



National Ethics Advisory Committee

Kāhui Matatika o te Motu

National Ethics Advisory Committee

NEAC Analysis – Clinical Trials

14 September 2010

Introduction

1. The Health Committee is currently conducting an 'Inquiry into Improving New Zealand's Environment to Support Innovation through Clinical Trials'. Set out below is a NEAC Analysis and recommendations on three of the five points of focus of the current Health Committee Inquiry:
 - streamlined ethics approvals systems (paragraphs 10 - 40)
 - benefit to New Zealand patients through clinical trials (paragraphs 41 – 57)
 - removal of unnecessary barriers to clinical trials conduct (paragraphs 58 – 66).

This NEAC Analysis concludes with recommendations (paragraph 67).

Clinical trials

2. A clinical trial is a kind of intervention study that assigns human beings to receive health-related interventions (e.g. medicines, procedures, preventive care) to assess the safety and/or benefit of these interventions for patients. Clinical trials contrast with observational studies which observe individuals or analyse their health data, and tissue studies which confine their focus to tissue samples from individuals.
3. Some clinical trials are investigator-driven, others are industry-driven.
 - Investigator-driven clinical trials are designed and conducted by investigators, often through co-operative trials group structures (e.g. the Australasian Gastro-Intestinal Trials Group). Driven by clinician-investigators, these trials tend to address questions about healthcare that are of particular interest to New Zealanders.
 - Industry-driven clinical trials respond mainly to international imperatives. This is because the clinical trials industry is mainly based in countries with larger markets than ours. Many questions addressed by industry-driven clinical trials are also important to New Zealand patients.

Fostering well-designed clinical trials

4. Clinical trials aim to make healthcare safer and more beneficial for patients, by producing the best evidence about the effects of healthcare that is trialled. The enormous advances in healthcare over the last sixty years are due in large part to the unique power of clinical trials to generate reliable answers to previously unanswered questions about life-or-death treatment decisions (e.g. Doll R., 'Controlled trials: the 1948 watershed', *British Medical Journal* 1998; 317: 1217-20).

5. In general, it is at least as safe and beneficial for patients – because it is more systematically planned, delivered, monitored and followed up – to receive both established and novel healthcare in a clinical trial rather than outside any clinical trial (e.g. Vist G. et al, 'Systematic review to determine whether participation in a trial influences outcome' *British Medical Journal* 2005; 330: 1175-81).
6. Clinical trials can bring new treatments to patients in a more timely way, because they sort out the treatment logistics during the trial phase.
7. In general, healthcare organisations that are active in clinical research are good for patient care, and they attract and retain key clinical staff (e.g. Majumdar S. et al, 'Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials', *Archives of Internal Medicine* 2008; 168(6): 657-62).
8. Only a small proportion of the clinical trials conducted in New Zealand is funded by public bodies such as the Health Research Council. There are relatively few of these 'public good trials' because clinical trials tend to be very expensive, especially in relation to the limited size of the public research funds.
9. For the reasons given in paragraphs 4 - 7 above, NEAC's Ethical Guidelines for Intervention Studies ('NEAC Guidelines') state: 'Organisations that provide health care and disability support should foster high-quality intervention studies, because these contribute both directly and indirectly to service safety and quality' (paragraph 3.5). This NEAC statement is consequently a 'nationally consistent ethical standard' for clinical trials, for purposes of section 16 of the New Zealand Public Health and Disability Act 2000.

Streamlined ethics approvals systems

10. This section:
 - gives background information about the ethics committee system in New Zealand
 - outlines researchers' established ethical responsibilities
 - recommends reform of ethics committees.
11. NEAC's recommendations on these issues are summarised in paragraph 19.

Background: the ethics committee system in New Zealand

12. National and international regulatory systems require each clinical trial to be approved by an ethics committee or equivalent body. New Zealand has a mix of publicly funded ethics committees established under statute; and 'institutional' ethics committees established by universities, private industry and other research organisations. This means our ethics committee system is in significant ways cross-sectoral, spanning the publicly funded health and tertiary education sectors and also private industry.
13. In 2002-3, NEAC reviewed the publicly funded health and disability part of the ethics committee system. In 2004 this generated major reform. In particular: public accountability was increased by establishing health and disability ethics committees (HDECs) under statute; HDEC quality was improved by strengthening the 'non-lay' HDEC member categories; and efficiency was more than doubled by replacing multiple HDEC review with 'one study, one review', reducing the numbers of HDECs by more than one-half.
14. NEAC considers that New Zealand's HDEC system is good by international standards. By contrast, for example, Australia's ethics committee system still includes multiple ethics committee review.
15. Any further reform of New Zealand's HDEC system should adhere to the international standard that each ethics committee 'must be independent of the researcher, the sponsor and any other undue influence' (*Declaration of Helsinki* 1964/2008, 15). At the same time, exaggerated understandings of what is involved in the 'independence' of ethics committees are not good grounds on which to resist reform.

Researchers' ethical responsibilities

16. Significant de-professionalisation of research ethics has coincided with the spread of ethics committees from the 1970s onward. NEAC work (e.g. *Ethical Guidelines for Intervention Studies* 2009 and *Ethical Guidelines for Observational Studies* 2006) has begun to reverse this in New Zealand, by re-directing guidance primarily to researchers, on the grounds that they have primary responsibility to address the ethical issues in the studies they perform.

17. Even so, many researchers still use the word 'ethics' to refer to external compliance with ethics committees, rather than to invoke their own internal sense of their professional responsibilities.
18. There are ongoing opportunities for researchers themselves, the Ministry of Health, NEAC, and the Health Research Council, to take the ethical professionalism of researchers more seriously. For example, there is a need to involve researchers more fully as partners in developing research ethics arrangements. Acting on this basis is also consistent with the Government's emphasis on clinical leadership.

Reform of ethics committees

19. NEAC recommends further reform of the HDEC system, as outlined below:
 - i. restructure HDECs and revise HDEC member categories, based on study type (e.g. clinical trials, other types of study)
 - ii. revise the National Application Form for HDEC approval, based on study type
 - iii. centralise at national level the process of applying to HDECs
 - iv. review locality assessment process
 - v. review Māori consultation process
 - vi. introduce pre-review of all applications to HDECs
 - vii. review and streamline the *Operational Standard for Ethics Committees*
 - viii. consider the longer-run options for 'hosting' of HDECs
 - ix. review the cross-sectoral ethics committee arrangements
 - x. implement the remaining accepted recommendation from the 2003 NEAC review of HDECs.

Restructure HDECs based on study type

20. NEAC recommends re-structuring the jurisdiction of HDECs on the basis of study type, with some HDECs to review just clinical trials and the others to review only the other kinds of study (e.g. epidemiological studies, tissue studies). The purpose of this recommendation is to improve the quality and efficiency of HDEC review, and to improve recruitment and retention of HDEC members – especially the professional or 'non-lay' members whose time is not best spent reviewing kinds of study on which they have no specific expertise.
21. An analysis of current and projected HDEC workload would be needed to determine appropriate numbers of the two re-designed types of HDECs. Refinement of the member categories for the two different sorts of HDEC would also be needed. A study-based HDEC system would replace the current region-based system. Eight years of NEAC work on research ethics have demonstrated that the ethical issues depend on the nature of the study, not on the region the applicant lives in.

Revise HDEC National Application Form based on study type

22. NEAC recommends that the National Application Form for HDECs be reviewed, to base it too on study type. The purpose is to improve HDEC quality and efficiency.

Centralise at national level the process of applying to HDECs

23. NEAC recommends: centralising the process of applying to HDECs, to replace the current region-based application process; spreading the monthly meetings of HDECs evenly through the month; and offering each applicant review by the appropriate sort of HDEC that has the next free agenda space. Such a system has worked very well in England for many years. The purpose is to improve efficiency of HDEC review – especially to reduce the time that HDEC review takes.

Review locality assessment process

24. NEAC recommends review of the ‘locality assessment’ process, to ensure it still adds value-for-money to the HDEC system and is time-efficient. For example, issues can arise over the timeliness and consistency of locality assessments for studies conducted at multiple sites; and other challenges arise when there is no locality organisation that is independent from the investigator(s) whose application is being assessed. The locality assessment process was introduced in accordance with the 2003 NEAC review of HDECs, because many in the sector believed there were important ‘local’ issues to address in studies.

Review Māori consultation process

25. NEAC recommends review of the Māori consultation process, to ensure it still adds value-for-money to the HDEC system and is time-efficient. Aspects of consultation with Māori have developed progressively over time. There would be benefit in reviewing the purposes of these processes and their overall fitness to meet those purposes.

Introduce pre-review of all applications to HDECs

26. NEAC recommends that, as part of its analytical support function, Ministry of Health staff pre-review each application to an HDEC. Such pre-review would address matters of low ethical significance that might otherwise waste HDEC time. It would also help identify ethically significant matters recommended for particular HDEC consideration. This would assist HDECs to do their work more effectively and efficiently, and would reduce bureaucracy. It is also consistent with the internationally established principle of ethics committee independence – see paragraph 15.

Review and streamline the Operational Standard

27. NEAC recommends review and streamlining of the Ministry of Health's *Operational Standard for Ethics Committees*. This would make it fit better its modest role as a set of addenda to the HDEC Terms of Reference, and would reduce overlap between this document and other established research ethics standards.

Consider the longer-run options for 'hosting' of HDECs

28. HDECs are established under section 11 of the New Zealand Public Health and Disability Act 2000. This makes them ministerial committees, with terms of reference and member appointments from the Minister, and support provided by the Ministry of Health. This 'hosting' arrangement for HDECs was established in 2004 on NEAC recommendation. Due to fact that the findings and recommendations of the 2001 Gisborne Inquiry were critical of HDECs, these committees were of interest to the then Minister of Health.
29. One alternative to Minister/Ministry hosting of HDECs would be Health Research Council (HRC) hosting. The HRC has responsibilities under the Health Research Council Act 1990 to advance knowledge by fostering high quality health research and to ensure that research meets established ethical standards. The HRC also has extensive practical experience with ethics committee matters.
30. Another alternative hosting for HDECs would be with the office of the Health and Disability Commissioner (HDC). The HDC has responsibilities under the Health and Disability Commissioner Act 1994 to advance the rights of health and disability consumers, including research participants. The HDC does not have any specific statutory responsibility to advance knowledge by fostering research, and has limited practical experience with ethics committee matters.
31. NEAC does not at present have any particular view as to the best hosting arrangement for HDECs in the medium-to-long term. In the shorter-term, NEAC's view is that the current hosting by Minister/Ministry functions well.

Review the cross-sectoral ethics committee arrangements

32. As noted earlier (paragraph 12), New Zealand has a mix of publicly funded ethics committees established under statute (HDECs); and 'institutional' ethics committees (IECs) established by universities, private industry and other research organisations. This makes the ethics committee system significantly cross-sectoral, spanning health and tertiary education sectors, and also makes it a mix of the public and private sectors.
33. Standards for New Zealand's ethics committee system are set mainly through the health sector. Some standards are set by the Minister of Health (e.g. Terms of Reference for HDECs), others by the Ministry of Health (e.g. Operational Standard for Ethics Committees), others by NEAC (e.g. Ethical Guidelines for Intervention Studies), and others by the HRC (e.g. Guidelines for Researchers on Health Research Involving Māori). In addition, further standards for each IEC are set by its parent institution. The sectors of tertiary

education; and research, science and technology, also have interests in ethics committee arrangements.

34. Overall, there is significant potential for the many sources of ethics committee standards and accountabilities to produce overlaps, inconsistencies, and related practical issues.
35. It is perhaps an exaggeration to call the current cross-sectoral arrangements for ethics committees a 'system'. As far as NEAC is aware, these cross-sectoral arrangements have never been reviewed.
36. NEAC considers that there would be merit in reviewing aspects of the cross-sectoral ethics committee arrangements, for example:
 - is it appropriate to charge some or all applicants for ethics committee review on a cost-recovery basis?
 - what mix of HDECs and institutional ethics committees (both public and private sector) should be allowed or encouraged?
 - should the emergence of ethics committees that are established by stand-alone businesses or trusts be allowed, or even encouraged? (Note: In 2008, an application was made to the Health Research Council Ethics Committee seeking its approval of such a body.)
 - are there any ethical standards or ethics committee review processes that apply already to health research, that should be applied also to other sorts of research (e.g. to social science research, or to research to inform central government agencies' policy advice)?
 - is the plurality of functions that various public agencies (e.g. Ministry of Health, NEAC, HRC) have to set standards for researchers and for ethics committees sufficiently clear and coherent overall?
37. NEAC recommends review of the cross-sectoral ethics committee arrangements.

Implement remaining NEAC 2003 recommendation

38. All recommendations of the thorough 2003 NEAC review were accepted in 2004, but six years later one of them has not been fully implemented. It is outlined below.
39. The 2003 NEAC review generated 'GO DO', '**G**oals, **O**bjectives and **D**esired **O**utcomes' for the Ethical Review System (attached as Appendix One), as an 'established ethical standard' under statute. The response has been limited. There remains an opportunity for the Ministry of Health, in consultation with HDECs, to develop performance measures based on GO DO, and for HDECs to begin reporting their performance on these measures in their annual reporting to the Minister of Health.
40. NEAC recommends implementation of the remaining accepted recommendation from the 2003 NEAC review of health and disability ethics committees (HDECs).

Benefit to New Zealand patients through clinical trials

41. This section covers:

- appropriate protections for participants in clinical trials
- compensation for treatment injury.

42. NEAC's recommendation on these issues is given in paragraph 57.

Appropriate protections for participants in clinical trials

43. Healthcare delivered through a clinical trial, like any other healthcare, has potential both for benefit and for harm to patients. The potential for benefit is discussed in paragraphs 4 - 7. The potential for harm is best minimised by focussing regulatory systems on sound research design and on free and informed participant consent. NEAC's overall view is that New Zealand's regulatory system has these features. NEAC also recommends further improvements to clinical trials regulation (see 'Streamlined ethics approvals systems' and 'Removal of unnecessary barriers to clinical trials conduct').
44. The clinicians who conduct clinical trials also care for patients who are not in any clinical trial. This generates potential for conflict of interest for clinician-investigators between their clinical trials responsibilities and their other responsibilities to patients (see NEAC Guidelines, paragraphs 4.18 – 4.23). In fostering well-designed clinical trials, clinicians and their employers must consequently maintain robust processes to ensure they give top priority to the quality of patient care, while also being mindful that the best healthcare option for some patients is to join a clinical trial.
45. There is some evidence that non-industry clinical trials are safer for patients and of higher methodological quality than industry clinical trials (e.g. Lexchin J. et al, 'Pharmaceutical industry sponsorship and research outcome and quality: systematic review', *British Medical Journal* 2003; 326: 1167-70).

Compensation for treatment injury

46. The Accident Compensation Act 2001 (AC Act) covers some treatment injuries in clinical trials. However, section 32 (6) of the AC Act specifically excludes from Accident Compensation Corporation (ACC) cover any treatment injury from any trial that is conducted 'principally for the benefit of the manufacturer or distributor of the medicine or item being trialled'.
47. NEAC understands that this statutory exclusion was motivated by fear that New Zealand might be targeted by industry seeking to conduct questionable clinical trials here and then leaving New Zealanders to bear the cost. NEAC considers that this motivation reflects a poor understanding of the clinical trials industry and an unjustifiable lack of confidence in the robustness of New Zealand's regulatory framework.

48. In 2009 NEAC completed a thorough project on the ethics of clinical trials, including sector and public consultation. This confirmed that current policy does generate significant issues about compensation for treatment injury for participants in industry-sponsored clinical trials. NEAC addressed these issues as far as its limited public powers allow by establishing, as a 'nationally consistent ethical standard' under statute, the principle of 'compensation cover for study participants to at least ACC-equivalent standard' (NEAC Guidelines, paragraph 8.4). Soon after the June 2008 publication of NEAC's discussion document on these issues, industry made a matching improvement to its own guidance (*Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting From Participation in an Industry-Sponsored Clinical Trial* (August 2008), 4.1).
49. Even given the work of NEAC, the medicines industry, and the health and disability ethics committees (HDECs), it remains difficult to meet the reasonable expectation of at least ACC-equivalent cover for participants in industry-sponsored clinical trials. One basic reason for this is that, unlike ACC, private insurance generally does not offer no-fault cover.
50. Based on its previous work, NEAC considers that section 32 (4 - 6) of the AC Act continues to generate the following issues:
 - a) by stating a statutory exclusion of participants in industry-sponsored clinical trials from ACC cover it disadvantages these people compared to all participants in all other research in New Zealand
 - b) it consequently requires researchers, ethics committees and research locality organisations (e.g. DHBs) to secure indemnity cover for study participants and researchers through private sector insurance
 - c) by requiring a researcher declaration and an ethics committee certification for every clinical trial it generates significant administrative activity for all clinical trials, including all those that are covered by ACC
 - d) because of these things it sends a negative signal about whether New Zealand welcomes conduct of clinical trials.
51. NEAC considers that the key policy question is: 'What feature of these New Zealanders justifies their statutory exclusion from ACC cover?'. NEAC considers that the statutory exclusion of participants in industry-sponsored clinical trials should continue only if a credible answer can be given to this policy question. This is because doing the right thing involves doing only what can be justified to the people to whom it is done (e.g. Thomas Scanlon, *What We Owe To Each Other*, Harvard University Press, 1998, pp. 4 – 5, 189 – 191).

52. The following two policy options would secure at least ACC-equivalent cover for participants in industry-sponsored clinical trials:
 - a) repeal of the statutory exclusion, in section 32 (4-6) of the AC Act, of participation in industry-sponsored clinical trials from ACC cover
 - b) extension of ACC cover for participation in industry-sponsored clinical trials without repealing the section 32 exclusion (e.g. by requiring industry to purchase ACC cover through payment of a levy for the clinical trials it conducts in New Zealand).
53. NEAC makes two observations about the above options. First, option a) does not in itself address the matter of industry payment of any increase in the compensation costs it might generate for ACC. But see also paragraph 56 below. Second, it is not clear that option b) can accommodate any credible answer to the key question: 'What feature of these New Zealanders justifies their statutory exclusion from ACC cover?'
54. In response to a written recommendation from chairs of HDECs that the section 32 exclusion in the AC Act be repealed, Department of Labour officials advised the Minister for ACC on 20 July 2007. They recommended against repeal, on grounds that are briefly considered below.
55. The officials argued that the current statutory ACC exclusion is justified because it does not 'overly influence international companies' choice to conduct clinical trials in New Zealand'. The underlying idea seems to be that conduct of clinical trials in New Zealand should not be encouraged.
56. The officials also argued that 'Industry should meet the costs of compensation, not the New Zealand public'. If ACC cover were to be extended to industry clinical trials, existing provisions of the AC Act could be used to ensure that this industry would meet that cost. The officials provided no evidence that this approach is impracticable. They also gave no analysis of the likely level of additional cost to ACC. NEAC understands that ACC does not systematically collect information on cost-of-claims from clinical trials; this may indicate that the costs to ACC arising from clinical trials are not significant. In addition, as noted in paragraph 5 earlier, there is evidence that it is at least as safe and beneficial for patients to receive established or novel healthcare within a clinical trial rather than outside any clinical trial. Overall, therefore, conduct of clinical trials is unlikely to produce any increase in treatment injuries.

Recommendation

57. NEAC recommends review of the current statutory exclusion of participants in industry-sponsored clinical trials from ACC compensation for treatment injury; with this review to be based on the principles that policy should be justifiable to those affected by it, and should secure at least ACC-equivalent cover for all clinical trial participants.

Removal of unnecessary barriers to clinical trials conduct

58. This section addresses two perceived barriers to clinical trials conduct:

- PHARMAC funding policies
- statutory barriers to conduct of clinical trials for patients who are incompetent to consent. NEAC's recommendation on these issues is given in paragraph 66.

PHARMAC funding policies

59. Some argue that PHARMAC funding policies are barriers to conduct of clinical trials in New Zealand. NEAC is not convinced of this. The Committee notes, for example, that the number of trials with New Zealand recruitment that were registered on the Australian and New Zealand Clinical Trials Registry rose from 88 in 2008 to 149 in 2009. This is a 68 percent increase in one year, though in part this may be due to increasing uptake of this recently established Registry.

Statutory barriers to clinical trials for patients who are incompetent to consent

60. The principle that participation in a clinical trial should be based on free and informed participant consent is firmly embedded in New Zealand statute, regulation, ethics guidance and research practice. NEAC endorses this.
61. There are three groups of potential participants in clinical trials: (a) those who are fully competent to consent, (b) those who are incompetent to consent, and (c) those who have some, but not full, competence to consent. The rest of the paragraphs in this sub-section concern people who are in group (b).
62. The appropriate emphasis on free and informed consent has unfortunately also generated barriers to conduct of clinical trials of benefit to patients who are incompetent to consent. It has done this by making it very difficult to conduct any clinical trials with this participant group. NEAC considers that review of law in this area is appropriate, to assess whether the right balance has been struck between access to clinical trials and to consequent improvement of healthcare, and protection of people whose loss of capacity makes them particularly vulnerable.
63. In general, Section 18 (1) of the Protection of Personal and Property Rights Act 1988 ('PPPR Act') disallows any welfare guardian from entering any person for whom he or she is acting in this role into a clinical trial. Some take this to imply that if not even a welfare guardian has this lawful power then no-one else has such a power either. On this interpretation, the general effect of this provision is to exclude from clinical trials those who are incompetent to consent. The anecdotal evidence – any other evidence is hard to get – is that this has inhibited conduct of clinical trials that would have been of benefit to these patient groups. Many excluded people, including the most unwell

Removal of unnecessary barriers to clinical trials conduct

emergency and intensive care patients, have vital need for the improved care that clinical research with them would bring.

64. In 2009 NEAC completed a thorough project on clinical trials, including sector and public consultation on consent to participate, and on the exclusion of those who are incompetent to consent. NEAC addressed the latter issue as far as its public powers permit, by establishing under statute in the NEAC Guidelines a 'nationally consistent ethical standard' to allow inclusion within well-designed clinical trials of those who are incompetent to consent, subject to the lawfulness of the study and the presence of strong ethical protections (NEAC Guidelines, paragraphs 6.24 – 6.29). The NEAC Guidelines will have little effect, however, if nearly all study participation by those who are incompetent to consent is unlawful.
65. More permissive interpretation of the current law is also possible. One such interpretation is that, consistent with the PPPR Act, Right 7 (4) of the Code of Health and Disability Services Consumers' Rights 1996 ('the Code') does allow, in significantly less limited circumstances than those allowed by the PPPR Act, an appropriate *health care provider* to enter into a clinical trial a person who is unable to consent. Right 7 (4) of the Code is attached to this NEAC analysis (Appendix Two).

Recommendation

66. NEAC recommends review of the current law concerning participation in clinical trials by those who lack the capacity to give free and informed consent; with this review to be based on consent to participate for all those who have the capacity, and (subject to the presence of strong ethical protections) on not necessarily excluding from clinical trials participation those who lack this capacity.

NEAC recommendations

67. The following is a summary statement of the recommendations contained in this NEAC Analysis. NEAC recommends:
- a) reform of ethics committees:
 - i. restructure HDECs and revise HDEC member categories, based on study type (e.g. clinical trials, other sorts of study)
 - ii. revise the National Application Form for HDEC approval, based on study type
 - iii. centralise at a national level the process of applying to HDECs
 - iv. review locality assessment process
 - v. review Māori consultation process
 - vi. introduce pre-review of all applications to HDECs
 - vii. review and streamline the *Operational Standard for Ethics Committees*
 - viii. consider the longer-run options for 'hosting' of HDECs
 - ix. review the cross-sectoral ethics committee arrangements
 - x. implement the remaining accepted recommendation from the 2003 NEAC review of HDECs
 - b) review of the current statutory exclusion of participants in industry-sponsored clinical trials from ACC compensation for treatment injury; with this review to be based on the principles that policy should be justifiable to those affected by it, and should secure at least ACC-equivalent cover for all clinical trial participants
 - c) review of the current law concerning participation in clinical trials by those who lack the capacity to give free and informed consent; with this review to be based on consent to participate for all those who have the capacity, and (subject to the presence of strong ethical protections) on not necessarily excluding from clinical trials those who lack this capacity.

Appendix One



The Ethical Review System

GO DO

Goals, Objectives, and Desired Outcomes

Goals
<p>Facilitate research and innovative practice that contribute to knowledge and improved health outcomes.</p> <p>Protect participants in health and disability research and innovative treatment.</p> <p>Find a balance that minimises risks and maximises benefits arising from health and disability research.</p> <p>Recognise and respect the principles of the Treaty of Waitangi by enabling Māori to contribute to the ethical review system for health and disability research.</p>

Objectives	Desired outcomes
Accountable	<p>Public accountability requirements are defined.</p> <p>Ethical reviews meet internationally recognised standards.</p> <p>Ethical reviews take into account relevant legislation.</p>
Enabling	<p>Research participants/subjects are protected.</p> <p>Quality research is facilitated.</p> <p>Review processes are clear about jurisdiction and coverage.</p> <p>Awareness of ethical practice among all stakeholders is developed.</p> <p>Good communication with affected communities is demonstrated.</p> <p>Local input is achieved.</p> <p>Positive relationships with all stakeholders are developed.</p> <p>System review mechanisms are in place.</p>
Informed	<p>Researchers consider ethical implications from the outset; for example, it is clear who will benefit from the research (participants, the public, and so on).</p> <p>The perspectives of affected communities are included.</p> <p>Review processes are proactive, attend to emerging issues, and are responsive to change over time.</p> <p>Review processes apply appropriate expertise.</p> <p>Scientific and ethical standards are considered alongside each other where appropriate.</p> <p>Decision-making is consistent.</p> <p>Review capacity and relevant expertise are maintained and developed.</p>

Objectives	Desired outcomes
Enabling of Māori participation	<p>A Māori ethical framework is developed and implemented.</p> <p>Consultation with Māori is collaborative, genuine, inclusive, and appropriate.</p> <p>Māori participation in the decision-making component of the system is facilitated.</p> <p>The potential for diversity of opinion across iwi and regions is recognised and respected.</p> <p>Māori research capability is facilitated.</p>
Fair	<p>Review processes are independent.</p> <p>Stakeholders have access to due process.</p> <p>Outcomes of processes are equitable.</p> <p>Applicants to review processes have the right of reply.</p> <p>Conflicts of interest are acknowledged and addressed.</p>
Efficient	<p>Time and resources are used productively.</p> <p>Reviews are timely.</p> <p>Sector guidance is updated regularly, with opportunity for all stakeholders to participate.</p>

GO DO is a 'nationally consistent ethical standard', determined in accordance with s.16 of the New Zealand Public Health and Disability Act 2000. For background, see *Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand* (NEAC 2003), available at www.neac.health.govt.nz

You can contact NEAC at: neac@moh.govt.nz

Appendix Two

The Code of Health and Disability Services Consumers' Rights 1996

(excerpt only)

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -

a) It is in the best interests of the consumer; and

b) Reasonable steps have been taken to ascertain the views of the consumer; and

c) Either, -

i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or

ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.