19 September 2018

NEAC Secretariat
Ministry of Health
PO Box 5013
Wellington 6011

By email: neac@moh.govt.nz

Draft National Ethical Standards for Health and Disability Research

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand’s largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our submission has been informed by feedback from our Advisory Councils and Board.

1. We welcome the work done to develop an updated draft National Ethical Standards for Health and Disability Research. However, we have a number of high level concerns relating to both the structure and content of this important resource. A major concern is the document’s inordinate length and convoluted structure that we believe make it difficult to be fit for purpose for busy researchers. There is also a failure to adequately acknowledge competing ethical principles (with autonomy given extreme ascendency over beneficence), overly onerous blanket requirements for researchers, and concerns about the impacts of informed consent requirements on important types of research. We have concerns that these issues could act as a disincentive to important public interest research, for little or no corresponding gain. We elaborate on our concerns in the following paragraphs and provide some suggested amendments for consideration.

Philosophical underpinnings and competing ethical principles

2. The overall philosophical approach underpinning the document tends to be legalistic (deontological) rather than consequentialist and pragmatic. The approach taken is very rigid and, in our view, does not adequately acknowledge the need to balance competing ethical principles. For example, the principle of autonomy, though clearly important, is given extreme ascendency over beneficence. As a result, the requirements and burdens placed on researchers seem at times to be disproportionate to the actual risk of harm the rules are presumably intended to mitigate against. An example is the requirement for informed consent as a default for retrospective observational research that uses routinely collected data, where both the probability and consequences of privacy breaches are actually very small. The possible unintended consequence of this approach could be to stifle valuable public interest research for little or no corresponding gain.
Style and structure of the document
3. From the point of view of busy researchers, the document is unduly long, repetitious and poorly structured. We contend that a more user-friendly structure would be to have sections divided according to the fundamental type of research. With respect to ethical concerns and requirements placed on researchers, there is a fundamental distinction between interventional and observational research, yet these very different types of research are conflated and discussed together in many places in the document. We suggest that the document be restructured to include dedicated sections for these two types of research. Furthermore, with respect to observational research, it would be helpful to have additional subsections for studies according to whether the data they use are ‘identifiable’, ‘re-identifiable’ and ‘non-identifiable’ as once again, the ethical requirements for each of these different types of research ought to be quite different.

Clarity for researchers about process
4. To be a fit for purpose resource for busy researchers, there needs to be easily locatable and clear advice about the need and process for ethics committee approval for interventional and observational studies. Currently, this information is difficult to find and access. For example, guidance about waivers on consent for observational studies is buried in a long list as point 14.21 on page 82 of the document. Yet the question of when waivers are needed for observational studies is likely to be one of the most common questions for researchers using the document. We suggest the use of high level flow charts or algorithms as a way to potentially reduce a lot of text and help researchers find the key information they need quickly and efficiently.

Unintended consequences of unduly onerous blanket requirements
5. We are concerned that the long lists of repetitive and exacting requirements for researchers that are being proposed may not always serve their intended purposes, and, in some cases, could lead to unintended negative consequences. For example, the sheer weight of compliance with these requirements could act as a disincentive to valuable research, particularly by smaller research entities that lack the administrative capacity to meet these requirements. In other cases, the requirements could simply lead to a time-wasting bureaucratic process that leads to little, if any, benefits.

Research involving Māori
6. We believe that this section must begin with mention of the Treaty of Waitangi. It should also include the three principles of partnership, participation and protection that are inherent in the Treaty, with notation as to what each of these principles entail. Partnership encourages and requires Māori to be involved at all levels of planning, decision-making and engaging with the Māori community. Participation enables Māori to participate across the health sector, while protection relates to the duty of health services to recognise and response to Māori cultural beliefs, values and practices of Tikanga.

7. It is important that the Treaty of Waitangi and its principles inform health and disability research in New Zealand. Beyond the obligation to consult with Māori there are also compelling grounds for researchers to consult with Māori given the major health inequities they experience. While we are strongly supportive of meaningful partnership with Māori when it comes to research, there are some concerns that taking a blanket approach to consultation, regardless of research relevance or risk to Māori, risks undermining and discrediting situations where meaningful consultation is vitally important.

8. The process of consultation therefore should ultimately be viewed as a means to an end rather than an end in itself. While the principle of consultation, and the value of consultation for major interventional studies, are not in doubt, consultation in the ‘real world’ has many potential limitations that should be borne in mind. Other competing ethical principles also need to be
considered. Legitimate questions include: How meaningful is the consultation process? Who is appointed to represent Māori views at a DHB level and what accountability mechanisms are these individuals and their advice subject to? What is the desired outcome of the consultation process? To what extent does the requirement for consultation improve outcomes for Māori? To what extent do the consultation requirements impede, delay or deter legitimate observational research for little gain?

9. We suggest that the objectives for consultation with Māori need to be more clearly stated. These should include the explicit goals of the consultation process and the risks the consultation process is aimed at addressing. A reasonable goal could include ensuring that any research in New Zealand should preferably improve, but as a minimum not exacerbate, existing inequities for Māori, either in the process of conducting the research or in its outcomes. In other words, the research process and outcomes must reasonably be expected to be either beneficial to Māori (preferable) or neutral. We are concerned that section 6 of the document comes close to going beyond this, to the point where the processes it mandates provide substantial opportunities for the research agenda itself to be heavily shaped and influenced (with some potential for the censoring of legitimate research proposals or questions). Some of the statements in this section, particularly point 6.11, border closely on suggesting that research proposals must all consider some kind of tangible benefits for Māori. We contend that this would be taking things a step too far and seek greater clarity on this point. The statement in point 6.11 that ‘every study can offer a training opportunity for a Māori researcher’ may create unreasonable burdens on small and poorly funded research groups, most of which have no funding for any researcher, let alone a Māori one. We suggest the addition of ‘if possible’ at the end of this sentence to convey that this is an aspirational statement.

10. As section 6 of the document is currently written, vastly different types of research are lumped together without any real sense of proportionality with regard to the degree of risk they pose to Māori and therefore the corresponding obligations placed on researchers. We would be concerned if the unintended consequences of this blanket requirement were to deter smaller less well-resourced research groups from pursuing their research, or to encourage bureaucratic less-than-meaningful consultation for research that is vitally important for Māori.

Informed consent

11. A foremost question most researchers have is whether or not their study requires informed consent. In point 9.61, we note the document states the following: The default position is that the use of health information or tissue requires consent at the individual level. However, a waiver is legally available for use of health information and human tissue in New Zealand; researchers must clearly justify why they need to apply that waiver, outline it in the study protocol and gain approval for it from an ethics committee.

12. Observational, epidemiologic research using data originally collected for another purpose is one of the most common forms of research conducted in clinical settings, but such research becomes essentially unfeasible if informed consent is required. The importance of this kind of research for health and healthcare in New Zealand should not be underestimated. The findings play an important role in generating and refining hypotheses, informing management and preventative policies, and shaping the broader research agenda. What researchers need is greater clarity about under what circumstances the waiving of informed consent for the use of data originally collected for other purposes is justified. We would like to see the document include an explanation of the principles governing ethical decision making with regard to the waiving of informed consent.
We presume that the main risk to be mitigated here is the use of private health data by third parties in ways that the study subjects would consider to be harmful. We submit that what is needed is a more consequentialist ethical view rather than simply an absolute rights-based view. If the risk of harm is vanishingly small, both in terms of its probability and impact, then this needs to be weighed against the public interest nature of the proposed research.

**Cluster randomised trials**

The requirement for individual informed consent to be obtained for cluster randomised trials essentially renders this type of research unfeasible. This type of trial is the ‘gold standard’ design for investigating preventative policy / practice / behavioural interventions in healthcare settings. They involve interventions being applied collectively to randomised units or services rather than individual patients. Any patient admitted to a unit participating in a cluster randomised trial will, by default, be ‘exposed’ to the intervention. Therefore, the logistics of managing patients that are unable or unwilling to provide informed consent in participating research units essentially make these trials impossible. We understand this problem is related to legislation in New Zealand rather than the position of NEAC per se. Nevertheless, we wish to highlight that this is a major impediment to quality research in New Zealand. We also seek NEAC’s opinion on whether there is any room for an alternative interpretation of current legislation on this point.

Cluster randomised trials typically involve randomisation of units or services to interventions for which there is equipoise and very little conceivable risk of harm. Typically, the interventions being compared would be considered well within the range of completely acceptable practice / policy, and there are no *a priori* reasons for believing one intervention necessarily poses significantly more risk than the other. For example, in the area of infection control and prevention, cluster randomised trials might compare ‘standard practice’ with regard to hand hygiene education with a combination of poster campaigns / focus groups, or involve a comparison in an ICU of daily patient washes with soap and water versus chlorhexidine wipes. Another example might be randomising to different cleaning practices. In these examples, each intervention is considered within the range of acceptable, normal, safe practice and there are no *a priori* reasons for believing one intervention necessarily poses significantly more risk than the other.

Notably, outside of a research setting, if a unit / service were to simply decide to change their policy / practice, then this would be considered an entirely acceptable decision. Moreover, if down the track, routinely collected outcome data at the unit level were to be analysed as a retrospective ‘quasi-experimental’ or ‘before-after’ study, then this too would presumably be considered entirely acceptable and wouldn’t require the researchers to obtain individual informed consent from everyone admitted to the unit over the study period. It appears anomalous, therefore, that randomising units to the same change in practice is somehow viewed as being an absolute requirement for informed consent, regardless of the nature of the interventions under examination and the accompanying risk of harm.

The requirement for individual informed consent for cluster randomised trials represents a major barrier for generating quality research on preventative healthcare policy / practice. We believe that it is in the public interest, therefore, for NEAC to make more pragmatic recommendations to the government about waiving the need for individual informed consent for cluster randomised trials—providing certain conditions are met. These recommendations could be informed by approaches in other jurisdictions. We contend that it would be reasonable to waive the need for individual informed consent for cluster randomised trials provided the following conditions are met: i) there is equipoise between the two interventions such that changing from one practice / policy to another would be considered entirely acceptable outside of the research.
setting, and ii) there are no strong \textit{a priori} reasons for believing that one intervention carries a greater risk of harm than the other.

**Innovative practice**

18. We note that in the section on innovative practice, the document rightly states:

\textit{4.15 Innovative practice must not be prematurely adopted into standard of care. Appropriate evaluative mechanisms should be put in place to assess the effectiveness of any innovative practice, which may include formal research, AND 4.16 Where innovative practice in health care requires research, it is an obligation of those practicing innovatively to ensure this happens at the appropriate time and in the appropriate way.} The problem is that the constraints imposed by this document essentially prevent the use of ‘appropriate evaluative mechanisms’ and thus run the risk of impeding valuable innovation in healthcare delivery. This in itself should be a prime ethical consideration (currently given no place in the framing of this document).

**Reframing the document**

19. We believe that it is important to reframe, and somewhat rebalance, the document to recognise the vital importance and value of health and disability research to inform clinical management and public health policy. We suggest the addition of an up-front statement in the introduction section of the document stating this. It needs to be acknowledged that if this document doesn’t strike the right balance between competing ethical principles, then an unintended adverse consequence could be to stifle and obstruct valuable public interest research for relatively little gain. We support the principle of autonomy being at the centre of considerations but not to a point where the principle of beneficence is over-ridden and effectively forgotten.

We hope that our feedback is helpful and look forward to learning the outcome of this consultation.

Yours sincerely

\[K.\text{Baddock}\]

Dr Kate Baddock
NZMA Chair