

**National Ethics Advisory Committee**

**20th July 2023**

**9:00am – 1:30pm**

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# **Attendees**

**NEAC members:** Professor John McMillan (Chair), Dr Penny Haworth, Associate Professor Vanessa Jordan, Shannon Hanrahan (Deputy Chair), Nora Parore, Dr Hansa Patel, Edmond Carrucan, Rochelle Style, Maree Candish

**Apologies:** Dr Cindy Towns, Seini Taufa, Dr Lindsey Te Ata o TūMacDonald

# **Declaration of Interests**

Members noted the declarations of interest.

# **Approval of minutes from NEAC’s 25th May 2023 Meeting**

Members discussed the minutes and reflected on discussions from the May meeting. Members asked the secretariat to make amendments to the minutes from NEAC’s meeting on 25th May 2023 and circulate via email for approval.

*Action*

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

# **Actions Arising**

The actions arising were noted.

# **Secretariat’s update**

*Staffing update*

The Manager, Ethics updated NEAC on staffing, welcoming a new Senior Advisor to the team to support NEAC’s work and also updated the Committee that an Administrator in the ethics team has accepted another role within the Ministry. The Manager noted that the Administrator role will soon be advertised.

It was also noted that an intern will start with the team in October to conduct a project around the data held and used by the Ethics team to monitor and improve the efficiency of the HDECs, and to look at the use of the Standards in practice.

In August 2023, we will be farewelling the short-term consultant who has been working with NEAC to take forward the EGAP work.

*Ministry update*

The Manager, Ethics updated NEAC on the election shut-down period and that the Ministry has also announced a restructure.

It was noted that ethics work would continue as usual and that the team is ready to draft a briefing for an incoming Minister (BIM), if required after the election. The BIM will familiarise the Minister with the work of the Ethics team and NEAC.

The Manager noted that at the time of meeting there was no news about appointments and that they were awaiting a ministerial decision.

*Work programme update*

The Manager outlined that the Ethics team is planning a sector day, where the main focus will be on health research. The Ethics team noted that relationship building across different committees was a key focus for the meeting, as well as the leadership and stewardship role for health that health research embodies. There was a discussion about possible presentations and training in the areas of the work supporting the Therapeutic Products Act, as well as the intersection of the Assisted Reproductive Technology committees work and their recent consultation and mahi on the topic of human reproductive research.

This will likely be an in-person event in December, with the potential dates to be confirmed.

*Action*

Secretariat to circulate a doodle poll to members for preferred dates.

# **Chair’s update**

The Committee discussed the historical work of NEAC and spoke about the possibility of the Secretariat creating a paper providing an overview of NEAC’s work in the past and looking to the future and challenges that the sector is facing.

It was suggested that this could be discussed at the September meeting and that a resource like this would be valuable in finding a sense of place and context and could feed into induction information provided to new members of NEAC and within the Ministry to help understand what NEAC is and where current projects are at.

*Actions*

The Secretariat to provide the Committee with an overview of relevant work for the September meeting.

**Therapeutic Products Bill update**

The Manager of the Therapeutic Products Bill team and a Senior Advisor within the Ministry attended the online meeting to give the Committee an update on the status of the Therapeutic Products Bill, and the recent passing of the Bill through Parliament and through the House.

NEAC have a role in ensuring the scrutiny and safety of the health and research system and setting standards for health and disability research. Although NEAC have an interest in the entirety of the Bill, of special interest is that the work provides an opportunity to firm up and give more weight to ethical review in New Zealand.

It was noted that there are still many examples of research that require ethical review that are not captured and regulated by the Bill because of the way that the Bill defines terms such as “controlled activity” and “clinical trial”. For example, trials not involving pharmaceuticals or medical devices might fall outside of the new regulator’s role even though there are ethical standards that need to be met. A member suggested it might be worth investigating what kinds of research aren’t captured and why that is an issue.

The Manager noted that although the Bill has passed through Parliament, there is a lot of detail to be drafted in regulations and secondary legislation to give effect to the Bill which will be developed in conjunction with key stakeholders.

Issues in the regulation of ethics and understanding what the next steps are for the Therapeutic Products Bill were discussed, and NEAC signalled an interest in the opportunity to be involved in the more detailed aspects of secondary regulation to strengthen the ethics system as work progresses.

NEAC members enquired about what the new regulator’s role looks like and discussed how that can best support the ethics review role and the work of NEAC. Members were informed that this will be developed over the next few years.

There was a brief discussion about the functions of NEAC and the Health Research Council’s Ethics Committee and their standards, and the potential for the Bill to allow for a code of conduct that would bring New Zealand’s research system closer in alignment to Australia.

# **Standards update**

For this item the Secretariat updated the Committee on the review of the National Ethical Standards for Health and Disability Research and Quality Improvement and updated the Committee on progress since the May meeting. Volunteers were sought for workshops to complete the review of the Standards.

The Secretariat also noted that the consultation on the revised Standards would be after the election.

The Committee discussed a suggestion for a review of the Standards that looks line by line at whether sentences are standards, requirements or “shoulds”, or commentary. The review could look at what parts are repetitive, necessary or could be improved by adding hyperlinks. There was a suggestion that this process be iterative and would be beneficial for the next review of the Standards.

Regarding Chapter 3 – Research and Māori, the Roopu are reviewing this chapter and seeking input from key experts. There was discussion about drawing from the language of the document Te Ara Tika and a brief discussion about consistency and tone of language.

Regarding Chapter 5 – Disability research, it was noted that there was a suggestion in the May meeting to be clear about the difference between research about disability and research involving participants with disabilities. It was agreed to be a clarificatory paragraph within the scope of the Standards section.

A member also noted that there needs to be consistency in the Standards with terms in the Pae Ora legislation and the HIPC.

The Secretariat sought clarity from members on post-trial access. It was noted that this is an important issue and that it should be covered appropriately in the revised Standards. A member noted that this could also be strengthened in the secondary regulation that will be developed to support the Therapeutic Products Bill. The Secretariat agreed to review post-trial access in the revised Standards.

The Secretariat also noted that further revisions are needed to the data and data technology chapters and asked for volunteers from the Committee to guide this work.

Going forward, the Secretariat will organise workshops and contact members to progress the outstanding chapter revisions and prepare a final draft.  The proposed final Standards will be brought back to NEAC for approval with a communications plan for launching the revised Standards.

*Action*

* Secretariat to facilitate the amendments to the outstanding chapters with subject matter experts.

**NEAC annual reports**

The Committee reviewed the draft annual reports for the years of 2021 and 2022 for accuracy and clarity. A few members sent in changes via email and there was agreement to circulate both reports for approval via email.

There was a discussion about using both the English and Māori references to Te Tiriti and it was confirmed that this approach is in line with other key documents and the Ministry’s communication standards.

The next steps for this work, once the Committee have approved the content, is to have the reports professionally edited and formatted and to then be tabled in the House before being published on NEAC’s webpage.

*Action*

* Secretariat to consider suggested changes to the reports and seek the Committee’s approval via email.

**Research Ethics Reform programme update**

The Principal Adviser, Ethics gave a brief update on the survey as part of the Research Ethics Reform programme. 436 responses were received, and the data is currently being analysed. The high-level messages are that there is satisfaction with the operation of the Health and Disability Ethics Committees (HDECs) but there are areas for improvement. Once the data analysis is complete, this will inform any future vision for making changes to the way that the HDECs work.

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

This session was facilitated by an external contractor who is revising the EGAP document on behalf of NEAC. The contractor sought feedback from the Committee on a series of proposed changes to the structure of the EGAP document. This included updating it to reflect the changes in the health environment, the responses to the consultation and the feedback from the committee.

The Committee agreed to the proposed changes and noted the significant amount of work that the contractor had done to develop the report.

The Committee also discussed what the key messages should be for the report to inform the development of the final draft. The contractor proposed to work with the Secretariat to summarise the discussion and share this with a sub-group of the Committee for review. The Committee agreed.

*Action*

* The contractor to share a summary of the discussion with the sub-group for review.
* The Secretariat will bring a final draft of the revised EGAP document to the September meeting.

**Correspondence**

The Committee noted the correspondence sent between meetings.

**Any other business**

In this section, a member raised concerns over the potential for family members to claim on insurance in a device study that had resulted in the death of a participant. The Secretariat provided further information regarding this case and that they would ensure that this was reported appropriately in their final report which is due at the end of 2023.

The Committee raised the transparency of the HDEC minutes and annual reports and the possibility to improve the information provided to the public to inform them of what research is occurring and being approved by HDECs. The Secretariat explained the current process and will develop a plan to improve this once the responses from the RER survey have been analysed as this will inform any changes.

# **Work between meetings**

The Committee agreed to approve the May minutes and the 2021 and 2022 Annual Reports offline via email and members agreed to send any outstanding comments to the Secretariat.

The Committee also agreed to progress the Standards between meetings.

END.