MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Clinical Trials and ACC Cover

Date:	7 August 2015	**Priority:**	Low
Security classification:	**In Confidence**	**Tracking number:**	0424 15-16

Action sought		
	Action sought	**Deadline**
Hon Nikki Kaye Minister for ACC	**Agree** not to pursue changes to extend ACC cover to industry-sponsored clinical trials at this time. **Sign** the attached letter to Hon Peter Dunne, Associate Minister of Health.	n/a

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Kathryn MacIver	Manager, Accident Compensation Policy	[04 901 3971]	s 9(2)(a)	
Ruth Isaac	Policy Director, Labour and Immigration Policy	04 916 6088	s 9(2)(a)	✓

The following departments/agencies have been consulted					
☐ Treasury	☐ MoJ	☐ NZTE	☐ MSD	☐ TEC	☐ MoE
☐ MFAT	☐ MPI	☐ MfE	☐ DIA	☐ TPK	☐ MoH
		☒ Other:	ACC		

Minister's office to complete:

☐ Approved
☐ Noted
☐ Seen
☐ See Minister's Notes
☐ Declined
☐ Needs change
☐ Overtaken by Events
☐ Withdrawn

Comments:

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Purpose

This briefing provides advice on clinical trials and ACC cover.

Recommended action

The Ministry of Business, Innovation and Employment recommends that you:

a **Agree** that extending ACC cover to industry-sponsored clinical trials is not currently a priority.

Agree / Disagree

b **Sign** the attached letter to Hon Peter Dunne, Associate Minister of Health, advising him that you support the current statutory framework for ACC cover in relation to clinical trials.

Agree / Disagree

Kathryn MacIver
Manager, Accident Compensation Policy
Labour and Immigration Policy, MBIE

07 / 08 / 15

Hon Nikki Kaye
Minister for ACC

..... / ..... / .....

Background

1. The National Ethics Advisory Committee (NEAC) has written a report to the Associate Minister of Health, Hon Peter Dunne, recommending a review of the current statutory exclusion of participants in industry-sponsored clinical trials from ACC compensation for treatment injury. NEAC recommended that its report (attached at Annex 1) be passed on to you as Minister for ACC on the grounds that this change could be considered for inclusion in a possible upcoming Accident Compensation Amendment Bill.

Current legislation & regulatory context for clinical trials

2. Section 32 of the Accident Compensation Act 2001 (the AC Act) sets out the circumstances in which a treatment injury can be covered. With reference to clinical trials, eligibility can be considered in the following circumstances:

   a. The claimant did not agree, in writing, to participate in the trial;

   b. An ethics committee approved the trial and was satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.

3. Section 32 specifically excludes from ACC cover treatment injuries arising from industry-sponsored clinical trials. This exclusion has been in place since 1992.

4. In order for clinical trials to be carried out in New Zealand, it must be approved by Medsafe (which is New Zealand's medicines and medical devices safety authority) through the Director-General of Health after advice from:

   a. the Health Research Council, through its standing committee on Therapeutic Trials; and

   b. an accredited ethics committee.

5. Both NEAC and Medicines New Zealand's[1] guidance recommend at least ACC-equivalent cover for participants in trials which are not covered by the ACC scheme.

NEAC's concerns and views

6. NEAC is concerned that the requirement for at least ACC-equivalent cover for participants is not currently provided, with recent evidence of two participants for whom timely access to compensation has not been forthcoming. The reasons for the delays in these two cases are not known.

7. NEAC accepts that the two cases suggest a failure to meet Medicines New Zealand's expectation of a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in clinical trials.

8. NEAC's view is that the current statutory exclusion:

   a. unjustifiably disadvantages these people compared to other New Zealanders, including participants in all other research and treatment in New Zealand;

   b. may affect future participation in clinical trials, and

   c. sends a negative signal about whether New Zealand welcomes the conduct of industry-sponsored clinical trials.

[1] Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines.

9. NEAC does not consider that the current exclusion is justifiable, and states that extending ACC cover would not likely increase costs to ACC for treatment injuries.

10. If the concern is that industry should meet such costs, rather than the New Zealand public, then NEAC suggests that existing provisions can be used to ensure that industry would meet that cost (by purchasing cover through ACC). However, NEAC cannot see any legitimate argument for this approach being applied only to the subset of patients involved in industry-led clinical trials (these patients being no different from other patients suffering treatment injuries in any relevant regard), and therefore prefers the option of repealing the section 32 exclusion.

Analysis

11. These issues were last considered in 2009 after NEAC raised similar concerns with the then Minister for ACC.

12. Previous analysis by MBIE and ACC concluded that industry should continue to meet the costs of compensation for trials conducted in New Zealand, and that a law change is not recommended as a response to the issues identified. This continues to be our advice.

13. Key reasons for this are as follows:

    a. The current requirement for indemnity insurance for industry-led clinical trials appears to be standard international practice – so it does not send a signal that New Zealand is hostile to clinical trials relative to other countries.

    b. It is not clear whether purchasing cover through a levy would be a practical option, nor whether any of the cases identified would in fact be covered by ACC following removal of the statutory exclusion (meaning you could end up making system level changes which have little to no impact).

    c. It would appear that the regulatory framework for the approval of clinical trials may not be sufficiently robust to ensure the welfare of participants in the event of injury, and this could be reviewed by the Minister of Health and appropriate authorities.

14. We do not agree that the *only* relevant issue for determining eligibility for ACC cover is whether these patients are any different from other patients suffering treatment injuries. Appropriate allocation of risk and incentives on researchers are also important to ensure appropriate commercial practices (ie to ensure that injury risks and costs associated with clinical trials are identified and managed appropriately by the companies undertaking the trials).

15. The Ministry of Health agrees that it seems likely that something does need to change in order to ensure participants in all clinical trials have timely access to compensation for injury. While the scale of the problem is unknown, it is likely to be low, with anecdotal evidence of up to one case per year. The Ministry of Health also agrees that further work to understand the problems with the status quo is needed and that a wider range of options can and should be explored.

Next steps

16. In our view, the action here is primarily for the Associate Minister of Health, Hon Peter Dunne – does he want to pursue further work in relation to ensuring that all participants in clinical trials receive adequate and timely compensation for injury?

17. In terms of next steps for you, we therefore recommend that you write to the Associate Minister of Health, Hon Peter Dunne, acknowledging the report and making the following points:

    a. Further legislative change to the AC Act is not on the current legislative programme, but may be considered in future years.

    b. Stating that you do not agree with NEAC about the rationale for changing the AC legislation to address this issue.

    c. Suggesting that NEAC and the Ministry of Health undertake further work in the first instance on the causes and extent of the problems occurring, and exploring options within the current regulatory regime for clinical trials to address the issues. That would put the issue on a stronger footing for any future consideration of options.

18. If you would like the option of extending ACC cover explored, then you would need to discuss with Hon Peter Dunne the commissioning of joint work by the Ministry of Health, ACC and MBIE, and agree the timing of this alongside other priorities on your respective work programmes and legislative programmes. In any case, we consider that the next step would be for NEAC and the Ministry of Health to explore more fully the gaps these cases point to in the current regulatory framework and mechanisms relating to clinical trials.

Annexes

Annex 1: Letter and report from NEAC

Annex 2: Proposed response letter to Hon Peter Dunne

Annex one: Letter and report from NEAC

neac
National Ethics Advisory Committee
Kāhui Matatika o te Motu

Report number: 20141482

21 NOV 2014

RECEIVED
27 NOV 2014
BY:

File number: AD20-69-1

Action required by: **routine**

Hon Peter Dunne (Associate Minister of Health)

National Ethics Advisory Committee (NEAC) advice on compensation for treatment injury in clinical trials

Executive summary

i. The National Ethics Advisory Committee (NEAC) is an independent advisor to the Minister of Health on ethical issues of national significance in the health and disability sector.

ii. NEAC has recently been made aware of two cases where participants in clinical trials have not yet received compensation for treatment injury that occurred in 2012. There is a risk that, if the public becomes aware of the difficulties faced by these participants, it could affect future participation in, and conduct of, clinical trials in New Zealand.

iii. These cases suggest that some companies conducting clinical trials in New Zealand may be failing to comply with NEAC's and Medicines New Zealand's guidance to provide compensation cover for study participants to at least Accident Compensation Corporation (ACC) equivalent standard, and to do so in an expeditious manner.

iv. NEAC has previously recommended, and continues to support, a review of the current statutory exclusion of participants in industry-sponsored clinical trials from ACC compensation for treatment injury, with a view to securing at least ACC-equivalent cover for all injured clinical trial participants. This would provide affected participants with prompt access to treatment, rehabilitation and, where appropriate, financial compensation to cover, for example, loss of earnings.

v. We are aware that the Ministry of Business, Innovation and Employment is undertaking work on possible amendments to the Accident Compensation Act 2001. It would be appropriate to consider the issues NEAC raises in this report as part of that work.

NEAC recommends that you:

a) **Agree** to provide a copy of this report to Hon Nikki Kaye, Minister for ACC. Yes / No

Victoria Hinson
Chair
National Ethics Advisory Committee

Minister's Signature:

Date: 25.11.2014

NEAC Contacts:

Victoria Hinson **Chair, NEAC**		Beverley Braybrook **NEAC Secretariat contact**	
Phone:	s 9(2)(a)	Phone:	s 9(2)(a)
Cellphone:		Cellphone:	

8. Medicines New Zealand[1] made a matching improvement to its own guidance, noting that compensation should be no less than would be awarded for similar injuries by New Zealand's accident compensation scheme (*Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*, 2008, paragraph 4.1).

9. NEAC's advice to researchers on providing at least ACC-equivalent cover for clinical trial participants will be revisited in 2015 as part of its review of *Ethical Guidelines for Intervention Studies*.

Previous NEAC recommendation to review current statutory exclusion

10. In 2010, NEAC provided advice to the then Minister of Health recommending a review of the current statutory exclusions of participants in industry-sponsored clinical trials from ACC compensation for treatment injury. This recommendation was part of NEAC's advice in response to the Health Select Committee's inquiry into improving New Zealand's environment to support innovation through clinical trials.

11. A copy of NEAC's original advice is appended (paragraphs 46 – 57 contain the advice on compensation for treatment injury).

Advice

12. While NEAC's and Medicines New Zealand's guidance clearly state a requirement of at least ACC-equivalent cover, the recent experience of two participants, which have been brought to the attention of NEAC, would suggest that this expectation is not being met. NEAC understands that the Ministry of Health has advised you on the details of these cases and so we only briefly outline the cases here.

13. The first case involves a male participant who took part in a trial for gout medicine in 2012. As a result of the trial treatment he suffered severe s 9(2)(a) s 9(2)(a) following the incident and to date has not received compensation.

14. The second case, which also took place in 2012, involves a male participant who took part in a diabetes trial administered by the s 9(2)(a) s 9(2)(a) Currently, there is the possibility of mediation with the clinical trial company by the end of year to reach an agreement about compensation but, at the time of writing, no date has been set.

15. NEAC notes that these two cases suggest a failure to meet Medicines New Zealand's expectation of a 'simple and expeditious procedure' in relation to the provision of compensation for injury caused by participation in clinical trials.[2] This delay in the provision of compensation means that these individuals have not been supported to access

[1] Medicines New Zealand is the industry association representing companies engaged in research, development, manufacture and marketing of prescription medicines.
[2] As noted in the preamble of the *Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial* (2008).

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National Ethics Advisory Committee

Kāhui Matatika o te Motu

National Ethics Advisory Committee

NEAC Analysis – Clinical Trials

14 September 2010

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.

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.

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

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.

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.

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.

Appendix One

National Ethics Advisory Committee
Kāhui Matatika o te Motu

The Ethical Review System

GO DO

Goals, Objectives, and Desired Outcomes

Goals
Facilitate research and innovative practice that contribute to knowledge and improved health outcomes. Protect participants in health and disability research and innovative treatment. Find a balance that minimises risks and maximises benefits arising from health and disability research. 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.

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

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.

Annex two: Proposed response letter to Hon Peter Dunne

Office of Hon Nikki Kaye

MP for Auckland Central

Minister for ACC
Minister of Civil Defence
Minister for Youth

Associate Minister of Education

Hon Peter Dunne
Associate Minister of Health
Parliament Buildings
Wellington

Dear Peter

I am writing regarding the issues raised with you by the National Ethics Advisory Committee (NEAC) relating to clinical trials and ACC cover.

NEAC was hopeful that an upcoming amendment to the Accident Compensation Act could be made to address the gaps they see in the current compensation framework for a small number of participants in industry-sponsored clinical trials. As you know, we have recently introduced the Accident Compensation (Financial Responsibility and Transparency) Amendment Bill which is implementing our priority changes to the framework for the way that ACC levies are set. At present, I do not have a further bill on the upcoming legislative programme.

I understand that ensuring adequate and timely compensation for injury is important, and would support further exploration of this issue by the Ministry of Health to understand the extent of the problem and why the current regulatory framework for clinical trials may not be working. I do not agree with NEAC, however, that the current law relating to ACC cover in the case of industry-sponsored clinical trials is unjustifiable or needs to change. My view is that industry should continue to meet the costs of compensation for trials conducted in New Zealand.

In particular, I do not agree that the only relevant issue for determining eligibility for ACC cover is whether these patients are any different from other patients suffering treatment injuries. Appropriate allocation of risk and incentives on researchers are also important to ensure appropriate commercial practices (ie to ensure that injury risks and costs associated with clinical trials are identified and managed appropriately by the companies undertaking the trials). Moreover, I do not agree that this sends a signal that New Zealand is hostile to clinical trials relative to other countries as the current requirement for indemnity insurance for industry-led clinical trials appears to be standard international practice.

Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand. Telephone 64 4 817 6837 Facsimile 64 4 817 6537

Finally, it is not clear whether purchasing cover through a levy would be a practical option, nor whether any of the cases identified would in fact be covered by ACC following removal of the statutory exclusion. On the other hand, I am advised that there are a number of options which could be looked at to strengthen the current framework for approval of clinical trials to address this problem if action is warranted, and I would expect these options to provide a more appropriate course of action in the first instance than considering extending ACC cover.

Yours sincerely

Hon Nikki Kaye
Minister for ACC