26 February 2015

National Ethics Advisory Committee Secretariat
Ministry of Health
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To whom it may concern

Cross-sectoral ethics committee arrangements for health and disability research

Thank you for the opportunity to comment on the National Ethics Advisory Committee's discussion document, "Cross-sectoral ethics arrangements for health and disability research".

The discussion document outlines for discussion issues associated with six aspects of cross-sectoral research ethics arrangements. My response is primarily focused on issues regarding monitoring and accountability for health and disability research.

Introductory comments
As you are no doubt aware, my role as Health and Disability Commissioner is to promote and protect the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code). The Code is a regulation under the Health and Disability Commissioner Act 1994 (the HDC Act), and sets out the rights of health and disability services consumers and the corresponding obligations on the providers of those services.

The duties in the Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, research (see Right 9 of the Code). Given the significance and complexity of this area, it is important that we have well functioning ethics mechanisms and I commend you in your consultation process.

Provider accountability
Under Heading 1.3, it is noted that health professionals undertaking research are required to follow the codes of practice issued by their respective health regulatory body, as well as the Code. Under Heading 1.2, it is stated that researchers are responsible for good design and conduct of research, including complying with all relevant legal requirements and adhering to the agreed and ethically approved study, although "it is not entirely clear who is responsible for ensuring researchers fulfil these obligations".

While it may be desirable to put in place a mechanism to monitor whether health and disability researchers adhere to the agreed and ethically approved study, and comply with all legal requirements, I note that the ultimate accountability for doing so remains with the individual health provider undertaking the research.

For completeness, I note that the Code applies to all health and disability services providers, as defined in sections 2 and 3 of the HDC Act, not just "health professionals". All health and

disability services providers carrying out health and disability research are legally obliged to comply with the obligations set out in the Code. Research approval by an ethics committee does not remove that individual responsibility from a researcher. In this respect, HDC has a key role in ensuring provider accountability when a provider carrying out health and disability research fails to comply with their legal obligations under the Code. I also note that the employer of a provider undertaking research has a role in ensuring accountability in such circumstances.

In my view, the individual legal and ethical responsibilities of health and disability researchers and their employers should be emphasized in any relevant documents.

I note the comment on page 12 of the discussion document, under Heading 1.3, that the disciplinary role for health professionals "is also shared with the Health and Disability Commissioner". For the avoidance of doubt, HDC's primary role is to uphold the rights of health and disability services consumers which, in a small proportion of cases, may involve bringing disciplinary proceedings in the Health Practitioners Disciplinary Tribunal.

Ethics committee accountability
Under the Heading 1.2, it is stated "neither the standard operating procedures nor the terms of reference for each HDEC indicate who, if anyone, is responsible for ensuring that HDECs meet their responsibility to act lawfully …"

HDECs and other ethics committees play an instrumental role in ensuring that the research community in New Zealand adequately understands and applies the law. It is axiomatic that each HDEC is itself ultimately responsible for acting both ethically and lawfully. In my view, a stronger regime for monitoring the performance of HDECs and other ethics committees, to ensure consistent and quality ethical review, is necessary. That monitoring regime should clearly reinforce that ethics committees are ultimately responsible for acting lawfully, ensure appropriate accountability for when HDECs and other ethics committees fail to comply with the law, and emphasise the primary role of HDECs and other ethics committees to protect health and disability consumers involved in research.

Other matters
In Figure 1, HDC is listed as an ethics advisory body. I note that this is not an accurate description of HDC's role, which is to promote and protect the rights of health and disability services consumers. While this may include educating providers and consumers about consumer rights in relation to research, I do not consider that HDC should appear in that list.

On page 26, under the Heading 5.3, it is noted that the Code "makes a distinction between research and external audit or evaluation of services". I note that that "distinction" is specific to the use of body parts and bodily substances (Right 7(10)), and is not generally specified.

I agree that it would be useful to improve definitions, guidance and classifications for observational research, audit, and innovative practice, for the purposes of giving better direction as to whether or not ethical review is required in any given case. In this respect, I note the reference to my Opinion in case 11HDC01072, regarding the prescribing of ketamine in Southern DHB. As I noted in that Opinion, "there can be a 'grey area' with no clear line between an accepted (although uncommon and off-label) treatment and an experimental treatment". As you note, my recommendations in that Opinion have led to positive change in the sector, with the District Health Board Chief Medical Officers' Group

having now developed a national policy for all district health boards on the use of unapproved medicines and the use of medicines for unapproved indications (off-label use).

As an aside, I note that the reference to Opinion 11HDC01072 appears in the section of the discussion document that relates to innovative practice. “Innovative practice” is not a term that is used in the Code.

Conclusion

I trust that these general comments are of assistance.

I would welcome the opportunity to comment on any further recommendations for change to the cross-sectoral ethics arrangements for health and disability research in New Zealand, or the above guidelines, that may be proposed as a result of this consultation.