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Dear Rohan

Submission on the Draft Standard Operating Procedures for Health and Disability Ethics Committees

Introduction

1. The New Zealand Law Society (Law Society) welcomes the opportunity to make a submission on the Draft Standard Operating Procedures for Health and Disability Ethics Committees (SOPs).
2. We note that a very short time was available for preparation of this submission.¹ The Law Society's Health Law Committee and Human Rights and Privacy Committee have considered the proposed Standard Operating Procedures, but in the limited time available it has not been possible to give the proposed changes the full consideration they warrant and only some aspects of the SOPs are commented on.
3. The Law Society is concerned that the proposed changes, together with the restructuring of Health and Disability Ethics Committees (HDECs), will not provide adequate protection for participants of health and disability research carried out in New Zealand that complies with human rights obligations and, in particular, the right of patients/participants to give informed consent or refusal to participate in research.
4. The proposed changes are a significant departure from the current standards for ethics committees as set out in Operational Standard for Ethics Committees² developed since the Cartwright Inquiry³ and from international instruments for the protection of human participants in research. Relevant international instruments include the Declaration of Helsinki 1964⁴ (most recently revised in 2008) and the World Health Organisation Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) (WHO Standards).⁵ Annex 1 to the WHO Standards sets out a list of other relevant international guidelines and codes of best practice.

¹ The Law Society received the Draft Standard Operating Procedures on 1 February 2012, with submissions due by 10 February; the Ministry of Health subsequently gave the Law Society a short extension to 15 February – which allowed a total of 10 working days for the submission to be prepared and filed.

² Operational Standard for Ethics Committees, Ministry of Health, 2006.

[http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6777/\\$File/OperationalStandard2006.pdf](http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6777/$File/OperationalStandard2006.pdf)

³ The Committee of Inquiry into allegations concerning the treatment of cervical cancer at National Women's Hospital. The Committee's Report: *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*.

⁴ Declaration of Helsinki, The Ethical Principles for Medical Research Involving Human Subjects, 1964 (revised 2008). <http://www.wma.net/en/30publications/10policies/b3/index.html>

⁵ WHO Standards: http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf

5. This submission questions the legal status of the draft SOPs and what legal effect they will have on the framework for ethical review of research in New Zealand. The Law Society submits that, as currently drafted, the SOPs purport to sanction standards by which research is ethically reviewed that are inconsistent with the New Zealand Bill of Rights Act 1990 (NZBORA) and the Code of Health and Disability Consumers' Rights.⁶

Status of the draft SOPs

6. The draft SOPs have been prepared as part of the Government's response⁷ to the Health Select Committee's clinical trials inquiry,⁸ but they are silent on the legal authority from which they are derived or what legal effect they will have on the ethics review system in New Zealand. Although the draft SOPs purport to be "procedural guidance"⁹ they intrude into areas which are more properly the domain of "ethical standards"¹⁰ and as such need to be consistent with international instruments which provide for best practice in this context.
7. The draft SOPs state that they "contain *procedural guidance* for HDECs. They do not set out established *ethical standards*"¹¹ in health and disability research that are to be found in the National Ethics Advisory Committee (NEAC) guidelines for observational and interventional studies. They also state that the Operational Standard for Ethics Committees (the current Standard)¹² will be superseded by the draft SOPs.¹³ The Law Society considers that it is important to recognise that the current Standard was derived following recommendations from the Cartwright Inquiry that "all research undertaken by health agencies should be reviewed by an ethics committee and that ethical standards 'must be applied rigorously to research and treatment protocols on behalf of patients.'"¹⁴ Following the Cartwright Inquiry, a 'Standard for Ethics Committees Established to Review Research and Ethical Aspects of Health Care' was developed by the then Department of Health in 1991, with subsequent revisions until the current Standard in 2006.¹⁵
8. The current Standard sets out the framework for the ethical review system in New Zealand, the purpose and principles of ethical review (including the protection of participants in research and innovative practice), and matters which require ethical review – the 'jurisdiction' of HDECs. It does not just provide 'process guidance' for HDECs. The current Standard is an 'ethical standard' for New Zealand's system of ethical review of health and disability research and recognises the framework that exists for the provision of ethical review in New Zealand, including the role of the Health Research Council Ethics Committee and the institutional ethics committees. It requires HDECs to ensure that research proposals are undertaken in accordance with NZBORA and have regard to international guidelines such as the Declaration of Helsinki, which was first formally adopted in New Zealand in 1968.¹⁶ If the current Standard is to be superseded by the SOPs, these safeguards will be lost unless they are carried forward to the SOPs or located elsewhere in the ethics review framework.

⁶ Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 (Code).

⁷ Government Response to the Report of the Health Committee on its Inquiry into improving New Zealand's environment to support innovation through clinical trials, Standing Order 248.

⁸ Inquiry into improving New Zealand's environment to support innovation through clinical trials. Report of the Health Committee. June 2011.

⁹ Draft SOPs, p4.

¹⁰ Draft SOPs, p4.

¹¹ Draft SOPs, p4.

¹² Operational Standard for Ethics Committees, Ministry of Health, 2006.

¹³ Draft SOPs, page 4.

¹⁴ History of Health and Disability Ethics in New Zealand, paragraph 7

[http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6761/\\$File/history-ethical-review-nz.doc](http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6761/$File/history-ethical-review-nz.doc)

¹⁵ New Zealand Health and Disability Ethics Committees website\ Ethical Review in New Zealand\ history:
<http://bit.ly/wKsmkY>

¹⁶ Declaration of Helsinki, The Ethical Principles for Medical Research Involving Human Subjects, 1964 (revised 2010).

9. The recently published WHO Standards provide standards for research including the responsibility for establishing a research ethics review system. 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)

10. The WHO Standards advance a ‘systems approach’ and 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”.¹⁷ The SOPs will not require all research to be subject to ethical review by HDECs and there is a proposed expedited review pathway where full review is not required. The Law Society submits that these changes in the SOPs from the current Standard would require legislative or regulatory authorisation to adhere to the WHO Standards.
11. The legislative framework for the structure, composition and jurisdiction of ethics committees in New Zealand is inadequate: there is no express recognition of the role and function of ethics committees and that they are independent decision-making bodies which have the power to determine when health and disability research may proceed, approval be withdrawn or be declined. Currently, HDECs are appointed and their functions and terms of reference are determined by the Minister of Health under s11 of the New Zealand Public Health and Disability Act 2000. However, this 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.
12. The Government response to the Health Select Committee Inquiry includes a decision to reduce the membership and numbers of HDECs. It may also have changed the terms of reference for the HDECs but the terms of reference for HDECs have not been made available as part of this consultation process. It is therefore difficult to reconcile the legal status of the draft SOPs with the role and function of HDECs appointed under s11 New Zealand Health and Disability Act 2000.
13. The Law Society submits that the draft SOPs are unclear as to their legal authority and status. The replacement of the current Standard with the SOPs will water down the substantive ethical protections recommended by the Cartwright Inquiry and implemented subsequently though the development of an ethical Standard for ethics committees including HDECs, under cover of issuing a new process guideline to HDECs. This may result in an even more fragmented ethics review framework than currently exists, where ethical standards and guidelines will be found in one set of documents and process directions for HDECs in another.
14. The Law Society recommends that the Government engage in a more comprehensive review of New Zealand’s ethics review system with a view to providing an over-arching legal

¹⁷ WHO Standardsa, Standard 1, p 4.

framework for ethical review of health and disability research involving human participants, in line with international instruments and guidelines.

No advice from the National Ethics Advisory Committee (NEAC)

15. There is no indication from the Government's response to the Health Select Committee Inquiry that the Minister of Health has sought advice from the National Ethics Advisory Committee on Health and Disability Support Services Ethics (NEAC). Pursuant to s16 of the New Zealand Public Health and Disability Act 2000, the Minister *must* appoint NEAC, for the purpose of obtaining advice on ethical issues of national significance in respect of any health and disability matters (including research and health services). The effect of the proposed changes to the current Standard for ethics committees is arguably a matter of national significance under s 16(1), which requires the Minister to seek advice from NEAC. The revision of the current Standard and the proposed SOPs may be regarded as ethical standards which are required to be determined by NEAC pursuant to s 16(2). Section 16(2) provides:

*The National Advisory Committee appointed under subsection (1) **must** determine nationally consistent ethical standards across the health sector and provide scrutiny for national health research and health services. (emphasis added)*

16. Section 16(4) requires that, before NEAC gives advice, it must consult with any members of the public, including persons involved in the funding or provision of services, and other persons that NEAC considers appropriate.
17. As the Government's decisions and proposed SOPs would implement significant changes to the ethics review system, the Law Society expresses some concern that it appears the Minister has not sought advice from NEAC. The Law Society acknowledges that there may be some ambiguity as to the interpretation of s 16 and the extent to which the Minister is obliged to seek advice from NEAC on such matters, however, the Law Society considers that it would be good practice for the Minister to do so. Section 16(4) would require NEAC to consult with interested parties. This would include, for example, the District Health Boards where the majority of health and disability research is carried out, as well as public and private research institutions and institutional ethics committees in the health sector. Consultation would require more than simply 'feedback' on draft changes to the SOPs and could also address the currently fragmented system of ethics review, including the jurisdictional boundaries between the existing HDECs and institutional ethics committees and options for an adequate legal framework for ethics review in New Zealand.

Human Rights

18. The proposed SOPs have significant human rights implications for the protection of participants in human research. As noted in paragraph 4 above, the current Standard for HDECs recognises that the Government has adopted the NZBORA standard for purposes of applying the Human Rights Act 1993 by promoting freedom from certain forms of discrimination, and requires HDECs when considering research proposals to ensure that any activities are undertaken in accordance with NZBORA. The draft SOPs make no mention of the legal requirements of informed consent for the protection of participants in health and disability research.

19. Section 10 of the New Zealand Bill of Rights Act 1990 provides that:
*Every person has the right not to be subjected to medical or scientific experimentation without that person's consent.*¹⁸

Section 10 is recognised as a fundamental human right of bodily integrity and bodily privacy. The section incorporates the principle that in New Zealand all participation in medical or scientific experimentation must involve the person who is to be subject of the experimentation providing informed consent. Informed consent is a medical ethics and legal doctrine developed by the courts over a number of years. The requirements for informed consent are recognised at common law and are set out in the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 (Code). In the research context there is a requirement to provide a participant with all relevant information about a proposed procedure or research to be undertaken prior to obtaining that person's consent. The Code recognises the importance of informed consent and a heightened threshold of written consent to participate in research. Right 7(6) of the Code provides:

- (6) Where informed consent to a health procedure is required, it must be in writing if –*
- (a) the consumer is to participate in any research; or*
 - (b) the procedure is experimental; or*
 - (c) the consumer will be under general anaesthetic; or*
 - (d) there is a significant risk of adverse effect on the consumer.*

20. In addition, Right 7(10)(b) provides that no bodily part or bodily substance may be stored or preserved for the purposes of research other than with the informed consent of the consumer or for research that has received approval of an ethics committee.¹⁹ The requirement for written informed consent only applies to health and disability research carried out by a health and disability provider, and there will be cases where research is not carried out by a registered health provider and the Health and Disability Commissioner will not have jurisdiction to consider a complaint under the Code (for example, a psychology student conducting research on people with mental illness or experiences of patients with cancer in hospice care).
21. The draft SOPs do not address the requirement for informed consent by participants in research, and the process laid down means that in some instances approval may be granted for research without the HDEC having any means of satisfying itself that the researchers will be adhering to the legal requirements. For example, in paragraph 35 it will not be necessary for all written information that is to be provided to participants to be submitted to an HDEC, and paragraph 34.5.5 only requires a Participation Information Sheet and Consent Form to be provided.²⁰ Without reviewing all written information to be provided to participants, the HDECs will not necessarily be in a position to assess whether the requirements of informed consent will be met. And the decision as to what is or is not relevant information should not fall on the researcher.
22. The Law Society submits that the draft SOPs will not provide adequate safeguards for enabling research participants to assess properly the risks and benefits of participating in research and the legal requirements of informed consent or refusal to participate in research.

In particular:

18 See also s11 – Everyone has the right to refuse to undergo medical treatment.

19 See also the Health Information Privacy Code and exceptions to the requirement of informed consent as approved by an ethics committee. There are also other exceptions to the requirements of informed consent to participate in research but where approval is sought from an ethics committee in accordance with guidelines. For example, research involving incompetent participants or children.

20 Draft SOPs, p 13.

- (i) The draft SOPs do not expressly include all intervention studies requiring ethical review (paragraph 21). For example, human participants recruited in their capacity as volunteers in early-phase clinical trials (including bioequivalence and bioavailability studies) will require HDEC review but there is no indication that later stage trials such as Phase 3 and Phase 4 clinical trials will require review. This is a negative definition of the scope of review and it is not clear what intervention studies are included.
 - (ii) A study involving a medical device classified as “low risk” will not require ethics review (paragraph 22).
 - (iii) Only observational studies involving ‘more-than-minimal risk’ will require ethical review (paragraph 23.2). The definition of ‘more-than-minimal risk’ in paragraph 23.2 may be open to wide interpretation and places the potential participants in the unrealistic position of having to assess the risk themselves rather than the ethical review process assessing what those risks are.
 - (iv) There is an assumption made that observational research conducted at or below Master’s level for an educational qualification does not potentially expose participants to risk and therefore ethical review is not required (paragraph 25). This is an arbitrary distinction as less experienced researchers may pose greater risks to research subjects than more experienced researchers, and students’ supervisors may not provide an adequate protection or assessment of risk.
 - (v) In defining what research should be subjected to HDEC review, the SOPs reflect inadequate consideration of how “risk” or potential to harm is to be assessed and the significance of scrutiny being provided to research projects where there may be unknown risk in the medical experimentation or research undertaken. The Cartwright Inquiry is a case in point, where withholding of standard treatment of the time from women with cervical cancer was not thought by the researcher to expose them to harm. The women concerned did not give informed consent to participate in the research and were unaware that they were participating in medical experimentation.
 - (vi) Situations requiring the full ethics review pathway do include those where standard treatment is being withheld from one or more participants (paragraph 44.6), but “standard treatment” is not defined. It appears that no ethical review will be required in the situation where a new or innovative treatment is being combined with some level of standard treatment. The SOPs do not require ethical review of “innovative practice” as required in the current Standard (previously referred to as “innovative treatment” in earlier Standards and “new or unorthodox treatment” in the Cartwright Report).
23. Pursuant to paragraph 4 HDECs will be excluded from considering the scientific validity of proposed research and must check that appropriate “peer review” is carried out. There is no definition of “peer review”, and no explanation of the mechanism for how it is to be carried out or how HDECs are to assess that “appropriate” peer review has taken place. Some health and disability research is undertaken by non-health professionals who do not have “peers” with professional or ethical Codes that they are required to adhere to as would a health professional under the Health Practitioners Competence Assurance Act 2003 or a medical researcher under the Declaration of Helsinki.²¹ Scientifically unsound research may put participants at risk with no individual or societal benefit.
24. The WHO Standards specifically provide that the scientific design and conduct of the study is part of ethical review:

²¹ Declaration of Helsinki, The Ethical Principles for Medical Research Involving Human Subjects, 1964 (revised 2008).

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. **REC's [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 REC's 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). (Emphasis added)*

25. An intrusion into robust ethical review is the expedited review pathway set out in Part 6 of the draft SOPs and, as submitted above, would require legislative or regulatory change to adhere to international standards. This review pathway would presumably allow some clinical trials – those that are deemed to not require full review – to be expedited on the basis of being lower risk. This approach would not provide an adequate safety net of ethical review and reliance is placed on researchers rather than an independent review process to assess what level of risk is anticipated.
26. The SOPs do not recognise that the nature of risk may differ according to the type of research being conducted. Risk may occur in different dimensions (for example physical, social, financial or psychological) all of which require serious consideration. Harm may occur either at an individual level or at the family or population level.²²
27. The Law Society notes that the definition of “participant” in the draft SOPs describes a participant as one who actively participates in a study “usually” after having given informed consent to do so. The Law Society recommends that this definition be revised by omitting the word “usually”.
28. The proposed reduction in the scope and level of ethical review in some instances will undermine the principles of informed consent. The safeguard that is available to participants in research is that the research has been reviewed by an ethics committee to ensure that there is a proper process in place for informed consent or refusal to participation in research. The very fact that a person is participating in a research study must be known and also that there has been an assessment of the risks and benefits. Consumers of health services and participants in research proposals are in no position to assess the risk or benefits of a “low-risk” clinical trial which under these procedures will not have the benefit of a full committee reviewing the research and may be reviewed by the expedited pathway.²³
29. The Law Society submits that the SOPs as currently drafted purport to sanction research practices and standards by which research is ethically reviewed, that are inconsistent with the NZBORA and the Code. The process of informed consent or refusal to participate in research may be compromised by either inadequate or no requirement for ethical review of the research by an ethics committee. Any intrusion into these rights as proposed in the draft SOPs would require explicit statutory authorisation and even then the words actually used would be read strictly and wherever possible consistently with NZBORA.²⁴ The Law Society acknowledges that this is unlikely to be the intention of the drafters, or of the Minister, but recommends that this inconsistency be remedied by a clear statement of the overarching legal and ethical obligations of researchers and ethics committees as specified in those instruments, particularly in relation to the requirements for consent.

22 WHO Guidelines, page 15.

23 Draft SOPs, p16.

24 NZBORA,s6, and see *Jeffcoat v Waetford* (1999) 17 CRNZ 7; (1999) 5 HRNZ 466, paragraph 12; *R v T* CA 302/98, 2 November 1998.

30. The Society recommends that the SOPs should include a statement that the procedures are subject to existing legal and ethical standards nationally and internationally, particularly the right not to be subjected to medical or scientific experimentation without that person's consent, and the rights in relation to informed consent set out in the Code.
31. The Law Society further recommends that the scope of ethical review of health and disability research and innovative practice by HDECs be reconsidered to ensure that the ethics review system in New Zealand complies with international guidelines and best practice for the requirement of informed consent and the protection of participants in research.

Compensation for research participants under the Accident Compensation Act 2001

32. For a clinical trial to be covered by the provisions under s 32 of the Accident Compensation Act 2001, an accredited ethics committee (approved by the Director-General of Health or the Health Research Council) must approve the trial and certify that he, she or it was satisfied that the trial was not conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32(4) defines treatment injury to include “personal injury as a result of treatment given as part of a clinical trial ...” and may include circumstances where the claimant did not agree, in writing, to participate in the trial under s 32(5).
33. The proposed SOPs will reduce the scope of ethical review and some clinical trials or intervention studies will not necessarily require ethical review – for example, volunteers in later phase clinical trials. This takes no account of the requirement of ethics committees to certify *all* clinical trials under this compensation provision. “Clinical trial” is not defined in the Accident Compensation Act 2001 and this requirement of ethics committees has been interpreted to include a broad range of public good research that is not commercially sponsored. Participants should be fully informed about the ACC compensation arrangements if harmed and the implications of participation in the research. Where a clinical trial is not certified by an ethics committee, participants should not have to rely on s 32(5) and the lack of informed consent to have ACC cover in these circumstances.
34. The Law Society recommends that the scope of ethical review includes all clinical trials to ensure compliance with the treatment injury provisions in the ACC Act.

Conclusion

35. The Law Society has focused in this submission on its key concerns regarding the proposed SOPs, and would appreciate the opportunity to discuss these concerns with the Ministry. Contact can be made in the first instance through the Health Law Committee secretary, Clare Needham (ph 04 463 2967 / clare.needham@lawsociety.org.nz).

Yours sincerely



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President