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**Cross-sectoral arrangements for health and disability research – discussion document**

*Introduction*

The New Zealand Law Society (Law Society) appreciates the opportunity to comment on the National Ethics Advisory Committee's (NEAC) consultation document, *Cross-sectoral ethics arrangements for health and disability research* (discussion document).

The Law Society notes that the scope of the discussion document includes governance arrangements for health and disability research ethics.[1] The Law Society concurs with the following statement on page 7 of the discussion document:

> *NEAC is aware that the research community continues to express concern about the absence of a comprehensive framework for all research bodies. This is considered particularly important given the changes to HDECs [Health and Disability Ethics Committees] in 2012.*

The Law Society made two submissions in 2012 on the changes to Health and Disability Ethics Committees (HDECs) and on NEAC's revised ethical guidelines for health and disability research (NEAC Guidelines).[2] The submissions emphasised the need for a comprehensive review of New Zealand's ethics review system, with a view to providing an overarching legal framework for health and disability research in line with international instruments and guidelines.[3]

The Law Society maintains the views expressed in those submissions, in response to the first issue raised in the discussion document: the complex research ethics landscape. The Law Society wishes to be involved in ongoing discussions about the legal framework for ethical review in New Zealand and the importance of protecting the rights and interests of participants in health and disability research.

The Law Society commends the cross-sectoral approach to a review of the ethical review system taken in the discussion document. Until the legal status and the interface between NEAC's guidelines and the existing standing operating procedures (SOPs) is clarified, there will be ongoing confusion about the scope of ethical review and what the ethical (and legal) standards are for health and disability research in New Zealand. The Law Society recommends that an overarching legal framework be

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1 Discussion document, p8.

2 Submission dated 16.2.12 (draft Standard Operating Procedures for Health and Disability Ethics Committees) http://www.lawsociety.org.nz/__data/assets/pdf_file/0004/49396/Health_and_Disability_Ethics_Committees,_draft_SOPs-16_2_12.pdf; submission dated 12.6.12 (Revised ethical guidelines for health and disability research) http://www.lawsociety.org.nz/__data/assets/pdf_file/0020/53183/I-NEAC-ethical_guidelines_review-120612.pdf.

3 Relevant international instruments include the Declaration of Helsinki 1964 (most recently revised in 2013), and the World Health Organisation Standards and Operational Guidance for Ethics Review of Health-related Research with Human participants (2011) (WHO Standards).

developed that is consistent with, and recognises international standards for, an ethical review system.

The discussion document is directed primarily at researchers and ethics committees and accordingly this submission responds only to selected questions, as set out below.

*1. Complex Research Ethics Landscape*

*Monitoring and Accountability*

Question 1.5(a): What could be done to achieve more cohesion across the ethical review system?

The legislative framework for the structure, composition and jurisdiction of ethics committees in New Zealand remains inadequate. There is no express recognition of the role and function of ethics committees and the fact that they are independent decision-making bodies with the power to determine when health and disability research may proceed, be declined or approval be withdrawn.

Currently, HDECs are appointed and their functions and terms of reference are determined by the Minister of Health under section 11 of the New Zealand Public Health and Disability Act 2000. However, that Act does not clearly articulate the role and function of ethics committees to protect human participants in research and the requirement for ethical review of health and disability research in accordance with ethical standards and international instruments.

Section 16(2) of the New Zealand Public Health and Disability Act 2000 requires NEAC to determine nationally consistent ethical standards across the health sector. NEAC complies with this obligation by producing guidelines for HDECs. HDECs are required to follow the guidelines under their Terms of Reference. However, there is a lack of clarity about both the status of the guidelines (whether they are standards or merely guidelines) and which other ethics committees are subject to them. Other than the requirement in the Terms of Reference for HDECs issued by the Minister of Health (which apply only to HDECs), there is no legal basis for requiring ethics committees to follow the guidelines.

The 2012 revision of NEAC Guidelines removed reference to "process guidance" and replaced it with "policy previously included in the Operational Standard for Ethics Committees".[4] The Operational Standards for Ethics Committees (2006, Ministry of Health) appear to have been superseded by NEAC Guidelines, yet only the "policy" of the Operational Standards was carried over. It remains unclear whether ethics committees other than HDECs are still following the Operational Standards, how they view the NEAC Guidelines, and whether they follow them or not.

According to NEAC, the guidelines they produce are intended to be consistent with the Standard Operating Procedures (SOPs) for HDECs. This again blurs the distinction between guidelines and standards and has the potential to create confusion.

The requirements for ethical review of health and disability research are found in three documents: the SOPs, the NEAC Guidelines and the terms of reference for HDECs. This has created further

[4] See the preface to the NEAC Guidelines.

fragmentation of and complexity in the ethics review system. Procedural fairness requires that those who are subject to research and those who submit research applications have clarity about which ethical "standards" or rules apply. The Law Society considers that addressing these matters by way of legislation would help to achieve more cohesion across the ethical review system.

Question 1.5(e): Is the plurality of functions that various public agencies (e.g. Ministry of Health, NEAC, HRC) have to set standards for researchers and for ethics committees sufficiently clear and coherent overall?

The Law Society's view is that the plurality of functions that various public agencies have to set standards for researchers and for ethics committees is not sufficiently clear and coherent overall. Ethical review systems remain fragmented. For example, the Health Research Council established under the Health Research Council Act 1990 is a funding body and does not have a statutory mandate to accredit ethics committees, yet historically and in practice it fulfils this function.

*2. Māori and Health Research*

Question 2.4(a): What additional support or guidance on Māori research ethics would be helpful?

The Law Society supports any proposal to increase Māori participation in ethical review processes. Previously, HDEC regional ethics committees were required to include at least two Māori members as part of wider membership and composition of ethics committees.[5] This is no longer a requirement in the current terms of reference for HDECs.

*3. Alternative Ethical Review Structures*

Question 3.5(a): What mix of HDECs and institutional ethics committees (both public and private sector) should be allowed or encouraged?

The Law Society does not support the concept of stand-alone businesses or trusts being encouraged or allowed to establish ethics committees, because it is important for ethics committees to maintain their independence. New Zealand is a small country, and the potential for conflicts of interest is high. To avoid fragmentation of ethics committees, the Law Society recommends that central government be responsible for setting their function and for their composition.

*4. Peer Review for Scientific Validity*

Question 4.5(a): What are the barriers to accessing scientific peer review?

There remains a lack of clarity as to what is required for peer review and who a researcher's "peers" are, especially for those researchers not employed by institutions within the health and disability sector. Appendix 1 of the NEAC Guidelines (Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research) merged the concept of

[5] See for example page 3, Terms of Reference – Northern X Regional Ethics Committee: moh.govt.**nz**/.../tor-northern-x-regional-ethics-committees-nov2010.doc.

peer review (which does not require independence) with scientific validity. Peer review, whether "robust" or not, remains an insufficient criterion for ethical review. It is important that review mechanisms be independent and scientifically robust. Scientifically unsound research puts participants at risk with no individual or societal benefit (as was borne out in the Cartwright Inquiry). As noted in the Law Society's February 2012 submission, the WHO Standards require ethics committees to review the scientific validity of a research proposal:

> *1. Scientific design and conduct of the study*
>
> *Research is ethically acceptable only if it relies on valid scientific methods. Research that is not scientifically valid exposes research participants or their communities to risks of harm without any possibility of benefit**. RECs [Research Ethics Committees] should have documentation from a prior scientific review, or should themselves determine that research methods are scientifically sound and should examine the ethical implications of the chosen research design or strategy.** Unless already determined by prior scientific review RECs should also assess how the study will be conducted, the qualifications of the researchers, the adequacy of provisions made for monitoring and auditing, as well as the adequacy of the study site (for example the availability of qualified staff and appropriate infrastructures).*[6] (Emphasis added)

*5. Audit and audit-related activity*

Question 5.5(a): Does the current classification of studies into observational research and audit or related activity act as a barrier to audit and related activity?

The Law Society notes the lack of clarity around the definitions of research and audit, and the scope of ethical review.

The Law Society questions the usefulness of separately categorising observational research and audit. Ethical issues arise independently of categorisation, for example an audit activity might involve very sensitive personal information. While the results will not necessarily identify individuals, those carrying out the audit will have access to personal information.

In order to fulfil their own ethical and professional standards, it would be reasonable for an investigator to elect ethical review of an "audit", even where that is not necessarily required. Publication of research, audits and related activities in peer-reviewed journals may require ethical review, in keeping with international standards such as the Declaration of Helsinki.

We recommend that all research involving human participants be presumptively subject to ethics committee oversight so that researchers follow an "if in doubt" policy and submit their research to the ethics committee. The depth and scope of ethical review can then be assessed by the ethics committee. The Law Society considers that a presumption in favour of ethical review should be

6 WHO Standards, Standard 7, paragraph 1.

extended to both research and audit activities (where there may be uncertainty by the researcher as to whether ethical review is required), with the ability for the ethics committee concerned to determine whether a lower-level review or none at all is appropriate for audit-related activities.

Ethics committees need to be able to make common sense judgements about the level of ethical review that is required on a case by case basis. The standards for ethics committees should give clear guidance as to the process an ethics committee is to follow to assess the level of ethical review required and to engage constructively with the researcher.

*6. Innovative Practice*

Question 6.5(a): Should further guidance be developed on innovative practice?

The Law Society agrees that future work should be done to develop guidance on innovative practice. It notes that the concept of innovative practice was developed extensively following the Cartwright Inquiry (with nomenclature changing from "unorthodox or new treatment" to "innovative treatment", and finally to the current "innovative practice").

The distinction between a new or unorthodox treatment and research was a key issue in the inquiry where there was failure to treat women with cervical carcinoma in situ (CIS) at National Women's Hospital.[7] In the intervening years the Operational Standard for Ethics Committees developed a definition of innovative practice and ethical review requirements for treatment, as well as provision of a specific protocol and informed consent requirements for patients to be set out in an application to an ethics committee.[8]

The SOPs are notably silent on innovative practice in view of New Zealand's research ethics history noted above. The NEAC Guidelines on Intervention Studies give little guidance other than noting that innovative practice is "practice that is a planned deviation from currently accepted practice".[9]

*7. Other Issues*

Question 7.1: What other issues are associated with the cross-sectoral ethics arrangements for Health and Disability Research and how might these issues be addressed?

As noted above, there is currently no express recognition of the role and function of ethics committees to protect research participants from harm, or to advance the legal requirements of informed consent and the right not to be subject to medical or scientific experimentation without that person's consent.[10]

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7 *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into other Related Matters*, p 210 ff.

8 Ministry of Health 2006 as set out in pp 24-28, Operational Standard for Ethics Committees (2006).

9 NEAC Guidelines, p5.

10 Section 10 NZBORA and the Code of Health and Disability Consumers' Rights.

The Law Society recommends a "systems" approach, as advanced by the WHO Standards, which includes a requirement to establish a research ethics review system.[11] Standard 1 of the WHO Standards provides:

> "Relevant authorities ensure that ethics review of health-related research is supported by an **adequate legal framework** that is consistent with the standards set forth in this document: that Research Ethics Committees (RECs) capable of **providing independent review of all health-related research** exist at the national, sub-national, and/or institutional (public or private) levels; and that an appropriate and sustainable system is in place to monitor the quality and effectiveness of research ethics review." (Emphasis added).

The guidance to the Standard goes on to state that "… unless attention is given to the larger system of human research protections of which RECs are a part, these committees may become isolated or unable to perform efficiently or effectively, despite their best intentions".

Part of the systems approach is that "all research with human participants is presumptively subject to REC (ethics committee) oversight". Whilst specific categories of research may be exempted from ethical review or subject to expedited review, such exemptions must be authorised "by national laws and regulations and consistent with international guidelines".[12]

The SOPs do not require all research to be subject to ethical review by HDECs. The Law Society submits that the applicable standards for the ethical review of research require regulatory authorisation in order to adhere to the WHO Standards.

*Conclusion*

This submission has been prepared with the assistance of the Law Society's Health Law Committee. If you wish to discuss the comments, please do not hesitate to contact the committee's convenor, Alison Douglass, via the committee secretary Jo Holland (04 463 2967, jo.holland@lawsociety.org.nz).

Yours faithfully

Chris Moore
**President**

11 See NZLS 16.2.12 submission, at paragraph 9.
12 WHO Standards, Standard 1, p4.