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**National Ethics Advisory Committee**

**ZOOM Meeting**

**21 January 2020**

Attendees: Neil Pickering, Maureen Holdaway, Dana Wensley, Wayne Miles, Gordon Jackman, Liz Richards, Hope Tupara, Kahu McClintock

Apologies: Mary-Anne Woodnorth

Ministry staff present: Nic Aagaard, Mark Joyce, Rob McHawk, Joel Tyrie

Apologies: Hayley Robertson

1. **Welcome and Opening Discussion**

The Chair opened the meeting at 1:00pm and welcomed Members.

The Committee noted the publication of the NEAC Ethical Standards in December 2019.

Nic reported that there has been positive feedback to the Standards, including from MRINZ.

1. **Ethical Standards – HDEC Training**

The Committee confirmed the upcoming training of the Health and Disability Ethics Committees, scheduled for the 29th and 31st of January. Gordon has volunteered to represent NEAC on the former date, and Wayne the latter.

Nic advised that there will be high attendance on both days by HDEC members, and the HDEC Secretariat will attend as well. Members of the Health Research Council have also confirmed their attendance.

Nic explained that the training will begin with an outline of administrative changes to the HDEC process. This includes things such as the proposed update of the Standards Operating Procedures and IT system.

It was explained that there will be an introductory talk, covering: concept introduction, history of and introduction to bioethics and research ethics, New Zealand case studies such as the Unfortunate Experiment and Warrior Gene Study (including an overview of what happened, consequences leading to the establishment of ethics committees), and a summary of why ethics is relevant (communicating the need to manage inherent ethical tensions in research, and that the Standards are the solution). The plenary talk will also go into detail on the partnership of principles, and how Western bioethics principles and Māori Te Ara Tika Principles co-operate. Questions have been developed to assist researchers in considering these. Emphasis is place on the notion of relationships rather than abstract theory and philosophical justification. For example, the principle of manaakitanga takes a strong stance here. The central message will be that the Standards solve ethical conflict and tensions through evidence-based application. This presentation will be replicated for the regional researcher-centred training sessions.

Nic introduced a key document called the Framework for Analysing the Ethics of a Research Study, which surveys the FACTS, ETHICAL PRINCIPLES, ETHICAL CONCERNS, and subsequent ANALYSIS of research applications. Nic demonstrated an example case study (unconscious adults) and discussed how these cases will be run in the training sessions, with frequent referral to the ethical principles. This framework was said to encourage researchers and HDECs to identify and consider how to resolve ethical concerns within research.

Nic summarised the focus as being on solutions-based bioethics:

1. Is the research a good thing to be done?
2. Is the research being done in the best way possible?

It was further reported that the HDEC training day will be attended by a guest speaker from CCDHB, Marina Dzhelali, who will give an overview of the locality approval process. The Secretariat has also reached out to DHB research offices and asked them to recommend a Māori review expert to speak about their experience with this aspect of the research process – this will be repeated for the generic training sessions.

As a point of difference from the nationwide training roadshow, the January afternoon sessions will cover HDEC processes as opposed to the new ethical standards.

The Committee offered the following feedback on the training content completed to date:

* It was suggested introducing two new slides on the Te Ara Tika principles, in particular to explain what tikanaga is and how it arises through relationships. There should also be a slide on the relevance of the Treaty of Waitangi, and on the historical and contemporary grievances of Māori (e.g. health inequities). Emphasis on a position of partnership is required much earlier in the presentation. It needs to be stated how tikanaga differs from ethics.
* The Committee requested that the Gisborne Cervical Screening ethical case study (the Gisborne inquiry) not be removed from the training content. The Committee further commented on the Warrior Gene ethical case study – the issue of tissue being taken for one purpose and used for another needs to be included, not just interpretation and publication harms. Thought is also need on the title of the latter case study, as NEAC does not wish to endorse the language of the ‘Warrior Gene’.
* Any mention of cultural safety was said to be accompanied by a Standards reference.
* Concerning the HDECs: some applications were said to contain a lot of Māori language, and support is required for both HDECs and researchers. Nic put forward the notion of a pool of researchers as opposed to pre-established HDECs, where tailored committees can be put together as required. These could contain expertise on, for example, kaupapa Māori research methodologies and medical device trials.
* The Committee raised concern over the definition of beneficence being reduced to improving outcomes, which sounds vague and consequentialist. Slide 63, about intentions, should further bring out the principles.
* The HDECs were asked to be informed that data will be collected on the quantity of Māori applications and subsequent review times.
* The Committee noted that if the Nuremburg Code is to be used as an example it is important not to gloss over the historical persecution of disabled people and those of non-heterosexual orientation.
* A disability case study is currently lacking.

Some members expressed a concern over the level of involvement the Committee has had in the development of the training material, and that the process has been undertaken more faster than desired. However, the Committee also commended the work of the Secretariat and acknowledged the short timeframe under which the training content is being completed.

Nic asked that any additional input on the training material be put to the Secretariat in writing.

Final training materials will be sent out by 24 January. Formal sign-off is to be given by NEAC following this review. In the interim, NEAC is happy for the Secretariat to proceed with development of the training.

1. **Ethical Standards – National Training Roadshow**

Nic advised that there has been confirmation of large turnouts for the regional training sessions, with the Auckland venue already reaching capacity. There should be NEAC members, working group members, and HDEC Chairs in attendance at each of these sessions.

Emphasis will be placed on a ‘living’ document, and on bridging the gap between researchers and ethics committees. Attendees will be advised that the document will continue to be updated through ongoing collaboration.

There will be further short talks on new content areas within the Standards. Nic presented a section on modifying the consent process, which is salient in light of emerging electronic consent, current tensions with the law, and NEAC’s upcoming work with the Health and Disability Commissioner. Short talks will be delivered on disability research, health system improvement research, data ethics and new technologies, and research benefits and harms.

The Committee asked for advance notice of who the local Māori expert at the respective regional trainings will be.

On the topic of the numbers of the at-capacity Auckland training session, several members spoke to the strong need for a second session in this region, as is important to capitalise on the current industry enthusiasm. Nic confirmed that there will be further engagement, and that the Secretariat is also attending meetings with the local institutional ethics committees in addition to the larger sessions. Training is also planned with other government departments. Discussion will need to be had with regard to a further Auckland meeting given budget restraints.

Rob explained the difficulty in getting venues, and the additional cost associated with recording the sessions.

1. **NEAC 2020 Meetings and Work Program**

Rob proposed the following dates for 2020 face-to-face NEAC meetings:

* 29 April
* 24 June
* 19 August
* 14 October
* 25 November

Plans are in place to invite the Health and Disability Commissioner to the meeting on 29 April in anticipation of NEAC’s collaboration with the HDC on research involving adults who cannot provide informed consent. The Secretariat administrators will begin to arrange meeting venues and flights.

Nic requested further items to be considered for NEAC’s 2020 work program.

Neil’s meeting, as Chairperson, with Associate Minister Salesa is still being arranged.

1. **Other business**

Rob advised the Committee that Mark Joyce has tendered his resignation and will be leaving the Ministry in February.