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NEAC Secretariat
Ministry of Health
PO Box 5013
Wellington 6011

**Draft National Ethical Standards for Health and Disability Research**

The New Zealand Law Society welcomes the opportunity to comment on the National Ethics Advisory Committee's *Draft National Ethical Standards for Health and Disability Research: Consultation Document* (consultation document).

The Law Society's Health Law Committee has reviewed the draft standards and has only a few comments to make on minor points (relating to chapters 6, 8 and 14 of the consultation document), as set out below.

*Chapter 6 – paragraph 6.23*

Paragraph 6.23 discusses sharing the benefits of research with Māori; it states that the research protocol should include information on how researchers will ensure that Māori benefit at least equally from research and gives as an example of extra measures "involving Māori in interpreting results or study findings". Consideration should be given to including Māori in all phases of research, and particularly in the preparation of research proposals and applications for ethics approval. Early involvement will increase the likelihood that potential inequities are addressed.

*Chapter 8 – paragraph 8.10*

Paragraph 8.10 states that research involving children should be conducted only if "the purpose of the research is to gain knowledge relevant to the health needs of children".

The ethical considerations regarding research involving patients who are unable to consent to their participation also apply to children,[1] and paragraph 8.10 should therefore make it clear that the purpose of the research is to gain knowledge which will be beneficial to the health needs of the individual child. (It is possible that the research might produce knowledge *relevant* to the health needs of children but not *beneficial* to the individual child's health needs.)

*Chapter 14 – health data*

- *Re-identification:*

Where researchers disclose research results to a wider audience (that is, not to the participants themselves or to their clinicians) they should take steps to make sure that individuals cannot be identified from those results, either alone or in combination with other readily accessible datasets. (Forthcoming changes to privacy legislation may result in there being protections against re-

[1] See paragraph 9.76 of the consultation document, which notes that participation in health research without consent must be in the *individual's best interests.*

identification, but the agency that publishes the dataset or research results will still be primarily liable for taking reasonable steps to stop people from being identifiable.)

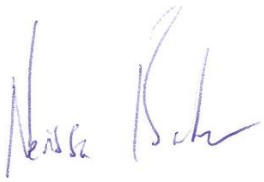
- *Disclosure – "serious and imminent threat":*

Paragraph 14.13 specifies that disclosure of participants' data is permitted where there is a "serious and imminent" threat to public health/safety or an individual's life/health. The legal standard in the Privacy Act 1993 and Health Information Privacy Code no longer includes imminence; the standard is now only that the risk is "serious". It may be that a higher standard is deliberately being set for the ethical standards; but if that is the case, it would be helpful to say so and to explain why, to avoid confusion.

*Conclusion*

We hope these brief comments are helpful. If you have any questions, please do not hesitate to contact the convenor of the Law Society's Health Law Committee, Adam Lewis. Contact can be made in the first instance via the committee secretary, Jo Holland (jo.holland@lawsociety.org.nz / 04 463 2967).

Yours sincerely



Nerissa Barber
**Vice President**