8th February 2012

Mr Tony Ryall
Minister of Health
New Zealand Government

Re: An open letter regarding the changes to ethics committee processes and the potential for harm to research participants

At the NZ Bioethics conference held on January 27th - 29th, a panel discussed the worrying implications of the forthcoming changes to the processes of ethical review of health research. The conference participants were concerned that the changes represented a major erosion of protection of research participants and a departure from international standards. For that reason they agreed it was vital to bring our concerns to the attention of the Government and the public.

The planned changes have been developed in response to a NZ House of Representatives report released in June 2011 entitled 'Inquiry into improving New Zealand's environment to support innovation through clinical trials'. In response to this report, the government made recommendations for change[i]. The consequent draft Standard Operating Procedures (SOPs) are due to be implemented by the middle of this year. These have significant implications for the functioning of the Health and Disability Ethics Committees (HDECs). The main changes that we believe will undermine the current safeguards for research participants include:

- Rules that reduce the scope of Health and Disability Ethics Committee (HDEC) review
- Mandating that some clinical trials be reviewed through the expedited review pathway, on the basis of risk; and that some moderate risk research not be reviewed at all.
- Reducing the number of HDECs from 7 to 4
- Reducing the size of HDECs from 12 to 8 members[ii]

The conference panel members (Professors Donald Evans, Tim Dare, John McCall, and Charlotte Paul) all voiced significant concerns about the future safety of research

participants as a result of the above changes. The key concerns raised by the panel are as follows:

- The reduction in the number of ethics committees from 7 to 4, will significantly increase the workload of each committee. To meet that workload, the committees are expected to reduce the level of scrutiny of clinical trials, provide expedited review by the chair, and not review some research. The outcome is that many studies will not receive full ethical review, and some will not be reviewed at all.
- As a result of the above change, research protocols for clinical trials that will be categorised as low risk, will receive only expedited review by a committee chair. While on the surface this sounds an appropriate way of making ethical review more efficient the draft SOP shows that it is likely on occasion to prove hazardous. For example trials of probiotic use in serious illness would be categorised as not requiring full review. Yet one such trial conducted in the Netherlands and published in the Lancet in 2008, reported a major excess of deaths in the probiotic group and subsequent investigation showed that the monitoring arrangements for adverse events were insufficient; hence some deaths may have been avoidable.
  Student research will also not receive review by HDECs (unless it is an intervention study conducted at PhD level). Hence the research carried out by a doctor into a clinical matter for the purpose of achieving a Masters degree, would not be reviewed by the HDEC (the appropriate committee for research with public hospital patients).
- The reduction in the numbers of members of ethics committees from 12 to 8 will result in both a loss of expertise, and reduction in lay participation.[iii]
- Ethics committees will not assess scientific validity, even though scientific validity is one of the standards required for research to be ethical.
- A central clearing house for allocating protocols will impersonalise the review process and undermine co-operation between researchers and HDECs and the communities they work in.
- Some major concerns have been raised about the processes around the creation and implementation of this policy. These concerns include:
    - The panel believed that the latest version of the ethical review system, prior to these changes, was working effectively and so the grounds for making wholesale change is not evident, and no review had been carried out to support these changes.
    - Major flaws in the quality of information received by the Select Committee that led to these changes.
    - In developing these changes, important steps have been omitted including analysis by and consultation with the government's own ethics advisory committee (National Ethics Advisory Committee).

- The policy has been developed too quickly with little time for reflection or a full understanding of the implications for protection of participants according to international obligations.

The above concerns raise issues about the independence of ethics committees housed within the Ministry of Health.

Conference attendees were very concerned that these changes are being implemented in haste and in the absence of adequate public debate around them. Given the vital role that participation of members of the public plays in enabling research aimed at improving the nation's health – it is owed to them that every reasonable effort is taken to ensure their wellbeing when doing so.

Yours sincerely

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Professor John McCall
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Professor Charlotte Paul
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[i] Government Response to the Report of the Health Committee on its Inquiry into improving New Zealand's environment to support innovation through clinical trials.' Presented to the House of Representatives in accordance with Standing Order 248. (2011)

[ii] Frizelle, F (2012) Proposed changes to the New Zealand Ethics Committees. *NZMJ.* Vol125 No 1348 p10.

[iii] Paul, C. (2011) Keep the ethical safeguards in medical research. *New Zealand Herald.* http://www.nzherald.co.nz/opinion/news/article.cfm?c_id=466&objectid=10758472)