



Kāhui Matatika o te Motu

National Ethics Advisory Committee

17 July 2025

9:00am – 4pm

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Attendees

- NEAC members:** Dr Elizabeth Fenton (Chair), Dr Lindsey Te Ata o Tū MacDonald (Deputy Chair), Julia Black, Maree Candish, Edmond Carrucan, Assoc. Prof. Vanessa Jordan, Dr Filipo Katavake-McGrath, Dr Fiona Miles, Dr Tania Moerenhout, Dr Hansa Patel, Dr Karaitiana Taiuru
- Guests:** Chair, National AI Algorithm Expert Advisory Group (NAIAEAG)
General Manager, Health Services Research and Evaluation, Te Whatu Ora
Clinician, Thames Hospital

The meeting was opened with a karakia and members approved the agenda.

Chair's update

The Chair welcomed the Committee and thanked them for their ongoing work.

Declaration of Interests

Members noted the declarations of interests and were asked to notify the Secretariat of any amendments.

- The Deputy Chair declared a potential conflict of interest as co-Chair of HRCEC and noted their intention to submit a proposal to AREC regarding approval for non-HDEC health research. The same member also noted involvement in initiatives to establish by-Māori-for-Māori and Indigenous Pacific ethics committees.
- A member disclosed that their spouse undertakes casual work related to ACC claims.
- Another member noted that, in their legal practice, they occasionally process ACC-related claims.

All disclosures were noted by the Committee, and no further action was deemed necessary at this time.

The Deputy Chair excused himself from the meeting briefly relating to discussions on the *Standards Review – Chapter 17: Compensation*. These discussions are noted in the minutes. This was not specified as a conflict of interest.

Action:

- Secretariat to update members' recorded declarations of interests if needed before the next meeting.

Approval of minutes from NEAC's 8 May 2025 meeting

Members approved the minutes from NEAC's meeting on 8 May subject to minor amendments.

Action:



- Secretariat to place the amended 8 May minutes on NEAC's webpage.

Actions arising

The actions arising and completed were discussed and noted. The group agreed to a formatting change, so that Standard Operating Procedure actions are separate from General Business.

Action:

- Secretariat to update actions arising for the next meeting.
- Secretariat to amend Actions Arising template to separate Standard Operating Procedure actions from General Business actions.

Secretariat's Update

The Manager, Ethics updated the Committee on Secretariat resourcing and upcoming staff changes.

The Secretariat also announced the appointment of a Health Intern through Victoria University of Wellington. The intern will undertake a comparative analysis of the National Ethical Standards, the Declaration of Helsinki, and the Guidelines for Good Clinical Practice, with a focus on identifying any significant inconsistencies. This work will contribute to NEAC's ongoing review of the Standards.

Action:

- Invite the Health Intern to present early findings at the 18 September meeting.

Standards review – Chapter 17: Compensation

The Chair set out the context for a long-standing issue associated with the ACC legislation; that it does not cover compensation for treatment injury for participants in commercially sponsored industry clinical trials (clinical trials).

Chapter 17 of the Standards focuses on compensation for injury in clinical trials and states that to ensure ethical conduct, clinical trial sponsors must hold insurance that will provide ACC-equivalent compensation for participants injured in a trial, including treatment costs, lost wages, and support for dependents in the case of death.

The Committee outlined examples of where ACC equivalence from sponsored trials has not been adequate. It discussed whether a law change that would require clinical trials sponsors to make payments to ACC could be a possible way to establish more protections for people. The Committee's discussion took into account points raised in The Health Research Council's recently drafted Ethics Committee Position Statement on compensation for injury in research. The HRCEC plan to consult with various stakeholders including NEAC to establish some baseline principles.

The Committee also discussed whether it could issue additional guidance in Chapter 17 that included clarifying the definition of 'commercially sponsored' trial, clarifying NEAC's position on compensation for injury in commercially sponsored trials and requirements for clearer communication with participants regarding insurance limitations.

Actions:



- NEAC will draft a response to the HRCEC position statement, offering feedback and identifying areas of concern, and circulate the draft advice among Committee members for feedback.
- The Chair will attend the HRCEC insurance roundtable on 6 August and report back to the Committee.
- NEAC will continue its deliberations on ACC equivalent compensation in future meetings. Further actions may include:
 - Writing to the Minister of Health reiterating NEAC's longstanding position on legislative reform regarding compensation for participants injured in commercially sponsored clinical trials.
 - Developing a position statement to inform future updates of Chapter 17 of the Standards.

Standards review – Chapter 18: Quality improvement

The Committee discussed the treatment of quality improvement (QI), quality assurance (QA), and audit activities in the NEAC Standards, particularly in relation to ethics review, publication, and Māori perspectives.

Members agreed that Chapter 18 of the Standards provides useful guidance on identifying low-risk activities. The Committee discussed a potential area of ambiguity in the Standards regarding publication, with several members noting that audit findings may be disseminated through channels such as conference presentations or internal reports, even if not published in scholarly journals.

Concerns were raised about the language used in the chapter, including its lack of reference to Mātauranga Māori and the evolving role of Māori concepts in QI work. Members highlighted the need for clearer guidance on how Māori frameworks and values intersect with audit and QI, especially as these approaches become more common. The Committee also discussed the motivations behind student-led audits and the need for appropriate supervision to ensure quality and ethical integrity.

Members supported further work to clarify the guidance on audit and ethical review in the Standards, specifically with respect to publication and the dissemination of audit findings. Members noted that there is a fast-track process for ethical review of low-risk audit activities within some large hospitals, this type of review is not available in all regions, which reinforces the need for development of practical pathways for ethical review of low-risk activities. The Committee discussed the role of a Health New Zealand ethics committee in providing review and oversight of such activities.

Actions:

- NEAC will respond to HRCEC's suggestion to remove the specification regarding scholarly publication from the Standards.
- The Committee will further consider clarifying the guidance on ethical review and audit activities in the Standards and mechanisms to communicate this clarification to key stakeholders in the research sector.



Standards review – Chapters 12&13: Health data and new technologies

The Chair, National AI Algorithm Expert Advisory Group (NAIAEAG), attended the meeting along with the General Manager of Health Services Research and Evaluation, Te Whatu Ora, to speak about AI in the New Zealand health system and in particular their work with NAIAIAG.

The presenters outlined the current lack of regulation around AI in health care and ‘software as a medical device’ in Aotearoa New Zealand, noting that future regulation is expected under the Medical Products Bill which is currently being developed. The speakers described the membership and functions of NAIAIAG, the types of AI tools it currently considers, and its framework for doing so. NAIAIAG’s AI framework was developed in 2019 and designed to incorporate clinical, Māori, and wider consumer perspectives into AI decision-making in the New Zealand health sector. NAIAIAG has also produced a checklist to guide ethical AI development and implementation.

NAIAIAG provides advice across research, procurement, and operational contexts, and maintains a transparency policy. Legal and privacy expertise is embedded in the group, and members noted the importance of safeguarding data in the event of company sales. It was noted that NAIAIAG is a committee that inputs into government AI decision-making but does not make decisions itself. The Committee acknowledged that this approach may present challenges in some contexts. Additionally, it was clarified that general practitioners and clinicians working in private practice do not fall under NAIAIAG’s remit.

The Committee discussed the varying risk levels of AI applications, distinguishing between back-end systems and clinical-facing tools. The Committee was also briefed on the establishment of the National Research Advisory Committee (NRAC) and the forthcoming HNZ Research Ethics Committee (HNZREC), which aims to address current inconsistencies in access to ethics review across regions for clinicians and other HNZ employees. It was noted that HNZREC will seek HRC accreditation and may take up to a year to become fully operational.

The Committee discussed Māori data sovereignty, the need for culturally grounded AI evaluation, and the importance of ensuring Māori leadership and values are embedded in AI development. Members discussed the emerging evidence for how AI tools perform with Te Reo Māori and acknowledged the role of Te Tiriti o Waitangi in guiding ethical AI use and the need for appropriate consultation and safeguards.

The presenters expressed interest in contributing to the review of NEAC’s Standards, noting that AI is not currently explicitly addressed in the document. The Committee agreed this presents an opportunity to update the Standards and ensure they provide clear, safe, and culturally appropriate guidance for AI in health.

The Committee discussed their planned review of Chapters 12 and 13. The Chair has asked NEAC members Vanessa Jordan and Karaitiana Taiuru to review the chapters in the first instance. The intention is that Chapters 12 and 13 will be reviewed together and NEAC may look to integrate the two Chapters as part of its review.

Actions:

- Vanessa and Karaitiana will present their initial high-level review of Chapters 12 and 13 at the September meeting.



Clinical ethics

A clinician at Thames Hospital spoke about access to clinical ethics support in rural healthcare settings. He noted that formal clinical ethics advisory structures are not well known or accessed in rural hospitals, and ethical decision-making often occurs informally through shared discussions with colleagues, patients, and whānau. The speaker emphasised the importance of context-aware, accessible support systems and highlighted the unique ethical frameworks that emerge in rural practice, where clinicians frequently navigate complex decisions with limited resources. He supported the idea of locally grounded ethics support and noted that relational, patient-centred approaches are central to rural clinical ethics.

The group discussed the importance of setting up clinical ethics support systems so that they work for currently underserved rural areas. Members also noted the value of ensuring clinicians have access to both clinical knowledge and ethics support to improve clinical ethical decision-making.

The Working Group introduced the *Clinical Ethics – Phase 1 Preliminary Report*. The group endorsed the report and agreed that the final advice to the Minister should clarify it is not endorsing access to unapproved medicines but rather supporting clinicians who are navigating these decisions.

Members also discussed the need for Māori input into the project, to ensure concepts and vocabulary of Te Ao Māori and Te Reo Māori are integrated appropriately and spelled correctly. The Committee also discussed broader ethical considerations, including the importance of recognising non-written forms of ethical knowledge in ensuring the work supports communities who struggle to access support within the health system, such as LGBTQIA+ groups.

Next steps include finalising a response to the Minister, which may include recommendations for a Phase 2 of the project. The Committee also agreed to develop early drafts of clinical ethics guidance and a decision-making tool for clinicians. These products will be aimed at different audiences but may be presented together. The Committee noted the need for further stakeholder engagement, particularly with Māori experts, and agreed to check in on progress at the September meeting.

The Committee discussed and approved the *Clinical Ethics Stakeholder Engagement Plan*. Noting this is a living document and many of the planned engagements have already taken place.

The Working Group highlighted the need for more Māori input into the project. They are seeking this from the Roopu, which will meet in August to discuss the project.

Actions

- Roopu to provide feedback on the *Clinical Ethics – Phase 1 Preliminary Report* in August.
- Working group to begin drafting NEAC advice on clinical ethics support, integrating feedback from NEAC members including the Roopu, and provide an update to the Committee in the September meeting.

Other business

- The Committee noted the Chair's Letter to the Minister of 27 June 2025
- The Committee discussed the email it received regarding hospital design and patient rights. Members noted previous NEAC work of a similar nature and agreed to include it on their Emerging Ethical Issues register, to be discussed and prioritised along with other emerging ethical issues in the November meeting.



- The Committee noted the letter from the HRCEC regarding ethical review of health and disability research by private ethics committees.
- The Committee briefly discussed the upcoming HRC/IEC/HDEC training day. The Chair and Secretariat will attend, and all members are invited.
- The Chair advised the Committee of correspondence from a new national advisory group for use of routinely collected data for research. The Chair will attend the next meeting of the group and report back to NEAC.
- The Committee noted the Forward Agenda and Other Papers of Interest.

Actions

- Secretariat to add the email regarding hospital design to the *Emerging Ethical Issues* register and respond to the author of the email outlining the discussion and action taken.
- Secretariat to provide all interested members with the invitation to the HDEC/IEC training day to be held on 25 July. The Chair and all interested members will attend the NEAC portion of this training day and provide an update to the Committee in the September meeting.
- The Chair will attend the next meeting of the national advisory group for use of routinely collected data for research and report back to NEAC.

Meeting ended 3:50pm

Next meeting scheduled for 18 September 2025