaluation and comment. The NSW Aboriginal Health Partnership has enabled this professional relationship which has increased the status and levels of research and involvement of scholars working collaboratively with the Aboriginal community.

The NSW Health Department in partnership with the AH&MRC have developed the *NSW Aboriginal Health Information Guidelines*.

“Its purpose is to ensure consistency and good practice in the management of health and health-related information about Aboriginal people in NSW.”⁷³

The document states that it should be read in association with the *NAHS* (1989) and the *NAIHO Report* (1987), which is attached to the *NH&MRC Guidelines*. (1991). The inextricable relationship between data and research makes the document very relevant to research into the health of Aboriginal people. In this context the prescriptive provisions within the documents are most relevant to the subject matter of this submission.

⁷³ *NSW Aboriginal Health Information Guidelines, Aboriginal Health Information Strategy*, August 1998, NSW Health Department and the AH&MRC, State Health Publication No. (AHB) 980128, p.1.

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Ethical use of Information

All requests for the use of health and health information about Aboriginal peoples must demonstrate compliance with all the terms of the *NSW Aboriginal Health Information Guidelines*.

Local and State Health Ethics Committees considering submissions involving the collection and use of health and health-related information about Aboriginal peoples should ensure compliance with all the terms of these Guidelines. In addition to consideration by local or institutional Ethics Committees, it is strongly recommended that proponents submit projects to the Aboriginal Health and Medical Research Council of NSW Ethics Committee (AH&MRC Ethics Committee) in association with the local community concerned, for consideration and advice if one or more of the following apply:

- Aboriginality is a key determinant;
- Data is explicitly directed at Aboriginal peoples;
- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities;
- Aboriginal health funds are a source of funding.

It is strongly recommended that the proponent of a submission which is considered but not endorsed by the AH&MRC Ethics Committee does not proceed with the project unless and until the difficulties identified by the AH&MRC Ethics Committee are resolved, regardless of endorsement by other ethics committees.

All Ethics Committees should monitor the conduct of approved studies to ensure ongoing adherence to agreed protocols and methods.⁷⁴

The support within this prescriptive document ensures that Aboriginal people's cultural interests in health research and health data are protected in this State and it has enabled positive outcomes and ongoing research relationships that have in no way thwarted the quality of research or undermined intellectual integrity of participating scholars. The prescriptive nature of the instrument has not been counterproductive and stands in sharp contrast to that proposed in the *Draft Guidelines* which impresses as a judicious attempt to appease those who would restrict the incisive role of the Aboriginal community in determining appropriate cultural processes in any given evaluation of health research.

The Committee is requested to seriously consider the wider implications of the *Draft Guidelines* as they relate to ethical processes for Aboriginal health research in other jurisdictions and to contemplate the incongruous position that would occur if support and confidence given to the Aboriginal community and Aboriginal Health Ethics Committees by certain State and Territory governments is not forthcoming from the national body responsible for ethical standards and governance in health research.

Whilst the above criteria and process may not be applicable to all jurisdictions it would be regrettable if official documents from AHEC and the MHMRC are incompatible with enlightened and progressive initiatives within other jurisdictions and it is urged that drafting be such that the ensuing documentation does not provide any basis to undermine prevailing Agreements in Aboriginal health and be a statement that can be embraced by and underpin current instruments utilised by those in other jurisdictions actively involved in ethical evaluation of health research in Aboriginal communities.

⁷⁴ *ibid.*, p. 6.

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It may be appropriate that should the proposed *Draft Agreement* proceed in its current format, questionable as that would be, to allay unnecessary concern within the Aboriginal community controlled health sector and its associated Aboriginal Health Ethics Committees, could prescriptive provisions within a succinct summary in the *National Statement* occur?

The NHMRC *Guidelines* indicated in 1991 that many Human Research Ethics Committees existed within Aboriginal and Torres Strait Islander controlled organisations and commented on their legitimate cultural and ethical function, not only for assessing research proposals from Aboriginal and Torres Strait Islander organisations but also approving research within Aboriginal and Torres Strait Islander communities initiated by other organisations.

The *Draft Guidelines* in 2002 considered this development is a quite recent phenomenon and then makes the somewhat pejorative assertion within the actual potentially definitive *Guidelines*:

However, not all research in Aboriginal health is able to be considered by properly constituted Aboriginal HREC.⁷⁵

The AH&MRC Ethics Committee, and other state Aboriginal Ethics Committees contacted, know nothing about this matter as they have considered the full spectrum of health research competently to the satisfaction of both individual scholars and academic institutions. Even if there were some substance to this assumption there is no pro-active suggestion offered to equip any such committee through educational programs or by other HRECs offering timely advice that such committees can invite outside specialist advisers for certain projects. A comparable arrangement would occur as a matter of course in the wider HREC community, as HREC workshops have demonstrated.

This assumption then enables the writers to proceed beyond the *Guidelines* and state:

This means attention needs to be given by non-Aboriginal HRECs to the question of how they will equip themselves to implement these guidelines when they encounter research involving Aboriginal and Torres Strait Islander Communities.⁷⁶

The *Draft Guidelines* proceed to make suggestions to non-Aboriginal AHECs to ensure informed review occurs, which include expanding Committees to include Aboriginal and Torres Strait Islander people; creating an Aboriginal and Torres Strait Islander sub-committee or referring relevant research to a properly constituted Aboriginal HREC.

Concerning the proposed strategy to create Aboriginal and Torres Strait Islander sub-committees to non-Aboriginal HRECs. AH&MRC delegates have no recollection that this was discussed in open forum at the Ballarat Workshop. There are serious questions that would arise in such a development with regard to transparency; representation; how authoritative members reflected the respective Communities; criteria for the selection of representatives; capacity to report back to Communities for advice and direction; perceived autonomy within an existing HREC; liaison of the sub-committee with the Communities; potential for the sub-committee to be at odds with

⁷⁵ *Draft Guidelines*, page 24

⁷⁶ *ibid.*, p. 26

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Communities following any approval of research considered inappropriate; just to mention a few. The inevitable question would always linger as to why the HREC did not refer the matter to an Aboriginal HREC in the first place. There would always be the lingering perception of it being seen as incestuous and experienced as a slight against the Community or the respective State/Territory Aboriginal HREC for perceived inability to assume their cultural responsibility. In short, vulnerable to the criticism that it is as an attempt to facilitate a process that bypasses the Community itself. It also could become the means by which Aboriginal HRECs, for some academics, could be considered dispensable or able to be circumvented.

There will always be the need for certain AHECs to consider research where no Aboriginal Ethics Committee exists and the *Draft Guidelines* are clearly designed to cover such contingencies, if not wider usage by non-HREC was intended. From the experience of the AH&MRC Aboriginal people appointed in good faith to departmental institutional ethics committees have found it difficult in having their Community perspective understood and as a minority voice tend to acquiesce or recommend the research be forwarded to an Aboriginal HREC. Another difficulty shared with the AH&MRC was that there is a major difference between being the sole Aboriginal representative on a health program or project committee and that of being the sole voice reflecting the Aboriginal community cultural position on a departmental ethics committee. The prescriptive support from the NSW Health Department has resolved any such difficulty in this State.

It must be clearly stressed that the proposed transition has moved considerably from the process for obtaining ethical approval enunciated in the *NAIHO Report*. It was observed at the Ballarat Workshop, when discussing indispensable ethical requirements, that when an Aboriginal community elder insisted that ethical approval for research must come from an Aboriginal Community Controlled Medical Service and/or a State/Territory Aboriginal Ethics Committee affiliated with NACCHO, the facilitator initially declined to insert this option in the group's summary as it was considered it would be unacceptable within their particular jurisdiction.

In this context it is important to note that while the *NAIHO Report's* position on obtaining ethical approval was omitted from the *Guidelines* the current proposed process compared to that defining Community document is no longer a difference in degree but potentially a difference in kind.

All associations with HRECs by the AH&MRC, and these have been many, have resulted in totally professional positive outcomes, however, Aboriginal HRECs have witnessed several instances of inducement by major interests when considering potential lucrative projects and have experienced deliberate attempts by certain academics circumventing and blatantly disregarding cultural imperatives and conventions. Whilst these instances are certainly exceptions and not the rule it would appear prudent and appropriate that no easy alternatives were available to bypass cultural scrutiny. The onus would be upon non-Aboriginal Ethics Committees to justify to the Aboriginal community why research relating to the health of Aboriginal and Torres Strait Islander people was not referred to a properly constituted Aboriginal or Torres Strait Islander HRECs for ethical consideration.

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The *NAIHO Report* covered various alternatives where local Aboriginal community controlled health services existed or did not exist, however, in each case the national peak Aboriginal community controlled health organisation was to be involved in the approval process. Since 1987 each State/Territory has established Aboriginal peak bodies affiliated with NACCHO, most of which having Aboriginal Health Ethics Committees or planning their establishment.

As these Committees work with and represent Aboriginal Community Controlled Health Services it is the recommendation of the AH&MRC that AHEC considers endorsing a process similar to that which exists in certain States and provide prescriptive support for referring health research on Aboriginal people to these bodies. Being associated with State/Territory affiliates of NACCHO they are in effect an extension of NACCHO, thereby complying with the intent of the *NAIHO Report*.

Aboriginal Ethics committees at this level, not excluding Aboriginal HREC already operating, can better recruit appropriate members to be properly constituted Aboriginal HRECs and easily accommodate training programs. It is recommended that the AHEC consider this valuable resource and support a professional education program facilitated by the NH&MRC, similar to educational workshops on recent privacy legislation offered previously to all HRECs, to assist those mentioned Aboriginal HRECs in understanding provisions within the *National Statement* as they impinge upon research being undertaken within Aboriginal communities.

The Aboriginal community as the ultimate determining body in ethical matters

The majority of the research proposals provided to the AH&MRC for ethical evaluation are proposals forwarded on behalf of the Aboriginal community through local Aboriginal Community Controlled Health Services. The need for this separate state wide ethical body is self-evident in light of the demanding workload and intricate and specialist nature of most medical research proposals. However, whilst the AH&MRC Ethics Committee accepts responsibility for providing advice and evaluating ethical matters related to specific research projects it is a task carried out in association with each Aboriginal community.

The *NAIHO Report*, specifically writing to address ethical issues for research into Aboriginal health, advocates Community involvement at each stage of the research and data collecting process. Stringent and appropriate guidelines for Aboriginal community involvement have to be met with the actual control over the consultancy and negotiation process vested in the Communities or Community organisations themselves.

It is incumbent upon researchers and data requesting repositories to acknowledge the necessity to seek the consent of each participating Aboriginal community rather than utilise an overriding, all inclusive authorisation from a state or federal body. In this regard the AH&MRC Ethics Committee has developed appropriate Consent Agreements for individual and organisational consent. A specific Aboriginal Community Controlled Health Service (ACCHS) consent form for research amongst its clients has been developed as well as a consent form for researchers working outside of ACCHS but wanting to reassure participants that they will comply with Aboriginal cultural and ethical imperatives and NH&MRC provisions. The latter form

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is witnessed by the ACCHS, which avoids any language difficulty and ambiguity and assists in conveying to lay people the nature of the research.

All three forms (copies attached) have been designed so that the onus is upon the researcher to reassure the participant or organisation that compliance with specific ethical criteria will occur.

Accordingly, in light of more recent privacy legislation and the pre-eminence of Ethics Committees for determining where written consent agreements can be overruled or negated, the deliberations of Ethics Committees should not be seen as a substitute for the Aboriginal community decision making process and ideally should work in association with Aboriginal community health organisations and Aboriginal Ethics Committees.

It is for this reason that the Community itself is considered the determining body in matters relating to Aboriginal health information rather than any institutional, departmental, regional, national, State or Territory Ethics Committee solely determining matters concerning Aboriginal health. This principle also applies to State and Territory Aboriginal HRECs associated with affiliate bodies of NACCHO. The underlying principle upon which the AH&MRC Ethics Committee operates is the inviolate and unfettered nature of the Aboriginal community itself to ultimately consider the appropriateness and relevance of research into Aboriginal health.

Epidemiological Research

The *Draft Guidelines* raise the matter of data collection and use. It is unfortunate that the National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine collection of standardised Data on Aboriginal & Torres Strait Islander Health (NACCHO 1979), although raised at the Ballarat Workshop failed to find any reference in the *Draft Guidelines*. A complete summary of the document with relevant comment was previously provided to the AHEC by the AH&MRC in its previous submission on the *Draft National Statement*.

A further 52 page statement *National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health (1997)*, endorsed by NACCHO, has clearly demonstrated the necessity for separate ethical guidelines for the gathering of research data into Aboriginal health.⁷⁷

The crucial relevance of this document in the area of Aboriginal health data cannot be underestimated and finds its formal authorisation within *Aboriginal Health Framework Agreements*, whose parties are the Commonwealth Health Department; respective States and Territories Health Departments; respective State and Territory Offices of ATSIC; and State and Territory peak bodies affiliated with NACCHO. One of its cardinal objectives is to:

⁷⁷ AH&MRC letter to AHEC, 24th August 1998. As the *NACCHO Data Protocols* and its summary published in an AIHW publication are omitted in *The Ethics of Aboriginal Health Research: An Annotated Bibliography*, 2002, a complete summary of the *National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health (1997)*, can be accessed in the appendix of an article by Pat Swan and JDB Williams, 'The Aboriginal community controlled health sector perspective on the collection and use of Aboriginal health data and its relevance for people with a disability' in *Indigenous Disability Data*, AIHW, 1998, pp.95-114.

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establish culturally sensitive and ethically sound, privacy and confidentiality protocols for the routine collection of standardised data of Aboriginal and Torres Strait Islander health. These protocols are to recognise Aboriginal and Torres Strait Islander ownership of the data including clarity about the collection and use of data. Any change in the use of the data will require agreement from the owners of the data;⁷⁸

Not only does the NACCHO document fulfil these requirements but it provides an ethical outline, content and process for much that has been discussed at the Ballarat Workshop and, accordingly, is considered appropriate that the Committee evaluate its relevance for this particular section of the *Draft Guidelines*.

One important benefit of this document is its summary of all relevant instruments that have bearing on Aboriginal health data, including the following pertinent reference from the Royal Commission into Aboriginal Deaths in Custody

Recommendation 270

“That:

- a) Aboriginal people be involved in **each stage of development** of Aboriginal health statistics

One final matter of importance is ‘Aboriginal de-identified health data’. This issue was raised at the Ballarat Workshop but has yet to surface within the *Draft Guidelines*. At the NH&MRC *National Statement* consultation in Sydney, in response to the proposed provision in the *National Statement* that de-identified data would no longer require approval from an HREC, the case was put to the former Chairperson of AHEC by AH&MRC Ethics Committee representatives, that, due to the sample size of the Aboriginal community and the tradition of remaining on Aboriginal land and within country, all Aboriginal de-identified health data is potentially identifiable.

Assurance was publicly given at that meeting that this concern was valid and that all requests for and research with Aboriginal de-identified data would still require HREC approval. This process has been successfully operating in NSW, due in part to the positive association with the NSW Health Department through the NSW Aboriginal Health Partnership.

The AH&MRC could document regrettable incidents where Aboriginal people have suffered serious angst and trauma as a result of academics disregarding this principle and identifying Aboriginal individuals through published aggregated Aboriginal health data. The AH&MRC requests that this assurance given verbally at a NH&MRC public meeting be given formal endorsement within the new *Guidelines*.

⁷⁸ *Agreement on Aboriginal and Torres Strait Islander Health between the NSW Minister for Health; the Commonwealth Minister of State for Health and Family Services; the [Relevant State or Territory peak bodies affiliated with NACCHO]; and the Aboriginal and Torres Strait Islander Commission (ATSIC), 3.12*

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14. APPENDIX 4



AH&MRC RESPONSE TO A REQUEST FROM NACCHO FOR COMMENTS ON THE NHMRC (AHEC) DOCUMENT

VALUES AND ETHICS GUIDELINES FOR ETHICAL CONDUCT IN ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH RESEARCH Final Version (6.3.03)

24th December 2004

This summary of concerns with the abovementioned document should be seen as complementary to the full AH&MRC submission to AHEC dated December 2002.

- The Inter-relationship of Ethical instruments and extant documentation
The current NHMRC *Guidelines* underpin several vital instruments, reports and health & ethical agreements in Aboriginal and Torres Strait Islander health at Commonwealth and State/Territory levels. The explicit new direction in the proposed substitution reflects a further serious departure from prescriptive standards considered necessary by the Aboriginal community within the NAIHO Guidelines, and indeed far removed from the prescriptive basis of the *National Statement*. It now presents as a potentially subjective interpretive process that is built on anticipated reciprocal trust between academics and Aboriginal communities and Aboriginal organisations. This nebulous process could jeopardise and undermine the confidence in and relevance of those crucial instruments that make reference to the ethical documentation.

The NAIHO Report (1987) and the extant NHMRC Guidelines (1991) & the Proposed Guidelines

- From an Aboriginal community perspective there is an important difference between the abovementioned documents with some scholars describing the 1991 NHMRC *Guidelines* as a “watered down” version of 1987 NAIHO Report⁷⁹ with its safeguards for ensuring Community control within research.
- In spite of the ostensible emphasis upon Aboriginal ‘core values’ in the proposed *Guidelines* the document is open to serious criticism in that it has departed even further from that NAIHO Report’s cultural and Community perspective.
- Notwithstanding this departure the bound NHMRC *Guidelines (1991)* document, circulated by the NHMRC to the public, always included an attached copy of the earlier Community NAIHO Report, namely, the *Report of the National Workshop on Ethics of Research in*

⁷⁹The position for Aboriginal community involvement and control in the health research process was ably defended by Ken Wyatt, ‘The Rights of Aboriginal Communities: The Obligations of Health Researchers’, *Aboriginal and Islander Health Worker Journal*, Vol. 15. No.2. 1999, pp. 7-8.

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Aboriginal Health (1987), which, in effect acknowledged the validity and importance of the Community's directives and cultural imperatives.

- Will the proposed *Guidelines* render the community document superseded, and if so, by whom and upon what mandate from the Aboriginal community?
- Will the NAIHO Report continue to be circulated by the NHMRC together with the proposed *Guidelines* as a historical yardstick of the Aboriginal communities' aspirations for ethical standards in research to continue to be used as an authoritative instrument to assess an application's compliance with community's approval, participation and consent at each stage of the research?

Legal Status and Authoritative Nature of the Proposed Guidelines

- The proposed *Guidelines* are, in addition to the *National Statement*, "the authoritative statement on health research involving Aboriginal and Torres Strait Islander Peoples." The proposed *Guidelines* mention its authoritative status, finding its legitimisation in the *NHMRC Act 1992*.
- The implications of the above are wide-reaching. For example, those Aboriginal Health Ethics Committees that continue to implement the Community principles in the NAIHO Report (1987) rather than the procedures recommended in the proposed *Guidelines* would be in effect breaking the law with serious implications for undermining, circumventing or dismissing ethical decisions from Aboriginal health ethics committees.

The NAIHO Report (1987) and the NAHS (1989)

- The importance of the NAIHO Report from the Aboriginal Community Controlled perspective can be seen in the embracing of that document by the National Aboriginal Health Strategy 1989 (NAHS),⁸⁰ specifically endorsing its 'Principles' as the basis upon which Aboriginal health research proposals were considered.
- Any momentum for change that has not been carefully considered by the Communities is vulnerable to being perceived with suspicion, regardless of any admirable motivation by the proponents for change. There is cause for much concern when it is realised that the serious flaws identified by this Aboriginal community controlled health organisation in both the underlying operating principles and procedures enunciated in the proposed *Guidelines* have not been recognised or acknowledged in the final document.
- Admittedly, even the 1991 *NHMRC Guidelines* did not incorporate all the recommendations in NAIHO Report (1987), for example, the discrete avoidance of the contentious matter of the ownership of data. However, this further diminution of actual Community control in the proposed document is exacerbated when it is realised that there is no acknowledgement of Aboriginal ownership of data as enunciated in all *Commonwealth/State Aboriginal Health Agreements* and in *Recommendation 270 (1) of the Royal Commission into Aboriginal Deaths in Custody* and any attempt to perhaps include some non-prescriptive terms related to Aboriginal health data in a NHMRC Aboriginal Ethical Handbook minimises its acknowledgement and compliance.
- Accordingly, instruments that have been acknowledged by the Community as protecting its cultural requirements need very careful scrutiny before amendment and revision. The old maxim that you don't discard proven policy until the ones that replace are demonstrably assured to be superior, should caution too radical a divergence from the status quo and to ensure comprehensive consultation with the Community. The process of the selective working group is not considered appropriate Community consultation.

⁸⁰ National Aboriginal Health Strategy 1989, p. 212

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- The proposed *Guidelines* can be seen as containing helpful information to researchers working or considering working in Aboriginal health, or HRECs seeking to ensure ethical appropriateness in the initial evaluation of any given research project where no Aboriginal State/Territory HREC exists. However, they are not seen as synonymous with Aboriginal culture nor a written substitute, which if perused and its core principles and values meditated upon by non-Aboriginal participants, would enable researchers and ethics committees to pre-emptively know the mind of the Aboriginal community – a perceived potential threat to Aboriginal autonomy and cultural integrity.

The Stated Purpose of the Revision

- The covering letter from the AHEC Chairperson that solicited submissions, indicates that the *Draft Guidelines* “ ... are different in their approach to the current NHMRC *Guidelines* ... [and] ... explicitly written around Aboriginal and Torres Strait Islander values.”
- The earlier stated aims of the workshop were:
 - to articulate the core values and principles that Aboriginal and Torres Strait Islander peoples value in research
 - to exchange ideas with researchers; and
 - the development of these core values and exchange of ideas to inform the drafting for the revision of the *Guidelines*.
- The post workshop retrospective aim of the AHEC Aboriginal Working Party, inserted into the proposed *Guidelines*, namely to aim to “get beyond the superficial compliance mentality identified in consultation”⁸¹ is considered lacking probity in procedural practice, presumptuous and without cultural mandate.

Core Aboriginal Values Relevant to Health Research Ethics.

- The following relevant values were suggested at the workshop.

Reciprocity, Respect, Equality, Survival & protection, and Responsibility

- These values are entwined with ‘Spirit’ and ‘Integrity’ and are all admirable precepts but wouldn’t these values be held in common in any society, indigenous and non-indigenous, and equally relevant in deliberations within all HRECs.
- Whilst valuable, these do not exhaust Aboriginal culture nor do they reflect the essential Community values and process by which Aboriginal Ethics Committees assess research, nor is it necessarily the case that the Indigenous Working Group at Ballarat considered the provision of this helpful summary and process would replace prescriptive provisions in the 1991 *Guidelines*, and certainly would not have seen it as any substitute for the Community’s voice in any evaluation of a given research project related to Aboriginal health.

Limited Cultural Use of Guidelines

- As a didactic tool for researchers the proposed *Guidelines* provide a suitable approach for non-Aboriginal researchers in cultural awareness, academic integrity and sensitivity in scholarship as well as providing a kaleidoscope of selective ethical and social matters for Ethics Committees to introspectively grapple with. In this endeavour the working group should be commended. As a complementary tool to current prescriptive provisions it could assist Aboriginal Health Ethics Committees and would benefit those unfamiliar with health and research issues within Aboriginal and Torres Strait Islander communities.

⁸¹ *Draft Guidelines* p. 9

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- The prevailing prescriptive provisions have enabled genuine Aboriginal control over endemic inappropriate academic intrusions into Community culture and societal mores and provided opportunities for positive reciprocal trust relationships between academia and Aboriginal communities. The proposed substitute is but a pale reflection of the former instrument at best and, potentially, a further distancing from the Community position as reflected in the *NAIHO Report (1987)*. Accordingly, it is hardly an instrument of probity ensuring conformity in ethical cultural practice.

Ethics Committees

- Attempts to erode controls within the Community in their assessment of what is considered appropriate research and identifiable data are fraught with the serious danger of jeopardising the whole ethical process and only buttresses the case for ensuring that existing endorsed prescriptive provisions continue.
- To eliminate the prescriptive parameters for ethical conduct in academic research in Aboriginal health, by virtually introducing nebulous ‘situation ethics’, renders the process at the mercy of the integrity and subjectivity of the dominant party to the exercise. There is potential for subjectivism in genuine disagreement and, accordingly, it is this subjectivism, in light of negative experience cited by the NAHS, that is too high a price to pay in this exercise of regression.
- Such an elimination of prescriptive provision within formal ethical guidelines in Aboriginal health - standard prudent precaution in both the *National Statement* and the NHMRC funding application - requires justification and explanation. It could be seen as compromising the *Guidelines* to a double standard at the expense of the Community itself.
- The basis of any instrument or document that encapsulates the importance of trust, recognition and values is commendable. However, it is not a matter of “moving away from a sole reliance on the quasi-legal consideration of compliance with rules.” but, rather, the actual dispensing of them altogether.
- The authors then comment on the difficulties that some scholars would have in meeting ‘rule-based requirements’ compared to those who can and, furthermore, to those who do meet requirements but do not engage honestly in the complexities of their research as it impinges upon Aboriginal communities. The question should be asked how do such researchers meet the prescriptive requirements of the *National Statement* and the NHMRC Funding Submission for research in general and still maintain a meaningful relationship of trust in honestly engaging with differences as they impinge upon any researched group or project and/or the respective ethics committee.
- It is the contention of the AH&MRC that this is an erroneous issue and that honest engagement between scholars in relation to the complexities of their research; their relationship with the researched; liaison with a given ethics committee; and ongoing involvement of Aboriginal people and communities is not in principle affected by prescriptive requirements that, in effect, are not dissimilar to those within the wider ethical arena.
- It is ironic that prescriptive provisions within the *National Statement* protecting “Collectivities” that would afford greater protection for Aboriginal and Torres Strait Islanders are conspicuously absent in the proposed *Guidelines*. It is mandatory for Ethics committees assessing research applications relating to Collectivities that they are satisfied that compliance has occurred with regard to individual consent; collective consent; negotiation; privacy; confidentiality; potential harming factors to individuals and the collectivity; ownership of data; the manner of dissemination of research findings; and the manner in which disagreements between researchers and collectivities will be resolved.⁸²

⁸² NHMRC, ‘National Statement on ethical Conduct in Research Involving Humans.’ 1999, p. 31

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Vulnerable Alternative Process in Certain Jurisdictions

- In one jurisdiction, namely NSW, there has been a major innovation in Aboriginal health ethics resulting from successful negotiations in Partnership between the ACCH and mainstream sectors. The proposed authoritative legal status of the proposed *Guidelines* would place the following amicable and workable arrangement in serious jeopardy and *ultra vires* action on the part of the parties.

Ethical use of Information

All requests for the use of health and health information about Aboriginal peoples must demonstrate compliance with all the terms of the *NSW Aboriginal Health Information Guidelines*.

Local and State Health Ethics Committees considering submissions involving the collection and use of health and health-related information about Aboriginal peoples should ensure compliance with all the terms of these Guidelines. In addition to consideration by local or institutional Ethics Committees, it is strongly recommended that proponents submit projects to the Aboriginal Health and Medical Research Council of NSW Ethics Committee (AH&MRC Ethics Committee) in association with the local community concerned, for consideration and advice if one or more of the following apply:

- Aboriginality is a key determinant;
- Data are explicitly directed at Aboriginal peoples;
- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities;
- Aboriginal health funds are a source of funding.

It is strongly recommended that the proponent of a submission which is considered but not endorsed by the AH&MRC Ethics Committee does not proceed with the project unless and until the difficulties identified by the AH&MRC Ethics Committee are resolved, regardless of endorsement by other ethics committees.

All Ethics Committees should monitor the conduct of approved studies to ensure ongoing adherence to agreed protocols and methods.⁸³

- The support within this prescriptive state government partnership document ensures that Aboriginal people's cultural interests in health research and health data are protected in this State and it has enabled positive outcomes and ongoing research relationships that have in no way thwarted the quality of research or undermined intellectual integrity of participating scholars. The precise and instructive provisions of the instrument have been most productive and stand in sharp contrast to that proposed in the proposed *Guidelines* document which impresses as a judicious attempt to appease those who would restrict the incisive role of the Aboriginal community in determining appropriate cultural processes in any given evaluation of health research.
- The NACCHO is requested to seriously consider the wider implications of the proposed *Guidelines* as they relate to ethical processes for Aboriginal health research in other jurisdictions and to contemplate the incongruous position that would occur if support and confidence given to the Aboriginal community and Aboriginal Health Ethics Committees by certain State and Territory governments is not forthcoming from the national body responsible for ethical standards and governance in health research and in effect renders such culturally appropriate agreements as illegal and irrelevant.
- The NHMRC *Guidelines* (1991) indicated that many Human Research Ethics Committees existed within Aboriginal and Torres Strait Islander controlled organisations and commented on their legitimate cultural and ethical function, not only for assessing research proposals from Aboriginal and Torres Strait Islander organisations but also approving

⁸³ *ibid.*, p. 6.

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research within Aboriginal and Torres Strait Islander communities initiated by other organisations.

- The proposed *Guidelines* considered that this development is a quite recent phenomenon and then makes the somewhat pejorative assertion within the actual potentially definitive *Guidelines*:

However, not all research in Aboriginal health is able to be considered by properly constituted Aboriginal HREC.⁸⁴

- The AH&MRC Ethics Committee, and other state Aboriginal Ethics Committees contacted, know nothing about this matter as they have considered the full spectrum of health research competently to the satisfaction of both individual scholars and academic institutions. Even if there were some substance to this assumption there is no pro-active suggestion offered to equip any such committee through educational programs or by other HRECs offering timely advice that such committees can invite outside specialist advisers for certain projects. A comparable arrangement would occur as a matter of course in the wider HREC community, as HREC workshops have demonstrated.
- This assumption then enables the writers to proceed beyond the *Guidelines* and state:

This means attention needs to be given by non-Aboriginal HRECs to the question of how they will equip themselves to implement these guidelines when they encounter research involving Aboriginal and Torres Strait Islander Communities.⁸⁵

- The proposed *Guidelines* proceed to make suggestions to non-Aboriginal HRECs to ensure informed review occurs, which include expanding Committees to include Aboriginal and Torres Strait Islander people; creating an Aboriginal and Torres Strait Islander sub-committee or referring relevant research to a properly constituted Aboriginal HREC.

Questionable Cultural Alternatives to Aboriginal HRECs

- Concerning the proposed strategy to create Aboriginal and Torres Strait Islander sub-committees to non-Aboriginal HRECs, AH&MRC delegates have no recollection that this was discussed in open forum at the Ballarat Workshop. There are serious questions that would arise in the event of such a development. It raises issues of transparency; representation; how authoritative members reflected the respective Communities; criteria for the selection of representatives; capacity to report back to Communities for advice and direction; perceived autonomy within an existing HREC; liaison of the sub-committee with the Communities; potential for the sub-committee to be at odds with Communities following any approval of research considered inappropriate; just to mention a few.
- The inevitable question would always linger as to why the HREC did not refer the matter to an Aboriginal HREC in the first place. There would always be the lingering perception of it being seen as incestuous and a slight against the Community or the respective State/Territory Aboriginal HREC for perceived inability to assume their cultural responsibility – a perception that is even evident in the proposed *Guidelines*. . In short, it would be vulnerable to the criticism of being seen as an attempt to facilitate a process that bypasses the Community itself. From the experience of Aboriginal communities it could provide the means by which some academics would consider Aboriginal HRECs dispensable or able to be circumvented.
- There will always be the need for certain HRECs to consider research where no Aboriginal Ethics Committee exists within a state/territory jurisdiction and the *Guidelines* are clearly designed to assist in such contingencies.

⁸⁴ *Draft Guidelines, page 24*

⁸⁵ *ibid.*, p. 26

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Community Consent and Ethical Approval

- It must be clearly stressed that the proposed transition has moved considerably from the process for obtaining Community ethical approval as enunciated in the *NAIHO Report*. The Aboriginal community controlled health sector has consistently communicated that in health research where Aboriginal Community Controlled Health Services or State/Territory Aboriginal Health Ethics Committees exist, it is an indispensable requirement that written Aboriginal community consent and ethical approval be obtained.
- In this context it is important to note that while the *NAIHO Report's* position on obtaining ethical approval was omitted from the *Guidelines* the current proposed process, compared to the defining Community document, is no longer a difference in degree but potentially a difference in kind.
- The *NAIHO Report* covered various alternatives where local Aboriginal community controlled health services existed or did not exist, however, in each case the national peak Aboriginal community controlled health organisation was to be involved in the approval process. Since 1987 each State/Territory has established Aboriginal peak bodies affiliated with NACCHO, most now having Aboriginal Health Ethics Committees or planning their establishment.
- The singular amendment to the proposed *Guidelines* that resulted from the NACCHO submission is that of inserting an acknowledgment of NACCHO and its state/territory affiliate bodies. However, no mention is made in this context of the State and Territory Aboriginal Health Ethics Committees associated with these affiliate bodies and this conspicuous absence is both incongruous and irresponsible.
- As these Committees work with and represent Aboriginal Community Controlled Health Services it is the recommendation of the AH&MRC that NACCHO requests that AHEC considers endorsing a process similar to that which exists in certain States/Territories and provide prescriptive support for referring all health research on Aboriginal people to these bodies, where such bodies exist. Being associated with State/Territory affiliates of NACCHO they are in effect an extension of NACCHO, thereby complying with the intent of the NAIHO Report.

The Aboriginal Community as the Ultimate Determining Body in Ethical Matters

- The majority of the research proposals provided to the Aboriginal Health Ethics Committees for ethical evaluation are proposals forwarded on behalf of the Aboriginal community through local Aboriginal Community Controlled Health Services. This may vary in different jurisdictions. The need for an autonomous state wide Aboriginal ethical body is self-evident in light of the demanding workload and intricate and specialist nature of most medical research proposals. However, whilst Aboriginal Health Ethics Committees accept responsibility for providing advice and evaluating ethical matters related to specific research projects it is a task carried out in association with each Aboriginal community.
- The *NAIHO Report*, specifically writing to address ethical issues for research into Aboriginal health, advocates Community involvement at each stage of the research and data collecting process. Stringent and appropriate guidelines for Aboriginal community involvement have to be met with the actual control over the consultancy and negotiation process vested in the Communities or Community organisations themselves.
- It is incumbent upon researchers and data requesting repositories to acknowledge the necessity to seek the consent of each participating Aboriginal community rather than utilise an overriding, all inclusive authorisation from a state or federal body.
- In this regard appropriate Consent Agreements for individual and organisational consent have been developed by NACCHO affiliated HRECs.

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- Accordingly, in light of more recent privacy legislation and the pre-eminence of Ethics Committees for determining where written consent agreements can be overruled or negated, the deliberations of Ethics Committees should not be seen as a substitute for the Aboriginal community decision making process and ideally should work in association with Aboriginal community health organisations and Aboriginal Ethics Committees.
- It is for this reason that the Community itself is considered the determining body in matters relating to Aboriginal health information rather than any institutional, departmental, regional, national, State or Territory Ethics Committee solely determining matters concerning Aboriginal health. This principle also applies to State and Territory Aboriginal HRECs associated with affiliate bodies of NACCHO. The underlying principle upon which Aboriginal Ethics Committees operate is the inviolate and unfettered right of the Aboriginal community itself to ultimately consider the appropriateness and relevance of given research into Aboriginal health.

Epidemiological Research

- The crucial relevance of the *NACCHO Data Protocols* in the area of Aboriginal health ethics cannot be underestimated and finds its formal authorisation within *Aboriginal Health Framework Agreements*, whose parties are the Commonwealth Health Department; respective States and Territories Health Departments; respective State and Territory Offices of ATSIC; and State and Territory peak bodies affiliated with NACCHO. One of its cardinal objectives is to:

establish culturally sensitive and ethically sound, privacy and confidentiality protocols for the routine collection of standardised data of Aboriginal and Torres Strait Islander health. These protocols are to recognise Aboriginal and Torres Strait Islander ownership of the data including clarity about the collection and use of data. Any change in the use of the data will require agreement from the owners of the data,⁸⁶

- Not only does the NACCHO document fulfil these requirements but it provides an ethical outline, content and process for much that has been discussed at the Ballarat Workshop and, accordingly, is considered appropriate that the Committee evaluate its relevance for this particular section of the proposed *Guidelines*.
- One important benefit of this document is its summary of all relevant instruments that have bearing on Aboriginal health data, including the following pertinent reference from the Royal Commission into Aboriginal Deaths in Custody

Recommendation 270

(a) Aboriginal people be involved in each stage of development of Aboriginal health statistics

The Possible Recantation of a Public Announced Position by the NHMRC.

- Another matter of importance is 'Aboriginal de-identified health data', raised at the Ballarat Workshop but yet omitted from the proposed *Guidelines*.
- At the NHMRC *National Statement* consultation in Sydney, in response to the proposed provision in the *National Statement* that de-identified data would no longer require approval from a HREC, the case was put to the former Chairperson of AHEC that, due to the sample size of the Aboriginal community and the tradition of remaining on

⁸⁶ Each state/territory has an *Agreement on Aboriginal and Torres Strait Islander Health between the NSW Minister for Health; the Commonwealth Minister of State for Health and Family Services; the [Relevant State or Territory peak bodies affiliated with NACCHO]; and the Aboriginal and Torres Strait Islander Commission (ATSIC)*, 3.12

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Aboriginal land and within country, all Aboriginal de-identified health data is potentially identifiable.

- Assurance was publicly given at that meeting that this concern was valid and that all requests for and research with Aboriginal de-identified data would still require HREC approval. This process has been successfully operating in some states, due in part to the positive outcomes resulting from Aboriginal Health Partnerships recommended in *Framework Agreements*.

Conclusion

- The proposed *Guidelines* provide much helpful insight into cultural awareness of Aboriginal society and values with regard to ethical issues related to research into Aboriginal health. As a didactic tool for researchers into Aboriginal health it has no equal to date but as a legal authoritative instrument to be used by non-Aboriginal ethics committees it circumvents the cultural right of Aboriginal communities to control the processes that affect their destinies. Certain conspicuous lacunae between the draft and final proposed document further bear out this propensity, together with unfortunate pejorative and paternalistic allusions within the document on the competence of Aboriginal people to determine complex ethical matters.
- Where there are Aboriginal Health Ethics Committees working in association with Aboriginal Community Controlled Health Services in various state/territory jurisdictions, whose very existence, viability and purpose is at stake, their participation and essential involvement should be the pivotal point upon which all ethical assessment and deliberation should hinge. The proposed *Guidelines* should have explicit prescriptive terms ensuring their role in approving research into Aboriginal health as occurs in certain States. In those Communities within various jurisdictions that require the Aboriginal community controlled health service to approve, or prefer alternative arrangements, these should be respected, always mindful of the primacy of each Aboriginal community in determining these matters.
- Comment should be made on the actual input of the Aboriginal Community Controlled Health sector in the process that resulted in the final document being developed by the working party. The written response by NACCHO was quite explicit yet its recommendations have been totally excluded from the document by the working party except for the mere statement that NACCHO had requested that its name and the structure of its state/territory affiliates be included in the text. The actual content of NACCHO's critique has been omitted.
- The NACCHO's request for a more prescriptive document similar to that within the *National Statement* and the *NHMRC Application Form* for funding has been ignored even when there has been no criticism of that process being unworkable. Accordingly, the proposed *Guidelines* are isolated and stand in sharp relief to other NHMRC documents, which beg the question as to why?
- This deficiency is replicated in the working party's negative response to any of the important criticisms and suggestions provided by the AH&MRC following advice to the Board by the AH&MRC Ethics Committee. There is no evidence in the final document to reflect this Community input. This impervious approach to Community input and intractable stance places in jeopardy, and could even dismantle, existing innovative working agreements and protocols in ethics evaluation that exist between state government health departments and the ACCH sector in some jurisdictions.
- Why is it that such a diametrically different ethical process has been developed by the working party to that developed by governments and Aboriginal people elsewhere in Australia and why is it such a radical departure from the NAIHO Report? Is it

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ethical for one selective working party to be so adamant in its perceived monopoly of ethical behaviour as it relates to Aboriginal cultural practice?

- It is incumbent upon the Working Party to show cause why the process of Community involvement and consultation should not be characterised as superficial and a pointless exercise, for reasons best known to the working party.
- In light of implausible information as to the reasons for this contrary action it might possibly be a beneficial exercise to investigate the number of participants on the Working Party who unconsciously represent institutions, agencies or organisations that could be potential recipients of Aboriginal health research funding in the future. It may well be the case that the amended proposed procedures would be considered preferable to academics and academic institutions. The proposed alternative to bypass Aboriginal HRECs by obtaining their own institutional ethical approval for Aboriginal health research may be envisaged as a more convenient and efficient process, albeit open to the criticism of the appearance of possible incestuous practice and lack of transparency without the unfettered scrutiny by the Aboriginal community that an Aboriginal HREC provides.

Postscript

- It is a sad day in Australian health ethics to witness the erosion of the inalienable rights of Aboriginal people to control the process in assessing health research applications against previously Community determined ethical standards and compliance criteria as summarised in the NAIHO Report.
- The witnessing of the development of an instrument that renders Aboriginal communities impotent to ultimately control and ensure ethical and cultural processes for research and data into Aboriginal health and welfare is a further example of enforced assimilation by a dominant culture, albeit this time an assault of its very cultural heart.
- The implied duress of enabling a statutory body, empowered by provisions of an Australian Act of Parliament, enforcing procedures through which scholars can potentially circumvent Aboriginal and Torres Strait Islander cultural imperatives and intentions by rendering Aboriginal Ethics Committees' evaluation as optional, is deeply regrettable.
- Any process, no matter how laudable its genesis and motive, that enables one group within the community to assume the role of determining perceived ethical conduct and relevance of cultural imperatives in another group is in itself the antithesis of ethical behaviour and an action vulnerable to the highest condemnation in international law.
- There is no mandate sighted for this cultural intrusion and transition which can be interpreted as a blatant and consistent disregard by certain academia to violate appropriate ethical conduct formulated by the Aboriginal community.
- The perceived need for the revision of these imperatives is one matter but their replacement and circumvention is altogether another, as if intrinsic ethical imperatives are transient and mutable. Notwithstanding the elasticity in 'situation ethics' such presumption as that displayed in this process and documentation reflects a dismal knowledge of the solidity, integration and permanence of an ancient yet ongoing Aboriginal civilisation and the lasting nature of its Law, in sharp relief to built-in obsolescence within certain transient societies.