



31 May 2021

Our ref: BB21-174

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National Ethics Advisory Committee
Ministry of Health
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Tēnā koe, e te Minitā

National Ethics Advisory Committee – National Ethical Standards for Health and Disability Research and Quality Improvement

Thank you for the opportunity to comment on the National Ethics Advisory Committee (NEAC), National Ethical Standards for Health and Disability Research and Quality Improvement activity.

The Royal New Zealand College of General Practitioners is the largest medical college in New Zealand. Our membership of 5,500 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. Our kaupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

Our comments on the NEAC Submission

The overall goal of the RNZCGP is to improve the health of all New Zealanders through high-quality general practice care. We note that:

1. The NEAC Standards apply whether research or quality improvement activities require review by an ethics committee.
2. Quality improvement activities are generally low risk, but nevertheless providers should conduct them according to the NEAC Standards.
3. The NEAC Standards supplement guidance provided by regulatory bodies, which take precedence.

In general practice settings GPs deal with challenging ethical issues daily when helping and caring for their patients. Some decisions can be complex, requiring consent and confidentiality. Coles Medical Practice¹ outlines principles of ethical behaviour for doctors and includes recommendations for ethical practice. Four principles sit at the heart of medical ethics: autonomy (the right of patients to make decisions for themselves), beneficence (doctors must work towards achieving the best possible outcome for a patient), non-maleficence (a duty to do no harm) and justice (equality and fair distribution of resources). For this reason, our submission provides comment on the sections below.

P.16 - Te Tiriti o Waitangi and the Standards – and Sections 2, 3

The RNZCGP recognises the status of Te Tiriti o Waitangi and accepts the principles of Te Tiriti as they apply to the health and disability sector, as most recently articulated in the Waitangi Tribunal's WAI 2575² Hauora report and guide: *Tino Rangatiratanga, Equity, Active protection, Partnership and Options*.³ These principles should act as the guide to relationships between Māori and the Crown. The RNZCGP notes and supports

inclusion of the Te Ara Tika principles as guidance to support ethical decision making. Based on the learnings from WAI 2575, we consider that the NEAC Standard is a minimum standard and note this may impact on cultural safety of participants. We suggest that the statement in the introduction is updated to reflect WAI 2575 outcomes, signifying a new phase in applying ritenga by influencing improvements in *cultural safety*¹ and its application of Te Tiriti o Waitangi within the health and disability system⁴.

Section: 7 - Informed Consent

The section on, *Consent must be informed* (p.74) states, *that obtaining informed consent involves balancing potential participants' right to be fully informed against not overburdening them with information that reduces their ability to provide effective informed consent.*

The RNZCGP notes the requirement to be informed but considers the approach outlined creates an expectation that participants should read a large amount of complex information prior to signing. This is onerous and inconsistent with the NEAC statement on p.74. Participants who are provided with this level of technical information may find it difficult to understand and potentially result in them not reading the information at all. We recommend the information on consent (7.1) provides information according to people's ability and interest.

The points in Section 7.1 should provide guidance to researchers and we suggest that additional information be developed for participants. We suggest that participants are provided with a half page summary, developed by a health literacy expert, to read before signing the consent form and are also given the option of reading the detailed information if they wish to do so. A standard summary would reduce duplication and compliance costs.

Section 18 - Continuous Quality Improvement

Te Tiriti o Waitangi is applied through translation of core principles within RNZCGP, including in the General Practice Education Programme (GPEP), models of teaching and learning, Continuing Professional Development (CPD) and its Quality programmes. We note that practical learning activities, such as peer review and CQI, require demonstration of competence and cultural safety, in response to the WAI 2575⁵ and requirements of the MCNZ⁶. RNZCGP programmes encourage GPs and general practice teams to explore determinants of health, equity of access and outcomes, and work to reduce Māori and non-Māori disparities in health outcomes.

As a principle, the RNZCGP considers that the first step towards achieving equity to eliminate avoidable and unfair systematic disparities in health outcomes is to engage in CQI activities. These aim to understand causes of inequity for patients and patient populations through CQI processes including, monitoring, evaluating, improvement support improvements in health care. As part of their commitment to equity GPs and general practices are required to give effect to the principles of the Te Tiriti o Waitangi, the MCNZ, and the Code of Health & Disability Consumers' Rights⁷. They are also required to uphold the right of patients to make their own decisions about involvement in CQI processes⁸.

The principle of all quality activity is that it leads to improvement through change, and that unless there is learning from evidence or information, it is unlikely that we would know, what or where, to improve.⁹ For this reason and depending on the scope of CQI activities, the RNZCGP expects that practices would uphold the NEAC standards which set out the ethical requirements that health service providers and disability service providers must meet or exceed when conducting research or quality improvement activities.

SUMMARY

The RNZCGP acknowledges the National Ethics Advisory Committee work to update, expand on its previous guidance, and combine the *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention Studies* into one document. We support the concept of all research ethics guidance being held in one document and expect that future versions will be refined and simplified as feedback is received on its use. We also suggest the NEAC Committee emphasises building relationships based on trust and reciprocity when research is undertaken with communities so that decisions are made in partnership with them, to ensure participants, and their community, are comfortable with the research.

If you have any questions, or require additional information, please do not hesitate to email us at policy@rnzcgp.org.nz

Nāku noa, nā



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References

- ¹ Medical Council of New Zealand. Coles Medical Practice in New Zealand. 2017. <https://www.mcnz.org.nz/support/support-for-patients/your-rights-as-a-patient/>
- ² Came H, O'Sullivan D, Kidd J, McCreanor T. The Waitangi Tribunal's WAI 2575 Report: Implications for Decolonizing Health Systems. *Health and Human Rights Journal*. 2020;22(1). <https://www.hhrjournal.org/2020/06/the-waitangi-tribunals-wai-2575-report-implications-for-decolonizing-health-systems/>
- ³ Treaty of Waitangi Tribunal. Haurora Report on Stage 1 of the Health Services and Outcomes Kaupapa Inquiry. NZ. 2019. <https://www.health.govt.nz/our-work/populations/maori-health/wai-2575-health-services-and-outcomes-kaupapa-inquiry>
- ⁴ Ministry of Health. Document to inform discussions to develop a Māori Health Action Plan to implement He Korowai Oranga 2020 – 2025. Ministry of Health, NZ. 2019.
- ⁵ Came H, O'Sullivan D, Kidd J, McCreanor T. The Waitangi Tribunal's WAI 2575 Report: Implications for Decolonizing Health Systems. *Health and Human Rights Journal*. 2020;22(1):209. <https://www.hhrjournal.org/2020/06/the-waitangi-tribunals-wai-2575-report-implications-for-decolonizing-health-systems/>
- ⁶ Medical Council of New Zealand. Statement on cultural safety and He Ara Hauora Māori: A pathway to Māori Health Equity. 2020. <https://www.mcnz.org.nz/about-us/news-and-updates/statement-on-cultural-safety/>
- ⁷ Health and Disability Commissioner. Code of Disability Services Consumers' Rights. 1996. <https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/>
- ⁸ RNZCGP. Foundation Standards & Cornerstone. <https://www.rnzcgp.org.nz/Quality/Cornerstone/Quality/Cornerstone.aspx?hkey=64ed2c77-cb06-4f23-a038-d44a97d326d6>
- ⁹ RNZCGP Curriculum for General Practice. https://rnzcgp.org.nz/gpdocs/New-website/Become_a_GP/2014-Curriculum-For-General-Practice.pdf