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**National Ethics Advisory Committee**

**24 March 2022**

**9.00am – 3.00pm**

**Attendees**

NEAC members: Professor John McMillan (Chair), Dr Mary-Anne Woodnorth,
Gordon Jackman, Dr Penny Haworth,

Associate Professor Vanessa Jordan, Shannon Hanrahan, Nora Parore, Dr Cindy Towns, Dr Lindsey MacDonald, Dr Hansa Patel,

Edmond Carrucan, Rochelle Style

Guests: Manager of Ethics, Ministry of Health

Chair of the Central Health and Disability Ethics Committee

**Declarations of Interests**

1. Members updated the committee and Secretariat with changes to their declarations of interests.

Actions:

* Secretariat to update members’ recorded declarations of interests.

**Approval of minutes from NEAC’s November 2021 meeting**

1. Members approved the minutes from NEAC’s meeting on 11 November 2021.

**Chair’s update**

1. The Chair outlined NEAC’s current work programme and the current sub-committees to gather the interest of new members in joining a sub-committee.

**National Ethical Standards Review**

1. Members from the National Ethical Standards (the Standards) review sub-committee provided a progress update. The sub-committee began its revision with Chapter 18 ‘Quality Improvement’ and acknowledged it was an umbrella term that encompassed multiple disciplines and it is challenging to provide guidance that is fit for purpose. NEAC discussed the nuance of health research versus quality improvement and that the principles in the Standards are applicable to quality improvement.
2. NEAC discussed the importance of communicating and engaging with the sector so research stakeholders are aware of changes before they are published.
3. NEAC identified Chapter 12 ‘Health Data’ as the next section that would soon undergo revision.
4. NEAC discussed the potential risks associated with the use of artificial intelligence (AI) technologies in quality improvement activities and whether this would bypass the Health and Disability Ethics Committees’ (HDECs’) scope of review. NEAC discussed writing to the Ministry of Health to raise these issues for consideration in the Modernisation of Ethics (MOE) project.
5. NEAC discussed Chapter 5 ‘Disability Research’ and queried whether the Secretariat had received feedback on it during the public consultation on the Standards. NEAC queried whether researchers were implementing the guidelines of the chapter into their research. The Secretariat agreed to use the HDECs’ online system, EthicsRM, to identify disability research and enquire with the HDECs.
6. NEAC discussed the remaining chapters and queried whether the Te Ara Tika principles could be better embedded throughout the Standards but otherwise the changes would likely be minor.
7. The Secretariat agreed to provide members of the sub-committee with the original submissions from the public consultation.
8. NEAC discussed the Standards being a ‘living document’ and how frequently it ought to be updated. NEAC acknowledged that the Standards document is lengthy and that frequent small changes can be difficult to keep track of and might be unfair on researchers if they are unaware of changes to the Standards. NEAC emphasised the end-user lens was important to consider whenever changes are proposed. NEAC discussed the necessity of the Standards to be flexible and able to be updated when needed in order to respond to technological advancements that may affect the ethics of health research. NEAC identified that proper version numbers and document control as essential to updating the Standards.
9. NEAC queried if the Standards were official Government regulations published in the Gazette. The Secretariat clarified that as a Ministerial Committee they are self-published and not gazetted.

Actions

* Sub-committee to present draft revision of Chapter 18 ‘Quality Improvement’ to the full committee at a future NEAC meeting
* Communication strategy for updating the Standards to be added to the next NEAC meeting agenda
* Secretariat to draft a letter on behalf of NEAC to the Ministry of Health regarding the MOE project
* Secretariat to gather data on disability research studies from the EthicsRM system and feedback from HDECs on how the new chapter has influenced disability research
* Secretariat to distribute consultation documents to the sub-committee.

**Research with adults who are unable to provide informed consent**

1. NEAC considered its draft letter to the Health and Disability Commissioner (HDC) regarding the ongoing review of the HDC’s Code of Health and Disability Services Consumers’ Rights (the Code) and, discussed the broader landscape and associated issues for HDECs in reviewing research that needs to meet Right 7(4) of the Code, the right to make an informed choice and give informed consent.

Background

1. Right 7(4) of the Code does not specifically mention research participants, however, it does cover participation in research by virtue of Right 9 (Rights in respect of teaching or research).
2. Because outcomes are uncertain in research, difficulty arises for researchers who wish to increase knowledge and understanding of conditions in patient groups where people are not able to provide consent. An HDC led review of Right 7(4) began in 2017 and, the former Commissioner released a report that contained proposals and recommendations. Recently, representatives from NEAC, the Health Research Council (HRC), and the HDC met to discuss the next steps in the process.
3. In relation to interpretation of Right 7(4) for research, there are differing views between legal experts, other agencies, and within and across HDECs. The Secretariat noted legal views are often relatively conservative, though that is understandable.

How NEAC might assist the HDECs with consistency in decision making

1. It is difficult for the HDECs to consider the issue of how Right 7(4) applies to research participants and make decisions in a consistent way due to the complexity of applying best interests to unique and different research studies and patient populations.
2. ICU researchers have developed a well thought through matrix of scenarios that might occur under Right 7(4), and this matrix could be included in NEAC’s letter to the HDC as it could be helpful for the HDC to view an outline of the process taken currently. It should be noted, however, that while the matrix is very useful it might need to be fine-tuned and updated.
3. NEAC’s Terms of Reference allows for it to: “monitor and review the decisions of the HDECs for the purposes of providing direction, guidance and leadership to ensure the ongoing quality and consistency of ethical review in the health and disability sector”. NEAC discussed mechanisms it might use to capture or understand how consistently guidance is applied. Options include education and refreshers for the HDECs and, to communicate more about the Standards and what they mean. For example, the ICU tool could be used for training in future to help with consistent decision making. The matrix could also provide a framework to aid consistency in decision-making across the HDECs and serve as a mechanism for NEAC to monitor how these decisions are being made.
4. With the new EthicsRM portal and the ability for refined data collection, there is an opportunity for NEAC to understand how committees are making decisions. Quarterly minute review by the Secretariat is planned within the MOE project to help understand how the HDECs are making decisions and where there are inconsistencies, and this information could also be fed back to NEAC.

Cluster randomised trials

1. NEAC noted the related issue of cluster randomised trials, which raise the issue of when consent should ethically be waived if providing a research related treatment option, when randomising patients at a system level. The ethical issues relate to the concepts of what is practical and what is impractical. There is currently no legal mechanism to waive consent in such trials. The Secretariat will raise this with the Ministry of Health internal working group on embedding research into routine care. The only option open to the HDECs currently is to decline such applications as they are not able to approve research that is contrary to law even when the research is considered to meet ethical standards.

Actions:

* Secretariat to circulate the most recent ICU matrix of scenarios to NEAC and to table it at NEAC’s next meeting.
* Secretariat to feedback to the Modernisation of Ethics project the options discussed for monitoring and reviewing HDEC decisions.
* Secretariat to raise the issue of cluster randomised trials and the implications with the Ministry of Health.
* Secretariat to meet with NEAC Chair to refine the purpose of NEAC’s letter to the HDC, emphasise what has been done, and raise further questions in a concise way that could enable further discussion with the HDC. Table letter at next NEAC meeting. Publish letter to the HDC to indicate to the research community and the HDECs that NEAC continues to work on this issue.

**Framework for NEAC decision making**

1. NEAC considered a draft decision-making framework that it might use to consider where it is best placed to exercise change and progress work on its programme.
2. The motivations for the proposed framework are twofold: a shared list of all the things NEAC might do and order of priority to allow NEAC to direct its effort in the best possible way it can and, to give NEAC accountability to say why it has chosen to devote work to a particular issue.
3. A framework can bring a degree of rigour and objectivity to how NEAC’s work programme will be ranked, and it was agreed that some further thought and work needs to be done around what the non-negotiables are/what work NEAC has to do, and a threshold discussion had about what to include over and above the mandatory things.
4. NEAC agreed there is a need for a framework that allows it to step back and ask what its values and purpose are. NEAC agreed to try the proposed framework and, to test whether the scoring system is helpful and if not, then it could be simplified possibly to 10 principles. Alternatively, a series of vignettes that NEAC could collectively work through.
5. In tandem, further thought can be given around a process for use and whether to make the process publicly available beyond the Secretariat and the Committee.

Actions:

* NEAC to trial the framework and at the same time give further thought about how to weight the points in the draft
* Secretariat to reframe points made in the introduction to give more emphasis to the framework being a guide and to give more emphasis to non-negotiables for NEAC that will automatically be on the work programme
* Statement 2 about ethics in focus is a stop/go point in the model and the Secretariat will rework to make this clear
* Statement 3 to be reworked so that what is meant by clarity of ethics question is clearer
* Statement 4 Ethical guidance/clarity/standards is needed by stakeholder groups Secretariat to include disability groups and patient groups, health researchers, and consultation groups noted in NEAC’s Terms of Reference
* Te Tiriti o Waitangi at 6b to be made its own point. Secretariat to change Statement 6 and include an additional statement 6b emphasising Te Tiriti o Waitangi.

**Draft National Ethics Pandemic Plan**

1. The draft National Ethics Pandemic Plan was discussed.

## The Secretariat asked new members for their feedback on the draft publication

Discussed but decided against/not agreed:

1. NEAC discussed whether the draft document should refer to Māori versus ‘Western’ bioethical principles. A member commented that there is no coherent ‘Western’ approach to bioethics and therefore the ethical principles should not be presented according to such a dichotomy. No decision was reached to change the presentation of the principles in the draft publication as a result of this discussion.
2. Chapter 3: Readiness and Reduction, should just refer to ‘readiness’ in its title because there is very little discussion of reduction in that chapter. Risk reduction is a part of readiness. It was note noted that Chapter 6 reverses the order of the wording, referring to ‘reduction and readiness’.
3. It was suggested that the popular saying from the Prime Minister, ‘wear a mask, wash your hands’ should be included.

Suggested/agreed changes to the publication:

1. The foundational ethical principles at the beginning of the draft document should recognise the Pasifika and Disabled communities, as COVID-19 has shown that these communities, alongside Māori, will be most highly impacted by a pandemic. This should be reflected throughout the draft document, where relevant.
2. The draft publication should be referred to as ‘guidelines’ rather than as a ‘plan’.
3. In Chapter 3, page 19, migrant diversity is not well represented, noting that in 2021 former refugees came into New Zealand from 21 different countries.
4. In Chapter 3, page 21, education is missing as a social determinant of health (especially in a pandemic context, where children are not attending school).
5. The draft document needs a further proofread.
6. Instead of referring to ‘pillars’ in the Te Whare Tapa Wha model of health, these should be referred to as ‘Tapa’ (the sides of the house).
7. An incorrect comment about being legislatively bound to protect Te Tiriti of Waitangi, which is not actually the case, was noted.
8. The flax and intervention ladder are useful as they provide visual stimulation to the reader. These should be brought forward or highlighted to the reader in advance so that they ‘have something to look forward to’.
9. There has been increasing racial tension towards the Asian population during COVID-19. This should be considered in the draft document.
10. Takatāpui should be included in the draft document.
11. A sense of having a strong cultural identity should be included as a social determinant of health, especially in the pandemic context of Māori not being able to return home to their marae. Cultural identity is part of Te Whare Tapa Wha.
12. The commentary on page 35 regarding vaccinations of police versus prisoners could be viewed as insensitive and more nuance is required.
13. Members corrected references to their official titles and asked the Secretariat to edit these.

The Secretariat asked members for their feedback on the draft consultation plan

Suggested/agreed changes to the consultation plan:

1. It was suggested that the consultation should be launched sooner rather than later, before momentum is lost.
2. The decision to host this consultation completely online was questioned, given the digital divide that is highlighted in the draft publication. The Secretariat responded that this was due to COVID-19/red level restrictions. NEAC noted that these restrictions are easing and questioned whether consultation still needs to be completely online. The Secretariat responded that in person meetings would not be possible for several months, with no current ability to propose anything in person. It was suggested that the consultation starts online-only, and can later consider adding in-person consultation. It was noted that in person consultation could also bring increased security and cost concerns.
3. The NEAC and ACART Chairs will meet to discuss a common approach to Māori engagement, with the goal to streamline this. Members suggested a broader piece of work regarding stakeholder mapping and engagement, and with disabled people in particular,rather than each member giving their ‘wish list’ for who they want to be contacted as part of this consultation.
4. It was noted that illiteracy levels in Aotearoa have the potential to exacerbate inequities in this consultation. It was noted that some of the language used in the draft document is inaccessible for some communities. It was suggested that some creative means could be used to broker the korero, including some familiar faces and some animations to represent the concepts more broadly. This could go a long way to addressing some of the inequities in accessing the content and consultation.
5. The following stakeholder groups were noted for inclusion:
	1. Ministry for Disabled People
	2. Uruta
	3. LBGTQIA+ groups
	4. Gender based groups e.g. white ribbon
	5. Disability groups
	6. Hui E (voluntary/community sector connections)
	7. Te Hunga Rōia Māori o Aotearoa
	8. Pacific Lawyers association
	9. Iwi Chairs
	10. Clinical ethics groups at DHBs and RACP ethics committee
	11. Principals Associations
	12. Red Cross (re: former refugees).

Discussed but decided against/not agreed:

1. It was questioned whether the draft publication can be made available in te reo Māori, given the importance of accessibility discussed in the content. The Secretariat responded that there is a considerable backlog within the translation services.

Actions:

* Members will send through their notes on the draft publication
* The Secretariat will implement the suggested/agreed changes to the draft publication, where appropriate
* The Secretariat suggested they show the foundational chapter/principles section to the Pacific Health team at the Ministry of Health to see if there are ways that the needs and values of Pasifika can be weaved into that section
* The Secretariat suggested working with the NEAC members with expertise in disability and/or the Disability Policy team at the Ministry of Health to improve the foundational chapter/principles section in regard to the needs and values of disabled people
* Secretariat to talk to the NEAC members with expertise in disability about the role of ‘reduction’ in the disability chapter of the draft publication. The Secretariat will explore whether ‘reduction’ can be removed from the Chapter 3 heading
* Update the title of the draft publication to include ‘guidelines’ and amend accordingly throughout the various documents
* Organise a sub-committee meeting to discuss the detail of the draft consultation plan
* Secretariat to update the stakeholder list and circulate to NEAC.

**Update on the Modernisation of Ethics project**

The Ministry of Health Secretariat provided an update on the Modernisation of Ethics Project, and confirmed NEAC has representatives on the group, and would also have an opportunity to engage on proposed changes once finalised by the Advisory Group, noting NEACs role in the ethics review landscape.

**Update from Chair of the Central Health and Disability Ethics Committee**

1. The Chair of the Central Health and Disability Ethics Committee (HDEC Chair) spoke to NEAC about the recent experiences of the HDECs.It was noted that the HDEC/NEAC Training Day was held the week before this meeting, and NEAC was mostly up to date on the HDECs in terms of study statistics and the current volume of applications being considered.
2. The HDEC Chair raised the issue about use and security of data that is used for screening participants. Particularly during COVID-19, a lot of personal information is being sent overseas for research studies. The HDEC Chair also noted that the HDECs have had to push back on overseas sponsors who have not carried out research in New Zealand for several years. In some cases, applications have not adhered to the current ethical parameters that are required in New Zealand.
3. The Manager of Ethics added that an HDEC Chairs’ Day is held whenever there is a fifth Tuesday in a month. Discussions at the Chairs’ Days will lead to more items for presentation at future NEAC meetings.
4. The Manager of Ethics noted that there are also ethical issues around the processes that happen before research applications are seen by the HDECs. For example, screening data, and how the Primary Health Organisations and District Health Boards are using this data to communicate to international sponsors about the opportunity to bring studies to New Zealand.
5. The Manager of Ethics also raised an issue regarding study advertisements. Commercial clinical trial sites have advertisements that require HDEC review. However, some sites also use generic advertisements that do not require ethical scrutiny and are beyond the remit of the HDECs. The generic advertisements do not fall within NEAC’s remit either. This causes a gap in ethical review and is an issue that the MOE project aims to resolve.
6. A member noted that the use of registries and overseas databases is an ongoing issue to consider. For example, international companies are building their own databanks. The Manger of Ethics noted that there is a chapter on Biobanks in the HDECs Standard Operating Procedures (SOPs), and the MOE project will ask whether a similar chapter for databanks and registries should be included in the SOPs, since they do not fit under the criteria for traditional research applications and have needed to be treated on an ad hoc basis over the past years.
7. The HDEC Chair noted an increase in electronic consent. She noted that it is important to ensure that the correct person is giving consent electronically, and to ensure that is done appropriately.
8. The Manager of Ethics also acknowledged that the HDECs are managing issues with Right 7(4) in research applications well. He noted that the HDECs are having to make decisions on whether research is in the ‘best interest’ of individual participants. It can be difficult to determine this.
9. A member asked how NEAC is perceived by the HDECs. The HDEC Chair stated that NEAC and its advisory role is clear and visible from the perspective of the HDECs. Further, the Standards were revised in 2019 and there were several discussions about this between NEAC and the HDECs.
10. A member asked how the HDECs are managing Te Tiriti o Waitangi obligations. The HDEC Chair advised that the HDECs are upholding Te Tiriti o Waitangi obligations and advocating strongly for Māori and Pasifika in research. The HDEC Chair also noted that she has seen a big difference in the quality of applications compared to 10 years ago, however, there are occasionally some applications that do not address Te Tiriti o Waitangi obligations sufficiently.
11. The Manager of Ethics advised that the Associate Minister of Health, Peeni Henare, who was delegated appointments from the Minister of Health focuses strongly on Māori and diverse membership for the ethics committees. The Principal Advisor of the Ministry’s Ethics team also improved the advertising process for members. This has impacted the way in which ethics committees make decisions. The Ethics team is also proposing to increase membership requirements from one member with expertise in Māori interests, to three members for each committee, in the next round of appointments. The Manager of Ethics also advised that the HDECs application form was updated to include direct questions, to require researchers to directly address Te Tiriti o Waitangi obligations.
12. A member noted that Chapter 5 ‘Disability research’ in the NEAC Standards is new and they queried what the HDECs’ experience has been regarding disability research and whether studies are including disabled people as participants. It was noted that there is currently not enough direct data/disability research available. It was also noted that in the HDECs application form, researchers are not currently required to answer direct questions about disability. The Manager of Ethics advised that the HDECs Secretariat can include mandatory questions for applications to answer regarding disability as these questions are likely already built into the form, however, they might be hidden behind a screening question to prompt them.
13. NEAC also discussed how the overall mindset should be shifted to involve disabled people in all research. It was noted that the emergence of new technologies, such as CRISPR (a technology that can be used to edit genes), will be hugely relevant for disabled people and their participation in research.

Actions:

* Secretariat to liaise with the HDEC Secretariat to arrange inclusion of mandatory questions regarding disability in the HDECs application forms.

**NZACRes’ submission to the Select Committee on the Accident Compensation Corporation Amendment Bill**

1. The President of the New Zealand Association of Clinical Research (NZACRes) shared a copy of NZACRes’ submission to the Select Committee on the Accident Compensation Corporation (ACC) Amendment Bill (the Bill). This information will also be made publicly available shortly.
2. The Chair provided an overview of the issue (exclusion of access to ACC for participants in commercially sponsored clinical trials), which has been ongoing for many years, and for which NEAC has provided advice about in the past to Ministers.
3. The main objectives of the Bill are to provide more equitable coverage for injuries covered by the Accident Compensation Scheme, and to provide greater clarity for claimants, and to better give effect to the policy intent of the Accident Compensation Act 2001 (the Act). The Bill is currently at Select Committee stage. NZACRes’ submission recommends the removal of the exclusion of commercial clinical trials from the Act.
4. NZACRes’ submission refers to the Ministry of Business, Innovation and Employment’s (MBIE’s) reluctance to repeal the exclusion of commercial clinical trials from ACC. The Chair noted that MBIE has concerns about the level of risk involved and that if commercial entities take responsibility for covering participant injuries in clinical trials, this might cause a disincentive to carry out research in New Zealand. It might also lead to companies providing less cover for participants.
5. A member noted that it is not uncommon for participants to be injured in clinical trials. This is often because the participant group is already very unwell. It was noted that if a participant is potentially injured due to their involvement in the study, and not due to their underlying condition, this can also cause a difficult and prolonged dispute between the sponsor and the sponsor’s insurance company. Further, sponsors can reject the assertion that a participant’s injury is directly related to the trial.
6. A member also noted that HDECs are required to assess whether clinical trial coverage is sufficient, however, they are only able to review the front page of insurance certificates. It is unknown what happens from an insurance perspective beyond that. The total number of participants in some multinational trials is not always known. The actual amount of participant cover is also unknown, because there is a limit per claim and in the aggregate, and the amount on some insurance certificates have been an average of $5 million each, which does not reach the same level of what ACC estimates a lifelong cost would be to someone who has been seriously injured.
7. A member raised the ethical issue of equity between New Zealand participants who are in a non-commercial sponsored trial, and those in a commercially sponsored trial. A participant in a commercially sponsored trial should not be prejudiced by compensation guidelines that are not legally binding and which do not provide no-fault compensation as ACC cover does.
8. The lack of visibility on this issue was discussed. The Manager of Ethics advised that data on participant injuries has only been collected since 2017 through researchers sending progress reports to the HDECs.
9. NEAC agreed on the option to revisit and update its previous advice on this matter and send a letter to the Minister of Health. The Chair also suggested that NEAC should write to the MOE project’s Advisory Group.
10. NEAC also discussed equity issues regarding general access to ACC cover and related discrepancies. For example, if someone is injured in an accident and unable to work, they may qualify for ACC cover, however, someone with the same injury caused by a genetic disease would not qualify.

Actions:

* Secretariat to locate NEAC’s previous advice
* Secretariat to draft a letter from NEAC to the Minister of Health
* Secretariat to draft a letter from NEAC to the MOE project Advisory Group.

**Work between meetings**

1. NEAC discussed work between meetings. NEAC noted that its member who represents disability perspectives attends the Asia-Pacific National Ethics Committee (APNEC) meetings as a NEAC representative. Attendance of another NEAC member was also encouraged for this presentation.
2. NEAC agreed that the following work will continue between meetings:
* the Standards sub-committee
* the pandemic guidelines sub-committee
* NEAC members involved in the MOE project.