

**National Ethics Advisory Committee**

### 28 July 2022

**9:00am – 3:00pm**

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# **Attendees**

**NEAC members:** Shannon Hanrahan (Acting Chair), Dr Mary-Anne Woodnorth, Gordon Jackman, Dr Penny Haworth, Nora Parore, Lindsey MacDonald, Dr Hansa Patel, Edmond Carrucan, Rochelle Style

**Guests:** Nic Aagaard, Manager, Ethics, Ministry of Health

 NEAC Secretariat, Ethics, Ministry of Health

Sarah Jones, Principal Advisor, Regulatory Assurance, Ministry of Health

 Monique Jonas, Health Research Council of New Zealand

Lana Lon, Health Research Council of New Zealand

 Catherine Garvey, Chair, Northern A Health and Disability Ethics Committee

**Apologies:** ProfessorJohn McMillan (Chair), Associate Professor Vanessa Jordan, Dr Cindy Towns

# **Approval of the day’s agenda**

1. The day’s agenda was approved.

## **Actions**

* Secretariat to publish July agenda on NEAC website.

# **Declaration of Interests**

1. It was asked if job titles should be included as a DOI and it was agreed that job titles should be added if there is a potential conflict of interest.

## **Actions**

* Secretariat to update members’ recorded declarations of interests.

# **Approval of minutes from NEAC’s 26 May 2022 meeting**

1. Members approved the minutes from NEAC’s meeting on 26 May 2022.

## **Actions**

* Secretariat to publish May minutes on NEAC website.

# **Actions Arising from NEAC’s 26 May 2022 meeting**

1. The Chair asked the Secretariat if there are any outstanding actions from last meeting and the Secretariat informed NEAC that there are a number of actions currently in progress.

# **Chair’s update**

1. The Chair informed the Committee that the Māori members of NEAC are meeting in a subgroup next week to discuss how they can best work together as individuals and as a collective, and to discuss further goals and principles of the group.
2. The Chair discussed the potential of further engagement with ACART around developing a shared approach to engaging with Māori and other stakeholders.

# **Secretariat update**

1. The Manager of the Ethics team gave a staffing update, including informing NEAC of a new Assistant Advisor will be supporting NEAC.
2. The Manager of the Ethics team also gave an update on the Health System changes, including that the Ethics team now sits in a new directorate called Regulatory Services

# **WHO Meeting in Portugal**

1. The Manager of the Ethics team updated NEAC on the WHO Global Summit of National Bioethics Committees in Portugal, 15-17 September 2022, which he will be attending. The NEAC Chair may attend also. He shared a draft agenda of the meeting.
2. He noted that the Steering Committee is particularly interested in NEAC’s work with indigenous populations and so he will be presenting on research with Māori, the Māori Health Authority, the Partnership of Principles and taking a strengths-based rather than deficit-based approach to indigenous populations.
3. It was agreed that the Manager of Ethics would work with the Rangatiratanga Roopu on this presentation.
4. It was suggested that the Government’s acceptance of equity and provision of health services as Treaty Principles could be discussed in the presentation. It was noted that this is an opportunity to present something unique from NEAC’s perspective regarding aspirations around partnership with Māori and what this looks like within a global discussion around the role of indigenous people.

## **Actions**

* Manager of Ethics to circulate next Steering Committee agenda to NEAC. NEAC members to send any questions through to the Manager of Ethics, to be fed back to the Steering Committee.

# **IEC and HDEC Ethics Committee Training**

1. The Manager of Ethics discussed training for Ethics Committee members in the health research space (including HDEC members, institutional ethics committee members and Health Research Council Ethics Committee members).
2. He noted that the Health Research Council (HRC) were holding a meeting where this would be discussed on 29 July 2022 and asked NEAC members to consider what they would like the Secretariat to feed back into that meeting, regarding the best ways to train existing and new ethics committee members in the health research space.
3. NEAC discussed the issue of national ethical standards for social science research, and the definition of ‘ethics committee’.
4. A member raised the fact that university ethics committees do not always follow the National Ethical Standards for Health and Disability Research, in the interest of approving research so that students can complete their research projects. The member noted that this raises a question of what students need in order to be able to do high-quality, methodologically sound, ethical research.

## **Actions**

* Secretariat to raise discussion points above with the HRC.

# **Safe Areas presentation**

1. Sarah Jones from the Regulatory Assurance team at the Ministry of Health delivered a presentation to NEAC on the implementation of Abortion Safe Areas.
2. Sarah explained that her team is responsible for implementation of the changes to Abortion services required under the Abortion Legislation Act 2020.. She explained that Safe Areas was initially part of this reform, but was removed due to Bill of Rights Act concerns. Safe Areas were reintroduced by a Private Member’s Bill and brought to a conscious vote. The NZBORA implications were worked through and the Safe Areas Amendment Act was passed in 2022, incorporated into the Contraception, Sterilisation and Abortion Act.
3. This Amendment aims to protect the safety, wellbeing, privacy and dignity of people who are accessing or providing abortion services. A Safe Area can cover an area of up to 150 meters from the perimeter of premises where abortions services are provided. Certain behaviours are prohibited within Safe Areas, including behaviours which may be considered distressing to a person accessing or providing abortion services, or attempting to stop a person accessing or providing abortion services.
4. She explained that Safe Areas need to be demonstrably justified in a free and democratic society as a reasonable limitation on people’s rights and freedoms.
5. NEAC raised and discussed issues of online safety, interim safety measures, and safe transport into Safe Areas.
6. NEAC agreed to add generic guidance for balancing ethical tensions in this space to its list of potential work projects to be run through its Prioritisation Framework.

## **Actions**

* Add generic guidance for balancing ethical tensions in this space to NEAC’s list of potential work projects to be run through the Prioritisation Framework.

# **EGAP**

1. The Secretariat discussed the launch of the public consultation for *Ethical Guidance for a Pandemic*, and asked members to invite and encourage their networks to participate in the online survey.
2. NEAC members shared some additional stakeholder groups to be added to the stakeholder list.
3. The Secretariat shared some draft promotional posters for the consultation on screen, and NEAC members requested some changes.

## **Actions**

* Secretariat to update stakeholder list.
* Secretariat to share draft email to stakeholders, and updated promotional posters, with NEAC members.

## **Standards**

## The Secretariat presented the revised version of Chapter 6 Ethical Management of Vulnerability for noting and approval. Notable changes to the chapter include:

## A revised introduction with a new diagram

## Refined terminology throughout the chapter (e.g. risk instead of exploitation, impairment instead of disability, rainbow community instead of LGBTQI).

## More guidance on diminished capacity.

## A new clause advising researchers they need to “ensure appropriate independent support is provided should any individual vulnerabilities be increased as a result of the research”.

## More guidance on managing unequal power relationships.

## Clarification that all participants who turn 16 are presumed to have competence and their consent for continued participation must be obtained.

## Guidance on managing a conflict of interest

## NEAC noted the chapter was incomplete and still required more guidance on researcher vulnerability and on the capacity to provide informed consent changing over time.

## NEAC noted a legal opinion on the children and young people section is necessary.

## NEAC reviewed the standards review timeline. Members agreed to focus on Chapter 5 Disability research as the next chapter for review.

## NEAC discussed the need for external reviewers for Chapter 4 Research and Pacific Peoples and Chapter 16 Research with stem cells and reprogrammed cells. NEAC noted it does not have expertise within these areas with its current membership. NEAC agreed the Secretariat would contact appropriate experts with an invitation to review the standards.

## **Actions**

## Secretariat to enter the chapter 6 revision into the revised standards document.

## Secretariat to organise expert reviewers of chapters 4 and 16.

## Secretariat to obtain legal opinion on the children and young people section of chapter 6.

## Standards review subgroup to draft more guidance on researcher vulnerability and the capacity for informed consent changing over time.

## Standards review subgroup to begin reviewing chapter 5.

##

## **HRC presentation preparation**

## NEAC discussed its role in relation to the Health Research Council (HRC) and noted a crossover and overlap of some functions but not others. NEAC noted the HRC funds health research in New Zealand and this gives it a great deal of power in shaping the health research landscape.

## NEAC noted its role is not limited to health research but includes health services too which gives it a broader scope than the HRC.

## NEAC noted one of its roles is to monitor the functioning of the HDECs but does not have a formal monitoring relationship with the HDECs to do so.

## NEAC discussed the lack of substantive reporting from the HDECs. NEAC noted statistical reporting of volumes of submission and turnaround time does not inform NEAC of emerging and pertinent ethical issues e.g. CRISPR gene editing studies, studies involving organoids and incidents such as participant deaths in New Zealand trials. NEAC noted this is an issue with HDEC's annual reports to the HRC as well.

## NEAC discussed developing a template for the HDEC Chairs that contained appropriate prompts for the HDEC Chairs and Secretariat to report the necessary information to NEAC.

## NEAC noted the relationship between the Advisory Committee on Assisted Reproductive Technology (ACART) and the Ethics Committee on Assisted Reproductive Technology (ECART) with both committees sending observers to attend meetings of the other. NEAC agreed a similar arrangement with the HRC or HDECs would be beneficial.

## NEAC queried whether it may co-opt non-voting ex officio members or whether this needs Ministerial approval. The Secretariat stated it is permissible to invite observers who would not count for quorum or decisions. The Secretariat agreed to investigate further.

## **Actions**

## Secretariat to investigate an observer arrangement between NEAC and HRC.

## Secretariat to investigate ability of NEAC to co-opt non-voting ex officio members.

## Secretariat to develop HDEC reporting template for updating NEAC.

##

## **HRC presentation**

## Two representatives from the Health Research Council (HRC) presented to NEAC. They explained the Health Research Council (HRC) was formed in 1990 in the aftermath of the Cartwright Inquiry and was charged with dispensing funds and ethical oversight of health research.

## They explained one of its functions is to ensure that any application that receives HRC funds also receives independent ethical review, either from the Health Research Council Ethics Committee (HRCEC) or from an independent ethics committee with HRCEC approval. In practice the HRCEC does not review applications and its core function is the work of approving ethics committees.

## They noted that one if the HRCEC’s functions is to provide ethical guidelines and this overlaps with NEAC's National Ethical Standards.

## They noted a previous Minister of Health requested it act as an appeal body for research applications declined by other ethics committees. They noted this has only occurred three times, with declined applications from the national Health and Disability Ethics Committees (HDECs).

## They noted it meets four times annually and sets guidelines on approval for ethics committees, including compositional requirements. They noted Māori membership on committees remains low and the burden placed on Māori members to attend meetings is high, which otherwise would have no Māori voice in their absence. They noted some committees struggle to meet this requirement and it tries to support them in meeting this requirement rather than withdrawing approval. They requested any guidance from NEAC on this matter.

## They discussed with NEAC the relationship between the two bodies, overlaps and gaps in remit and agreed to pursue a more collaborative relationship in the future.

## NEAC noted some of the HRC ethical guidance did not align with NEAC's National Ethical Standards such as the guidance on children and young people and the guidance on tissue.

## The HRC and NEAC noted some researchers, particularly those not based at a university, may encounter uncertainty around the governance structure of ethical oversight for health research and the two bodies should produce work to clarify this.

## NEAC noted a further gap in the ethical oversight structure with other governmental ethics committees such as ACC and the Ministry of Social Development.

## NEAC discussed whether the HRC should become involved in broader social research and noted it had caused difficulties overseas when biomedical ethics is applied to social science.

## The HRC noted challenges with training ethics committee members and the cost associated. The HRC stated it would be holding a workshop to begin developing training materials and invited NEAC to participate in the process.

## **Actions**

## Secretariat to liaise with HRC to establish a working relationship and future meeting attendance.

# **Prioritisation Framework**

1. The Secretariat discussed the updated Prioritisation Framework and NEAC tested a potential work programme project through the Framework.
2. Members expressed that they found the process very useful and enlightening, but that the process for using the Framework needs to be finetuned, including ensuring that NEAC members are given a clear briefing of each proposed project before attempting to run it through the Framework.
3. It was suggested that rather than running through each potential project down the list of the criteria before moving onto the next potential project, rather each criteria should be run against each project before moving on to the next criteria.
4. It was agreed that scoring should be done individually before being shared anonymously with the Committee, to avoid group bias.
5. Members commented that they found the scoring process to be helpful in evaluating their own biases.
6. The following process was suggested:
	1. NEAC members or external stakeholders send Secretariat a problem-statement/project briefing to the Secretariat
	2. The Secretariat screens the project through the Framework (and potentially scores as well)
	3. The problem statement is framed by the Secretariat (and given ahead of the meeting so members have time to consider)
	4. NEAC discuss
	5. Score anonymously
	6. Go with the majority, but members have an opportunity to speak to their issue and have everyone re-score
7. It was discussed that consideration needs to be given for how much resource is required to undertake a given project, and that this could be part of the screening process before running a potential project through the Framework.
8. An additional criteria was suggested: the work projects fits within Government’s health strategy, and therefore the Minister is more likely to agree the project.
9. Clarity was suggested around what is meant by “guidance is needed”, and whether this entails NEAC deciding of its own accord that guidance is needed, or if it entails external stakeholders approaching NEAC for guidance.
10. It was agreed that the wording around the Te Tiriti o Waitangi criteria needs more work, which could be undertaken by the Rangatiratanga roopu. ‘Give effect’ rather than ‘honour’ was suggested.
11. It was agreed that a record should be kept of suggested projects that do not make it onto the work programme, so that there is opportunity for them to be reassessed against the Framework in the future.

## **Actions**

* A subgroup will meet to:
	+ Confirm process
	+ Discuss and agree the above suggestions

# **Update from Chair of Northern A Health and Disability Ethics Committee**

1. The Chair of Northern A relayed that all HDECs are now at full membership after appointments with a range of diverse backgrounds. The HDEC website has been updated with all bios of new members for the Committee and the public to look at.
2. The Chair gave an overview of submissions received to date and reported that turnaround times were within target dates, noting that the new system allows for easier review for members.
3. The range of high-risk studies were broad, with a high number involving vulnerable participants (which varies), participants under 16 years of age and some participants enrolled under Right 7(4). The Chair noted that the applicants are always willing to have good discussions around risk.
4. The HDECs along with the Secretariat developed advertising guidelines for clinical studies which is now available online. The participant information sheet (PIS) templates were also updated to remove gendered pronouns as well as the inclusion of more explicit references to the GP being informed of participation. In addition, the HDEC application form is being updated to include further disability questions to better assist researchers to meet chapter 5 of the National Standards.
5. The Committee queried with the Chair any incidence of deaths and the increase in complex genetic studies. The Chair summarised key issues linked to age-related consent and noted that the HDECs ensure children are getting information in a way they can understand and not be pressured.

# **Clinical ethics query**

1. A letter was received that was revisiting prior correspondence from 2020. The Committee were in agreement that the author is welcome to discuss their query with NEAC directly about clinical ethics.

## **Actions**

* Secretariat to invite author of letter to discuss their query directly with the Committee

# **Research involving participants who are unable to give informed consent**

1. The Secretariat gave an update on Right 7(4) and confirmed there will be a review of the Act and Code of Rights with public consultation in 2023-2024. It was noted that the consultation on proposed changes is unlikely to happen until the Ministry puts processes in place and NEAC updates the Standards. After discussion, it was agreed that further discussion between NEAC and the HDC is required to determine what is meant by risk and ensure both are in agreement on what cases should be prohibited.

## **Actions**

* Secretariat to circulate paper that raised issues about the terminology the HDC are proposing.

# **Work between meetings**

1. The Rangatiratanga subgroup, Ethical Guidance for a Pandemic subgroup and Standards sub groups are all active, with the Secretariat in contact with each of them about next steps and meetings. A subgroup to progress the Framework was formed.