New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

28 April 2017

Anthony Hill
Health and Disability Commissioner
PO Box 11932
Wellington 6142

By email: hdc@hdc.org.nz

**Health and disability research involving adult participants who are unable to provide informed consent**

Dear Anthony

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 5,500 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, Ethics Committee and Board.

1. We welcome the current consultation on research involving adult patients who are unable to consent to participation in that research. At present, research on a person who is unable to give consent can take place only if participation in the research is in **that person's best interests**, as per Right 7(4) of the Code of Health and Disability Services Consumers' Rights. You will recall that we wrote to you in February 2015 with the views of the NZMA Ethics Committee and asking that your Office initiates a consultation on Right 7(4) conducted separately from the regular reviews of the Act and Code.[1]

2. The NZMA Ethics Committee has previously considered this issue and concluded that there are strong grounds to widen Right 7(4). Furthermore, it is clear that Right 7(4) as it stands is not aligned with the World Medical Association Declaration of Helsinki–Ethical Principles for Medical Research Involving Human Subjects.[2] This document is the international gold standard; the issues are well covered in the General Principles, and in the sections on Vulnerable Groups

[1] Letter to Health and Disability Commissioner. HDC Right 7 (4) – research involving incapacitated patients. 20 February 2015. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0010/55189/Letter-to-HDC-re-review-of-Right-74-research-involving-incapacitated-patients.pdf

[2] World Medical Association. Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. JAMA, November 27, 2013; 310 (20) 2191-4. Available from http://jamanetwork.com/journals/jama/fullarticle/1760318



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and Informed Consent. The current position in New Zealand is also at odds with other jurisdictions including the UK and Australia, both of which allow research involving participants who are unable to give consent to proceed in a broader range of circumstances than in New Zealand.

3. The NZMA continues to believe that New Zealand's laws regarding the research of patients who are unable to provide informed consent are too restrictive. The 'best interests' test does not provide for any consideration of the potential for advances in knowledge that may benefit other people. As the consultation document identifies, research on patients who cannot give informed consent may provide valuable information about the conditions that cause patients to lack or lose capacity, and about the diagnosis, treatment, care and needs of such patients. In some cases, this information is not obtainable through research involving only competent consumers. There is a view that the current restrictions in the Code diminish, rather than protect, the rights of those persons who cannot consent to participate in research, by depriving them of the class benefits arising from the gains in healthcare that are the result of good clinical research.

4. We consider that making New Zealand's health and disability research laws consistent with those of some other countries may also allow for collaborative research opportunities with international partners.

5. We draw attention to a publication (attached) by a member of our Ethics Committee that elaborates on the ethics of research on patients in intensive care units, many of whom cannot give prospective informed consent.[3] In general, patients are better served in units where research is actively taking place for several reasons: i) they do not fall prey to therapeutic prejudices without clear evidential support; ii) they get a chance to access new and potentially beneficial treatments; iii) a climate of careful monitoring of patients and their clinical progress is necessary for good clinical research and affects the care of all patients; and iv) even those not in the treatment arm of a trial of a new intervention must receive best current standard care.

6. We submit that there should be a broadening of the current restriction on research involving adult patients who are unable to provide informed consent. This could incorporate the concept of proportionality with respect to potential benefits and risks to the individual patient. It should also include potential benefits to the wider population, particularly those affected by a similar condition. The approach taken by the UK may provide a helpful model. There, research can take place on people who lack the capacity to consent only if that research either:[4]

- has the potential to benefit the participant without creating a disproportionate risk

or

- is intended to provide knowledge of the causes or treatment of, or care of, people affected by a similar condition. If so, researchers must have good reason to believe that any risks to individual participants are negligible, will not significantly affect their freedom or privacy, and will not be unduly invasive or restrictive.

7. We consider, however, that careful consideration is needed of the perspectives of Māori, Pacific peoples and other non-European ethnicities on any changes to New Zealand law on research involving adult patients who are unable to provide informed consent. This will help

[3] Gillett GR. Intensive care unit research ethics and trials on unconscious patients. Anaesth Intensive Care. 2015 May;43(3):309-12

[4] Mental Capacity Act 2005 (England and Wales), Section 31 (5) (a,b). Available from http://www.legislation.gov.uk/ukpga/2005/9/contents

ensure that any changes are culturally safe and appropriate and uphold Te Tiriti o Waitangi and other obligations.

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

Yours sincerely

Dr Stephen Child
NZMA Chair

**Attachment**

Gillett GR. Intensive care unit research ethics and trials on unconscious patients. Anaesth Intensive Care. 2015 May;43(3):309-12