



National Ethics Advisory Committee

11 November 2021

9.00am – 3.00pm

Attendees

NEAC members: John McMillan (Chair), Elizabeth (Liz) Richards, Dr Mary-Anne Woodnorth, Dr Dana Wensley, Gordon Jackman, Dr Penny Haworth, Dr Vanessa Jordan, Hansa Patel, Shannon Hanrahan, and Nora Parore

Guests: Nic Aagaard (Manager, Ethics, Ministry of Health)
Kate O'Connor (Chair, Northern B Health and Disability Ethics Committee)
Oliver Poppelwell and Helen Loveridge (Representatives from the Health and Disability System Reform)

Apologies: Dr Hope Tupara and Dr Cindy Towns

Getting Through Together: Ethical Principles for a Pandemic

The November update to the *Getting Through Together: Ethical Principles for a Pandemic* (*Getting Through Together*) draft was discussed. The document had been amended after NEAC's meeting in September 2021.

The Chair asked the *Getting Through Together* sub-group to summarise the changes, before the document is sent to the Minister's office and publicly consulted on. The sub-group noted the constructive process and positive discussions it had about the overarching principles. The sub-group also acknowledged the amount of work in between NEAC meetings that had been put into updating the document.

NEAC provided comments on and requested changes to the document.

NEAC discussed the public consultation plan. NEAC requested that public consultation be delayed to early February 2022.

NEAC enquired whether using a third party to run the consultation would lead to loss of knowledge and ownership of the work. The Secretariat explained the role of the third party and advised that it does not preclude NEAC members from attending the consultation meetings. Members also noted that as there are several groups discussed in the document, NEAC must uphold its own equity process and explore what methods of engagement are appropriate for each group, in particular smaller scale rural-based engagement.

Actions:

- Members to send the Secretariat tracked change versions of the document, any reference materials, and other content to include in the document
- Secretariat to send the design template to the sub-group for confirmation
- Secretariat to amend the document and send to NEAC prior to the Minister's Office and public consultation
- Secretariat to confirm public consultation to begin in early February 2022.

Presentation to NEAC on the Health and Disability System reforms

The Committee welcomed Oliver Poppelwell and Helen Loveridge to present an overview of the Health and Disability System reforms.

One of the key themes in the reforms includes strengthening health research across the sector and NEAC will have a role to play here.

The overall framework

The Bill establishes new entities Health New Zealand and the Māori Health Authority, sets new planning and reporting requirements and guidelines for all health system corporate entities, and carries over provisions from the Public Health and Disability Act 2000.

A government policy statement that is issued by the Minister at least once every three years sets out the overall objectives, priorities, concerns, monitoring requirements for the health sector. The New Zealand Health Strategy will continue, and the Bill has provisions for Māori, Pacific and Disability health strategies. The New Zealand Health Plan is the main planning document jointly developed by Health New Zealand and the Māori Health Authority which will be agreed before it takes effect.

A set of health system principles that guide crown entities

The principles include that the health system should be equitable and engage with people to develop services that reflect their aspirations.

The principles are framed to reflect Te Tiriti o Waitangi principles, language and principles from the United Nations Convention on the Rights of Indigenous people and People with Disabilities.

The legislative process

The Bill had its first reading on 27 October 2021, a new committee, the Pae Ora legislative committee, has been established to consider the Bill in the next six months to and report back to the house (by 27 April 2022). Public submissions will close 9 December 2021 followed by oral hearings when that becomes possible.

Health New Zealand

This will be a crown agent with a board that is responsible to the Minister of Health and will lead the system operations in partnership with the Māori Health Authority. Health New Zealand will own and operate health services such as public hospitals and will commission primary community services. The main planning units for primary and community services will be called 'localities', which are yet to be determined.

Māori Health Authority

This will be an independent statutory body rather than a crown agent responsible for most of the planning and reporting requirements. The Crown Entities Act 2004 will apply to this authority to allow them the funding to do their work. This authority will work in partnership

with Health New Zealand and commission kaupapa Māori services and monitor performance of the health system for Māori. The Māori Health Authority also has an explicit policy function and function to advise the Minister of Health directly.

Iwi Māori partnership boards

Currently these bodies are consultive bodies attached to District Health Boards with no particular statutory presence, but the Bill formally recognises them and enables them to represent local Māori perspectives on various issues and, places an obligation on the Māori Health Authority to support them administratively and financially.

It has been decided that the interim Māori Health Authority that exists will engage with Māori and other relevant groups to develop advice on specific functions and powers these boards will hold.

Establishment of a Hauora Māori Advisory Committee

This will be a standard ministerial advisory committee with members appointed by the Minister of Health. Some of the ministerial powers relating to the Māori Health Authority Powers can only be exercised in consultation with the committee. Uniquely, the Minister of Health has to seek agreement from the advisory committee before appointing a crown observer to the Māori Health Authority or appointing a commissioner in place of the board.

In the discussion that followed the presentation, NEAC noted that it would be interested to see how the principles it has identified for its pandemic ethics guidance align with the principles in the Bill and further discussion in relation to existing barriers to access and care and how the new system will address these issue and measure success (for example, how communities with historical access issues will be accounted for and continue to receive health services and use of data and data sets improved).

Intensive Care Unit prioritisation

This was not discussed in the meeting.

Verbal update from Chair of the Northern B Health and Disability Ethics Committee

Mrs Kate O'Connor, Chair of the Northern B Health and Disability Ethics Committee (HDEC) spoke to the Committee about the recent experiences of the HDECs. She noted that the rollout and implementation of the new IT system, the Ethics Review Manager (ERM), has been a huge success. The new IT system has coincided with a large round of appointments to the HDECs. She presented some statistics about the number of submissions made to the HDECs via ERM since it launched on 1 September 2021.

Vaccine passports and health research

Mrs O'Connor discussed participant vaccine status in the health research context. She noted that the HDECs are starting to see a number of study amendments asking to introduce double COVID-19 vaccination as an inclusion criterion to participate in studies. She noted that this exclusion criterion has, as of yet, only been seen as an amendment to previously approved studies rather than in new applications. She noted that this amendment has only been received from New Zealand-led research. She believed it would be unlikely to receive this request from international studies, as international sponsors are interested in making studies as inclusive as possible in order to produce generalisable results.

Mrs O'Connor noted that vaccination status as an inclusion criterion raises the question of equity in accordance with the *National Ethical Standards for Health and Disability Research and Quality Improvement*, 2019 (the NEAC Standards). As per the NEAC Standards, all persons should have equal opportunity to participate in research. So far, the HDECs have taken the stance that researchers can take measures to keep staff safe without the exclusion of unvaccinated participants. However, sites are enforcing vaccine mandates for access to

their sites. Although not stated as an exclusion criterion in the protocol, vaccination as a site requirement is a proxy exclusion by design. Mrs O'Connor argued that this will have an impact on equity and the generalizability of research results, but that there is little that the HDECs can do to regulate site safety policies. She noted that institutional ethics committees are also having difficulties navigating this space.

After further discussion between Mrs O'Connor and NEAC, NEAC agreed to provide advice to the HDECs on this matter.

Actions:

- Draft letter in response to the HDEC Chairs.

Query from New Zealand Clinical Research about consultation requirements for studies that do not involve Māori participants

The Committee noted a query from New Zealand Clinical Research (NZCR) about consultation requirements for studies that do not involve Māori participants. It was noted that the NEAC Standards clearly state that *all* health research is of importance to Māori. Although some studies are not directly related to Māori, they are still of interest. The Committee considered whether this query from NZCR was raised out of concern that the requirement to consult with Māori might result in an over-burdening of Māori consultation services. The Committee noted that this is up to the Māori consultation service, not NEAC or the researcher, to determine whether or not they are willing to review a study.

It was agreed that a response to NZCR will be drafted.

Actions:

- Draft letter in response to NZCR.

Update from the Minister on Gendered Wards letter

This was not discussed in the meeting.

Discussion of 2022 meeting dates

The Committee discussed meeting dates for 2022.

One member expressed a preference that the July meeting does not fall within the school holidays. The other proposed meeting dates were agreed in principle.

Work between meetings

The Committee discussed work between meetings. It was noted that:

- the *Getting Through Together* subgroup will meet again,
- a member will do some quality improvement work on the NEAC Ethical Standards (the Standards) review,
- the Secretariat will go through submissions on the Standards review and implement as tracked changes to the Standards document, and
- the Secretariat will organise another meeting to discuss the Standards review.