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**National Ethics Advisory Committee**

**8 June 2021**

**10:00am-2:00pm**

Attendees: Dr Neil Pickering, Dr Wayne Miles, Mr Gordon Jackman, Ms Liz Richards, Dr Mary-Anne Woodnorth, Dr Dana Wensley, Dr Penny Haworth, Dr Vanessa Jordan, Dr Cindy Towns (away 11:45am-1pm).

Ministry staff present: Nic Aagaard, Hayley Robertson, Kirsten Forrest, Lucy Campbell, Hazel Irvine, Leonie Parminter, Mirae Wilson, Thomas Coulston.

Apologies: Dr Hope Tupara.

1. Welcome and Introductions

The Chair opened the meeting and the Committee did a round of introductions to welcome new members of the Secretariat, including a Principal Advisor, Advisor and Administrator.

1. Declaration of interests

No updated conflicts of interest were noted by members. However, Mr Gordon Jackman advised that he recently stepped down as CEO of the Duncan Foundation.

1. Minutes of NEAC’s 6 April 2021 meeting for approval

The Committee approved the minutes from the 6 April 2021 meeting with no changes.

**Actions:**

* Secretariat to publish 6 April 2021 minutes on NEAC’s webpage.
* Secretariat to update Gordon Jackman’s biography.

1. NEAC work programme – standing item for noting

The work programme had been updated after the Committee’s last meeting and the Secretariat advised that a contractor will not be hired for the update of Getting Through Together (GTG update) due to increased Secretariat support alongside access to other teams within the Ministry. It was advised that the GTG update project plan is still in play and will continue to be updated. A first draft of the GTG update will be in NEAC’s August 2021 meeting agenda pack.

It was noted that NEAC should plan how to balance the update of the Standards and the Getting Through Together Update. For instance, adding further detail to NEAC’s work programme to ensure the workload within NEAC’s workstreams are balanced, including a goal consultation date on the revised Standards.

**Actions:**

* Secretariat to send GTG project plan if requested by members.
* Secretariat to prepare a summary of submissions and propose updates to the Standards for NEAC to consider, and a consultation plan.

1. Ministry of Health updates

* 10 August 2021 in-person meeting

The Secretariat confirmed the in-person meeting is going ahead at the Rydges Wellington Airport venue. It was agreed that an in-person meeting will be useful.

* Staffing update

The Secretariat reiterated that a new Principal Advisor and Advisor started in May 2021, and the Administrator very recently in June 2021. The importance of strong support for NEAC within the Secretariat team was recognised, especially for the GTG update. It was noted the Principal Advisor will lead the GTG update and that other members of the Secretariat will also assist NEAC with project planning, writing and peer review.

Two contractors, a Policy Analyst and a Principal Advisor, finish at the end of June 2021. Their work with NEAC was acknowledged.

* Committee Appointments update

NEAC was then advised of delays in approval of membership appointments for the Health and Disability Research Ethics Committees (HDECs) and NEAC. The Secretariat updated NEAC on the risks identified for the HDECs and NEAC, including risks associated with delayed membership which composition (e.g. Māori members to ensure culturally appropriate decision-making that is consistent with Te Tiriti o Waitangi, medico legal input) and the workload appointment delays have caused for existing members. The Secretariat and Ministry’s Appointments team have also escalated this issue with the appropriate people, including an upcoming meeting to discuss the issue. The HDEC Chairs had also expressed concern and had organised a meeting with the Minister.

The Secretariat is also in the process of writing a joint briefing on improving the appointments processes, which will link into wider projects including a fees re-banding project for the HDECs to attract more diverse candidates. The Ministry of Health has scheduled wider review of Committee Terms of Reference and Standard Operating Procedures.

Members agreed that appointments for HDECs is an urgent matter in light of the associated risks outlined by the Secretariat. Members felt it is important that NEAC provides support to the HDECs on this matter. It was agreed that the Committee will send a letter to the relevant Ministers expressing concern about delays in HDEC appointments and reiterating the urgency of the matter.

NEAC’s Māori membership was also raised as an issue, especially in light of Dr Kahu McClintock’s recent resignation and Dr Hope Tupara, was acknowledged. NEAC will not progress work without Māori membership. The Secretariat explained the plan to ‘co-opt’ Māori membership and input in the interim as well as support from the Ministry’s Māori Health Directorate, while the appointments process continued.

* Ministry of Health COVID-19 Ethics update

The Secretariat updated the Committee about the Ministry facing project based on the 2007 ‘Getting Through Together: Ethical Values for a Pandemic’ (‘Getting Through Together’) document. It provides a high-level analysis of the Ministry’s COVID-19 response retrospectively, including human rights, Te Tiriti o Waitangi, equity and legislation, and provides ethical guidance for present and future-facing decision-making for the ongoing pandemic response. It also aligns with NEAC’s approach to Te Tiriti o Waitangi e.g. principles and the principle of equity in the recently published ‘Ethics and Equity: Resource Allocation and COVID-19’ framework (resource allocation framework). It was advised that the work done in this project connects to, and should provide relevant information for, NEAC’s update of ‘Getting Through Together’. It is going through Ministry sign-out.

The Secretariat then updated NEAC on the Intensive Care Unit (ICU) prioritisation project. Namely, that two meetings had occurred in relation to the project. These meetings had brought a range of people with different views together for discussion, including clinicians, Māori and equity advocates. The meetings had included discussion of structural inequities and racism e.g. how to develop an ICU tool that is both equitable and practicable. These discussions were frank but fostered a deepened understanding of the differing perspectives which is important to ongoing collaboration. It was noted that the work is ongoing and there will be a point where the tool will need to be tested live if it does, eventually, go ahead. The work is COVID-19 focused, but the learning it has engendered will be relevant beyond this context too. This also includes cross-over between with the update of ‘Getting Through Together’, especially through the relationships it has built/ contacts NEAC may draw on for consultation. The Secretariat is currently completing a write up of the two meetings. The resulting report will then be socialised with the relevant people and groups including NEAC.

It was explained that the ICU prioritisation tool is a multi-criteria analysis and was developed by a company called ‘1000minds’ last year. It had been developed by a group of clinical people (including Māori and ethicists) in urgency due to concern that Aotearoa New Zealand’s health systems would become overwhelmed by COVID-19, as evidenced by international experiences like Italy. Part of this rationale included alleviating the burden on healthcare workers from burn out and mental distress caused by having to make difficult triage decisions without sufficient support. However, the tool was never tested or implemented due to the strong reaction it received. It is highly complex and needs further work if it is to be used.

The Secretariat noted that ‘1000minds’ is a private company, but the data belongs to the Ministry. As such, the data is part of the Ministry’s privacy remit too. The Chair then clarified that it is important to remember that ‘1000minds’ provides a format, or tool, that puts weight on different issues, but this is informed – and depends on – the information put into it. Consequently, the right values need to be factored into it to get the right output. As such, ‘1000minds cannot work these dilemmas out, for instance, is the ICU tool ultimately data or information? A member also advised of the equity related issues NEAC had raised when the ‘1000minds’ tool was first presented the Committee. A concern was then raised about data ownership too.

NEAC agreed that this is an issue the Committee will continue to be interested in.

* HDC report and modifications of consent update

The Secretariat noted that they had not heard back from the Deputy Commissioners regarding the status of the Health and Disability Commissioner (HDC) report on research with adults who cannot provide their own informed consent. NEAC noted that they will write to the new Commissioner to progress this work.

* Update on Asian Bioethics Meeting

NEAC were advised that the 20th anniversary of Asian Bioethics meeting will be hosted by Singapore. The meeting runs over three dates; 10, 17 and 18 June 2021. The Secretariat will provide a brief overview of NEAC and ACARTs work at the pre-meeting on 10 June 2021. The Chair and Manager of the Secretariat will be attending and will feedback to the Committee.

**Actions:**

* Members to notify the Secretariat Administrator if they have preferences about flights for meeting in August.
* The Secretariat to draft a letter for NEAC to review and send a letter to the Minister of Health and associate Ministers expressing concern about the delays in appointments and the urgency for this issue to be addressed.
* Secretariat to keep NEAC updated about progress of appointments.
* Secretariat to share report on the ICU prioritisation project with NEAC once it is completed.
* Secretariat to send NEAC the NZ Law Commission’s public consultation document regarding supported decision-making when it is released.
* Secretariat to draft a letter to the HDC Commissioner on modifications of consent and contact the HRC Chair about co-signing the letter. NEAC to review letter.
* Secretariat to send links to talks given at Asian Bioethics meeting to members who indicate interest.

1. NEAC’s Annual Report for 2020 – for approval

The Secretariat advised NEAC that the Annual Report for 2020 has been edited and formatted through the Ministry of Health and requires the Committee’s approval.

Members approved the Annual Report on the provision that members have one last opportunity to provide minor feedback via email. The Secretariat requested that this be done as soon as possible so that it can progress to be tabled by the Minister of Health (the Minister).

**Actions:**

* Members to send any final, minor feedback on the Annual Report for 2020 to the Secretariat by email.
* Secretariat to progress the Annual Report for 2020 once final feedback has been received and any amendments made.

1. Project work – review of ‘Getting Through Together’

The Committee was advised that the Secretariat’s new Principal Advisor will lead the update of ‘Getting Through Together’ and that this is an opportunity for NEAC to reiterate what the update should focus on e.g. content and structure, before drafting begins.

A broad summary of what the Secretariat understands the Committee would like the update to contain was then provided. The structure so far was reiterated, including equity as a central focus, balancing ethical tensions and giving a wider voice to experiences of people within a pandemic (e.g. a wide audience of government leaders, policy makers, clinicians, regional groups and the community). Separate chapters might also be included on specific groups, such as Māori and people with disability. The rough stages of a pandemic were also highlighted as a potential structural form to guide the document, that is:

* *before* (preparedness/ initial response mechanisms),
* *during* (responding) and
* *after* (recovery).

The health system, including how it operates in ‘normal times’ would also be noted as an important setting for the pandemic response.

The Secretariat recommended the usefulness of aligning the document with wider governmental documents to further enhance its usefulness, for instance, the ‘4 Rs’ approach to civil defence emergency management developed by the National Emergency Management Agency (NEMA). It was also suggested that case-study stories could be included throughout the document to ground it in the types of experiences people might have in a pandemic, including those experiences brought on by government interventions. The Secretariat advised that members would be contacted to help inform these case-studies.

Members then identified specific topics they would be interesting in assisting with in the drafting process. The Secretariat noted this and advised that members will be contacted about these respective topics as they are drafted.

The Committee discussed the role of case-studies in the update. It was agreed that case-studies can be a useful device and should be included in the update of ‘Getting Through Together’, but that it must be grounded in a strong evidence-based approach too. For instance, statistics. NEAC noted that the audience is very wide, and that the document should be well referenced but accessible to a broad range of people.

Members also noted that justice has been a crucial aspect of the COVID-19 response, the principle of treating ‘like cases alike’, the nuances of intersectionality and equity, the importance of strong health infrastructure (which will subsequently strengthen a pandemic response) and ensuring that Te Tiriti o Waitangi is woven throughout the document.

It was agreed that a draft of the update of ‘Getting Through Together’ will be presented and discussed at the next meeting for feedback and further direction.

Members agreed that Māori should select who works with NEAC on the update of ‘Getting Through Together’ as a co-option to align with Te Tiriti o Waitangi. The Committee felt that further guidance is needed to ensure that the process for this is culturally appropriate and that work on the update should not be done without substantive contribution from Māori. It was agreed that the Secretariat will contact the Ministry’s Māori Health Directorate for advice and to help facilitate the process.

**Actions:**

* Secretariat to contact members about topics they are interested in contributing to throughout the drafting process.
* The Secretariat to draft the update of Getting Through Together with contributions from NEAC members.
* Secretariat to contact the Ministry’s Māori Health directorate for guidance on how to potentially engage with the candidates identified by NEAC, and to move forward, in a way that is culturally appropriate.
* Secretariat to update NEAC about progress regarding Māori expertise for the update of ‘Getting Through Together’.

1. NEAC Standards for Health and Disability Research and Quality Improvement

The Secretariat advised that submissions for the NEAC Research Standards (the Standards) closed on 31 May 2021. Six submissions had been received and an initial analysis of themes from these submissions had been completed for the Summary of Submissions document. This initial analysis will be further expanded on and refined.

Medicines New Zealand (Medicines NZ) had made one of the submissions, and two representatives from the organisation joined the meeting to discuss their feedback in relation to the exclusion of commercial clinical trials under current ACC legislation and the issue that this exclusion creates in terms of determining the appropriate compensation provisions for participants in commercial clinical trials.

It was acknowledged that the issue of equity of compensation provisions for commercial and non-commercial trial participants is a long-running matter; the ACC Act was amended in 1993 to exclude clinical commercial trials from ACC financial cover for treatment-related injury.

The Medicines NZ submission made specific reference to the interpretation and application of clause 17.1 of the Standards which states that “Researchers must make ACC-equivalent alternative compensation available to participants for the whole period of the clinical trial”, including but not limited to the requirement for sponsor companies to provide compensation for injuries related to registered comparator treatments and the alignment of this requirement with industry guidelines for commercial clinical trial compensation provisions.

Medicines NZ noted that where participants receive a comparator drug that has not been produced by the sponsor of the study, it is less clear where responsibility lies for the quality/safety of the comparator drug and therefore for determining the appropriate compensation provisions in the event of treatment injury.

Medicines NZ acknowledged that ACC is a unique Aotearoa New Zealand institution and internationally led studies, without an understanding of ACC, can find the unfamiliar context challenging to navigate.

Medicines NZ explained that they were researching whether it was justifiable to continue the exclusion from compensation. Medicines NZ sought empirical evidence for adverse events in commercial clinical trials by reviewing HDEC minutes from 2016-2020 with a view that if there were significant issues regarding trial safety, they would be reported to the corresponding HDEC and, any cancellation or suspension of a study for safety reasons would then be reported in the publicly available meeting minutes. The review found reports were infrequent and, Medicines NZ concluded that if this is the case, then it is unlikely that ACC would have increased financial burden.

Given that there are wider conversations going on in the clinical research space to support innovation and improve health infrastructure in clinical trials in both private and public spheres, Medicines NZ noted that this could be an opportune time for NEAC to write to the Minister with a request to re-open the conversation on this issue.

NEAC commented that trial adverse events are considered monthly in some research institutions such as research offices in DHBs. Adverse events are not, therefore, as uncommon as the HDEC minutes might indicate. It was also noted that a company’s ethical stance does not negate the risk posed to participants in commercial trials who are not able to receive compensation if injured during the trial.

The Secretariat advised that the ACC Act does not distinguish between an arm of a trial and a ‘commercially sponsored’ trial as a whole. It was the Secretariat’s view that a strict reading of the Act in conjunction with the Standards meant that commercial sponsors should cover costs of any injury suffered in a commercial trial, irrespective of whether it was the comparator drug.

NEAC queried whether international companies would want to rely on ACC cover in the first instance, given it can be a tricky process to navigate and, also noted that it is unlikely that changing ACC legislation will remedy this long-standing issue. What is ‘ACC equivalent’ can be difficult to determine and may need to be expanded on in the update of the Standards, including what the term ‘commercial’ trial entails.

NEAC and the Secretariat noted that the Standards are under review, as will be the HDEC Standard Operating Procedures and Terms of Reference, and that ACC and compensation will be further explored. NEAC will have input into the HDEC review, and the issues discussed at this meeting will continue to be of interest for the Ministry, HDECs and NEAC.

The Chair thanked Medicines NZ for attending the meeting and raising its concerns, adding that NEAC will further review Medicines NZ’s written submission for the Standards update. It was agreed that the conversation on the issue of commercial clinical study exclusions will continue.

**Action:**

* Secretariat to continue working on Summary of Submissions to inform update of the Standards

1. Mixed gender wards letter to Minister of Health – discussion about process

The Committee was advised that the letter regarding mixed gender wards is ready to be sent to the Minister. It will also be sent to the Associate Ministers due to the equity issues it raises. The Chair noted that sending the letter will be the main action for this work item. Other Ministry teams had been consulted on the subject before this meeting, including for confirmation that this issue is not currently part of any Ministry work programme, and the Secretariat will update those teams once the letter is sent.

A member noted that the new authority, Health New Zealand, should be targeted instead of district health boards with the upcoming health system reform.

**Actions:**

* Secretariat to make minor changes to the letter based on the meeting discussion, including a decision for the Minister to agree that mixed gender wards is an issue that requites further work.
* Secretariat to send updated letter to NEAC for final approval.
* Secretariat to send letter to the Minister.

The meeting closed at 2:00pm.