Submission to the National Ethics Advisory Committee:

Cross sectoral ethics arrangements for health and disability research.

Submitted by Dr Sandra Hall with thanks to Jo Fitzpatrick for her expert advice

On behalf of Women's Health Action

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We are a non-government organisation that works with health professionals, policy makers and other not for profit organisations to inform government policy and service delivery for women. Women's Health Action is in its 31st year of operation and remains on the forefront of women's health in Aotearoa New Zealand.

We provide evidence-based analysis and advice to health providers, NGOs and DHBs, the Ministry of Health, and other public agencies on women's health (including screening), public health and gender and consumer issues with a focus on reducing inequalities. We have a special focus on breastfeeding promotion and support, women's sexual and reproductive health and rights and body image.

Thank you for the opportunity to provide this feedback.

You have identified six aspects of the cross-sectoral research ethics arrangements for discussion. They are:

1. Complex research ethics landscape
2. Māori and health research
3. Alternative ethical review structures
4. Peer review for scientific validity
5. Audit and audit-related activity
6. Innovative practice

We wish to make the following comments about some of the issues raised in your discussion document:

The Complex research ethics landscape

We agree the current system is complex and involves a range of disparate organisations.

We believe the current system

- Does not address conflicts of interest
- does not do ongoing monitoring
- relies on too much on the integrity of those involved
- the complexity of the system creates ambivalence and confusion which leads to a diffusion of responsibility and a lack of consistency

We believe consumers are concerned about

- a system that is difficult to navigate
- that they have signed away too much as part of 'informed' consent procedures which lack clarity
- that they bear both the consequences of harm and the failings of the system

This means we need a system that is:

- where the safety and well-being of consumers is paramount
- where all the roles and functions of the various bodies are clear
- which is transparent
- which includes strong consumer voices at every level
- where quality improvement is encouraged and QI culture supported
- which has education and training as a key function - for researchers, EC members - and is committed to increasing public understanding. Firstly amongst research participants and then more generally in the wider population.

Overall responsibility

There is no single body in New Zealand with overall responsibility for the ethical review process for health and disability research. The ethical review process is characterised by a complex set of relationships and responsibilities across a range of organisations which raises the question: “Do we need overarching review body and a process of contesting approvals” or should an existing independent structure set standards, monitor EC practice and establish and implement guidelines for ongoing monitoring of research, process and resolve complaints, provide training for EC members and researchers and engage the public.

We note there are components of this in different parts of the existing system. The natural homes are the HDC and the HSQC but given their current orientation, this is not a primary focus for them and risks becoming an unwanted 'add-on.' A new body would provide focus and could be integrated into the current landscape.

Ethical approval processes

We are concerned about disparate ethical approval processes and the lack of clear paths for consumers who are concerned about the ethics of a particular project or who wish to complain. We are also concerned about how the category of 'low risk' is established and by whom. We note that many of the institutions undertaking research have a vested interest in outcomes and are influenced by both academic and business considerations.

Applying guidelines and standards

We agree a clear framework is required for guidelines and standards, including review processes. We believe they currently rely too heavily on the judgement of the researcher. Clear consistent guidelines and an accessible 'one stop shop' should be applied across the sector and would give consumers more confidence that research was being conducted in a safe and ethical manner

Monitoring and accountability

The reliance on researchers and the lack of an agreed accountability framework for ethics committees provide two more reasons why an overarching body is needed which could establish an agreed accountability framework and monitor ethics committees.

The NEAC goals cover four areas: contributing to knowledge and improved health outcomes; protecting participants; balancing risks and benefits; and recognising and respecting the principles of the Treaty of Waitangi. Desired outcomes are specified for six objectives: accountable, enabling, informed, enabling of Māori participation, fair and efficient. These are laudable goals but we believe that there is insufficient clarity around input from diverse consumer groups and by Maori and the objectives need to be more robust. Once again they rely primarily on the researcher's assessment of what is important. Monitoring and accountability is an area of great concern to us. There is no clear

complaints process and no one body to which consumers can turn to. Information about complaints is not readily available to the public.

Ethical review structures

We agree there are a number of alternative ethical review structures set up in District Health Boards (DHBs) and institutions to undertake ethical review of research. However, once again this relies too heavily on the researchers and in some instances on institutions who may have a vested interest in the research outcomes.

Applying guidelines and standards

We agree it is unclear how useful NEAC's statement of *Goals, objectives and desired outcomes of an ethical review system* is as a strategic framework for the ethical review system.

We support and enhanced framework but also believe that guidelines , however good they are, need to be underpinned by clear and enforceable rules about ethical conduct in the sector and robust and clear complaints processes

Accessing ethical review

We agree it is particularly important that new ethical review structures are developed for specific types of research where specialist knowledge is important, for example, innovative practice and trials of medical devices. The current system has Medsafe relying on overseas research when approving medical devices. This has caused a great deal of public disquiet and in the case of mesh, hip and implant devices, patient injury. Independent ethical review of new and existing research is urgently required in these areas where patient safety may be at risk.

Consequent to the above we need a feedback and complaints resolution process which a quality based framework would provide.

In response to your questions about GODO, we maintain that GODO needs to add public accountability to its other review features. While it is a good statement of principle it is not particularly useful beyond that. It needs to be given teeth and substance alongside resource and guidelines for implementation. It could be improved with more emphasis and importance on goals 2, 3 and 4. Currently Goal 1 is seen as paramount. Recent changes were aimed to encourage research investment and have impacted on participant safety. It is not efficient to increase participant risk. An efficient system weighs up and considers all GODO goals equally.

The current plurality of functions that various public agencies (e.g. Ministry of Health, NEAC, HRC) have to set standards for researchers and for ethics committees is absolutely not sufficiently clear and coherent overall. This becomes very apparent when a consumer has a complaint.

We suggest we need a system that is easy to navigate, where roles are clear and is transparent and makes sense to members of the public and sector professionals alike.
A well supported and resourced existing independent structure set standards, monitored EC practice and implemented guidelines for research and resolved complaints

Mechanism(s) could be built into existing structures to facilitate access to ethical reviews rather than adding complexity to the current systems. Advice on 'borderline' cases should be formal and minimal risk should be clearly defined.

Researchers put a lot of effort into getting ethics approval and provide a lot of information. The problem is that after this process is complete there is very little follow up. Improvements are needed here including a system of audit and review. This could be quite simple and involve a random sample of approved studies. This needs to be supplemented with clear communication to participants on what to expect from a good study and a complaints or review process.

Accountability mechanisms for ethics committees can be improved by providing training for members and independent oversight of their operation within a QI culture.

Māori and health research

We agree that all health research conducted within New Zealand is of relevance to Māori and that as a Treaty partner and a priority population requiring appropriate health intervention, Māori involvement in health research is critical.[1] The principles of partnership, participation and protection implicit in the Treaty should be respected by all researchers, and, where applicable, should be incorporated into all health research proposals.[2]

We believe, in the spirit of partnership, participation and protection and in keeping with treaty obligations Maori should be asked to comment on all these issues in a separate process which is led by Maori but which involves the whole sector. Maori must be represented on all sector research and ethics committees and the question of te reo is one for them to decide

We agree that that much more needs to be done to ensure that Māori interests and issues have an impact on the way research is designed, conducted, analysed and disseminated and understand the concerns have been raised about the adequacy of Māori consultation undertaken by researchers and the ability of researchers to identify benefits for Māori and manage cultural issues and issues such as consent, data collection, storage of tissue and other samples, and in particular genetic research. When consultation is required, it needs to be done at a much higher level than is currently the case.

We agree that the potential for community disruption, stigmatisation, stereotyping or undermining either through research processes or outcomes pose risks particularly in research investigating human variation and diversity in indigenous populations.[3]

We agree with Smith's (2014)[4] comments supporting an "inclusive approach where Māori ethical ideas and frameworks are at the centre of ethical codes and guidelines. Cultural constructs would impact the whole research exercise and not be seen merely as 'add-ons'. Such an approach would ensure that Māori issues and interests are at the centre of ethical conversations and result in

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1 Health Research Council. 2010. *Guidelines for Researchers on Health Research Involving Māori*. URL: http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL[1].pdf (accessed 22 September 2014)

2 Health Research Council. 2005. *Guidelines on Ethics in Health Research*. URL: http://www.hrc.govt.nz/sites/default/files/Ethics%20Guidelines%20Oct%202005%20-%20under%20review_0.pdf (accessed 22 September 2014)

3 See footnote 6.

4 Smith B. 2014. Māori-centred codes of ethics: championing inclusiveness in creating professional codes of ethics across the New Zealand health sector. *The New Zealand Medical Journal* 127(1397): 9-12.URL: http://journal.nzma.org.nz/journal/127-1397/6192/

research outcomes that are genuinely relevant to Māori interests, aspirations and wellbeing. Getting the ethics right for Māori could also mean, as some commentators have stated, that we will get it right for everyone".

Alternative ethical review structures

We believe the government has a responsibility to keep its citizens safe. Ethical review of research is an important part of this. All structures for ethical review must be carefully monitored.
We to have concerns about consistent governance, unaccredited nature of some arrangements, standards and quality.

Review structures must be accountable. We are also concerned about ethical review structures in in the private sector and for private sector funded research done by universities. There is a lack of clarity and transparency in this area of the sector in particular.

Fee-for-review

We suggest this area requires in depth investigation of both the positive and possible negative outcomes across the sector. Most certainly this would require complete transparency.

Peer review for scientific validity

We agree with the concerns around access, adequacy and limitations you have identified that are associated with peer review.

We agree with the suggestion that the peer review process for journal articles is a good model which is streamlined, enables access to a wide range of peer reviewers (including internationally) and is transparent and that the lack of expertise on HDECs suggest they need a panel of independent peer reviewers that they could seek advice from.

Audit and audit-related activity

We maintain all audits require independent review and the structure of audits require guidelines including patients knowing their information may be audited. The results must be available to the public.

We also agree that the primary purpose of audits or related activity is to improve delivery of health or disability support services or to control a threat to public health and that there is an expectation that health professionals will undertake such activity to monitor the quality of their work.

This is part of a QI landscape and needs to be part of the new central infrastructure. A risk-based approach is positive if consumers are an integral part of establishing the criteria and benchmarks within them.

Pharmacovigilance (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population. This must be independent not done by company or sponsored institution and must include information that reflects gender differences and the diversity of our population. All adverse events must be reported.

Current ethics arrangements re Innovative practice

Significant examples abound of this being an area where products and medicines and procedures may be 'tested' without ethics oversight or proper informed consent procedures. They include the use of surgical mesh in urogynaecological surgeries, off label prescribing and in the cited example of the prescribing of ketamine.

We agree the current processes are inadequate across this area and that there is inconsistency across the DHBs. We do not think the current responses of either the HDC or the DHBs have addressed this. We are concerned that proper informed consent processes are not being undertaken and that there is potential for conflict of interest that puts consumers at risk.

Off label prescribing in particular needs review and there are numerous anecdotal reports of patients not being told that a medication is off label or not understanding what this means.
We suggest education and training and clear guidelines and parameters are required along with more robust informed consent processes and public education.

Other issues

We believe it is not ethical to conduct research that does not include disaggregated gender information in its results. This is a particular problem in pharmacological research where many trials have been conducted on predominantly male populations. Similarly we believe that research

conducted on products, devices, services or procedures which are made available to all New Zealanders, must be carried out on representative populations. We also maintain that the current approval processes for medical devices require examination and the application of some ethical oversight.

As a final general comment we believe ethics arrangements in this sector need to be representative, maintain a QI focus and put consumers and consumer safety first.

Thank you for the opportunity to provide this feedback.