

**National Ethics Advisory Committee**

### 24 November 2022

**9:00am – 2:25pm**

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# **Attendees**

**NEAC members:** Professor John McMillan (Chair), Dr Penny Haworth, Associate Professor Vanessa Jordan, Shannon Hanrahan (Deputy Chair), Dr Cindy Towns,

Dr Lindsey MacDonald, Dr Hansa Patel, Edmond Carrucan, Rochelle Style, Maree Candish

**Guests:** Gordon Jackman

**Apologies:** Nora Parore, Seini Taufa.

# **Declaration of Interests**

1. A member updated the Secretariat about a potential conflict of interest regarding a potential appointment to the University of Canterbury Ethics Committee. This could create the perception of a conflict regarding the discussion of the HRC Guidelines, as the University of Canterbury Ethics Committee is not approved by the HRC. It was agreed that as long as the minutes record this conflict, the member could participate in the discussion.
2. Another member corrected a typo on their declaration of interest.

## **Actions**:

1. Secretariat to update members’ recorded declarations of interests.

# **Approval of minutes from NEAC’s 22 September 22 meeting**

1. Members approved the minutes from NEAC’s meeting on 22 September 2022.

# **Actions Arising**

1. The actions arising were noted, and it was suggested that priority needed to be given to some of these actions in order to get them progressed. In particular, a member noted that the work item around how the HDECs report to NEAC could be prioritised. This was discussed further in the Chair’s update.

# **Secretariat’s update**

#### Ethics team staffing update

The Manager of Ethics updated NEAC on staffing, noting that NEAC would have support from the newly appointed Principal Advisor.

#### Global Summit of National Bioethics Committees meeting update

The Manager of Ethics updated NEAC on the Global Summit of National Bioethics Committees. All slides and talks will be shared on the organisers website.

*Ministry update*

The Manager of Ethics updated NEAC on a possible Ethics Sector Day to train ethics committee members from NEAC and HDEC, as well as progress consultation and engagement on modernising the operational ethics committees. This would be in person in the next financial year, possibly in August.

# **Chair’s update**

1. The Committee discussed the relationship between NEAC and the HDECs, noting that section 92 of the Pae Ora (Healthy Futures) Act, under which NEAC is established, states that “the committee must determine nationally consistent ethical standards across the health sector and provide **scrutiny** for national health research and services.”
2. Furthermore, whilst not legally binding, NEAC’s TOR state that “in undertaking its functions, the Committee is expected to… monitor and review the operation of the health and disability ethics committees for the purposes of providing direction, guidance and leadership to ensure the ongoing quality and consistency of ethical review in the health and disability sector”.
3. NEAC discussed that the ‘scrutiny’ referred to in the legislation should entail maintaining a mana-enhancing relationship with the HDECs, noting that the HDECs are not bound by a legislative requirement to report to NEAC. A strengths-based relationship between NEAC and the HDECs can allow NEAC to understand the ethical issues arising for the HDECsand provide support to the HDECs to navigate these issues, not only through the ethical standards but also through additional guidance as required.
4. Each HDEC Chair attends a NEAC meeting every year, on a rotating basis, to provide an update to NEAC. It was agreed that the Secretariat should provide some more guidance to the HDEC Chairs on what ethical issues NEAC are interested in hearing about at these updates. These updates are also an important opportunity for the HDEC Chairs to feedback to NEAC on issues that they think are pressing.
5. The Secretariat will keep track of issues raised in these updates, so that NEAC can respond accordingly and continue to build the NEAC-HDEC relationship.

## **Actions**

* Secretariat to pull HDEC data from ERM that NEAC is interested in hearing about and share with the attending HDEC Chair and NEAC ahead of their meeting, for discussion.

# **Ethical Guidance for a Pandemic (EGAP) update**

1. The Secretariat updated NEAC on the preliminary findings from the EGAP consultation.
2. The survey received 428 submissions. There were 22 questions which were a mix of multi-choice and open-ended. Many of the comments made were in opposition to the Government’s Covid-19 response and, on that basis, may not be in scope as this document is a future-focussed document for pandemics generally, rather than a review of the Covid-19 response. However, where applicable to the EGAP document, their comment will be in scope for NEAC’s consideration. In addition to the survey submissions, approximately 14 written submissions were received. Two focus groups have also been held to date.
3. The summary report provided with the NEAC papers shows the data analysis for the multi-choice questions and the Secretariat talked through the findings noting the characteristics and key points the data has shown so far.
4. A submission analysis of the comments and feedback is the next step for the Secretariat and will be provided to NEAC next year for discussion in the form of a summary report for NEAC to consider in its next iteration of the guidelines.

## **Actions**

* Secretariat to provide a summary report for NEAC in 2023 to consider in its next iteration of the guidelines.

# **Standards review update**

1. The Secretariat gave an update on the Standards Review project. The Secretariat has hired a summer intern to review updates other countries have made to their equivalent National Ethical Standards for Health and Disability Research. The ethical standards of nine countries will be reviewed to determine if there are any emerging ethical issues or trends which NEAC should consider including in its update to the National Ethical Standards.
2. A secondary focus will review the latest academic literature on emerging technologies such as artificial intelligence and CRISPR / gene-editing studies to ensure the National Ethical Standards can offer clear and relevant guidance in these evolving areas.
3. The Secretariat will also review guidance on training ethics committee members and applying ethical standards so the HDECs will be well-equipped to implement the updated National Ethical Standards.
4. NEAC noted an external expert has agreed to review the revised data chapter but stated it would be worthwhile to have this review done now as the chapter may be out of date already and could use expert input at the draft stage.
5. NEAC noted the guidelines on children and young people in Chapter 8 of the Standards will undergo legal review by the Ministry's legal team. NEAC noted a forthcoming Supreme Court decision may have legal implications on capacity and competence in young people as New Zealand law is rather fragmented on this subject. It was noted the Health Research Council has separate legal guidelines and there may be benefit in seeking additional input.
6. NEAC discussed how weaving Te Ara Tika principles throughout the National Ethical Standards was another primary aim of the review. It was noted that bias in artificial intelligence is a significant risk and this is one area that would benefit from a Te Ao Māori lens.

## **Actions**

* Secretariat to produce document on relevant international standards for review.
* Secretariat to determine milestones and deadlines for completing the project.
* Secretariat to produce draft revisions of chapters for consideration by NEAC.
* Rangatiratanga roopu to begin discussion on how to best weave Te Ara Tika principles throughout the standards and if any chapters in particular would benefit from this.

# **Rangatiratanga roopu update**

1. The Deputy Chair updated NEAC on the previous Rangatiratanga roopu meeting in October. The main agenda items included a broader review of NEAC’s terms of reference, including where NEAC sits within the Pae Ora (Healthy Futures) Act and what the Pae Ora principles might mean for NEAC. Other issues within the Terms of Reference include reference to principles of equity and the role of the Deputy Chair. The Deputy Chair of ACART attended this meeting to discuss the amendment that ACART made to their ToR regarding ensuring either the Chair or the Deputy Chair of the Committee is Māori. Some of the words in reference to Māori may also need review and wider discussion. NEAC’s scope of consultation was also discussed.
2. It was noted that a review of the ToR will need to be approved by the Minister of Health.
3. Cultural work overload and the idea of utilising outside expertise was also discussed.
4. A member commented that NEAC members are representatives rather than subject matter experts. Therefore, it is important to reach out to the scholarly community that hold expertise in these areas.
5. This member also commented that research ethics with indigenous people is reconciliation work.
6. A member noted that when bringing in experts, care must be taken in navigating conflicts of interest.

## **Actions**

* Secretariat and Chair to consider timeline for revising the ToR, including getting this approved by the Minister of Health.

# **Prioritisation Framework and NEAC’s work programme**

1. The Manager of Ethics noted that all NEAC’s work must be approved by the Minister of Health. Typically, this is done at the start of every year as the Manger of Ethics, the Minister, and the Chair meet to agree on NEAC’s work programme. The Secretariat noted the importance of this during an election year and that they aim to meet in February or March. Meetings also tend to include updates of current pieces of work.
2. The Chair suggested a full Committee meeting prior to the meeting between the Manager of Ethics, the Minister, and the Chair to discuss the work program.
3. The Chair suggested that an invitation is extended to the Minister to attend a full Committee meeting in 2023.
4. The Committee noted that there wasn’t a clear problem statement arising from the request from the Regulatory Assurance team regarding assisted dying and conscientious objection. Ethical guidance was noted; however, concern was raised over people not following the guidance. NEAC noted that enforcement of guidance is out of their scope, and it is unclear how they would assist in changing that.

## **Actions**

* NEAC agree at March 2023 meeting what they want to propose to the Minister for their work programme.
* Chair of NEAC and Manager of Ethics to meet with the Minister of Health after the March 2023 meeting to agree NEAC’s work programme.
* Contact the Ministers Office to arrange for the Minister to attend a full committee meeting.
* Secretariat update the Regulatory Assurance team that NEAC seeks clarification about how they want NEACs help on the assisted dying issue.

# **Review HRC guidelines**

1. NEAC discussed the draft Health Research Council (HRC) Guidelines which the HRC had asked NEAC to review.
2. Members discussed several different comments and queries they had regarding the HRC Guidelines, including the different statutory roles of the HRC and NEAC and suggested that the HRC research Guidelines and the NEAC research Standards should align with each other. Members also gave feedback on specific sections of the draft Guidelines.

## **Actions**

## The Secretariat to put the feedback into a letter to HRC. This will be reviewed by the Chair and Deputy Chair before being sent.

# **Clinical ethics inquiry**

1. The Manager of Ethics opened the discussion for this item, noting that clinical ethics has been a recurring topic within the Ethics team over recent years. The Manager of Ethics provided an overview to the Committee of the wider context for clinical ethics in New Zealand and highlighted the importance of this work. The Manager of Ethics views it as within NEACs scope to produce standards, principles or guidelines for clinical ethics at a national level. Whether it is within NEACs scope to assume a role, similar to the role of the HRC, and issue a framework for the composition of clinical ethics committees was discussed.
2. Committee members identified the need for NEAC to provide a statement on moral distress of the health workforce and the importance of clinical ethics.
3. NEAC acknowledged that there is variability in terms of reference, process, membership and expertise across the different clinical ethics advisory groups. A lack of patient voice within clinical ethics advisory groups were discussed. The member with expertise in ethics suggested a national framework be developed to allow for consistency over processes across groups.
4. The Chair noted that communication regarding ethics with clinical staff is within CEAGs remit, and the possibility of NEAC working with CEAGs to provide overarching support was discussed.

## **Actions**

* NEAC to send a letter to the Minister of Health regarding the moral distress of the health workforce.
* The Ministry will support early discussions with Te Whatu Ora and Te Aka Whai Ora on clinical ethics capacity and planning with the new health entities.

# **Letter to the Health and Disability Commissioner re: Research with Adult Participants who are Unable to Provide Informed Consent**

1. The Manager of Ethics provided an update on the letter to the HDC regarding Research with Adult Participants who are Unable to Provide Informed Consent. This letter has been sent with minor changes. A response to queries from the HDC was included, and the requirement for all research consent to be in writing was addressed. This requirement overlooks cultural preferences for verbal consent, collective consent, and other variabilities. The broader issue of trial designs and intervention studies that do not seek consent were also noted.
2. A meeting has been requested for February 2023 to discuss this with a Principal Advisor from the HDC.
3. The Manager of Ethics acknowledged the requirement for the Ministry of Health to strengthen its own ethical review processes for research with adults who cannot provide their own informed consent, which is a piece of work that is planned to begin in 2023.
4. A member raised the issue of the definition of ‘consumer’ in the Code of Health and Disability Services Consumers’ Rights, noting that this differs from the definition of ‘representative’ in the Health Information Privacy Code. This discrepancy could become an important point for NEAC to consider.

## **Actions**

* The Secretariat to send a copy of the signed letter to NEAC members.
* The Secretariat will engage with NEAC members and the Chair once a meeting date is set with the HDC.

# **Briefing to the Minister of Health re: exclusion of access to ACC for participants in commercially sponsored clinical trials**

1. The Manager of Ethics provided an update on the Briefing to the Minister of Health regarding exclusion of access to ACC for participants in commercially sponsored clinical trials. This update included the response from Minister Sepuloni to the jointly signed letter from the New Zealand Association of Clinical Research. This response indicated that there was not sufficient evidence to support a change in the exclusion for access to ACC compensation for participants in commercial clinical trials.
2. A member noted that this has been a long-standing issue.
3. NEAC plans to issue advice to the Minister of Health and the Minister for ACC regarding this issue, noting that it would be within NEACs remit to issue the advice, even though the NZACRES letter did not result in a change programme.

## **Actions**

* The Secretariat to follow up with the Minister’s office regarding a letter to accompany the advice, in order for Minister Little to write to Minister Sepuloni.

# **Work between meetings**

1. NEAC discussed work between meetings. A short Standards subgroup meeting was proposed for December. The Secretariat will discuss timeframes for NEAC’s work programme, to be proposed to the committee in the new year.