



Maori responsiveness in health and medical research: key issues for researchers (part 1)

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Abstract

Introduction Application for contestable government-research funding and ethical approval requires researchers to outline how their intended research project contributes to Maori development or advancement.

Methods and Results When formulating their research proposals, the key issues for researchers are research utility, defining Maori, informed consent, confidentiality, issues with human tissues and genetic material, participant remuneration and recognition (koha), intellectual property, and involvement of local Maori health or social services.

Conclusions The most common Maori responsiveness issues in research applications can be readily approached by researchers who address straightforward methodological concerns, by working through precedents established by peers and colleagues, as well as by working with end-users of their research.

In 1998, the Health Research Council of New Zealand (HRC) published the *Guidelines for researchers on health research involving Maori*.¹ These Guidelines were produced by the Maori Health Committee of the HRC to assist health researchers intending to undertake research that involved Maori as participants, or was on a topic relevant to Maori health.

The HRC guidelines were not binding on researchers but were more than 'points to consider' as they were to be used in the consideration of applications for HRC funding in future years. The 1998 revision of the '*National application form for ethical approval*' incorporated the principles contained within the HRC guidelines. As a result, all applicants from all research fields were required to indicate if they had read the guidelines and to specify what consultation with Maori had been undertaken in developing the research. The current HRC research proposal application form requires the host institution to ensure that consultation with Maori has occurred.

Anecdotal reports and the authors' personal experiences indicate that this requirement for all researchers has led to confusion among researchers and ethics committees as to what constitutes appropriate and meaningful consultation with Maori. This is confirmed by a study on researchers' views of the functioning of ethics committee in New Zealand.² There is also anecdotal evidence that the requirement for consultation by researchers is placing demands on Maori communities or organisations with limited resources and their own, more pressing, matters to attend to.

This paper attempts to clarify the issues regarding consultation with Maori in the development of biomedical and clinical research. Our experience (in assisting health researchers improve the Maori responsiveness of their intended projects) has

highlighted that there are nine key areas that researchers can readily address in their proposals.

These issues are outlined in this paper, together with possible strategies to manage them. The paper concludes with a review of the first year of functioning of the Maori Research Review Committee of the Auckland District Health Board—an initial institutional committee formed to address these issues. A second paper³ will review the historical development of the Maori responsiveness requirement for health research funding to demonstrate that this process follows similar requirements of the rest of the health sector, and will outline an institutionally based model to assist researchers in meeting the obligations related to Maori responsiveness.

Common issues of Maori responsiveness in research applications

In their roles (within research-funding bodies, universities, and healthcare providers) the authors have provided advice to biomedical, clinical, and public health researchers on ways of improving the Maori responsiveness of their intended research projects.

Over the last 5 years, nine issues have predominated in such discussions with researchers. All of these issues are readily addressed, as outlined below.

Utility

Whenever possible, health research on a health issue relevant to Maori should have clear benefits for Maori health. Such benefits need to be clearly articulated, and the research process must be designed to realise those benefits.

Research undertaken in New Zealand can often overlook its relevance for Maori health, and this may significantly undervalue the research project. The first step is for the researcher to recognise the relative impact of the health issue being researched upon different population groups—including Maori. This should include an assessment of likely future relevance given the marked changes in New Zealand's population over the next 50 years.

For public health and clinical research, this assessment of relative impact on population groups is usually straightforward (as the burden of most health issues falls disproportionately upon Maori). Occasionally, the ethnic specific burden of a health issue may not be known, but addressing this gap in knowledge can then be an additional research outcome.

For example, the initial planning of an investigation into possible causes of abdominal aortic aneurysm in New Zealand had not included consideration of ethnicity. However, a detailed examination (of ethnic specific incidence and mortality) highlighted a previously unknown higher mortality and earlier incidence of aortic aneurysm in Maori.⁴ This was a key research finding, as it was the first time such elevated rates have been described outside a population of non-European descent, and the results are now being used to inform further research into potential modifiable causes of aneurysm for Maori.

The second step is to ensure that the benefits of the research reflect the relative impact of the health issue. A vital part of this process is the identification of, and consultation with, potential end-users of the research results. Both HRC and the Foundation for Research, Science and Technology (FRST) applications require researchers to

indicate the relevance of their project, the relationship with endusers and the strategy for the dissemination of results.

Addressing Maori responsiveness requires a similar process, but made Maori-specific. Where a research team has a focus on a specific issue, the consultation with Maori or non-Maori endusers is likely to involve an ongoing reciprocal relationship that may shape the research focus, design, and methods—or the dissemination strategy across the team's research portfolio. Suitable Maori end-users may be any combination of Maori staff or sections within mainstream organisations working with Maori on the health issue, or Maori-specific health or other community organisations.

One strategy is to include a specific focus on Maori within the project. This may involve undertaking ethnic-specific analyses, or ensuring there are sufficient Maori participants to enable Maori specific analyses. Some projects include a distinct Maori segment, involving Maori specific research processes and Maori staff.

With clinical studies, the combination of small participant numbers and sampling strategy can preclude a distinct ethnic analysis, especially when the research is exploratory in nature. In such instances, the researcher should specify in their application the anticipated proportion of the sample that will be Maori (based on previous clinical activities) and determine whether this enables a statistically valid ethnic specific analysis. If not, then the option of an ethnic over-sampling should be explored, and the decision regarding its practicability justified within the application.

Where ethnic-specific analyses are not possible, then the research and dissemination process can be designed to enable the research to form the basis of later work that is more directly relevant to Maori health.

Some researchers have chosen to exclude Maori as subjects from studies due to investigator-perceived difficulties in consultation, recruitment, or analysis. This is an effective means to ensuring that the Crown-funded research has an unknown applicability to Maori. Of note, the United States' National Institutes of Health (NIH) insists that women and minorities be included in all NIH biomedical and behavioural research involving human participants—to ensure that the results are applicable to all population groups. Furthermore, where there is prior evidence of differential clinical or public health importance of the health issue, then both 'the primary question(s) to be addressed by the proposed ... trial and the design of that trial must specifically accommodate this.'⁵

Subgroup analyses are required where the evidence of differential impact is equivocal and strongly encouraged, even when there is no prior evidence of differential impact. Exceptions are possible, but only when 'a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate.'⁵ New Zealand's research and health policies would suggest a similar requirement could be made for Crown-funded research in this country.

For biomedical research, the benefits for Maori health may not be so readily identifiable—as the research is concerned with more fundamental biological processes, many steps removed from application in a health setting. However, there may still be ways the research could contribute to Maori health development—these need to be explored and practicable options (if any) outlined in the research proposal.

In such instances, the research process may be able to provide workforce development opportunities via studentships or scholarships that can assist in addressing the low levels of Maori participation in biomedical research. Another option is for biomedical researchers to focus on an issue of high Maori health relevance.

In 1964, a paper was published that described a Maori family in which members had died of diffuse gastric carcinoma.⁶ However, this Maori family did not benefit from this research in terms of improved surveillance or treatment. Nearly 30 years later, a joint venture between the family and biomedical researchers at Otago University resulted in definition of an inherited genetic defect in cell adhesion proteins integral to the development of diffuse gastric cancer.⁷ This partnership led to an innovative research process that has resulted in major publications, development of local community health services, further research projects and the establishment of improved surveillance and treatment protocols for family members.

The Royal Society of New Zealand has recently published a report outlining good practice guidelines for working with Maori in scientific research.⁸

Defining and identifying Maori

Undertaking ethnic specific analyses can be a useful way of highlighting differences in morbidity and mortality between population groups as well as highlighting differences in effectiveness of services or other interventions. All of these analyses can be useful in informing improvements in health policies and practices for Maori. To make this possible, research projects need to use standardised definitions and processes for determining the ethnic identity of participants.

The use of non-standardised definitions and processes makes the results non-comparable with other studies (or even official data), and introduces bias that reduces the usefulness of the results in informing improvements in Maori health. Although this problem has plagued official health statistics in the past,⁹ it does not need to affect current or future research.

The solution is to use the content, delivery, and counting methods of ethnicity questions contained in the most recent New Zealand Census. The use of the standard Census question ensures that the results are comparable with the Census data (that forms the baseline population data for the determination of incidence or prevalence rates).

As ethnicity is a self-defined concept, and the Census is (usually) self-completed, researchers should get participants to answer the question (if possible). The researcher then needs to use the standard means of aggregating the results (especially multi-ethnic responses) into ethnic categories.¹⁰ Finally, it is also important for authors to describe the methods used when writing up the project.

In 2001, Thomas¹¹ reviewed research reports, which made comparisons between Maori and non-Maori samples from 1980 to 1996. Only 19% reported any information on the criteria used for categorising ethnicity, and only three papers mentioned how people of dual or multiple ethnicity were defined. As with other research methods, outlining ethnicity criteria and their application in publications is essential for the audience to assess the validity and applicability of the research results.

Informed consent

Obtaining informed consent for involvement as a participant in a research process usually involves the consent of the individual concerned, or (in certain circumstances) proxy consent from parents, family, guardians, or persons with power of attorney.

However, for Maori, a more collective approach to consent may be required depending on the nature of the research processes involved. This is especially true when the research process involves traditional Maori knowledge or processes that challenge Maori values or tikanga.

For Maori, traditional knowledge is entrusted to individuals. As such, it is not universally available despite it remaining the property of the collective and cannot be shared with the consent of the collective stakeholders. With the exception of genealogical information and traditional therapies, most mainstream health research will not involve such information. When traditional knowledge or potential breaches of tikanga (Maori lore and protocol) are involved in research processes, then individual consent is insufficient. For traditional knowledge, the consent of the collective (whanau [family], hapu [subtribe], or iwi [tribe]) is required.

Where issues of tikanga are involved, then the HRC guidelines require that the mana whenua (people with authority) of the region (such as the local iwi) need to be consulted, and the results of the consultation documented in the application. In addition, it is prudent for researchers to provide opportunity (including the necessary time) during the consent process for potential Maori participants to discuss their involvement with whanau.

Confidentiality

Participation in research usually involves confidentiality of participant identity. Maintaining this confidentiality can be difficult for Maori, especially with smaller or regional studies. The combination of extensive Maori social networks and (possibly) small numbers of eligible Maori participants requires researchers to minimise the inclusion of identifiable information in any research reports or publications—to avoid the unintentional identification or mis-identification of an individual, community, or organisation.

Conversely, Maori participants may ask that their research information is made available beyond themselves (in line with collective accountability, or to ensure wider benefit from the research process for their communities). The research application should specifically indicate if either of these situations could apply to the intended project, and (if so) they should include a strategy to address the issue.

Handling and disposal of tissue

Maori view all tissue and body fluids as taonga (to be treated as a treasure). However, body fluids and tissues are also regarded as tapu (and therefore need to be treated with caution) rather than noa (neutral). This distinction is important, since biological specimens must be treated with great care and kept away from food and cooking utensils.

The process of consent to the taking of tissue and body fluids (as part of a research protocol) amounts to entrusting the researcher with this taonga. Consent for tissue or

body fluid collection is not given lightly, and consequently all tissues should be handled with respect. Many universities and hospitals already have protocols for the sampling, storage, and disposal of tissue from Maori. These can include Maori supervision of the process, and rituals for the cleansing of the storage site or samples.

Where samples are required, it is important that the researcher seek and follow the advice of the local Maori advisory or management team and document this in their application.

It is expected that where tissues and body fluids will be transported (particularly outside of New Zealand), there will be evidence of specific processes in place to ensure that samples are used only for the purposes for which consent has been provided and then disposed of in a suitable manner. The application form should outline what protocols are being followed for handling human tissue and what, if any, specific processes are being followed for any Maori specimens.

Genetic information

The use of genetic material from Maori, as well as from indigenous flora and fauna, is highly contentious and there is a general reluctance amongst Maori to be involved in genetic research. Many of these contentious issues have been discussed by Baird et al,¹² or are outlined in the submissions to the Royal Commission on Genetic Modification.¹³

However, several Maori-specific genetic projects have proceeded, including at least two researcher-initiated projects. In all cases, extensive consultation was required with whanau, hapu, and iwi. Involving Maori in mainstream projects is less straightforward. Possible strategies include excluding Maori from such a study or not collecting ethnicity data, making Maori samples non-identifiable. Again, researchers should familiarise themselves with the issues, then follow local protocols in determining how to address this issue and refer to these in their applications.

Intellectual property

Intellectual property issues are an important consideration for researchers, particularly those involved in the development of patentable knowledge or new services.

If a research project involves a unique contribution from Maori organisations or individuals, then that contribution needs to be given due recognition in the research process. Important issues for Maori are retaining control over things that are viewed as being owned by them, and the prevention of exploitation.¹⁴ Researchers must remember that ownership of Maori knowledge is often collective, and that intellectual property rights need to be negotiated with organisations or kin groups (whanau, hapu, or iwi) rather than individuals.¹⁵ Previous mechanisms to acknowledge intellectual property within the research process have included authorship (primary and joint) on publications as well as joint ownership of intellectual property.

In the case of Guilford et al⁷ the intellectual property relating to discovery of the e-cadherin gene in gastric cancer is jointly owned by both whanau and the institution hosting the research. This is clearly defined in a contract between the researchers' host institution and the whanau trust.

If this issue is relevant to an application, then the applicant should either include a description of how any intellectual property would be managed, or outline the process that will resolve how the issue will be managed.

Koha

It may be appropriate to provide koha (a gift) to participants in recognition of the contribution that participants make to the research process. The recent Operational Standard for Ethics Committees¹⁶ allows for reimbursement for participation, including any costs incurred by the participant. Such reimbursement needs to be reasonable, and indicated in advance to potential participants.

Financial incentives to participate can negate the basis of informed consent as well as create a source of bias in recruiting a research sample, and should therefore be discouraged. However, it may be appropriate to provide participants with a small gift in recognition of their time and contribution. Often this will be in the form of a letter or certificate of thanks/acknowledgement. Other possible examples are petrol or book vouchers, or gifts of food. One way to ensure that a koha is not regarded as an inducement is not to signal it in advance to participants.

In projects where reimbursement or koha may be provided, researchers should include (within their applications) a description of any reimbursement and or koha, clearly outlining the amount or form of the koha and whether potential participants are advised in advance.

Involvement of regional Maori health services

Most biomedical centres in New Zealand have now established Maori health services within the District Health Boards (DHB), which work to assist Maori undergoing medical treatment—either by advocacy, or by more practical assistance such as accommodation and transport.

In the case of clinical research, discussion of the intended research protocol with the regional Maori Health services is one important avenue of consultation. In addition, Maori Health services are often able to assist with patient recruitment, interaction between researchers and primary healthcare providers, and dissemination of results.

Any such involvement should always be negotiated during the development of a research proposal—to ensure the Maori health service staff workload is not compromised, and to ensure any required costs are built into the research budget.

Inclusion of a regional Maori Health Services' contact phone number on patient information sheets for clinical research protocols also allows Maori Health Services to assist researchers in supporting Maori patients and their whanau through the research process.

The Maori Research Review Committee of the Auckland District Health Board

At the Auckland District Health Board (ADHB), a Maori Research Review Committee has been developed. The Committee meets once a month to review Treaty of Waitangi and tikanga aspects of all research to be carried out within Auckland District Health Board institutions.

The Committee was formed by Maori working within the ADHB in response to issues that have been outlined in this paper. Prior to its formation, most research proposals were being directed informally toward Maori working in the organisation for review—this was an unsatisfactory arrangement for both researchers and Maori.

All research applications are now directed through the District Health Board Research and Development Office, and are reviewed by the Maori Research Review Committee. This committee includes a Maori clinician, a Maori nurse, a representative from the Research Development Office (who provides secretarial and administrative support), representatives from the local ethics committee, and mana whenua.

All research is assessed in terms of adherence to the guidelines prepared by the Committee to assist researchers. Research that deals with difficult or contentious areas will be directed to a group of Maori kaumatua/leaders (the kaunihera) who regularly advise the ADHB on all aspects of their work.

The Committee does not rewrite the Treaty components of a submission but simply indicates whether the research meets the institutional guidelines in this area or points out deficiencies and makes suggestions regarding improvement. Furthermore, the Committee strives to be constructive and to help researchers develop research proposals that are relevant to Maori, and to answer questions that are important to all New Zealanders.

Summary of the first 12 months of the ADHB Maori Research Review Committee

During its first 12 months, the ADHB Maori Research Review Committee convened 13 times and reviewed 128 separate research proposals, thus emphasising the significant amount of work involved in this process. The significant issues highlighted in the Committees' reviews are presented in Table 1 (in 6-month blocks).

Table 1. Summary of the review outcomes for 128 proposals assessed by the Auckland District Health Board Maori Research Review Committee during its first year. (For most proposals, changes were recommended in more than one area.)

Review outcomes	First 6 Months	Second 6 Months	Total
No consultation	5	1	6
No consultation documentation	5	6	11
No definition of ethnicity	5	1	6
Tissue handling and disposal	14	10	24
Maori Health Service contact details	38	23	61
Koha	5	-	5
Unvalidated questionnaires for Maori	4	4	8
Complex language patient information sheet	1	7	8
Intellectual property issues	-	1	1
Approved without change	7	37	44

The principle areas highlighted by the Committee pertain to a lack of written documentation of consultation with the proposal, a lack of detail on patient consent

tissue handling and disposal, and the inclusion of contact details for regional Maori health services.

The planned use of questionnaires developed outside New Zealand to examine psychological and other parameters in Maori, and the use of complex technical language in patient information sheets were also significant issues.

Table 2. Summary of the review outcomes for 128 proposals assessed by the Auckland District Health Board Maori Research Review Committee (stratified by the first and second 6 months of the Committees functioning)

	Changes Recommended	Approved Without Change	Total
First 6 Months	47	7	54
Second 6 Months	37	37	74

Table 2 presents (in 6-month blocks) summary statistics for approved research projects, or where changes were recommended. It indicates an increasing proportion of research applications approved without change in the second 6 months of the Committees' tenure (due to clarification of the goals and requirements of consultation).

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