

**National Ethics Advisory Committee**

**25th May 2023**

**9:00am – 3:00pm**

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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 Lindsey MacDonald, Dr Cindy Towns, Seini Taufa

# **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 16 March 2023**

1. Members approved the minutes from NEAC’s meeting on 16th March 2023.

# **Actions Arising**

1. The actions arising were noted, and it was suggested that greater priority be given to large language models such as ChatGPT given the risk of using these AI in a clinical setting. The Chair requested that a letter be written to NEAC from NAIAEAG and noted that this may need to be raised with the Minister during the BIM.

# **Secretariat’s update**

1. The Secretariat noted that induction packs were being worked on for new members.
2. Additional to this a survey of all HDEC stakeholders had been sent out and the results of this would be shared with NEAC upon completion.
3. The consultant to be contracted for work on EGAP was detailed to NEAC and the potential timeline for this laid out, awaiting confirmation based on resourcing via Manatū Hauora.

*Staffing update*

1. The Manager of Ethics updated NEAC on staffing, noting a Senior Advisor had returned to the team on reduced hours. The remaining FTE of this Senior Advisor will be backfilled.
2. The Manager of Ethics noted that an intern was being finalised to conduct a project around the data held and used by the Ethics team to monitor and improve the efficiency of the team.

*Ministry update*

1. The Manager of Ethics updated NEAC on the election shut-down period and that there were several briefings going from the Ethics team to the Minister prior to this.
2. Three appointment updates were provided by the Manager of Ethics, noting Vanessa Jordan is seeking reappointment to the Committee and acknowledged that Penny Haworth and Cindy Towns were finishing their terms. The NEAC appointments should be made before the election.

# **Chair’s update**

1. The Committee discussed the ‘*National Ethical Standards for Health and Disability Research and Quality Improvement*’ (the ‘Standards’) as per their relevance to the Pae Ora (Healthy Futures) Act 2022, and the legal basis that governs how the standards are weighted, applied, and upheld.
2. Further to this, NEAC noted that the audience of the Standards necessitates the repetition of some information across the chapters. The Committee discussed the way in which this may cause some issues for the users and how this may create unwieldy Standards.
3. On this point, the Secretariat noted that there would be some time to work on this during the election shut-down period.
4. The Chair proposed to move the “Summary and next steps” section for 2:20pm-2:40pm to the beginning of the meeting in order to ensure that there was sufficient care given to how NEAC will move ahead with a rewrite of the Standards.

## Actions

* The Committee to continue to discuss the Standards and a potential re-structure after the current tranche of edits are made.

# **Rangatiratanga Roopu update**

1. The Deputy Chair raised that there had been significant discussion at the meeting around how the Roopu was intended to function and the ways in which they work both together and on their respective committees.
2. An issue was raised around specific support within the Secretariat for Māori members. The Manager of Ethics noted that an update on this would be sent to NEAC once resourcing had been established.

## Actions

* The Chair requested a presentation from the Roopu on how NEAC should be including Māori perspectives and expertise.
* The Deputy Chair and Chair to follow up on Māori cultural competence training for NEAC Secretariat and discuss with Manager, Ethics.

# **Summary and next steps**

1. The Chair noted that the Standards were broadly set for a 5-year review period, noting this was similar to other sets of Standards, noting the Health and Disability Commissioner (HDC) being on a similar cycle with the Code of Rights.
2. Conversation relating to historic legal use of the Standards opened a conversation as to how appropriate it would be for there to be too frequent changes to the document and the way in which the Standards could be developed in the future.
3. The use of repetition in the Standards was defended per the use of the Standards in practice, as there is some requirement for self-containment in the chapters to ensure that there be enough information in each chapter so that they could be read in isolation and still provide sufficient detail to meet the requirement of specific groups.
4. A 5-year update cycle was noted to be sufficient for the timing of updates but that there would need to be some reactivity in the nature of the document in the event of legislative changes in this field. It was agreed that there could be a lot of benefit in having sections that could be appended for specific topics to ensure that the Standards remain relevant.
5. The Committee additionally noted that there needed to be more consistency in the terminology used. Decision trees and hyperlinks and a glossary or definition of terms section could be of value.
6. The Committee noted that during the next round of consultation on the Standards there would be an opportunity to get feedback on any suggested changes to the format.

## Actions

* The Committee to continue work on the Standards format and updates.
* Secretariat to move forward with the continued Standard review and bring the revised Standards back to NEAC for further review.

# **Chapter 5 – Disability**

## Actions

* The Secretariat to organise a meeting to discuss Chapter 5.

# **Chapter 6 – Ethical Management of vulnerability**

1. The Committee had no further changes to Chapter 6 and agreed to the changes in the papers.

## Actions

* Secretariat to update the Standards per the discussion.

# **Chapter 7 – Informed consent**

1. The Committee discussed the balance of informed consent without inundating the participants with information.

## Actions

* Secretariat to update the Standards per the discussion.

# **Chapter 8 – Research benefits and harms**

1. The Committee had no further changes to Chapter 6 and agreed to the changes in the papers.

## Actions

* Secretariat to update the Standards per the discussion.

# **Chapter 9 – Research development and design review**

1. NEAC agreed to incorporate the Te Ara Tika principles into the body of the text.
2. NEAC requested that all reference to “pregnant women” be replaced with “pregnant people”.

## Actions

* Secretariat to contact other health agencies who are working on co-design to inform the revised Chapter 9.
* Secretariat to update the Standards per the discussion.

# **Chapter 10 – Ethical features of studies**

1. The Committee had no further changes to Chapter 10 and agreed to the changes in the papers.

## Actions

* The Secretariat to organise a meeting to discuss what should be accessible to participants post-trial.
* Secretariat to update the Standards per the discussion.

# **Chapter 11 – Research conduct**

1. The Committee noted that as there are many trials that do not have sponsors, there should be some rewording through this section to add the Co-ordinating investigator for studies that do not have a sponsor.
2. It was noted that the timely release of data that should be made available one year after the completion of collection.

## Actions

* Secretariat to add Co-ordinating investigator to the glossary of the Standards.
* Secretariat to update the Standards per the discussion.

# **Chapter 12 – Health data**

1. Discussion on the retention of data led to the decision to take further conversation regarding the review of this chapter offline.

## Actions

* The Secretariat to organise a meeting to discuss Chapter 12.

# **Chapter 13 – Health data and** **new technologies**

1. The Committee noted that there needs to be the addition of some AI and Machine learning guidance in this chapter and that as such there should be some greater consideration of items for the future development of this chapter.
2. “Individual’s data” should be amended into the consideration of “consumers or participants”.

## Actions

* The Secretariat to organise a meeting to discuss Chapter 13.
* Members to provide diagrams for use in Chapter 13.

# **Chapter 14 – Human tissue**

1. The Committee moved to include that there be an addition to the Standards to include images of participants as health data.
2. Mention of data that is stored for vulnerable populations should contain a hyperlink to that section which has specific guidance.

## Actions

* Secretariat to update the Standards per the discussion.

# **Chapter 15 – Biobanking**

1. The Committee noted that the use of the term “Tissue warehouse” could be viewed as disrespectful. The terms “Storehouse” or “tissue bank” should be used.

## Actions

* Secretariat to update the Standards per the discussion.

# **Chapter 16 - Research with stem cells and reprogrammed cells**

1. The Committee noted that there were currently no provisions for additions based on stem cells not derived from foetal tissue and that this would need to be considered in the future for a more sizeable restructure of the Standards.
2. Few changes were made as researchers in this field that had been consulted stated that the HART Act was too prohibitive to allow for changes to the Standards that could be meaningful.

## Actions

* Secretariat to update the Standards per the discussion.

# **Chapter 17 – Compensation for injury in commercially sponsored intervention studies**

1. The Committee noted the differences between the Medicines New Zealand Guidelines and ACC including (1) the availability of compensation per se; (2) the type of compensation; (3) the value of the compensation; and (4) length of time over which the compensation is payable. Furthermore, the HDECs are restricted in their ability to make an assessment of equivalence because of the constraints in the HDEC Standard Operating Procedure regarding the type of documentation they may consider and the provision of information to them on the parity of entitlements available from ACC.
2. The Committee noted that any changes to this chapter will also necessitate review of the HDEC SoP, HDEC templates and application form questions.

## Actions

* Secretariat to produce an analysis paper for NEAC to consider at the September meeting.
* Secretariat to update the Standards per the discussion.

# **Chapter 18 – Quality improvement**

1. The Committee had no further changes to Chapter 18 and agreed to the changes in the papers.

## Actions

* Secretariat to update the Standards per the discussion.

# **Work between meetings**

1. Chair and Deputy-Chair of NEAC provided feedback on their meeting with the HDC and the conversation about teaching, research, and the Code of Rights.
2. Chair and Deputy-Chair of NEAC and the Manager of Ethics will be meeting with the Minister of Health on 9 June 2023.
3. The Manager of Ethics to meet with Maree Candish to discuss resourcing and support for a restructure of the Standards.
4. Secretariat to arrange a meeting of the rangatiratanga Roopu to discuss research with Māori.