

**National Ethics Advisory Committee**

### 22 September 2022

**9:00am – 3:00pm**

**Table of Contents**

[22 September 2022 1](#_Toc119061974)

[**Attendees** 2](#_Toc119061975)

[**Whakawhanaungatanga session** 2](#_Toc119061976)

[**Presentation by Dr Huhana Hickey MNZM** 2](#_Toc119061977)

[**Declaration of Interests** 2](#_Toc119061978)

[**Approval of minutes from NEAC’s 28 July 2022 meeting** 3](#_Toc119061979)

[**Actions Arising** 3](#_Toc119061980)

[**Secretariat update** 3](#_Toc119061981)

[**Actions** 4](#_Toc119061982)

[**Chair’s update** 4](#_Toc119061983)

[**Rangatiratanga Roopu update** 4](#_Toc119061984)

[**EGAP update** 4](#_Toc119061985)

[**Actions** 5](#_Toc119061986)

[**Standards review** 5](#_Toc119061987)

[**Update from Chair of NTB Health and Disability Ethics Committee** 5](#_Toc119061988)

[**Actions** 6](#_Toc119061989)

[**Assisted Dying Presentation and Discussion** 6](#_Toc119061990)

[**Actions** 6](#_Toc119061991)

[**Running Assisted Dying proposal through Prioritisation Framework** 6](#_Toc119061992)

[**Actions** 7](#_Toc119061993)

[**Work between meetings** 7](#_Toc119061994)

# **Attendees**

**NEAC members:** Shannon Hanrahan (Acting Chair), Dr Mary-Anne Woodnorth,
Gordon Jackman, Dr Penny Haworth, Dr Vanessa Jordan, Nora Parore, Dr Cindy Towns,

Lindsey MacDonald, Hansa Patel, Edmond Carrucan, Rochelle Style

**Apologies:** Prof, John McMillan

 Dr Cindy Towns

**Guests:** Dr Huhana Hickey MNZM

Margaret Earle, Ministry of Health

Rob McHawk, Manager, Regulatory Services, Ministry of Health; Secretariat, Assisted Dying Committee

Sue Morgan, Principal Advisor, Regulatory Services, Ministry of Health; Secretariat, Assisted Dying Committee

Kate O’Connor, Chair, Northern B HDEC

# **Whakawhanaungatanga session**

1. The day began with a whakawhanaungatanga session, noting that this was the first time many of the NEAC members had met in person.

# **Presentation by Dr Huhana Hickey MNZM**

1. Dr Huhana Hickey MNZM, from Whaikaha, Ministry of Disabled People, delivered a presentation to NEAC on her experiences as a disabled person and her interest in ethics.
2. Some key topics of discussion were:
	1. The difference between having lived experience of disability versus being a disability expert.
	2. Eugenics, euthanasia and sterilization of disabled people.
	3. Pandemic protections and support for disabled people.
	4. Te Tiriti and rights of disability people.
	5. Medical versus social models of disability, and the need for a whanau centered approach.
	6. The need to question assumptions about disability and explore understanding of disability from one’s own cultural background.
	7. Māori and disability statistics.

# **Declaration of Interests**

1. Members updated the Committee and Secretariat with changes to their declarations of interests.
	1. Actions: Secretariat to update members’ recorded declarations of interests.

# **Approval of minutes from NEAC’s 28 July 2022 meeting**

1. Members approved the minutes from NEAC’s meeting on 28 July 2022, subject to some changes.

# **Actions Arising**

1. The Actions Arising were noted and a suggested change to the tabling was agreed.

# **Secretariat update**

WHO Global Summit of Bioethics Committees

1. The Manager of the Ethics team gave an update on the World Health Organisation (WHO) Global Summit of Bioethics Committees he recently attended in Portugal, where he delivered a presentation that he had created with the Chair and Deputy Chair, titled ‘He Mahi Raranga – the weaving of different cultural approaches in health research: the Aotearoa New Zealand experience’. Slides and a recording of this presentation will be distributed to NEAC.
2. He also moderated a session on new strategies and tools to address literacy in bioethics, for both committees and the public. He discussed a number of other talks that were given at the Summit.
3. He noted that there was a side-line meeting of the Asia Bioethics Network.

Commercial Clinical Trials and ACC Exclusion Update

1. The Manager of Ethics provided NEAC with an update on their advice on the exclusion of access to ACC compensation for participants in commercially sponsored clinical trials.
2. He noted that the Minister’s office received the advice and had requested more information. The Secretariat explained the request for information to NEAC.
3. He also updated NEAC on the New Zealand Association of Clinical Research’s letter that proposed the Accident Compensation Amendment (Maternal Birth Injury and Other Matters) Bill include a provision for repealing section 32(5) and (6) of the Accident Compensation Act 2001. Those subsections exclude participant injuries suffered in commercially-sponsored clinical trials from ACC cover and access to no-fault compensation in New Zealand. The letter was co-signed by several clinical research organisations and was sent to the Minister of Health and Minister for ACC.
4. NEAC discussed the ethical issues raised by the exclusion to ACC compensation for participants in commercially sponsored clinical trials and noted that HDEC were also in a difficult position due to their role in determining whether a trial was commercially sponsored and had adequate insurance. NEAC discussed the challenges involved in determining whether a study had adequate insurance.
5. NEAC raised the need to collect information on commercial trial injuries and resulting payments to better understand the ethical risks. The Manager noted this data was now being collected, enabled by the new ethics database, but there was only 18 months' worth of data.
6. NEAC agreed to continue the process for sending advice to the Minister of Health and asked the Secretariat to respond to the request for information from the Ministers office.

HDC Correspondence regarding research involving adults who can’t provide informed consent

1. The Manager of the Ethics Team informed NEAC that the Health and Disability Commissioner wrote to the NEAC Chair in response to NEAC’s letter querying whether there would be any next steps resulting from the report that was produced by the prior Commissioner. The Commissioner responded noting that a review of the Code will be occurring, and noted that NEAC, the Ministry and the HDECs were stakeholders who ought to be involved. He explained that there is a Principal Advisor who will be working on the review at the HDC who NEAC have been offered to meet with.
2. The HDC have also asked whether NEAC have any issues with any other aspects of the Code. The Manger of Ethics asked NEAC to consider this.
3. The Manager and NEAC discussed the importance of being involved in this work, particularly in relation to risk and the language used to describe it.
4. Four NEAC members volunteered to be part of the meeting with the Principal Advisor at the HDC.

## **Actions**

* Distribute papers and recording of the Summit when available.
* Progress sending the ACC briefing to the Minister of Health.
* Send letter to HDC and then meet with the Principal Advisor at the HDC.

# **Chair’s update**

1. The Acting Chair updated the Committee on the joint ethics committee hui that he attended with another NEAC member, the HRC and the HDECs on Friday 29 September 2022.
2. He noted the challenges discussed around accreditation of ethics committees in regard to appropriate or safe levels of capability, for example in terms of Māori membership.
3. The meeting also raised the issue of how to train HDEC members around the NEAC Standards.

# **Rangatiratanga Roopu update**

1. The Chair gave an update on the first Rangatiratanga Roopu meeting, which had focused around how NEAC’s Māori members might work together and support each other.
2. He noted that the next hui is in two weeks’ time and would progress these concepts.
3. A member asked for an update on the EGAP presentation another member had delivered to the Bioethics Centre at Otago University, as Rangatiratanga members had been asked to support this presentation but had been able to in the time frame.
4. It was agreed that in the future, NEAC members should be supported by another NEAC member when giving presentations.
5. The issue of cultural overload was noted, and it was questioned how NEAC might build that capacity.

# **EGAP update**

1. The Secretariat gave an overview on the submissions received so far in the ‘Ethical Guidance for a Pandemic’ (EGAP) consultation and noted that the submission deadline had been extended.
2. The next step is for the EGAP subgroup to host focus group meetings with interested organisations.
3. A member queried the level of Māori engagement in the online survey, and the Secretariat responded that, to date, 11% of survey respondents had answered that they are Māori.
4. It was suggested that NEAC members should re-circulate the survey amongst their networks.
5. It was questioned how NEAC will analyse and incorporate the consultation feedback. The Secretariat responded that they are seeking advice around this. It was also noted that typically a summary of submissions document would be created, which would detail NEAC’s response to these submissions.

## **Actions**

* NEAC members re-circulate EGAP survey amongst their networks.
* Secretariat to seek advice around completing submission analysis.

# **Standards review**

1. The Secretariat gave an update on the progress of the Standards review, noting that Chapter 5, Chapter 8, Chapter 14 and Chapter 15 are currently being reviewed and that some external subject matter experts have been contacted for input. He noted that Maui Hudson has agreed to review the data chapter once it is ready.
2. A NEAC member gave an update to work he had done to update Chapter 5 on disability and subsequent updates to the the disability questions in the HDEC screening form, noting that the HDEC Chairs have approved these changes to the form.
3. Some of the new questions include:
	1. Are there any barriers in your study that may exclude disabled people? If so, why?
	2. How are those barriers going to be addressed, to give equal opportunities for people with disabilities to participate in research?
	3. How will exclusion of disabled people invalidate the study?
	4. What funding is available for making this research an inclusive study?
	5. Will you study disability data?
	6. How are you working with disabled people in this study?
4. The NEAC member discussed with NEAC the difference between ‘health research’ and ‘disability research’, noting that all research should include people with disabilities. He discussed the terminology ‘people with disabilities’, versus ‘disabled people’, versus ‘impairments’, as well as different models of disability. He noted that disability is not located in the body. Rather, it is located in relationships and socially understood barriers to inclusion, and impairments are located in the body, and can be described as a functional limitation. Disability research looks at the barriers in society which are in the way of a person fulfilling their potential function in life and to being included. This is different to medical research.

# **Update from Chair of NTB Health and Disability Ethics Committee**

1. The Chair of the Northern B HDEC gave an HDEC update to the Committee.
2. She presented some data to NEAC, showing that volumes have reduced by about 20%, and that often studies are postponed or cancelled. NZ allocation in therapeutic trials often <5, sometimes 1. Recruitment is slow.
3. Investigator-initiated intervention trials of a medicine/device comprised 34% of studies between 01 September 20221 and 21 September 2022. Commercially sponsored trials of a medicine/device comprised the remaining 66%.
4. The top 2 organisations are responsible for 25% of all intervention studies, 32% of all trials, and 41% of commercial trials. This will be reported to the HRC in the HDEC annual report.
5. She informed NEAC of a trend she has observed whereby, increasingly, women of childbearing potential are being excluded from Phase 1 studies, coinciding with the overturning of Roe v Wade. She suggested that NEAC Standards 9.11-9.13 should go further in acknowledging that all women should have an equal opportunity to participate in research and that by excluding them in early phase trials there is a gap in biomedical knowledge that is filtering through in the science.

## **Actions**

* Secretariat to incorporate a review of Standards 9.11-9.13 into the Standards Review.

# **Assisted Dying Presentation and Discussion**

1. Representatives from the Regulatory Assurance Secretariat who administer the End of Life Choice Act 2019 presented to NEAC about what The Act entails and gave some examples of the feedback the team has received in relation to conscientious objection, in particular the risks that medical practitioners who conscientiously object are facing in this health service.
2. The Act provides that health practitioners are not obliged to assist any person if they have a conscientious objection, but they must tell the person that they are a conscientious objector and inform them that they have the right to contact the Support and Consultation for End of Life in New Zealand (SCENZ) group to help them initiate the process.
3. Training developed by the Secretariat is available to practitioners but there seems to be a tension between legal responsibility and individually held moral views that do not agree with assisted dying.
4. There is also a tension between the requirements of the Act to not advertise this service and equitable service provision. Information is available digitally, but it is hard to find, and some people do not have access to the internet.
5. The Secretariat gave examples of patient feedback that showed where practitioner conscientious objection has given rise to challenging experiences for those who wish to enquire about or access the assisted dying service.
6. The Secretariat noted that they were seeking advice from NEAC on the best way the service can help medical practitioners manage their conscientious objection before it reaches the scrutiny of the assisted dying service Registrar or the Health and Disability Commissioner through a complaint served against them.
7. NEAC noted there is potential for the legal tools to come down hard on health care professionals when patient and whānau experience has not been a mana enhancing one. It acknowledged the work already being done by the Secretariat and other agencies to educate health practitioners about this service and suggested that there could be scope for a broader conversation with practitioners that would result in constructive talk about how things need to change to uphold the mana or integrity of a person and their whanau.

## **Actions**

* Assisted Dying Secretariat to send NEAC Secretariat information that the HDC has published and intercepts with the End of Life Choice Act.

# **Running Assisted Dying proposal through Prioritisation Framework**

1. This was an exercise to look at how the Prioritisation Framework might work when NEAC has a basis of shared information.
2. NEAC noted during the exercise that it wasn’t clear what additional guidance the Assisted Dying Secretariat was asking for from NEAC. It noted that a number of other agencies appear to be working in this space and NEAC would need more information to determine on what basis it should act.
3. An additional question for the Prioritisation Framework was suggested: Are other agencies dealing with this issue?

## **Actions**

* NEAC to send a letter to the Assisted Dying Service Secretariat seeking clarification as to what additional guidance NEAC is being asked to give. Secretariat to draft letter with NEAC guidance and advice on content.

# **Work between meetings**

1. NEAC discussed work between meetings. NEAC noted:
* The Rangatiratanga Roopu and it was suggested that Karaitiana Taiuru be invited to talk the work ACART is doing in this space.
* NEAC Health and Disability Research Standards
* NEAC members to flag with NEAC Chair and NEAC Secretariat what it considers to be urgent work to consider for its work programme.