

**National Ethics Advisory Committee**

**21st September 2023**

**9:00am – 2:20 pm**

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# **Attendees**

**NEAC members:** John McMillan (Chair), Shannon Hanrahan (Deputy Chair), Rochelle Style, Julia Black, Tania Moerenhout, Vanessa Jordan, Hansa Patel, Lindsey Te Ata o Tū Macdonald, Edmond Carrucan, Maree Candish and Nora Parore.

**Apologies:** Seini Taufa.

# **Declarations of Interest**

New members declared interests.

*Action*

* *Secretariat to update the declarations register.*

# **Approval of minutes from 20 July 2023 meeting**

Members discussed the minutes and reflected on discussions from the July meeting. The Committee approved the minutes from the 20 July NEAC meeting, and that they could be published once the changes discussed in the meeting were instituted.

*Action*

* Secretariat to update July minutes and place on NEAC’s webpage.

# **Actions Arising**

The actions arising were noted.

# **Secretariat’s update**

*Staffing update*

The Manager informed the Committee that a new administrator had been recruited which increased the secretariat to fourteen staff. It was noted that Senior Advisors will be splitting their time across NEAC, HDECs, ECART and ACART, which has caused a slight reshuffle in work priorities. Additionally, there will be an intern starting in October to support the team.

*Ministry update*

The Manager acknowledged that the Secretariat is awaiting further advice as to the Regulatory Directorate merger with Monitoring and Assurance. The new directorate will be led by the acting Deputy Director General. The effect of the merger may slow down some work streams. The Manager advised that more information would be made available at the next meeting after the elections once there was more certainty provided on the direction of a new Government.

*Report back from NZACRES conference*

The Manager updated the Committee on the presentations given by members of the Secretariat in Auckland at the NZACREs conference and reported that they were well received. Representatives from across the Ministry attended, and the conference discussed a range of topics in relation to clinical trials.

*Sector Day*

The Manager updated members on the planned Sector Day which will be held in Wellington. This is a chance for ethics committees to meet and discuss emerging ethical topics, medical research and policy developments. Several notable speakers will present including the Prime Minister’s Chief Science Advisor and the Deputy Director General for Māori Health. The Manager noted that Te Whatu Ora and the Health Research Council officials would also be invited.

*Action*

* Secretariat to confirm that all NEAC members attending Sector Day have travel and accommodation.

*Update on Royal Commission of Inquiry into COVID-19 Lessons meeting and next steps*

The Deputy Chair shared that the meeting between the Chair, Deputy Chair, Manager and the Commission went well and that the Commission is interested in the revised Ethical Guidance for a Pandemic.

**Work programme update**

The Manager advised members that NEAC received ministerial approval for its work programme for 2023/24. This means that NEAC will continue on with the two main projects of updating the Research Ethics Standards and the Ethical Guidance for a Pandemic, as well as having an interest in changes to research with adults who cannot provide their own informed consent. The Minister also confirmed two new workstreams on NEAC Terms of Reference and clinical ethics as resourcing allows.

# **Chair’s update**

The Chair provided an update on the meeting of the Asian Bioethics Network attended by the Chair and the Deputy Chair. They provided a short presentation on the work of NEAC and initiatives around the use of artificial intelligence in Aotearoa New Zealand.

# **Rangatiratanga Roopu Update**

The Deputy Chair advised on the status of Roopu discussions on amending the NEAC terms of reference and suggested working with others, including the Māori Health Directorate and, Te Aka Whai Ora |Māori Health Authority. He also noted that the Roopu will be seeking support from the Secretariat to progress this work.

*Action*

* Secretariat to support the Deputy Chair in this work.

# **Standards Update**

The Secretariat provided an update on the Standards work. The Secretariat is incorporating final content changes and preparing the revised Standards document for review at NEAC’s November meeting. Chapter 3 is undergoing review by the Rangatiratanga Roopu and Chapter 18 is being reviewed by the Ministry’s quality insights group. Further work is being undertaken on AI and emerging technology for Chapter 13. Feedback from the HDEC Chairs on proposed changes has been sought and will be provided to NEAC at the November meeting.

The Secretariat has developed a checklist tool to review the language of the Standards with a particular focus on ‘shoulds’ versus ‘musts’ and improving the usability and structure of the Standards for researchers and reviewing committees. This work will be progressed over the remainder of the year in preparation for a public consultation on the Standards in 2024.

The Committee discussed the need to update Chapter 17 and the compensation requirements for commercially sponsored intervention trials. A member raised concerns that the current wording for ACC-equivalent insurance may be misleading to participants as Industry guidelines on compensation are voluntary and not legally binding. They also differ from the ACC regime in a number of respects, including that the Industry guidelines may take into account fault. This creates a situation where New Zealanders who participate in commercially sponsored trials may assume greater risks, in terms of receiving compensation for injury, than those who participate in other types of trials. The Chair agreed to work with NEAC and the Secretariat on this chapter.

The Committee discussed the Te Ara Tika principles and noted Te Ara Tika was published in 2010 and there may be subsequent developments in Māori research ethics.

*Action*

* Secretariat to organise working group with NEAC on updating Chapter 17.

**Ethical Guidance for A Pandemic (EGAP)**

The Principal Advisor updated the Committee on the revision of the EGAP report, including summarising the key changes to the document since the Committee last reviewed it. She outlined the key themes in the document, how it was being streamlined and where new material had been added. The Principal Advisor noted that as part of the streamlining of the document, it had been focussed on the ethical principles and had removed advice on planning for a pandemic or epidemic generally as this was covered by other documents.

The Principal Advisor suggested a change in the Māori health model used in the document, which led to a discussion of how the different models are used and which would be most appropriate in this context. The Committee agreed that the Te Whare Tapu Whā should be used and that Te Pae Māhutonga should be included as well, if appropriate.

The Secretariat outlined the timetable for the finalisation of the EGAP document and advised the Committee they would be receiving the document for review in advance of the papers for the November meeting to ensure they had sufficient time to review it. The Secretariat also asked for additional members to join the working group and three members of the Committee volunteered.

*Actions*

* Principal Advisor to continue working on the document to finalise and update references.
* Secretariat to organise a subgroup meeting for mid-October to review the document before the full Committee review.

**NEAC History and Future Focus**

The Committee reviewed the paper prepared by the Secretariat outlining NEAC previous work. The Chair thanked the Secretariat for its work and noted the paper is valuable and will assist new members in understanding NEAC’s work and mandate.

The Committee discussed the health reforms and whether they might change the focus of NEAC’s work. It was noted there is a challenge in accessing information to understand how the health system is functioning and this impacts the ethical issues that the Committee has highlighted. It was suggested that there could be an MOU in respect to information sharing between NEAC and other health agencies and that in future NEAC projects there may be an opportunity to work with Te Whatu Ora | Health New Zealand to understand how this could be facilitated.

*Actions*

* Secretariat to include history of NEAC paper in the introductory materials for new members.
* Secretariat to assess which future projects might need data access from other health agencies and explore how it will be accessed.

**Learnings and challenges from the risk assessment of complex data requests**

Carole Barnay, Principal Advisor, Information Privacy & Governance, Te Whatu Ora | Health New Zealand and Amanda Mark, Principal Legal Advisor, Privacy, Hira Programme gave a presentation about their work to build a process and framework for assessing applications to use health data to train algorithmic or AI products.

The speakers outlined that Te Whatu Ora’s role in the AI space was to balance responsible guardianship with how the technology can benefit New Zealanders and its health system. They presented how they developed the process, including the different areas that needed to be consulted on to ensure the proposals were assessed against a wide range of different areas of risk. They noted the input of the HDEC Secretariat and providing guidance on the ethical review of research and how it could inform their process.

Following the presentation, the Committee had a discussion with the presenters about ethical issues arising from accessing health data for AI development, the use of AI in healthcare and at which stages of the development of algorithmic and AI products ethical issues arise.

**Correspondence**

The Committee noted they had received the publication of the Long Term Insights Briefing and that it had been significantly revised, including incorporating the comments that NEAC had provided. It was agreed that NEAC would send a letter to the team to credit them on the work and noting the areas of improvement including capturing Māori needs.

*Action*

* NEAC to send letter to the Long Term Insights team.

# **Work between meetings**

The following work was noted between meetings:

* Meeting of the EGAP working group for mid October
* Mahi of the Roopu
* Potential consultation on Sector Day.

Meeting ended 2:20pm.