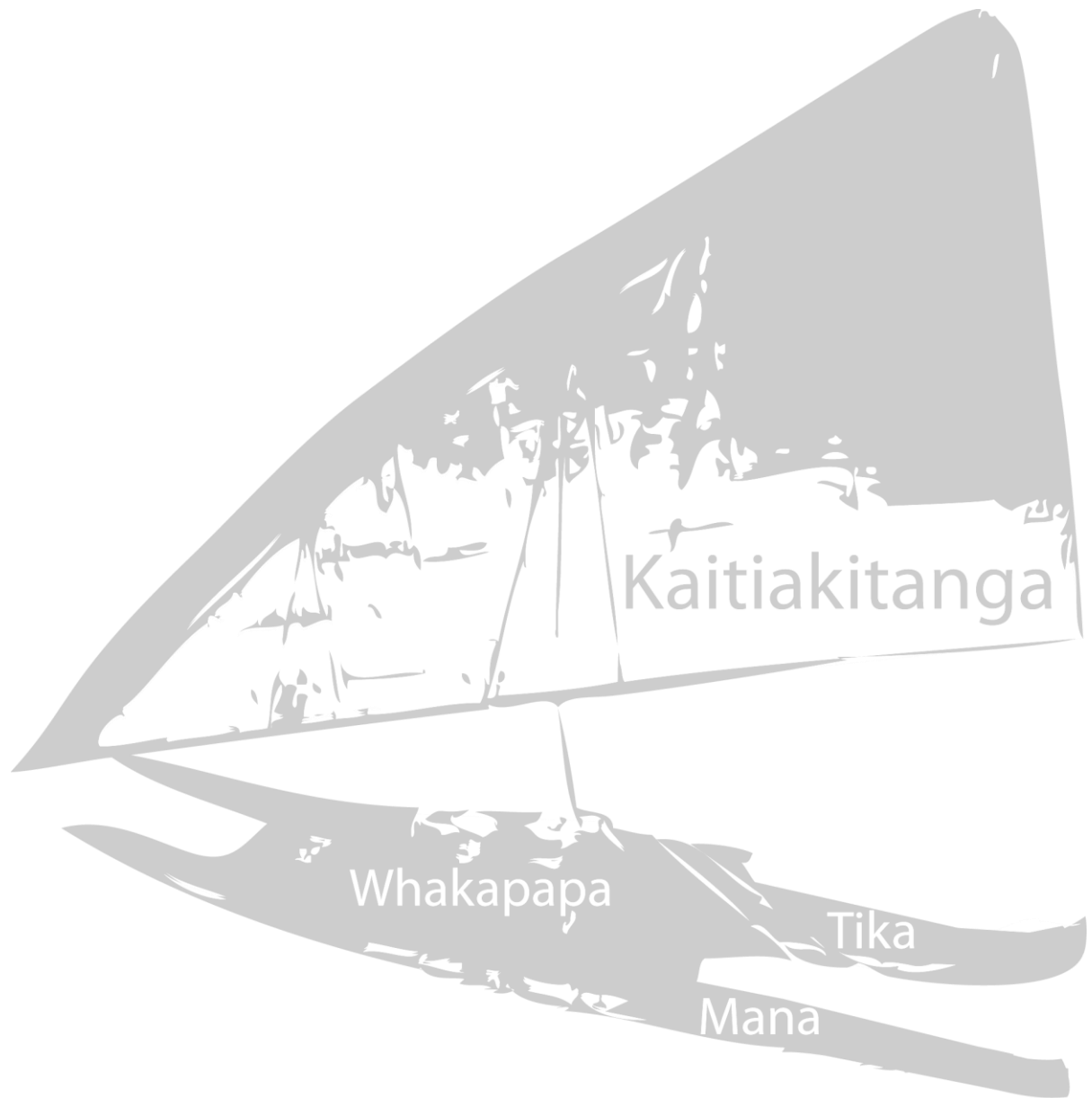


TE TAURANGA WAKA

An action-plan for addressing Māori concerns about the system and process for ethical review of issues relating to human participation in research and innovative technologies



written & compiled by Stephanie Palmer
Tumana Research
March 2009

Ngā Mihi

This document is a kōha to Pūtaiora, and Māori engaged in the system of ethical review. It has been written at great personal cost. The image of Te Tauranga Waka was created by Raukawa, one of our rangatahi with a bright future in graphic design. We thank the Robert Reisinger Memorial Trust for their financial support during the writing period and ask that they understand why this document had to be written. Māori have been waiting for a Māori Ethical Framework that addresses their concerns for many years. In 2002, Tariana Turia instructed the National Advisory Ethics Committee (NEAC) to write it. Here we are in 2009, still waiting. This document should have been properly funded from the start.

We are grateful for the mentorship, support and tautoko received from the Pūtaiora Writing Group - Khyla Russell, Barry Smith, Moe Milne, Paul Reynolds and Maui Hudson. Te Tauranga Waka was fashioned around their discussions about a waka unua, or the double-hulled canoe, as symbol of protection for Māori engaged in the processes associated with ethical approval and review. This document is grounded in the thoughts, concerns and aspirations of Māori who have knowledge of the NZ ethics system, particularly Māori ethics committee members, Māori health researchers and the author's own experience of sitting on a Health & Disability Ethics Committee.

We acknowledge the Health Research Council of NZ (HRC), Ngā Pae o te Māramatanga and the National Ethics Advisory Committee (NEAC) and their funding for two meetings of the Pūtaiora Writing Group.

This document requires further work, for example, peer review and fine-tuning of the recommendations is clearly needed. There has also been lengthy discussion about who is actually responsible for improving the quality of New Zealand's ethical review system because that is the Agency who should take ownership of this work. Given their role in the accreditation and monitoring of ethics committees, we believe it is the Health Research Council who needs to ensure the thoughts, ideas and recommendations contained within Te Tauranga Waka form the basis for a useable action plan. Our hope is Te Tauranga Waka provides a starting point for critical thinking about kaitiakitanga and how this can be achieved within the process of ethical review.

Nō reira, kia piki te kaha ora me te maramatanga ki runga ki a koutou katoa.

Mauri ora



Director

Tumana Research

Introduction

Te Tauranga Waka is an action plan for addressing Māori ethical issues within the context of decision-making about health research by ethics committees in Aotearoa. It should be read in conjunction with two other documents¹ - *Te Aratika* and the overview of Māori Research Ethics - which will together provide a more comprehensive understanding of the issues that are relevant for Māori. *Te Tauranga Waka* looks at the current system of ethical review, from a mātauranga Māori perspective. It considers the structural, legislative and administrative processes currently associated with decision-making by ethics committees and highlights the actions, or changes, that are needed to resolve Māori concerns and ensure Māori aspirations are actually achieved. *Te Tauranga Waka* has relevance for researchers, ethics committee members, administrators and anyone who engages in consultation or advice about Māori ethical issues from a local, regional, national or international perspective.

Context

Research sits within a domain of knowledge generation that can support the broader development goals of society, including indigenous or minority groups. Discussions about values, ethics and what constitutes appropriate behaviour are an integral part of how cultures maintain a sense of stability and continuity but also respond to changing environments and new experiences that can be a consequence of the research process. Ethical reasoning is, therefore, an important mechanism for informing decisions and protecting culturally valid views of the world. Within the context of human research, ethics has a specific role in guiding key behaviours, processes and methodologies.

Codes of Ethics such as the Nuremburg Code, the Helsinki Declaration, the Belmont Report and, more recently, the UNESCO Universal Declaration on Bioethics and Human Rights have shaped ethical standards and professional expectations for researchers throughout the world. Most countries have also created particular codes to protect basic human rights and the privacy, or confidentiality, of health information. The development of such codes has generally been triggered by experience of adverse outcomes for participants and their communities.

In Aotearoa, participants in health research, alongwith their health information and basic human rights, are protected by numerous regulations, codes and statutory provisions particularly the Human Rights Act 1993, New Zealand Bill of Rights Act 1990, the Health Information Privacy Code 1994, the Code of Health and Disability Services Consumers' Rights 1996, New Zealand Health and Disability Act 2000 and the Health Research Council Act 1990. Specific protection for participants taking part in clinical trials or medical research involving new technologies, gene therapy and highly invasive procedures is also offered under the Medicines Act 1981, Human Assisted Reproductive Technology Act 2004,

¹ both documents are still in progress but have been submitted to NEAC, HRC or Ngā Pae o te Maramatanga

Injury Prevention, Rehabilitation and Compensation Act 2001 and the Human Tissue Act 1964, 2008.

For tangata whenua, however, as a partner of the Crown, Te Tiriti o Waitangi reminds ethics committees of a constitutional obligation to ensure Māori participation, protection and partnership when considering approval for research applications. In recent years, a range of documents have aimed to assist understanding of the Treaty and its relevance in decision-making about health research (reference Nga Pou Rangahau Hauora Kia Whakapiki Ake Te Hauora Māori 2004-2008 (2004); He Korowai Oranga (2002); Guidelines for Researchers on Health Research Involving Māori (2008) and HRC Guidelines on Ethics in Health Research (2002, revised 2005). When viewed from a Treaty perspective, it is clear that research which includes Māori is of paramount importance to Māori but *all research is of interest to Māori* because every project may carry risks, or produce benefits and contribute to the achievement of Māori health aspirations. An understanding of the Treaty is, therefore, integral to understanding the specific rights, roles and responsibilities of researchers and those involved with the process of ethical review.

Beneath this raft of constitutional and statutory provisions, New Zealand has a system of accredited ethics committees. Six regional and one multi-region health and disability ethics committees (HDECs)² have responsibility for the review and approval of health research applications involving human participants. The HDEC system is accountable to, and overseen by, the Health Research Council Ethics Committee (HRCEC) and National Advisory Committee on Health and Disability Support Services Ethics (NEAC). HRCEC also co-ordinates, monitors and administers (1) the Standing Committee on Therapeutic Trials (SCOTT), which contributes to the HDEC process for review of studies involving new medicines; (2) the Gene Technology Advisory Committee (GTAC) which contributes to the HDEC process for review of gene technology studies including xenotransplantation, (3) the Data Monitoring Core Committee (DMCC), and (4) registration of New Zealand based clinical trials in the Australian New Zealand Clinical Trials Registry (ANZCTR). In addition to the HDEC system, a separate Ethics Committee on Assisted Reproductive Technology (ECART)³ has been established to review and approve research involving new technologies or treatments for human reproduction and infertility. As with the HDEC process, ECART review is supported and informed by an Advisory Committee on Assisted Reproductive Technology (ACART).

This system of ethical review recognises the innovative and highly invasive nature of technologies associated with some of the methodologies they consider - such as tissue banking, genetic engineering, the manipulation and storage of human embryos, therapeutic cloning, selection of embryos using pre-implantation genetic diagnosis, splitting of embryos and the creation of hybrid embryos or transgenic life-forms - may be sources of particular risk and concern for Māori. GTAC, for example, broadly refers to booklets produced by Toi te Taiao, or the Bioethics Council, in 2004, that discuss some of the concerns Māori may have about mixing animal and human genes. In a more specific approach, one of ECARTs

² established under the New Zealand Health and Disability Act 2000.

³ under the Human Assisted Reproductive Technology Act 2004.

seven guiding principles states “the needs, values and beliefs of Māori should be considered and treated with respect”. Within a recently released consultation document⁴, ACART has highlighted Māori concerns about the protection of whakapapa and need for collective discussion about cultural implications, kaitiakitanga and appropriate tikanga. In practice, however, the way in which Māori concerns are identified and considered within the HDEC and ECART decision-making process is firmly tied to the Operation Standard for Ethics Committees (MoH, 2002 updated 2006)⁵⁶.

Main principles	Additional issues for Māori
Respect for persons	Respect for Māori collectives – whānau, hapū, iwi
Informed consent	Gaining consent of collectives
Privacy & confidentiality	Collective ownership of information
Validity of research proposal	Kaupapa Māori and Māori focused methodologies
Minimisation of harm	Minimising harm to te taha whānau (family and community), te taha hinengaro (emotional wellbeing and state of mind), te taha wairua (spirit), te taha tinana (the body or physical self)
Justice	
Cultural & social responsibility	Cultural diversity, koha (donation, present or gift)
Compensation for research participants	

Table 1: The Eight Principles of Ethical Review and Additional Issues for Māori (in the Operation Standard for Ethics Committees, Ministry of Health, 2006)

The Operation Standard is shaped around eight ethical principles, but identifies “additional issues for Māori” that must be considered when research proposals are reviewed. It is important to understand the Operation Standard specifically reassures Māori the process of ethical review will give due consideration to:

- incorporating Treaty principles (Sections 1.4 and 8), ie
 - partnership and consultation with iwi, hapū, whānau and Māori communities to ensure individual and collective rights are respected and protected;
 - Māori participation in the design, governance, management, implementation and analysis of research as well as the use of kaupapa Māori research methodologies;

⁴ on The Use of In Vitro Maturation in Fertility Treatment, available at www.acart.health.govt.nz on 5 March 2009.

⁵ replaced the National Standard for Ethics Committees (1996).

⁶ Under their Terms of Reference, ECART members need only adhere to Sections 1-4 of the Operation Standard for Ethics Committees (2006).

- protection of Māori participants, Māori individual or collective rights, Māori data, Māori ownership of data, Māori culture, Māori cultural concepts and Māori values, norms, language and practices;
- respect and support for Māori cultural concepts (Section 1.5), including:
 - Māori perspectives of health and wellbeing, kaupapa Māori and tikanga Māori;
 - applying Māori ethical perspectives to ensure high-quality Māori health research and the protection of Māori participants, tikanga, cultural concepts;
 - Māori collectives and the representation of collective views (Section 2) through, for example, collective consent (pt 41) and collective ownership of information or data (pt 55);
- ensuring the process of obtaining informed consent presents information in a form and manner that is able to be understood, with all foreseeable risks explained (Section 2.2);
- demonstrating the validity of research in terms of its potential contribution to knowledge (pt 59) (in light of Section 1.5 this is presumed to include Māori knowledge);
- minimisation of harm to Māori participants and Māori whānau, hinengaro, wairua, tinana (pts 66 & 67) through partnership with Māori and Māori participation in the design, implementation, management and analysis of Māori data.

Various mechanisms are, therefore, designed to ensure the protection and participation of Māori. In particular, the composition of HDEC and ECART membership is legally required to have at least two Māori members who must have an awareness of Māori language, culture and tikanga. Most of the associated advisory or monitoring groups must also appoint Māori members. Although not a legal requirement, there is an expectation ethics committees will establish processes for consultation with local iwi, hapū and/or other Māori groups who should be duly consulted, and involved, in the identification or selection of Māori ethics committee members. Since 2005, Māori members sitting on the seven health and disability ethics committees (collectively called Pūtaiora) have had the opportunity to attend annual one-day meetings for training and discussion of Māori ethical issues⁷.

Another mechanism for the participation and protection of Māori is Section F of the HDEC application form for ethical review. Under Cultural and Social Responsibility, researchers are required to (a) read the Guidelines for Researchers on Health Research Involving Māori (HRC, 2008), (b) indicate whether the proposed research will have an impact on Māori, (c) explain how the intended research is consistent with provisions of the Treaty of Waitangi and (d) identify, describe and produce evidence of consultation with Māori. To a lesser degree, the Locality Assessment Form provides another opportunity to identify “cultural issues” specific to the research site.

Researchers who obtain HDEC approval must submit annual progress and end of study reports. These reports provide further opportunities to gather information about cultural

⁷ Prior to 2005, there were three Pūtaiora hui held in 1996, 2000 and 2002.

issues. In particular, researchers are asked to provide information about changes in the proposed methodology, the number of participants recruited, whether any have withdrawn, whether findings have been presented and ethical or other problems that have been experienced.

In addition, each HDEC committee is required to submit an annual report summarising the following cultural issues:

- ☐ the number of applications deferred because researchers did not read the Guidelines for Researchers on Health Research Involving Māori;
- ☐ the number of applications for which consultation with Māori was considered inappropriate and returned because of insufficient consultation;
- ☐ the process for following through on consultation;
- ☐ the number of unsatisfactory reasons for not including Māori with examples of when this happened, and
- ☐ the mechanisms each committee has in place to facilitate consultation with Māori by researchers.

ECART, in comparison, has few mechanisms for ensuring Māori participation and protection. Part 10 of the ECART form for research approval simply asks the applicants to “explain how they have addressed cultural issues including issues pertinent to the Treaty of Waitangi in relation to all aspects of the research project”. No evidence of consultation with Māori is required. When the application is for ECART approval of surrogacy or donation of gametes and embryos, respective medical specialists for the donors and recipients are asked to explain “how the different ethical, spiritual and cultural perspectives in society, including the needs, values and beliefs of Māori will be considered and treated”. Similarly, counsellors for the donor and recipients are respectively asked “how they ensured their counselling was culturally appropriate” and, if the party is Māori, “how whakapapa, and the needs, values and beliefs of the parties, have been considered and managed”. A statement from a key person such as a whānau member, kaumatua, Māori counsellor may also be attached, but is not required for approval. The ECART annual report must contain the ethnicity of surrogates, donors and recipients but no analysis of cultural issues is required.

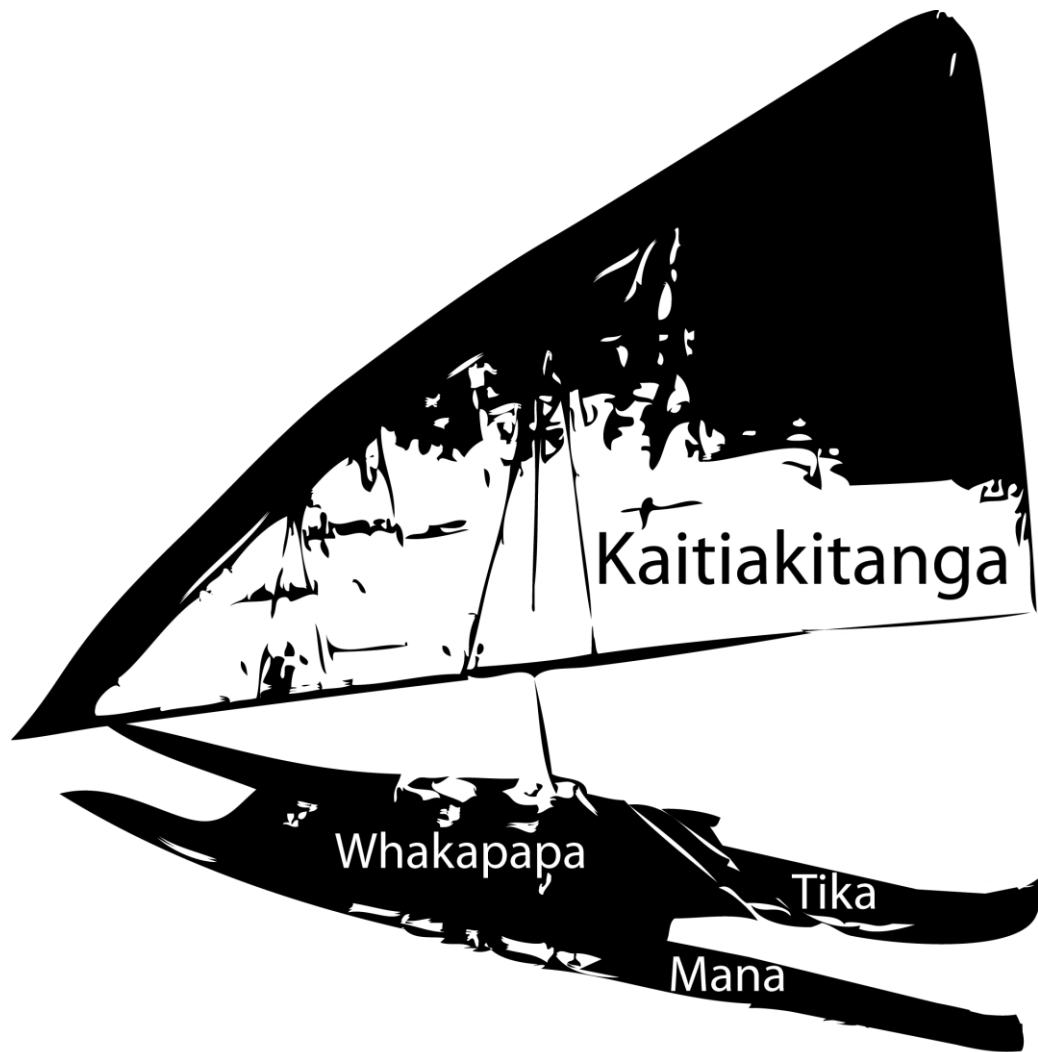
Mātauranga Māori

Despite the Operation Standard, along with its scaffolding of well-intentioned principles and mechanisms for participation and protection, Māori have become increasingly dis-illusioned with the process of ethical review and repeatedly called for the development of a Māori ethical framework (Te Puni Kōkiri, 1994; Pūtaiora 1996, 2001, 2002, 2005; Hui Whakapiripiri 1996, 1997, 2006). There is underlying despair the current system of ethical review has not addressed long-standing concerns such as those which prompted the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous People (1993) and Indigenous People’s Council on Bio-Colonialism (1993) along with various models of Māori ethics (Henare 1998, Durie 1998, Smith and Cram 2001, Mead 2003) and an array of submissions on issues like xenotransplantation (2004), tissue banking (2004), the use of human stem cells (2006) and the Human Tissue Bill (2008).

Within these forums, and others, there has been a strong and consistent message that kaitiakitanga is the overall objective of ethical review, from a mātauranga Māori perspective. In accordance with this view, the sole purpose of a Māori Ethics Framework is the empowerment and facilitation of kaitiakitanga. *Te Tauranga Waka* must, therefore, clarify the meaning and intention of kaitiakitanga within the context of decision-making by ethics committees and demonstrate how this can be achieved within the process of ethical review.

Te Timatanga o te Ao, or the Māori creation story, is the reference-frame for Māori thinking about elements that are essential for sustaining human life and wellbeing (refer reader to reference doc for fuller discussion of Māori models). Within the creation story, kaitiakitanga, or the guardianship of ngā taonga tuku iho⁸, is a core responsibility, and obligation, of Māori living in Te Aronui. Conceptually, Te Aronui is neither the past nor the future, but the process of preparation, integration and creating pathways within the present realm, the world as we know it, to ensure human resilience, adaptation and survival. As with any knowledge-generation system, capacity for kaitiakitanga is dependent upon access to good information, opportunity for analysis and effective representation.

⁸ ancestral treasures including physical, spiritual, intellectual and cultural capital such as mana, whakapapa, whenua, hinengaro and tinana or the human body with its inherent life-force, eg mauri, te ira tangata, human DNA, embryo's, gametes, sperm.



The waka unua, or double-hulled canoe, is an ancient Māori symbol of protection, survival, innovation and prosperity within both the spiritual and physical realms. Crossing the ocean, therefore, is a common metaphor for exploration of the unknown and the search for new knowledge to ensure survival. Within the context of ethical review, *Te Tauranga Waka* encapsulates the spiritual and physical support structures that will enable the type of knowledge-generation and representation necessary to ensure a successful search for kaitiakitanga. From Te Timatanga o te Ao, Māori have an opportunity to demonstrate the proper implementation of *mana*, *tika* and *whakapapa* will provide all the support structures needed for effective knowledge-generation and representation.

Mana

The concepts of mana and tapu are closely aligned and can sometimes seem interchangeable. Both are associated with power and authority. By way of distinction, mana is said to be the manifestation, or expression, of potential power whereas tapu is a state that is caused by the indwelling of mana and the mechanism through which mana is protected. Mana can be inherited through birthright or bloodline, acquired through personal endeavour or ascribed through appointment and delegation. No matter which way it comes, mana is a legitimate power and authority to represent others, or act on behalf of the group. Mana is a collective property, it engages with spiritual, intellectual and emotional energies and can wax or wane. Mana reflects the condition or quality of interactions within and across groups, it thrives when relationships are active, dynamic, vibrant and functional. Mana-aki-tanga, therefore, is a protocol for the mutual elevation of mana, it seeks to maintain balance and harmony by informing kaupapa and protecting the quality or integrity of relationships among groups.

As Māori have gained experience in the current process of ethical review, numerous concerns have been raised about the quality of representation:

- *there are no formal guidelines for ensuring mana whenua/mataawaka engagement in the nomination/selection of Māori ethics committee members* – the process is primarily self-nominating with the Minister of Health having final say;
- *Māori ethics committee members are appointed as individuals rather than representatives of a collective Māori voice* - even when nominated by others, the Māori member is instructed to sit on the committee as an individual⁹, collective mana whenua/mataawaka views can only be represented through consultation;
- *mana whenua are not routinely engaged in the consultation process and their views may not be represented* - the level of engagement with mana whenua varies widely across the country, eg Ngai Tahu, Te Arawa have established pathways for communication with HDECs but most iwi are not involved, eg 80-90% of NXREC¹⁰ consultations are with DHB/university based committees, primarily the Auckland DHB Māori Research Review Committee (MRRC)¹¹; even when institution-based research committees have a mana whenua member(s) there is no clear process for ensuring the consultation, communication and representation of collective mana whenua views¹²;
- *institution-based consultation groups (ie DHBs/University) often work to achieve their own research agenda which may not reflect the concerns/aspirations of wider whānau/hapū/iwi* eg did Māori whānau agree with ADHB MRRC recommendation to

⁹ eg Chair of NXEC (Tim Dare) instructions to newly appointed Māori member (Stephanie Palmer);

¹⁰ Northern X Regional Ethics Committee (NXREC)

¹¹ see NXREC Annual Reports 2005-2007

¹² eg ADHB MRRC has a Ngati Whatua member but Ngati Whatua there is not formal process for consultation or communication with Ngati Whatua, personal communication with Ngarimu Blair, Te Runanga o Ngati Whatua on 19 July 2006.

waive consent for access/storage/future use of aborted foetus cells in April 2006? Do whānau/hapū/iwi agree with current proposal to waive consent for access to full medical records, LMCs or specialists involved with (predominantly Māori) cases of neonatal encephalopathy (alive or deceased)?;

- *information about ethics committee decisions and/or the outcomes of approved research is not disseminated to mana whenua/mataawaka and whānau/hapū/iwi* – there is no process for ensuring Māori are aware of projects that have been approved; Māori have no opportunity to refine/improve/assess the benefits/risks/impacts of research for themselves; potential Māori participants have no opportunity to appeal EC decisions; Māori are not able to advise representatives of collective perspectives/views;
- *responses to the questions on cultural issues (eg Section F) are often incomplete or inadequate, comprising standardised cut and paste statements, with insufficient or inappropriate consultation*¹³ – there is no policy on the minimum requirements for approval; HDECs have different approaches to this issue, eg most approve anyway, some approve subject to more information, a few will defer or decline applications that do not meet mana whenua requirements¹⁴;
- *it is too difficult and burdensome to include mātauranga Māori in the Participant's Information Sheet (PIS)* – Māori EC members often struggle with this issue, each application requires a time consuming, often repetitive, discussion about possible wording and intent; Māori EC members may have to write the PIS section themselves; informed consent is not consent at all if it is not written in a language that Māori understand;
- *diversity is undermining the representation of Māori views* - Māori EC members sitting within/across committees may have different perspectives or disagree with the views of consultation groups; consultation groups may not represent the views of whānau/hapū/iwi; there is no process for recording or resolving differences, dealing with diversity or fostering consistency in Māori views¹⁵; Māori EC members may lack direction and purpose, some feel as if they are operating in a void;
- *Māori social and cultural perspectives are over-ruled by other ethical principles* – precedence may be given to principles of public good, individual consent, justice, equity, minimisation of harm and unreasonable researcher burden even when there is strong evidence of Māori consensus on an issue eg submissions on the Human Tissue Bill (2007) demonstrated wide-spread preference for whānau involvement in decision-making about future access to tissues, data and body samples from

¹³ Of applications to the Multi-region Ethics Committee in 2007, almost half did not have an appropriate or sufficient level of consultation with Māori (see Chair's comments in MREC Annual Report 2007)

¹⁴ eg the Lower South Regional Ethics Committee requirements are closely aligned with mana whenua expectations or advice from Ngai Tahu Research Consultation Committee

¹⁵ HDEC members can formally record an objection to committee decisions in the minutes

deceased family members¹⁶ but HDECs continue to waive the requirement for whānau consent, deny the validity of collective consent and give precedence to non-Māori perspectives about the meaning of ethical principles;

- *it is difficult to integrate information about cultural transgression within the decision-making process*, eg there is no policy for dealing with evidence of researcher deception or inappropriateness; how does this impact on future EC approval? eg in 2006 Dr Rod Lea collected gene samples from Ngati Rakaipaaka for one purpose but used them for other, unconsented purposes;
- *Māori HDEC members do not have the opportunity to review cultural responses on all applications* – the number of HDEC applications is rapidly increasing and involves more applications with invasive and innovative technologies; to reduce the workload of HDECs roughly a third of applications are approved under delegated authority (without full committee review)¹⁷, up from 14 percent in 2006 for NXC;
- *there is no process for monitoring, assessing or informing the outcomes/quality of Māori consultation and representation*, eg Māori EC members and consultation groups vary in their knowledge/awareness of Māori issues/concerns; EC members may not be aware of appropriate consultation groups; whānau/hapū/iwi may not have the capacity to engage in consultation due to resourcing, time or access barriers eg access to people with the right mix of mātauranga Māori/scientific skills to identify potential benefits/risks or recommend changes/negotiation points eg the wording of Participants Information Sheets (PIS); HDEC/ECART reporting processes contain no information about the content of responses to cultural issues or recommendations from consultation groups;
- *annual reports do not inform the representation process* eg Māori positions are not adequately represented, no information is retained from progress or end of study reports.

By the Operation Standard and associated Terms of Reference, decision-making about Māori ethical issues is shared by all members of an ethics committee but responsibility for the representation of Māori positions is seemingly delegated to Māori ethics committee members, Māori consultation groups and health professionals who may, or may not, be Māori¹⁸. The breadth and content of above concerns suggests this process does not work well for Māori and is unlikely to produce the type of representation or knowledge-generation needed for kaitiakitanga. The introduction of *mana* as a reference-frame for thinking about the role, and purpose, of Māori representation, within the process of ethical review, helps to identify a number of ways in which current system could be improved.

Most importantly, there is a fundamental need to clarify “who” has power and authority to represent Māori positions?, “what” positions do they present on Māori behalf? and “how”

¹⁶ refer Tariana Turia submission on Human Tissue Bill: Third Reading, 8 April 2008

¹⁷ see HDEC annual reports for 2007

¹⁸ Counsellors and medical specialists, of any ethnicity, respond to the ECART questions on Māori cultural issues.

can we whakamana, or empower, the representation process? Open discussion of these few points would help to

- ☐ define the role and function of respective representatives
- ☐ improve the quality and effectiveness of Māori representation, and
- ☐ empower Māori representatives to be the kaitiaki, toa or guardians of mātauranga Māori positions within the process of ethical review.

Tika

Tika encapsulates concepts of just, fair, truth, genuine, sincere and right. When used in an active sense, the word tika becomes *tikanga* and refers to doing the right thing, in a given context, with sincerity and honesty. An understanding of *kawa* helps to further explain the conceptual implications of tikanga. Kawa is an ancient set of precedents, it is a blueprint or rule-book for decision-making about what is appropriate and right. Kawa identifies the kaupapa for which tikanga are needed but tikanga is the customisation and application of kawa to meet the requirements of normal, everyday life. Tikanga is kaupapa-driven, it provides a mechanism for the transmission and protection of Māori values, worldviews and beliefs but continually changes and evolves as old rules are applied to new situations.

Within the context of ethical review, *Te Tauranga Waka* asks Māori to identify the tikanga that are needed to ensure and enable kaitiakitanga. From consideration of the current system for reporting and review, a number of gaps in the information gathering process can easily be identified. Systematic collection and integration of this information would clearly reduce the burden of Māori representation, advance the opportunities to generate knowledge and improve Māori capacity for kaitiakitanga. Indeed, appropriate data collection is a fundamental tikanga for Māori engaged in decision-making about human participation in clinical trials, radical new technologies and the manipulation or banking of human genes.

From a kaitiakitanga perspective, Māori have an interest in any information that improves the quality of representation and knowledge-generation processes. From a governance perspective, however, it is clearly important to build on existing systems and be mindful of administrative workloads or costs that may be created by change to current procedure. Before attempting to implement change, key parties would need to reach a mutually beneficial compromise about the most efficient and effective strategies. In some instances, for example, the implementation of tikanga may simply involve development and use of standardised templates, tick boxes or rating scales to collect data. The remainder of this section considers how the data collection systems associated with representation, progress/end of study reports and annual reports could be improved.

Representation

Māori ethics committee members, alongwith their respective colleagues, can lack basic knowledge about the opportunities for representation in their region. There is a need, therefore, to gather background material about current levels of participation and mechanisms for further engagement. The gathering of this material would probably need specific funding but the outcomes would provide a valuable resource and training tool for ethics committee members. This information would need to be updated regularly but will provide a mechanism for identifying strengths and weaknesses in regional or national processes and, thereby, highlight priorities for improvement or change. The following table identifies some of the gaps in current knowledge about Māori representation.

	Mana Whenua / Tangata Whenua	Institution-based group (DHB/University)	Other consultation group (eg Mataawaka)	Health professionals (eg ECART counsellors)
Who are they				
Expertise/key interest areas				
Level of engagement in selection of Māori EC members				
Level of participation in consultation process				
Use of evaluation techniques eg risk assessment tool, checklist				
Relationships with other groups eg DHB representative				
Current process for feedback, discussion, reporting				
Capacity to engage in consultation, eg time, resources, expertise				
Willingness to engage with ethics committee				

Table 2: Background information on opportunities for Māori representation

In addition to awareness of the opportunities for representation, there is a need to gather information about the nature of responses to cultural issues, within the process of ethical review. Although ECART and HDECs have different approaches, both systems collect information about the perceived impact of research on Māori and way in which Māori issues, including the Treaty of Waitangi, have been addressed¹⁹. The HDEC system also requires evidence of consultation. This information is meant to inform the decision-making process but Māori EC members regularly complain about the quality of responses, precedence given to other ethical principles, need for consistency across committees and inability to integrate collective Māori views. To ensure researchers address relevant cultural issues within their applications for ethical review, the Lower South Regional Ethics

¹⁹ fully explained above

Committee (LSREC) have worked with mana whenua to develop a 10-point checklist²⁰. This checklist helps LSREC to identify the applications that do not meet minimum requirements and should be deferred or declined²¹.

As a tikanga for ethical review, *Te Tauranga Waka* suggests the systematic collection of data about the quality of responses to Māori cultural issues is an integral component of the decision-making process. A checklist approach will not only help to identify the applications that fail to meet the minimum standards for cultural review but also highlight the exemplars, or examples, of good and best practice. The development of such a tool will greatly assist the decision-making process, ensure consistency across committees, reduce the burden of Māori representation and enable the measurement of progress towards addressing Māori issues defined within the Operation Standard. It would also provide benchmarks for comparing the decision-making rationale of an ethics committees against those which may operate in consultation groups. In this way, therefore, key differences in the process of representation within ECs and consultation groups would be identified.

Given the requirement for Māori EC members to have specific knowledge and awareness of Māori cultural issues, there is an implicit expectation the Māori members, on respective EC committees, will take an active role, and interest, in the review of responses to Māori cultural issues. Māori EC members can struggle with this responsibility. The development of a checklist approach to the assessment of cultural responses will help to clarify, and define, the particular role and function of Māori EC members as well as the objectives of cultural review. Although it is not envisaged Māori EC members will always have sole responsibility for the review of Māori issues²² this may be necessary, in the first instance, while the process of using a checklist is being established and non-Māori members develop the relevant skills. Irrespective of who does the review, the use of a standardised, consistent approach will give Māori representatives a reliable mechanism, and associated mana, to uphold cultural responsibility, above other principles if needed, and recommend appropriate courses of action such as amendment of the PIS or the need for further consultation.

Table 3 aims to assist thinking about possible variables, or indicators, that could be included in a checklist approach to the ethical review of cultural issues. This table is drawn from the Operation Standard and relevant sections of the ECART and HDEC applications forms. It shows the mere consolidation of information about Māori issues would provide a template, and valuable mechanism, for collection of data about:

- ☐ the types of consultation that occur with Māori;
- ☐ the nature of Māori participation in research;
- ☐ research design including the use of culturally appropriate protocols;
- ☐ the impacts and benefits for Māori including relevance to Treaty of Waitangi;

²⁰ personal communication, Dr Khyla Russell on 12 March 2009

²¹ LSREC members receive training on how to utilise the checklist/consider cultural issues.

²² The Operation Standard for Ethical Review reflects the Treaty of Waitangi principle that responsibility for the protection of Māori is shared by Māori and Pākehā (non-Māori) members.

- ☐ appropriateness of the Participant Information Sheet;
- ☐ nature of consent, and
- ☐ intended process for feedback and reporting to Māori.

	not addressed	Minimum requirements	Good practice	Best practice
consultation with Māori <ul style="list-style-type: none"> <input type="checkbox"/> Mana whenua <input type="checkbox"/> institution-based group (eg DHB/University/Crown) <input type="checkbox"/> other group eg mataawaka, Māori collectives <input type="checkbox"/> health professional (Māori) <input type="checkbox"/> health professional (non-Māori) 				
Māori participation <ul style="list-style-type: none"> <input type="checkbox"/> as participants <input type="checkbox"/> in research design/data collection/analysis <input type="checkbox"/> as collaborators eg governance/reporting role <input type="checkbox"/> partnership, ie equal responsibility 				
Research design <ul style="list-style-type: none"> <input type="checkbox"/> mainstream <input type="checkbox"/> Māori centred <input type="checkbox"/> Kaupapa Māori 				
clearly identifies impact for Māori (eg risks, benefits, relevance to Māori health goals)				
addresses cultural issues (eg values, world-view)				
explains relevance to Treaty of Waitangi				
use of culturally appropriate protocols (eg koha, kaumatua, kanohe kitea)				
Participant Information Sheet <ul style="list-style-type: none"> <input type="checkbox"/> clearly written for Māori <input type="checkbox"/> explains requirements for informed consent <input type="checkbox"/> includes Mātauranga Māori <input type="checkbox"/> contains consensus statements eg Māori risk 				
Consent form <ul style="list-style-type: none"> <input type="checkbox"/> seeks individual consent <input type="checkbox"/> provides opportunity for collective consent <input type="checkbox"/> provides opportunity for oral consent <input type="checkbox"/> seeks to waive/delay consent <input type="checkbox"/> seeks consent for future access to tissues/samples/data 				
Expected Outcomes <ul style="list-style-type: none"> <input type="checkbox"/> health benefits <input type="checkbox"/> Māori workforce development <input type="checkbox"/> mātauranga Māori <input type="checkbox"/> intellectual property <input type="checkbox"/> commercial partnership/assets 				

identifies process for reporting/feedback to Māori				
<input type="checkbox"/> participants				
<input type="checkbox"/> consultation groups				
<input type="checkbox"/> wider dissemination				

Table 3: Checklist for EC review of responses to cultural issues

Progress/End of Study Reports

Progress and end of study reports provide the only opportunity to gather information about ethical review *from a researcher's perspective*. Under the HDEC system, for example, researchers are asked to provide information about the number of participants recruited, changes in the methodology, whether findings have been reported and their experience of ethical issues or problems. This information is submitted to the administrator and normally filed, without consideration by the committee, unless problems have arisen. None of this information is collated in annual reports. From a kaitiakitanga perspective, there is a need for tikanga that ensure the collection and reporting of any data which may help to assist understanding of Māori issues. The progress and end of study reports provide opportunities to collect information that is grounded in the researcher's experience of:

- ☐ recruitment, eg the proposed number/proportion of Māori participants versus the actual number/proportion of Māori participants recruited;
- ☐ Māori methodologies, eg were they effective, ineffective or adequate;
- ☐ other Māori issues, eg difficulties with ethical approval;
- ☐ the outcomes of this research for Māori, ie benefits, risks, achievements;
- ☐ whether the research produced intellectual or commercial property.

Annual Reports

Chairs have the opportunity to comment on particular issues for their committee but the main purpose of annual reports, for HDECs and ECART, is to collate existing information rather than introduce new material. Mechanisms which enable the collection of data that is of interest to Māori must, therefore, be incorporated within the routine administration process for each committee.

The reporting template, for both committees, generally aims to collate information about committee membership, meeting dates, attendance and training, terms of reference and the outcomes of decision-making. Although HDECs and ECART must also describe the applications they receive, there are notable differences in the information that is reported. In addition to the cultural issues mentioned above, HDECs report the number of applications and process for review such as approval by full committee or expedited review under chairperson's delegation. The HDEC report also lists each application separately with the project key, full title, primary investigator, review date, outcome, date of approval, why it was deferred or declined, locality organisation, sponsor or funder and consultation group.

By comparison, the ECART report does not contain information about responses to cultural issues nor the clinical and non-clinical trials they approve but each procedure is listed

alongwith the dates of review, decision, date treatment commenced and additional comments, such as whether treatment was successful. In response to Māori concerns about the protection of whakapapa, ECART report the ethnicity of recipients and donors who have taken part in fertility treatments over the last two years. They also list the total number and type of applications approved since 1998. From the ECART report, therefore, the reader can quickly see how Māori are engaging with fertility treatments and how many applications have been approved for surrogacy, innovative treatment, within-family gamete donation, embryo donation, use of sperm from a deceased man and clinical or non-clinical research. In the last 10 years, for example, 79 percent of 154 approved applications have been for surrogacy and innovative treatment; approvals for surrogacy and within-family gamete donation have increased four-to-six-fold since 2005 and 9 percent of those involved with these latter treatments are Māori.

Ongoing refinement of the tikanga for annual reporting is necessary to not only improve or remove ineffective items but also ensure the collation of information that is meaningful for Māori. In this regard, there is an urgent need for ECART to report the content of responses to cultural issues. Although the HDEC template does attempt to collate this information, at least two of seven items designed to report on cultural issues do not seem to be working effectively. In particular, HDECs are currently required to report the number of applications deferred because HRC Guidelines for Researchers on Health Research Involving Māori (HRC, 2008) were not read. Throughout 2006-2007 no applications were deferred for this reason. This item, therefore, does not provide useable information and should be refined or removed. Similarly, HDECs are currently required to report the cases, or number, of unsatisfactory reasons for not including Māori in research. Although informal discussions within and among HDEC members suggest otherwise²³, the annual reports for 2006-2007 suggest HDECs are always satisfied with the reasons given. This is simply not true. This item, therefore, should be re-written to ensure the information captured is relevant, meaningful and useful.

From a kaitiakitanga perspective, the annual report provides an opportunity to consolidate information that is particularly important for Māori. This opportunity is worthless, however, unless the right information is routinely collected by each committee. There is an urgent need for mechanisms which enable Māori to participate in decision-making about the data that is collected and reported within the HDEC and ECART process.

At the very least, Māori have repeatedly called for information about Māori participation in high risk studies, particularly those involving highly invasive technologies, tissue banking and the collection or manipulation of genetic material. In this regard, a recent informal review suggests reason for considerable concern²⁴. Of the studies approved by NXC during 2005-2007, for example, roughly a third of those considered by the full committee, that is at least 131 projects, involved the collection of human tissues, genes or body samples with researchers seeking consent for future use.

²³ see minutes of discussions among Māori EC members attending Pūtaiora Hui.

²⁴ informal review of agenda, minutes and papers for meetings attended by Stephanie Palmer

Building on the ECART process of collating ethnicity data and the types of projects approved, it would be possible to compile an annual reporting table which presents information about Māori participation in high risk studies. For example, Table 4 presents a template for collecting data about the number of Māori participating in clinical trials, gene studies, innovative technologies and fertility treatments alongwith information about the nature of consent, storage of samples, intentions for future use and storage location. For context purposes, it would be useful to have corresponding information about the applicants or particular project key.

	consented	refused consent	consent waived	project key	storage location	how long samples are retained
clinical trial						
gene study						
innovative technology/treatment						
xenotransplantation						
fertility treatment						
access to data						
access to stored tissue/samples						
banking/storage of body samples <input type="checkbox"/> genes <input type="checkbox"/> fluids <input type="checkbox"/> tissues						
samples sent off-shore						
future use						
destruction certificate						
future contact for consent						

Table 4: Applicant/location details and number of Māori participants

Tables 2 and 3 above, provide examples of additional information that could also be collated within the annual report. This information is not only meaningful for Māori but would also inform progress towards the achievement of objectives outlined within the Operation Standard for Ethics Committees.

The tables and templates presented in this section would need review and refinement by Māori before being incorporated within the administrative or reporting processes of an ethics committees. Other strands of data, such as the outcomes of audit or newly introduced appeals may also be relevant to include. In this regard, Te Tauranga Waka

merely aims to stimulate Māori thinking about the tikanga needed to inform kaitiakitanga within the process of review.

Whakapapa

Everything has a whakapapa which explains the reason and purpose for being. Whakapapa is an analytical tool for not only understanding why we exist but also monitoring progress through various stages of growth and development ... *mai i te whai ao ki te ao mārama*. Whakapapa records the journey, the rationale for establishment, it is layer upon layer of information, to track every nuance and change, it describes why relationships are formed, what they aim to achieve, how they are nourished or supported, the impacts of interaction, whether aspirations are achieved. Whakapapa provides a framework for gathering, organising and making sense of information, it is the weaving together of information to generate knowledge, understanding, wisdom.

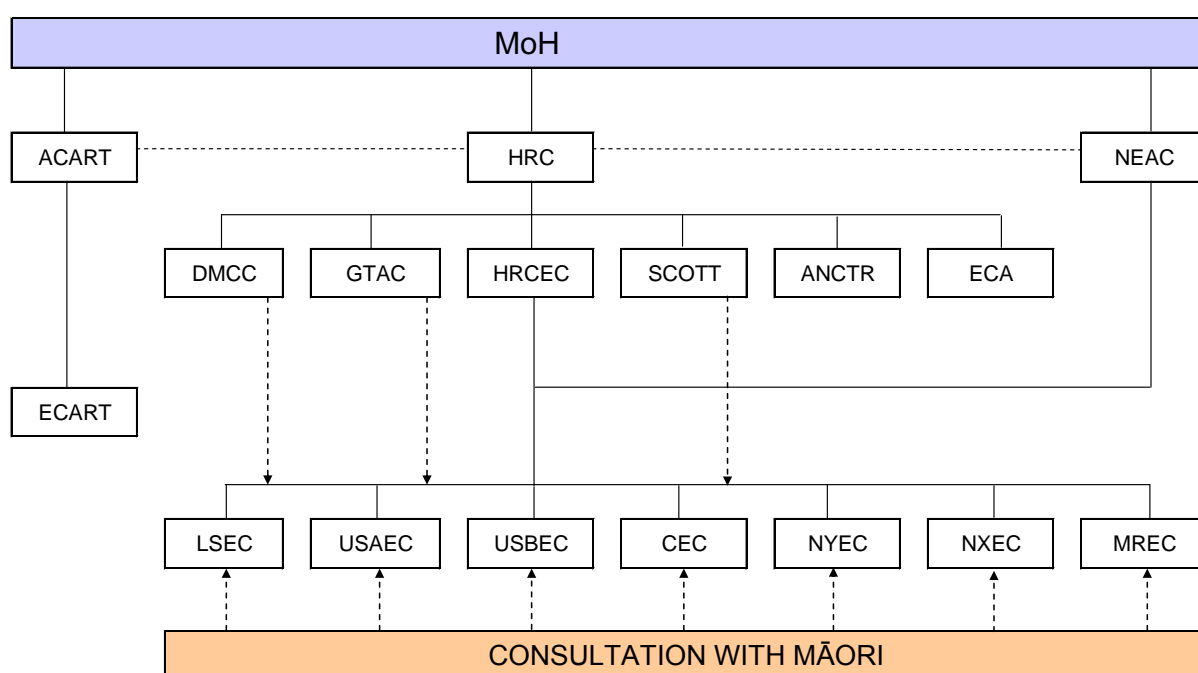


Figure 1: Overview of system for ethical review

Within the context of ethical review, whakapapa refers to the generation of knowledge about kaitiakitanga. In this regard, the capacity for kaitiakitanga relies utterly and completely on the integrity, and quality, of systems for gathering and processing information. In the generation of knowledge about kaitiakitanga, Māori must be actively and pro-actively engaged in the weaving together of information gathered through data collection and reporting. Whakapapa is the process of analysis, the creation of mātauranga Māori, the establishment of a platform for knowing and understanding, it is the pathway that will lead to kaitiakitanga.

Figure 1 presents an overview of New Zealand's system for ethical review. Each committee is governed by their own terms of reference alongwith statutory, policy and procedural obligations including consultation with Māori and the principles of ethical review. Beneath this complex arrangement of information-generating mechanisms further opportunities for understanding Māori ethical issues can be found within respective committee minutes and annual reports alongwith the content of various application forms and progress or end-of-study reports. Additional information about Māori ethical issues can also be obtained from

public submission processes as well as formal and informal discussion forums such as Pūtaiora or Hui Whakapiripiri.

The introduction of whakapapa, as an analytical platform for promotion of kaitiakitanga, raises a number of questions about the current process of ethical review, namely:

- *who* is consolidating, integrating or weaving together the various strands of Māori relevant information that is generated within and across the system of ethical review?²⁵
- *how* is this process nourished, supported and acknowledged?
- *what* are the mechanisms for ensuring kaitiakitanga is integrated into the system for decision-making about ethical review?

For some time, Māori have been debating possible solutions to these core issues. At the 9th Global Forum on Bioethics in Research (2008)²⁶, Professor Mason Durie articulated long-held views when he advocated the establishment of a Māori Advisory Committee or Māori Commissioner or National Māori Ethics Committee or simply the appointment of Māori leaders as the guardians of Māori process and data within the system of ethical review. Among the roles proposed for this group, Professor Durie highlighted the importance of:

- an interface between Māori custom, science and the environment;
- demonstrating the benefits of Māori participation in research, ie - that this not only does no harm but actually does some good;
- addressing the wider ethics of eco-connectedness including the protection of indigeneity, the unique characteristics of species and synergistic relationships between people and the natural world²⁷;
- clarifying and improving the processes of Māori engagement and representation;
- empowering Māori capacity for authority, guardianship and capability.

In accordance with these themes, *Te Tauranga Waka* has identified the need for *tikanga* to *whakamana*, or empower, the representation process as well as improve the collection and reporting of data. The development and implementation of these fundamental tikanga will strengthen and advance the opportunities for *whakapapa*, in which Māori weave together relevant strands of information to generate knowledge about kaitiakitanga. Indeed, Māori as well as those concerned with implementing the Operating Standard, and system of ethical review, have an obvious, common interest in a range of themes, including:

²⁵ in 2007, for example, some HDECs returned almost half of their applications because consultation was insufficient or inappropriate (see HDEC Annual Reports, 2007). Nobody is collating or monitoring this information under the current system of ethical review.

²⁶ Durie, M (2008). *Bioethics in Research: the Ethics of Indigeneity*. Paper presented at the 9th Global Forum on Bioethics in Research. 3-5 December 2008: Stamford Plaza, Auckland.

²⁷ Country Calendar recently presented a documentary which showed that genetic engineering of fruit and vegetable seeds has irrevocably reduced the nutritional value of our foods – who is monitoring the impact of manipulating human genes? (TVNZ, 14 March 2009)

- the quality of consultation with Māori, eg level of involvement, capacity to engage, role of mana whenua and institution-based committees, consistency or diversity of opinion and position, effective mechanisms for dissemination;
- how to reduce the burden of Māori representation for EC members, researchers and consultation groups through, for example, the introduction of reliable checklists and evaluation tools or PIS consensus statements to reflect mātauranga Māori views and aspirations;
- consolidation of information about Māori ethical issues, such as:
 - the level of Māori participation in research and research design, eg as participants, investigators, collaborators or partners
 - use of Māori methodologies, Treaty principles and culturally appropriate protocols
 - the nature of consent for Māori participation, eg are the consent forms written in a language Māori understand? do Māori prefer individual, collective, oral consent? was consent waived? do researchers seek consent for future use?
 - the number of Māori participating in high-risk projects, eg gene studies, innovative technology, xenotransplantation, tissue banking
 - the reliability and trustworthiness of researchers and sponsors
- the actual outcomes of Māori participation particularly the benefits, ownership of intellectual property and development of commercial partnerships or assets
- effective processes for feedback, reporting and dissemination to Māori
- researchers' experience of Māori issues such as the process of gaining ethical approval, recruitment of Māori participants and the use of Māori methodologies.

The recognition of whakapapa as an analytical tool for knowledge-generation will hold numerous advantages for Māori engaged in the current system of ethical review. In the first instance, the responsibility for this function will need to be delegated. Whether this takes the form of a Commissioner or Advisory Group or yet another committee, the mere delegation of this function will give *Te Tauranga Waka* a rangatira, or the leadership and support processes needed to enable a fruitful search for kaitiakitanga. Those responsible for whakapapa will engage in the consolidation, analysis and reporting of Māori data, they will actively establish a knowledge-base to inform decision-making about kaitiakitanga. This analysis and gathering of knowledge will help to empower, unite and whakamana Māori representatives, particularly consultation groups and EC members, who are the kaitiaki, or guardians, of Māori positions within the process of ethical review. It will also provide a foundation for recommending tikanga or improvements to current practice and systems. More importantly, however, those who have the whakapapa will be in a position to meaningfully consider, respond to, and provide leadership on, the wider, more complex ethical issues that can overwhelm the achievement of Māori aspirations.

*“E mea ana koe, kua oti i ngā tohunga Pākehā te hahae i te kahu o te Ao? E taea e rātou te tuitui? Nā, koia tēnā te mate o te whāngai i ngā mātauranga tapu ki ngā tūtūā, ka tūkinotia ia rātou.” nā Māori Marsden in Royal, C (eds) *The Woven Universe* (2003).*

Key Actions & Recommendations

empower the representation process!

gather and report data that is relevant and meaningful for Māori!

invest in the generation of knowledge about kaitiakitanga!

1. Peer-review²⁸ with a focus on:
 - the content, direction and recommended projects (outlined below);
 - identifying the gaps and additional points for consideration;
 - considering the need to invest in improvement of the symbol, the actual waka;
 - the value of publication, specifically (a) whether the compilation, or merging, of a document containing Te Tauranga Waka, Te Aratika and the historical overview of ethics systems for Māori, and (b) whether the image of Te Tauranga Waka could be improved, ie is investment in graphic design needed.
2. Whakapapa
 - invest in development and implementation of a strategy for establishment of a Māori Ethics Commission.
3. Tikanga
 - recommend immediate amendment of cultural questions in annual reporting template (in progress)
 - invest in validation and piloting of tikanga templates and checklists for data collection, monitoring and improvement of quality
4. Mana
 - invest in the development of a resource which helps EC members to understand the opportunities for consultation/representation, both within their region and nationally (eg begin with one EC, gather the data identified in Table 3, pilot usefulness of the resource for that EC)
 - invest in process (eg hui, korero) to (a) raise awareness, clarify, gather consensus on the meaning of consultation and consent for Māori whānau, hapū, iwi, communities; (b) develop resource for dissemination amongst whānau, hapū, iwi.

²⁸ Moana Jackson, Mason Durie, Aroha Mead, Jessika Hutchings and Angeline Grensill have the skills and expertise needed for peer-review of Te Tauranga Waka.