

**National Ethics** Advisory **Committee meeting minutes**

**7 March 2017**

## Present

Neil Pickering (Acting Chair)

Julian Crane

Adriana Gunder (QSM) (by phone until 12.20pm)

Maureen Holdaway

Fiona Imlach

Monique Jonas

Wayne Miles

Kahu McClintock

Liz Richards (from 10.00am)

Hope Tupara

Dana Wensley (from 10.00am until 1.30pm)

## Secretariat in attendance

Beverley Braybrook

Isabel Ross

## Guests in attendance

Philippa Bascand, Manager Ethics, Ministry of Health (12.30pm – 1.30pm)

## Welcome

1. The Acting Chair welcomed members to the meeting.

## Member declaration of interests

1. The record of current declarations of interests was included with the meeting papers. No new declarations were made.
2. Neil Pickering asked members with no current declarations of interest to confirm that they have no competing interests. This would be recorded in the declarations of interests table.

*Action*

* Members with no current declarations of interests to confirm they have no competing interests to the Secretariat.

**Upcoming events and reports back**

1. Julian Crane reported back on his and other presentations at the Bioethics conference in January 2017.

* Research using big data is not new; this type of research has been possible for around 10 years. However, advances in information technology and analytical tools have created new opportunities and risks.
* Databanks already exist in large numbers and in many locations around the world. People do not necessarily know that their data is in there, or that it is being used.
* Research using big data needs to contribute to improving health outcomes for New Zealanders; if big datasets are sold to companies, it will be difficult to ensure New Zealanders get value from any future research.
* While there is an expectation that people will consent to the future use of their health information, it is not really feasible to achieve fully informed consent as there are a lot of unknowns at the point of collection.
* Using data without informed consent will only work if there is a high level of trust. People need to know what is happening with their information and what protections are in place.
* Significant effort needs to go into establishing public trust. The Data Futures Partnership work on social licence (gauging public opinion on the collection and use of big data) is a start.
* It is important for researchers to focus on ensuring privacy and confidentiality of information but absolute confidentiality is not possible. Given this, there also needs to be a focus on governance, accountability and transparency.

1. Members noted that some aspects associated with secondary use of health information and databanks are outside of the scope of the guidelines review. NEAC could provide separate advice to the Minister on the need for:

* governance arrangements – how data can be accessed, used and protected; representation of all those with relevant interests including Māori and lay people; people who are marginalised or discriminated against are likely to have the greatest concerns
* accountability – there needs to be a dedicated approach to researching data breaches, the public needs to be informed when breaches occur, and there should be consequences for researchers who abuse their access to information
* transparency - New Zealanders need to know what is happening with their data, what research is being undertaken by whom and the value that is being gained.

1. Wayne Miles reported back on the session he jointly facilitated with the New Zealand Association of Clinical Research at North Shore Hospital on 23 January 2017 to discuss NEAC’s research guidelines and ethical oversight in New Zealand. He advised that there were about 30 attendees, representing a wide range of research areas. Attendees agreed that researchers were responsible for identifying and addressing ethical issues in their research.
2. They also thought that thinking about a research continuum was useful but there needed to be a clear framework to help researchers determine what level of ethical consideration was required and be confident they were taking the right steps. They agreed that everything needs ethical consideration but not everything needs independent ethical review. Factors that might impact on the level of ethical consideration required include harm, benefit, how the research will be used, vulnerability of participants and size of resource.
3. Adriana Gunder reported back on the Assisted Reproductive Technology Symposium hosted by the Advisory Committee on Assisted Reproductive Technology on 10 February 2017. Presenters talked about the lack of public debate on new developments, the need to review the legislation, genetic screening of embryos and surrogacy.
4. Neil Pickering reported back on the New Zealand Health Symposium held on 21-22 February 2017, hosted by Chai Chuah, Director-General of Health. Presenters talked about disruptive innovation – starts as a small and inefficient innovation for a small niche market, then grows exponentially and replaces technologies or services that are meeting needs of a much larger proportion of consumers.
5. Presenters also talked about innovation in health such as artificial intelligent diagnosis. At some point this diagnosis may be better than one made by a health professional. Other discussion points were the need for DHBs and local councils to be more connected (eg, in ensuring access to new technologies), and regulating technicians providing health-related support (eg, monitoring sleep patterns).
6. Members agreed that there were a lot of benefits with innovation but that there needed to be a way for promoting new developments in a sensible, ethical way.
7. Members agreed that Kahu McClintock attend Te Ritorito 2017 on 3-4 April 2017 given the focus on Māori data and indigenous data sovereignty. Kahu will report back to NEAC at the 2 May 2017 meeting.
8. Members agreed that NEAC should consider presenting a paper at this year’s New Zealand Association of Clinical Research conference. The theme of the conference is ‘innovation in research and clinical trials’.

*Action*

* Secretariat to put Julian Crane’s presentation at the Bioethics conference on NEAC’s Quickr site.

**Guidelines Review (peer reviewers feedback)**

1. Members noted that the re-worked introductory sections and Chapters 1-4 were sent to the peer review panel on 2 February 2017. Peer reviewers were asked for any feedback they may have, including additions, corrections and other relevant sources/reference material.
2. Members noted the favourable feedback from the peer reviewers and that no major gaps were identified. The peer reviewers noted that further work was required to develop Māori content and address privacy and confidentiality issues with secondary use of health information.
3. Members discussed concerns raised about the ability of ethics committees to give retrospective approval to a research project that deviated from the original approved project. One way of addressing this could be to require researchers to get ethical approval before implementing the new approach. Alternatively, researchers could be required to get approval at the beginning of implementation. It is important that researchers are encouraged to revisit ethics when making a change, but not discouraged from innovating.

*Action*

* Secretariat to address the peer reviewers’ feedback as the work progresses.

**Guidelines review (Chapters 1, 3 and 4)**

1. Members provided feedback on the revised Chapter 1: Ethical values, Chapter 3: Research conduct and Chapter 4: Communicating research results.
2. Members discussed other values that were important including privacy, trust, consent, confidentiality and transparency. Members agreed to continue with the eight values (tika, manaakitanga, whakapapa, mana, beneficence, non-malificence, autonomy and justice) but explore how the other values can be captured. One suggestion is to talk about the other values in terms of application of the core values. For example, being transparent through fully disclosing risks and publishing all results contributes to non-maleficence (minimise harm) and beneficence (increase benefit).
3. Members discussed transparency and the need to weave this concept throughout the guidelines. Transparency is particularly important for research where it is not possible to seek informed consent. Members agreed there needed to be transparency across the entire research process. Members suggested transparency should be introduced in Chapter 1 and referred back to in the ethical standards.
4. Other feedback included:

* providing definitions for terms such as ‘mana whenua’ or including a link to the Māori dictionary (http://maoridictionary.co.nz/)
* ensuring that the section on informed consent is consistent with the Health and Disability Commissioner Code of Rights and any changes resulting from the current consultation on research involving adult participants who are unable to provide informed consent
* amending standards relating to research with people who are not competent to decide to participate (under informed consent section) so that they are consistent with relevant standards in the research population section
* making it clear that an individual who is supporting a person with ongoing diminished competence to make a decision should be suitably positioned to avoid any conflicts of interest
* separate the discussion on collective consent from community-based research where individual consent to participate is impracticable (this second discussion will need to be expanded to increase clarity)
* amend standards in the communicating research results section to recognise that sometimes research results will be released in a form that could allow identification of individual participants
* add a standard about participants having special access to research results and communicating them in an accessible way.

*Actions*

* Secretariat to make changes to chapters as requested and put updated version on NEAC’s Quickr site.
* Secretariat to provide updated version of introduction and Chapters 1-4 to HDEC Chairs for their feedback once peer reviewers and members’ feedback has been addressed.

**Guidelines review (Chapter 2 – risk and ethical review)**

1. Members discussed a proposed new section on risk and ethical review. Members noted that while procedural matters are determined by ethics committees, NEAC’s research guidelines could provide guidance on what level of ethical consideration is recommended for research with particular characteristics. Members agreed that all research requires ethical consideration but the expected level of independence and competence of those undertaking the review function will vary.
2. Members agreed that further work should be undertaken on this section. Wayne Miles noted that a matrix approach had been discussed at the New Zealand Association of Clinical Research’s session in January 2107. A matrix could show the level of independence and competence required for research with particular characteristics. Members suggested that the section discuss:

* benefits of ethical review
* features of review rather than who should undertake the review
* association between risk and other research characteristics and level of ethical consideration
* value of having an environment with systems and expectations around ethical review.

1. Members agreed that it would be helpful to provide guidance on how to weigh up risks and benefits. It is unclear whether this would fit best with the section on ethical review or elsewhere in the guidelines.
2. Members suggested that the Secretariat refer back to NEAC’s work on cross-sectoral ethics arrangements. Guidance provided by New Zealand universities might also be helpful. Members suggested that NEAC seek feedback from a small group of stakeholders including institutional ethics committees and research offices as this work progresses.

*Action*

* Secretariat to work with Wayne Miles to draft up a section on ethical review.

**HDEC Secretariat**

1. Philippa Bascand joined the meeting to give an update on the HDECs.

* Two extra HDEC meetings were held in December and January to manage the application volume and meet time limits for making decisions on applications. Every meeting is at capacity with 12 applications plus amendments. In January 2017, HDECs reviewed 50 applications, about double the number of applications (26) in January 2016.
* HDECs have noticed growing interest in dementia research and non-consensual research.
* Training for HDEC members continues to be a priority. Training was provided to ten HDEC members in February. Training on Te Mata Ira will be provided from March to May. GCP (Good Clinical Practice) training is scheduled for late June.
* HDEC vacancies are being advertised for Central and Northern B.
* HDEC annual reports have been accepted by the HRC Ethics Committee for 2016. All four HDECs are due for re-accreditation in 2018.
* The HDEC Secretariat met with four Auckland research organisations (private provider, two DHBs and a university) in February to hear about any issues with the application process.

1. A member asked whether any work was under way to introduce a fee for review. Any such funding could be used to manage the increasing volume of applications. Philippa advised that there was no current work on introducing a fee.

**NEAC’s 2016 Annual Report**

1. Members discussed the draft 2016 annual report to the Minister of Health and agreed that it was a good summary of NEAC’s activities during that year.
2. Members noted that the final report would be provided to the Associate Minister of Health for his comment. It would then be edited and formatted before being printed, tabled in the House, and published on NEAC’s website.

*Action*

* Secretariat to make requested changes and provide NEAC’s 2016 Annual Report to the Associate Minister of Health for his comment.

**In Committee**

1. NEAC held an in committee session.

**Correspondence**

1. Members noted the correspondence sent by the Secretariat on behalf of the Committee and the correspondence received by NEAC.

**Chair’s report**

1. Members noted that Neil will be meeting with the Minister on 8 March 2017 to discuss NEAC’s work programme and the Minister’s priorities. Neil will also seek an update from the Minister on the NEAC Chair appointment.

**Secretariat report**

1. Members discussed the Health and Disability Commissioner’s consultation on health and disability research involving adult participants who are unable to provide informed consent and agreed that NEAC should make a submission.
2. Members discussed the teleconference facility at the Airport Conference Centre and how difficult it was for the person phoning in to hear discussion around the table.

*Actions*

* Secretariat to work with interested NEAC members to prepare a draft submission on the HDC’s consultation. The draft submission will be provided to all members for feedback before being provided to the HDC by 30 April 2017.
* Secretariat to find out whether other teleconference facilities are available, particularly those that allow for multiple microphones.

**Minutes of 6 December 2016 meeting**

1. The minutes for NEAC’s 6 December 2016 meeting were confirmed as a true and accurate record of the discussion and approved for publication on NEAC’s website.

**Next NEAC meeting**

1. The next NEAC meeting will be held on 2 May 2017.

Minutes confirmed as a true and accurate record.

Neil Pickering, Acting Chair: 

Date: 2 May 2017