



28 April 2017

Mr Anthony Hill  
Health and Disability Commissioner  
PO Box 11934  
Wellington 6142

Dear Mr Hill

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

Thank you for seeking feedback from the New Zealand Society of Anaesthetists (NZSA) on the above consultation.

#### **About the NZSA**

The NZSA is a professional medical education society, which represents over 550 medical anaesthetists in New Zealand. Our members include specialist anaesthetists in public and private practice, and trainee anaesthetists. We facilitate and promote education and research into anaesthesia and advocate on behalf of our members, representing and championing their professional interests and the safety of their patients. As an advocacy organisation, we develop submissions on government policy and legislation, work collaboratively with key stakeholders, and foster networks of anaesthetists nationwide. The NZSA, established in 1948, also has strong global connections, and is a Member Society of the World Federation of Societies of Anaesthesiologists (WFSA).

#### **Overview**

Executive members of the NZSA have reviewed the consultation document and have also sought the opinion of members who are actively involved in research. All commend you for examining whether New Zealand's current law relating to nonconsensual research is appropriate. Without research and indeed without audit, in which healthcare systems and individuals routinely collect and pool significant amounts of anonymised data to enable the analysis of outcome according to patient, operator and institution risk<sup>1</sup>, improvements in the quality of care for patients would not be possible.

The NZSA is a membership based organisation and we believe that it is important for members with a particular interest in this issue to have an individual voice, so that all points of view may be considered by the Commission. Accordingly, NZSA members' individual responses to selected consultation questions are attached (Appendix I and II).

As a Society, the NZSA supports research with adult participants who are unable to provide informed consent, provided there are strong safeguards in place to protect the rights of this vulnerable group. The NZSA, and the Australian New Zealand College of Anaesthetists

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<sup>1</sup> Dennehy L, White S. Consent, assent, and the importance of risk stratification. BJA (2012) 109 (1): 40-46

(ANZCA), support research with the following criteria, extracted from an article by Professor Grant Gillett (2015)<sup>2</sup>:

- Ethics committee oversight that is robust and dynamic so that what we do to our patients – both in established therapy and experimental treatment – meets the standards of a duty of care properly reflective of scientific evidence and a dedication to wellbeing.
- External scientific review to ensure what is being proposed in such a trial will see that appropriate existing standards of care are upheld for all trial participants.
- Solid preclinical data to exclude any known harm and support a real prospect of benefit for a new experimental therapy.
- A commitment to trial new treatments against best standard regimens.

The NZSA also recommends that the Commission refer to the International Conference on Harmonisation's Guideline for Good Clinical Practice E6. This was originally an agreement between the United States, the EU and Japan, which is now ratified by other countries. This guideline was created to ensure consistent standards for drug research and includes universal issues relating to practice and research.

### **Recommended papers**

We would like to draw your attention to key points from various papers from recent anaesthetic publications as follows:

*Consent, assent, and the importance of risk stratification.* Dennehy L and White. BJA (2012) 109 (1); 40-46

- I. Valid consent depends on patient voluntariness and the capacity to make a treatment decision based on the information provided
- II. A person with capacity understands, remembers, and uses the information provided
- III. Information should be provided to a standard which a reasonable patient would want to know in the patient's circumstance
- IV. There are logistical and theoretical difficulties in delivering on each of these principles of consent
- V. Information provision during the consent process inadvertently incentivizes data collection for perioperative outcomes research.

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<sup>2</sup> Gillett, G R. Intensive care unit research ethics and trials on unconscious patients. *Anaesthesia Intensive Care* 2015; 43 (3): 309-312

This paper includes a discussion on the British Mental Capacity Act 2005, enforced since 1 April 2007. Patients who are not competent to make decisions about treatment are administered treatment, provided that it is necessary and in their best interests. “Best interests” must be determined by the treating clinician (or less commonly the Courts) in a nondiscriminatory manner, taking into account information outside the clinical episode, including for example, the patient’s known wishes as previously expressed to relatives and other third parties. The Act recognises the legality of advanced decision making.

In New Zealand, the introduction of Advanced Life Care Planning has allowed advanced decision-making and should include decisions relating to research.

*Ethics in Research.* Bevan J C. Current Opinion in Anesthesiology 2007, 20:130-136.

This paper discusses the ethical principles adopted by the Universal Declaration on Bioethics and Human Rights (2005) including:

I. Consent

Any procedure or research is only to be carried out on a person with the prior, free and informed consent of the person concerned, based on adequate information (exceptions only under international human rights law). The person may withdraw consent at any time and for any reason without disadvantage or prejudice. For research in communities, additional agreement of community leaders or legal representatives is needed.

II. Persons without the capacity to consent

Authorization in accordance with best interest of the person concerned in accordance with domestic law. Research only carried out for direct health benefit to person or exceptionally when risk is minimal and research benefit is great.

*Ethics of research for patients in pain.* David Waisel. Current Opinion Anesthesiology. 2017, 30:205-210.

This review describes advances in rising and continuing ethical issues in pain research. Some of the issues focus directly on research, such as neonatal pain, while others focus on widespread ethical issues that are relevant to pain research, such as scientific misconduct, deception, placebo use and genomics. Key issues, which are relevant to this submission, are:

I. Neonatal pain management research for routine ICU procedures often uses placebo instead of other validated, non-pharmacologic methods for the control group. There are well recognized, long term behavioral harms to neonates of repeated painful stimuli, even of this nature.

II. Potential remedies to what appears to be increasing scientific misconduct include recognizing the warning signs of repetitive irreproducibility, scrutinizing data omissions, improving whistle blower protection and harshly sanctioning researchers, their mentors and institutions for scientific misconduct.

A crucial component of informed consent for research participants is the provision of written information. Generic templates are provided for Participant Information and Consent Forms (PICFs) by the Harmonisation of Multicentre Ethical Review Reference Group, which states that the language should be readily understood by a grade eight equivalent. Taylor and Bramley<sup>3</sup> found that the average grade level of patient information and consent forms for anaesthesia research exceeded the average literacy and comprehension of the general population in both Australia and New Zealand.

For all patients involved in research, and particularly those vulnerable patients reliant on others (such as family/whanau, EPOA, or legal representatives) to provide informed consent on their behalf, all information and consent forms must be understandable to the levels required by the Health Research Council of New Zealand and as recommended by the Harmonisation of Multicentre Ethical Review Reference Group.

*Informed consent in psychiatry clinical research: a conceptual review of issues, challenges and recommendations.* Gupta U and Kharawala S. Perspectives in Clinical Research 2012; 3.1; 8-17

Although not part of the anaesthetic literature, the NZSA recommends this paper as it discusses the issue of voluntarism, and details consent capacity assessment, proxy and surrogate consent and screening the decisional capacity of a participant. The paper also looks at various informational/educational techniques that may need to be considered to enhance the understanding of participants.

### **The distinction between research and audit**

It is important for the legislation, as well as ethicists, to distinguish between audit and research. In current practice, there is often no distinction made between research, which tests a new way of doing something, from an audit which is simple observation and appraisal of results without making changes. The recent shift towards labelling all reviews of medical practice as research prevents the necessary methodical examination of patient outcomes. Therefore, we are unable to know our current results or to consider how to improve what we do. Not all studies which collect patient outcome information are correctly labelled as research: when results of normal, currently accepted therapies, or of different approaches in common use are monitored, this is an audit, not research. The ability to do regular audits is vital to maintain the high standards of medical practice for patients. The regular conduct of audits is mandated by the Medical Council of New Zealand for all doctors, as audits monitor clinical results and ensure that standards of practice are maintained and improved wherever possible. Audit results are usually anonymised aggregated patient information and where individual patient information is described, the patient's consent is required.

### **Summary**

Thank you once again for the opportunity to provide feedback on this consultation. The NZSA believes that it is important that adult participants who cannot provide consent are

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<sup>3</sup> Taylor H E, Bramley D E P, An analysis of the readability of patient information and consent forms used in research studies in anaesthesia in Australia and New Zealand. Anaesthesia intensive Care 2012; 40: 995-998



able to benefit from research. As Atul Gwande suggests, we must “count something” to enable analysis of outcome according to patient, operator and institution specific risks.<sup>4</sup>

If you would like further information or have any questions please email:  
[president@anaesthesia.nz](mailto:president@anaesthesia.nz)

Yours sincerely

A handwritten signature in black ink that reads "David Kibblewhite". The signature is written in a cursive style with a large initial 'D'.

**David Kibblewhite**  
**President**

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<sup>4</sup> Gwande A. Better. A Surgeon's Notes on Performance, 2007 London Profile Books

## APPENDIX I:

### HDC Consultation Response Form

#### Case Study A: An observational study measuring clearance of antibiotics during dialysis

**A1. If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?**

Yes

**A.2 Please give the reasons you formed this view.**

Blood and urine tests, even if additional, or not that invasive. If I'm in ICU septic they will be doing regular bloods anyway. The potential impact of sub-therapeutic levels of the AB in septic patients is an important one and even though it won't benefit me it may benefit someone in my position in the future.

#### Case Study B: Clinical trial comparing two products used following neurosurgery

**B1. If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?**

Yes

**B.2 Please give the reasons you formed this view.**

If both products are in use then I would be equally likely to get either, even if not in the trial, depending on the surgeon preferences in the hospital I am being treated at. If one is shown to be better than the other, this would be beneficial for future patients. I would not agree if it was testing a new product that was not already in clinical use.

**B.3 What are your views about "delayed consent?"**

I think delayed consent is appropriate, although how long would you wait? If I regain capacity I would want to be involved in a discussion about the trial in the same way I would if I had capacity at the time of enrolment. I would be unlikely to withdraw, given that the data has already been collected, but I think it gives some autonomy back to the patient.

### **Case Study C: Trial regarding care provided to consumers with severe dementia**

**C1. If you were a person with dementia and unable to consent, would you want to be a participant in this research?**

Yes

**C.2 Please give the reasons you formed this view.**

Again, if a new model of care is proven to be beneficial that would be good. It seems to make sense that increased contact would be a good thing, but the study is looking at the negative impacts of such contact too. The goal of this is to improve the QAL of those with dementia; this can be hard to assess. It would be inappropriate to conduct such a study only with those that can consent, as that would skew the results. We are potentially denying this group of patients a better care model if it turns out to be better if we exclude them because they cannot consent.

### **Case Study D: Clinical trial regarding use of adrenaline**

**D.1 If you suffered a cardiac arrest, would you want to be part of the study?**

Yes

**D2. Please state the reasons you formed this view.**

The evidence is weak, but adrenaline is a standard treatment. In my medical mind it is a great study, but if I had just had an arrest, I would want adrenaline, not saline. However, I think such a study would be one of the main benefits of allowing research on those unable to consent.

**D3. What are your views about the proposed “opt out” process?**

I don't think the opt out consent is appropriate. How can you ensure adequate coverage of the opt out bracelet? What if I forget to wear it on the day I have my arrest?

### **Case Study E: Clinical trial of drug for people with Down syndrome**

**E.1. Do you think people with Down syndrome who are unable to give informed consent should be part of this research?**

No

**E.2 Please state the reasons you formed this view.**

I think there should be a trial first looking at the effects of the drug in those with Down's syndrome, to ensure there is no difference in effect. You could look at a small group who had capacity to consent. If this study showed no difference in effects/side effects compared to non-downs, then I would be happy with the original study to go ahead using those who cannot consent.

**E.3 Do you think the proposed consultation with family/whanau/caregivers gives sufficient protection for participants who are unable to give consent?**

Unsure.

#### **E.4 Please state the reasons you formed this view**

Taking into account family thoughts is valuable, especially if the family are intimately involved in the care of the patient, but it is not fail safe. The family may not always have the patient's best interests at heart.

#### **Part 5 Consultation questions**

##### **1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent? If yes, please state the reasons why. If no, please state the reasons why not.**

Yes. This is a valuable group of patients who are currently missed from research when it could add important information.

##### **1.2 If you think such research should be allowed, please make any general comments about the circumstances/restrictions that you think should apply.**

There must be clear ethics discussion and guidelines around the study as is the norm anyway.

##### **1.3 Do you think the same laws should apply to all health and disability related research?**

Unsure

##### **1.4 Please make any general comments you have about question 1.3**

Potentially a wider base for abuse?

#### **Dissent**

##### **2.1 Should the law state expressly that irrespective of the person's level of competence any expression of dissent or refusal to participate in research must be respected?**

Unsure

##### **2.2 Please give reasons for your answer.**

If someone is clearly objecting and it is not necessary for their care, then you must respect their objection, however many patients will become agitated having tests and it may be unclear what they mean if unable to communicate. For example, a demented patient may refuse to go to the toilet, but that is clearly in their best interest.

#### **Delayed consent**

##### **3.1 Do you think the law should be changed to allow researchers to obtain delayed or retrospective consent to research after incompetent participants regain competence to consent?**

Yes



### **3.2 Please give reasons for your answer**

It acknowledges my autonomy once I regain capacity, and informs me of the study I was involved in and gives me the choice about removing my data.

### **Alternative participants**

#### **4.1 Do you think that there should be a legal requirement that, before research on incompetent persons is permitted, the researcher must show that research of a similar nature cannot be carried out on competent persons?**

Yes

#### **4.2 Please make any further comments you have about question 4.1**

If this is not in place, it may mean that a researcher may use incompetent adults to perform a study as easier to get the numbers if they don't need to get consent.

### **Interests of others to be taken into account**

#### **5.1 Should research on an incompetent participant be permitted if the research may or may not benefit the individual participant, but may benefit other people?**

Yes

#### **5.2 Please give reasons for your answer.**

This is the only way that the care of future patients can be improved

#### **5.3 If the proposed research may or may not benefit the incompetent participants, but may benefit others, should there be criteria about the group of people that it is intended to benefit?**

Yes

#### **5.4 If the answer to 5.3 is yes, please indicate the criteria that you think should apply and indicate the order of importance of the criteria with 1. Being the most important and 5. Being the least important**

Those with the same condition and similar demographics.

### **Ethics Committee Approval**

#### **6.1 Do you think researchers should be required by law to obtain ethics committee approval before conducting health and disability research with adult participants who are unable to give consent?**

Yes

#### **6.2 Please give reasons for your answer.**

To prevent abuse, particularly because they cannot consent.

## **Ways to assess the advantages and disadvantages of participation by incompetent consumers in research**

**7.1 Do you think the current best interests test, which requires that the consumer would be better off participating in the research than not participating, strikes an appropriate balance between protecting the rights of consumers who are unable to give consent and allowing research to proceed?**

Unsure

**7.2 If you answered “No” to question 7.1, please answer 7.2. If research were to be permitted to proceed without consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?**

As long as there is no harm, it is okay to participate if no direct benefit to the patient, but there is a potential benefit to future patients.

## **Who decides**

**8.1 Do you think there should be any change made to NZ law regarding who decides whether an incompetent consumer will be enrolled in a study?**

No

**8.2 Do you think there should be any change made to the roles played by the various possible decision-makers under current NZ law?**

Yes, if consent has to fulfil section 7(4) then it will exclude all incompetent patients from studies, as usually unable to say it is in the best interests of the patient. I think the emphasis should be no harm.

**8.4 Who do you think should be the final decision maker when making a decision as to whether to enrol an incompetent person in a research project? Set out below are some options.**

EPOA, researcher, care provider not involved in research, family/whanau.

## **Appendix II:**

### **Case Study A: An observational study measuring clearance of antibiotics during dialysis**

**A1. If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?**

Yes

**A.2 Please give the reasons you formed this view.**

Observational study. Study will benefit the greater population and body of knowledge.

### **Case Study B: Clinical trial comparing two products used following neurosurgery**

**B1. If you were having this surgery and unable to consent, would you want the research to go ahead with you as a participant?**

Yes

**B.2 Please give the reasons you formed this view.**

Both products already approved. No risk to patient and again allows increase in body of knowledge. Delayed consent is necessary especially if there are ongoing followup issues with respect to the study. Everyone who is in a trial without consent must be informed and placed in a position to relinquish their presumed consent if they become competent to do so. Delayed consent could also be called delayed non-consent and as such should be mandatory.

### **Case Study C: Trial regarding care provided to consumers with severe dementia**

**C1. If you were a person with dementia and unable to consent, would you want to be a participant in this research?**

Yes

**C.2 Please give the reasons you formed this view.**

There is some evidence to support this hypothesis. Could perhaps include some measure of patient distress during assessments to reassure that the assessments are not causing harm. There is the potential for significant benefits of inclusion in this study and the harms, although relevant (distress etc.) are likely to be non-significant in nature as long as they are considered and mitigated for.

### **Case Study D: Clinical trial regarding use of adrenaline**

**D.1 If you suffered a cardiac arrest, would you want to be part of the study?**

Yes

**D2. Please state the reasons you formed this view.**

However, this is difficult. One could argue that this is not experimental as adrenaline is already part of cardiac arrest therapy. This study would again contribute to a greater body of knowledge but ethics approval would be necessary.

**D3. What are your views about the proposed “opt out” process?**

I suspect the opt out option would be very difficult and expensive to administer.

**Case Study E: Clinical trial of drug for people with Down syndrome**

**E.1. Do you think people with Down syndrome who are unable to give informed consent should be part of this research?**

No

**E.2 Please state the reasons you formed this view.**

There seems to be very little potential benefit and in addition with support a significant group may be able to give consent. In addition, if the drug is successful to then make it unavailable seems questionable.

**E.3 Do you think the proposed consultation with family/whanau/caregivers gives sufficient protection for participants who are unable to give consent?**

No, I don't think that discussion with whanau is sufficient. In this situation, there is the ability to use the drug on those with Down syndrome who are able to consent, so there should not actually be a need to trial the drug on those who cannot consent.

**Answers to Part 5**

1.1 Yes, provided that the study is thought ethical and will add to the total body of knowledge in a beneficial manner. Many people like to be involved in such ventures as they want to “give back” to the community in some way.

1.2. The same rules should apply to all research; consistency is important.

2. Difficult and probably no. Many impaired people refuse treatment that is clearly of benefit to them. If there is a clear benefit from being included in a study, one could argue that it would be unethical to not include.

3. Yes, delayed consent may well be useful.

4. Yes

5.1 Yes. Legislating for all possible contingencies is probably impossible. However, agreeing on underlying ethical principles to guide the discussion of a well selected group who are empowered to make decisions on a case-by-case basis may be more useful.

6. Probably yes, for the safety and accountability of all.

7. I like the concept of “balancing tests” but the two tests suggested still seem to be very limiting in what studies would ultimately proceed. I refer to the comments I made in Q5.

8.1 No

8.2 No

8.4 Hopefully, the final decision will be a consensus between all. However, if consensus cannot be reached, in my opinion the EPOA must have the final say.