HDC Research Submission on behalf of The College of Intensive Care Medicine of Australia and New Zealand (CICM)

Board of the College of Intensive Care Medicine of Australia and New Zealand (CICM)

Executive Summary

The College of Intensive Care Medicine of Australia and New Zealand (The College) is the body responsible for the training of Intensive Care Medicine (ICM) Specialists and the accreditation of Intensive Care Units (ICU's) for training in New Zealand and Australia. The College is committed to achieving the best health outcome for critically ill patients, through training high quality specialists, increasing specialty knowledge and improving standards of care[1].

The College fully supports the notion that increasing knowledge to improve patient care is best achieved by following the principles of Evidence Based Medicine (EBM). EBM is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the best available research information[2]. In order to implement EMB to achieve the best outcome in our patients, Intensive Care clinicians will be expected: a) to use evidence summaries in clinical practice; b) to help develop and update evidence-based guidelines in their area of expertise; and c) to enrol patients in studies of treatment, diagnosis and prognosis on which medical practice is based[2].

An integral part of improving standards of care involves using best evidence to inform which interventions maximise the chances of achieving good patient outcomes, and allow those interventions which are either non-beneficial or harmful to be discarded. There are numerous examples of therapies which on initial 'experience' or low-level evidence- appeared to have been beneficial to patients, only to have been shown to be potentially harmful in the context of a well-designed multi-centre Randomised Controlled Trial (RCT), for example the CHEST, NICE-SUGAR and the SAFE-TBI studies[3],[4],[5].

New Zealand and Australia has produced some of the largest and well conducted ICM research, driven by the Australia and New Zealand Intensive Care Society Clinical Trials Group (ANZICS-CTG)[6]. and we believe

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[1] The College of Intensive Care Medicine of Australia and New Zealand (CICM) Strategic Plan 2016: https://www.cicm.org.au/News-Summary/College-Strategic-Plan-2016-2020

[2] Masic I, Miokovic M, Muhamedagic B: Evidence Based Medicine- New Approaches and Challenges. *Acta Inform Med*. 2008; 16(4): 219–225.

[3] Myburgh J, Finfer S, Bellomo R *et* al. Hydroxyethyl Starch or Saline for Fluid Resuscitation in Intensive Care (CHEST). N Engl J Med 2012; 367: 1901-11.

[4] NICE-SUGAR Study Investigatoers. Intensvie versus Converntional Glucose in Critically Ill Patients. N Engl J Med 2009; 360: 1283-1297.

[5] The SAFE Study Investigators. Saline or Albumin for Fluid Resuscitation in Patients with Traumatic Brain Injury. N Engl J Med 2007; 357: 874-884.

[6] ANZICS CTG Publications: Accessed 14th March 2017: http://www.anzics.com.au/pages/CTG/publications.aspx

this is reflected in our world-leading outcomes from diseases such as sepsis, and a reduction in the relative risk of death from sepsis of 47% between 2000 and 2012[7].

However, the College acknowledges that research on patients who lack capacity is a very sensitive issue, and that the role of Intensive Care Physicians is firstly (and foremostly) as an advocate for and carer of the patient.

The four key ethical biomedical principles; Autonomy, Beneficence, Non-Maleficence and Justice[8] are potentially under tension in the context of research[9]. Failure to respect autonomy in the pursuit of the 'greatest good for the greatest number' has been at the heart of some of the worst historical atrocities in the name of advancing knowledge through research. The Nuremberg Code of 1947[10] and the Declaration of Helsinki in 1964[11] cemented autonomy as the most important principle in this regard.

The following details our response to some of the specific questions raised in the consultation document.

Answers to Specific Questions:

Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent?

Yes, but with appropriate safeguards:

In clinical practice, the Intensive Care Physician will have the patients best interests of the patient as the only motivator, are therefore are in a strong position to make surrogate decisions about the patients care when they are not in a position to do so [12]. The undertaking of a clinical trial acknowledges that clinicians don't always know which therapies are in the patient's best interests, and therefore to resolve this conflict, explaining this to a third party in each circumstance and obtaining their agreement that this is something the patient would agree to, introduces an appropriate safeguard.

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[7] Kaukonen KM, Bailey M, Suzuki S, Pilcher D, Bellomo R. Mortality related to severe sepsis and septic shock among critically ill patients in Australia and New Zealand, 2000-2012. JAMA. 2014 Apr 2;311(13):1308-16.

[8] Beauchamp TL, Childress JF. Principles of Biomedical Ethics. Oxford: Oxford University Press; 1978.

[9] Rincon F, Lee K. Ethical considerations in consenting critically ill patients for bedside clinical care and research. J Intensive Care Med. 2015 Mar;30(3):141-50.

[10] Trials of War Criminals Before the Nurenberg Military Tribunals Under Control Council Law N. 10. Washington, DC: U.S. Government Printing Office; 1948–1949.

[11] Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. N Engl J Med 1964;271:473–480.

[12] Freebairn R, Hicks P, McHugh GJ,. Informed consent and the incompetent adult patient in Intensive Care – a New Zealand perspective. Critical Care and Resuscitation 2002; 3: 202 – 205

Denying patients the opportunity to participate in properly conducted research would potentially deny them the opportunity to benefit either directly from a beneficial therapy, or therapies found in previous patients to be beneficial (and therefore become a 'standard of care'), and benefit from an improvement in the quality of service/protocol delivery that comes from an ICU being involved in well conducted clinical research. **In short, if research in patients unable to give consent is not allowed, all research in the sickest patients (cardiac arrest, shock, severe sepsis) would stop, as would improvements in their care.**

The Declaration of Helsinki[8] and its revisions, to which New Zealand is a signatory, sets out provisions for medical research in patients unable to consent, where research is of potential diagnostic or therapeutic value for the individual participant. It also contains additional recommendations for when the patient is unable to consent, as well as provision for situations where research may require no patient consent[9].

Recommendations include an independent committee to consider whether to approve the research. The regional ethics committees, acting as the independent review boards, have generally adopted a conservative but facilitative approach, consistent with the Declaration of Helsinki and the revisions[9].

This ethos has been incorporated into legislation in Australia, England/Wales and Scotland, making clear provision for research on such patients, as outlined in the consultation document.

We support a change in NZ law in line with these jurisdictions, and appropriate safeguards, to allow patients with critical illness the right to be included and to ultimately benefit from advances in the knowledge of 'best practice' as applied to Intensive Care Medicine.

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?

This is a very difficult question to answer. On one hand, when a loss of mental faculty creates uncertainty regarding a patient's capacity to be both informed and autonomous, ethical practice obliges medical practitioners to provide as much information and self-determination as is possible to the patient. The right to be involved in the decision making process, even with a diminished competence is protected by the Code (Right 7 (3)). At the same time the other three principles of beneficence, non-maleficence and social justice must be protected.

However, ICU patients who lack capacity are unable to comprehend the context or intention of the therapies which are being undertaken with the intention of preserving life and health. Patients would only find themselves on an ICU if they have become critically unwell (either through illness, trauma, or following major emergency or elective surgery). These processes all have the capacity to generate pain and fear. Most ICU therapies also have the capacity to induce discomfort, fear and anxiety during a consumer's journey in ICU (e.g. monitoring, pharmacological restraint, vascular access, diagnostic tests, basic nursing cares, mobilisation, weaning from ventilation, emergence from coma, removal of monitoring devices), and the careful steps we take to minimise their distress would add to the level of incapacity. Furthermore, many of our studies of two or more interventions as part of 'standard care' would be impossible for a patient to identify. It would therefore be very difficult to differentiate the transient expression of fear and discomfort in the context of the above as a specific unwillingness to participate in research.

In practice, involving those who know the patient best (the family) in a conversation about whether they feel the patient would consent to being part of a trial may be the best way of incorporating an appropriate safeguard. Notwithstanding, Intensive Care Physicians are after all the guardians of very vulnerable patients, whose best interests must remain the priority.

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; the reality is that this the current mechanism of conducting research in ICU's in NZ currently. If a consumer has been entered into a study based on the best-interests rule, and subsequently regains capacity ('recovers'), then the principle of informed consent means that delayed consent is a natural consequence of this process, and should be recognised by law. This remains preferable to the assumption that 'best interests' can override a patient's subsequent withdrawal of presumed consent. An appropriate process of delayed consent with safeguards is outlined in Section 4.4.13 and 4.4.14 of the Australian National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, updated in 2015[13]

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, although as outlined above, therapies of use in the critically ill should be proven to work on the critically ill.

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

The key-word here is 'may'. Yes, presuming the research has the *potential* to benefit the patient. Again, this is a very difficult question: There are several *potential* benefits to the individual participant: In his analysis on this area, Gillet noted that "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 of accessing 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

[13]Australian Government : National Health and Medical Research Council- National Statement on Ethical Conduct in Hujan Research 2007 (Updated May 2015): https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf

new intervention must receive best current standard care (according to international evidence-based treatment guidelines)"[14].

The NHMRC Document states: "Research involving people who are highly dependent on medical care may be approved where: -it is likely that the research will lead to increased understanding about, or improvements in, the care of this population....People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into research might seem unfair. However, those people are entitled to participate in research and, when the conditions of paragraph 4.4.1 are met, their involvement is not unfair"[13].

UK law contains the appropriate safeguards in this regard: Research can take place on people who lack the capacity to consent only if that research:

"Either

- *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 impact their freedom or privacy, and will not be unduly invasive or restrictive.* "

The law could be amended to allow research to be conducted more in accordance with UK law: such that the wider public benefit can be a consideration only If there's 'minimal' harm/burden to the patient.

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: The College fully supports the notion that there should be independent checks and balances, for example as outlined by Rincon et al: *" [with] the imposition of safeguards such as consultation with the community in which the study were to take place, oversight in patient screening and recruitment process by institutional review boards, special study designs, retrospective and prospective consent processes, and independent safety monitoring"* [6].

The College supports a process in line with Section 4.4 of the Australian NHMRC Statement.

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?

This question has several qualifiers, and is therefore not a straightforward yes or no. Intensive Care Physicians have a duty to *always* act in the best interests of the patient, however the best interests test is inferior to a model of delayed consent after obtaining family assent, due to the fact (as outlined in the

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

HDC document) *"that it is difficult to predict accurately to a participant the risks and benefits of the research. The benefits could include a potential improvement in a medical condition, the prevention of further deterioration, and/or the prolongation of life. Best interests may also encompass non-medical factors such as emotional and other benefits."*

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

See above

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 or welfare guardian- NO yes in the instances in which it applies, given the formal transfer of decision making to this person at a time of competence.
- Family/whānau- although technically there is no guarantee that they have the best interests of the consumer at heart, it would be culturally inappropriate to ignore the wishes of the family. We believe it more valid to ask what the consumer would say (to the best of their knowledge) given the opportunity to take part.
- Provider not involved in the research (e.g., the consumer's responsible clinician or GP) Yes the responsible clinician has specific training in management of the critically ill patient (the GP does not), and is able to address both the benefits and risks[9]. This must form an integral part of any informed consent process when discussed with the family and eventually the patient.
- Researcher Yes, as long as the checks and balances of a HDC Research Ethics Committee and practice in accordance with GPC as part of a MDT.
- Other

27 March 2017

Health and Disability Commissioner
P.O Box 11934
Wellington 6142

Health and Disability Research – Consultation Document

Introduction

I would like to respond to your consultation document inviting the public to make comment regarding different scenarios you have chosen to identify what ethical choices should be made in the furtherance of knowledge regarding health researchers trailing different health interventions on vulnerable populations.

I have chosen not to use the template that you have created, as I have been involved in health issues for over four decades or more and was an observer of the issues involved in both the Cartwright Inquire and the Mason Inquiry where health professionals predominately, medical physicians and administrators acting poorly and put their interests first above consumers of health and disability services.

Health and Social Inequalities

Poor people and those with poor health often do not have advocates to speak for them when they cannot and therefore are vulnerable to be used by opportunist health professionals whom often will state that those with particular conditions could personally benefit or alternatively they could help others, yet often they are not informed or

acknowledged in the research or intellectual property that arises. Alternatively, if individuals do not agree to participate in research an alternative person may be approached to encourage the subject to become a participate in research.

The unequal balance of power in any health relationship or clinical situation needs to be acknowledged at all times and of course is linked to Kawa Whakaruruahau or clinical safety, clinical competence and cultural competency and humility. This fact is not recognised or acknowledged in the discussion document

Treaty of Waitangi

I am concerned that after almost thirty years working with to improve the health of Maori and support communities to become self-determining and self-directing that the Treaty of Waitangi is still not included as one of the rights that any health and disability consumer in the public, private and ACC system in New Zealand can expect to occur, especially as New Zealand is now a signatory to the United Nations Declaration of Indigenous Peoples Rights.

The scenarios the Expert group have provided for the public to comment on do not provide a clear picture or profile of those communities and populations whom are more likely to experience these conditions.

For example, it is now recognised that health and social inequalities occur throughout the life course and many of the conditions that the Expert Group have highlighted affect disproportionately Maori and Pacific whanau, such as, the effects of diabetes, mental health and co addictions and now dementia or cognitive impairment. These health conditions are related to non-communicable diseases, may be genetically related or related to the social and economic environments we live in and also intergenerational trauma. Understanding of health conditions and those populations at risk require an in-depth understanding of their migration and settlement in Aotearoa, their social status in stratified society and the degree of stress and discrimination experienced, whakapapa connections and choices made in life. There should be no need to change the current Code of Consumer Rights for Health and Disability Services if health researchers and clinical health

professionals can successfully engage with health and disability consumers and or their whanau to seek informed consent. Whanau ora as a government policy is currently missing from this consultation document and the Government's strategies to support improvement of the health of Maori and other populations.

Ministerial National Health Ethics and Clinical Research

I was involved in the Ministerial National Health Ethics Committee and the development of ethical standards to protect New Zealanders from not being exploited or to be used by international companies, universities and drug companies to be used as subjects for research in which New Zealand as a country receive little benefit, there is no ownership of public owned intellectual property and information collected is often not held here in New Zealand.

Clinical researchers involved in such research often have little input into the design of such studies, as they are part of a wider study or program of research in which those whom are involved primary role is to recruit subjects which meet a demographic or health profile. Furthermore, researchers here in New Zealand often do not report the results and findings from their research firstly to participants here in New Zealand and also to the New Zealand public which has funded such research or funded the health services.

Research and International Networks

Researchers and universities are encouraged to look outside of New Zealand for their kudos in using New Zealanders primarily as clinical material for research, for clinical practice for health professionals and also to support the training and education of health and related professionals.

Unique New Zealand Populations

Maori and an aging European population are now likely to be the subject and focus of researchers for we are both populations of interest to research institutions in the different scenarios discussed. The Maori population is particularly young with one in two under 25 years of age and so a young body suffering the effects of chronic health conditions, such as

diabetes, heart disease, mental health conditions, intellectual impairment, is perhaps more robust to be involved in different research projects with little benefits to Maori or other indigenous populations.

Similarly, an older European population with one in four soon to be aged over 65 years of age are likely to be interested in being involved in research for this is one area they are likely to get special attention and treatment for mainstream society often sees this population as being in their senior years and are of little value to society. Furthermore this population is often seen as a burden on society due to cost of health care and superannuation. I noted this view from my experience in being Principal Investigator for the Life in Living in Advanced Age New Zealand Study (LiLAC NZ Study) which recruited non Maori aged 75 years of age and Maori aged 75-79 years to investigate what was the experience of those whom had reached advanced age, were elite survivors and what was their experience of living in New Zealand. The views of participation were quite different for Maori and non-Maori and the results of this study have been published, as well as methodology and recruitment approaches taken.

This study was a longitudinal study funded by the Health Research Council, Nga Pae o Te Maramatanga and later by the Ministry of Health to provide policy advice on these two distinct populations. Each year we met with participants to share results and findings and to invite them to identify areas which we should study further, despite many having complex health and social challenges and cognitive impairment.

Many participants enjoyed being part of this study, as it gave them the opportunity to contribute to assist those following in their footsteps and also to leave a legacy for their whanau, in which their personal information could be provided to them if they had agreed earlier. Ethical approval and options for participants as to which part of the research they were interested to be involved in this research was a key to its success, as well as researchers who were experiencing the process of ageing.

As the lead Maori researcher in this study for a number of years, it was at great personal and professional cost, for my role seemed to be one of being a policeman or acting on

behalf of the Office of the Health and Disability Commissioner, to ensure that senior medical researchers and academics acted ethically in relation to this study. Furthermore, I found that most had no consideration or little interest in the Code of Consumer Rights for Health and Disability Services or Privacy requirements to be met all times with participant's personal information provided and clinical sample information provided such blood samples collected. We had to develop ethical guidelines to protect the wairua of Maori participants in this study and in particular how blood was collected, stored and what clinical tests could be undertaken as part of informed consent. Researchers could not collect information and then used for another purpose and this includes clinical information.

A Code of Conduct had to be developed to ensure that all involved in the research both researchers and participants had clear roles and responsibilities and that information could not be taken off shore without or out of Auckland without approval and all researchers both here and overseas had to agree to the code of conduct required and this included ownership of intellectual property and publication requirements to be met and presentation at conferences. Students also had to sign the code of conduct required of students.

Clear guidelines needed to be developed for any research that involves indigenous and vulnerable populations and they need to be monitored to ensure that they are up held and the Office of the Health and Disability Commission should be part of ethical decision making bodies or processes so that all requirements of the Code of Rights for Health and Disability Consumers are upheld at all times.

Health Advocacy and Costs Involved

I have had experience involved in leading the Health Advocates Trust, which was established following the Cartwright Inquiry and from my experience this organisation was scapegoated by the previous Health and Disability Commissioner (Mr Ron Patterson and Director of Advocacy) for requesting sufficient funding in the Auckland and Northland regions for sufficient number of Health Advocates to support health and disability consumers, in relation the population size of Auckland and the distribution of the population in Northland . Insufficient funding for health advocacy services tailor made for

specific populations makes it difficult for people to complain if their rights have been breached in their access use of health and disability services, such as those currently in prison for complex physical and mental health problems.

Involvement in the legal case for adequate funding for health advocacy services which went from the District Court, to the High Court and to the Court of Appeal has been reported and published, it has documented that health and social inequalities for disadvantaged populations does not only occur in the way people are treated when accessing health services but there is also a systemic failure in the way the Office of the Health and Disability Commissioner operates and this Crown entity supports structural discrimination and institutionalised racism.

I do not make this statement lightly but in our advocacy to negotiate appropriate funding for health advocacy services our governance board was treated disgustingly with our proposal for providing services within the Auckland and Northland region considered too brown and our staff was also brown and of course we also had to interconnect with another system which is equally prejudice towards Maori, that is, the justice and judicial system. The legal judgement was highlighted that this was case of interest to those interested in human rights. Human rights legislation and international human rights now need also to be included in the Code of Consumer Rights for Health and Disability Service.

Code of Consumer Rights for Health and Disability Services

The proposal to weaken and not strengthen the Code of Rights for Health and Disability Services concerns me at a time when New Zealand's population is becoming more ethnically diverse, Treaty of Waitangi rights are not recognised and respected as required in the planning, funding and delivery of health and disability services, including mental health services and universities whom require academics to be involved in research to maintain their position in a hierarchical competitive environment, Further there is now a requirement for academic and clinical staff to maintain competency to: publish or perish, maintain relationship with universities, attract overseas students, to mentor PhD students, and to offer position to overseas and local academics.

With the above environment where active engagement in research is crucial, there is now a requirement to have more stringent standards in place in relation to research and informed consent processes to be in place at all times to actively protect and engage consumers of health and disability services in all aspects of their care, treatment or contribution to data bases and collection of new information. As mentioned at the beginning there is imbalance of power between health professionals consumers and members of the public, in which there is fear, if they do not do what a doctor or nurse wants them to do, they may be subject to being treated as being difficult, may have to wait longer for care and assistance, may have to be subject to higher expenses individually and as a whanau, may be stigmatised by information placed on their notes and if they decide to move on may have to engage with new health professionals if they do not want to be involved in research. Declining not to participate in a research project where a clinician or researcher wishes to make his or name or to become known as an expert in a small narrow area of medicine or clinical practice, is a difficult issue for any consumer let alone those whom are vulnerable.

The Office of the Health and Disability Commission has duty of care or kaitiakitangi responsibilities and it is this lack of duty of care by group of researchers and clinical staff that led to the Cartwright Inquiry, Mason Inquiry and further inquiries regarding patient safety. This role is not mentioned or discussed in the discussion document.

Conflict of Interests and Transparency

Doctors and nurses are often paid by a drug company or by another research team to recruit participants and so conflicts of interests become confused to the disadvantaged of those whom are led to believe that involvement in research would help others, especially those with a similar condition that they experience. Transparency in research and areas of conflict of interests should always be declared so that consumers of research are aware of what are the upstream and downstream benefits of their involvement.

The benefits of participating in any form of research generally positively supports those whom are part of the research team, and engagement of participants in their research

defined as important by the research team supports their involvement in further research, participation and engagement in medical and health conferences, and increased funding for research. Through such engagement in research career and clinical pathways for established for employment, upskilling and involvement in further issues often at the expense of those whom participated in the research and their family members whom often have supported them throughout to be a research participant.

Recommendations

I would like to recommend that no change be made to the Code of Consumer Rights for Health and Disability Services as a change in this area cannot occur until such time the whole system that supports research is reviewed and adequate resources are put in place to protect those whom are likely to be participants in such research as identified in the scenarios and that their families and whanau are also protected and all involved have the right to decline.

Different ethnic populations have different views regarding health and especially the tapu or sacredness of the human and spiritual body. From my experience of being a senior academic and health and medical researcher, there are insufficient protections in place to protect participants of research and especially for Maori and also for vulnerable populations.

The Office of the Health and Disability Commissioner, for example, still does not have a designated Maori Health Commissioner despite this organisation's requirement to recognise the Treaty of Waitangi in the operation of this organisation and all of its functions. Health and structural barriers and discrimination are experienced by Maori and vulnerable populations daily and this needs to be addressed by looking at whole set of ethical and safety requirements to be met for health and disability consumers and focusing on one right alone will create changes or imbalance of importance for the other requirements to be met.

It is recommended that the Expert Advisory Group should look at the whole system of how medical and health research is undertaken in New Zealand, the relationship to universities, international research teams, requirements of drug companies internationally to find

suitable subjects to test drugs or treatment regimens so as to understand particular health conditions or change them in some way. This requires understanding how all parts of the Code of rights are operationalised, monitored and evaluated to reduce harm for patients.

It seem that increasing health researchers are trying to address social problems and non-communicable conditions with biological solutions. To facilitate change there is a need to support communities and populations to develop their own strategies to prevent, manage or delay chronic health conditions, support health and wellness in different communities and support people to achieve their maximum potential. All of these matters may involve community developed and driven research. The scientific process of research cannot be imposed on communities, populations or individuals there must be engagement, respect and acknowledgement of different rights, values, beliefs and benefits.

References

Durie M (2003) The health of indigenous peoples depends on genetics, politics, and socioeconomic factors *BMJ* March editorial

Dyall L Marama M (2010) Health Advocacy Counting the Costs *International Journal of Mental Health and Addictions* Issue 8 No 2 190-210

Te Whanau O Waipareira Trust (2016) Kaupapa Maori Models of Psychological Therapy & Mental Health Services : A Literature Review Te Whanau o WaIpareira Trust, Auckland

Right 7(4) Consultation: Health and disability research involving adult participants who are unable to provide informed consent

Feedback from the Office of the Chief Nursing Officer, Ministry of Health
Contact: Jill Clendon, Chief Advisor, Ph

The Office of the Chief Nursing Officer (OCNO) thanks you for the opportunity to comment on the public consultation currently being undertaken by the Health and Disability Commissioner (HDC) on health and disability research involving adult participants who are unable to provide informed consent.

The purpose of the HDC Code of Patient Rights is to protect vulnerable people and nothing must compromise this.

There are a number of broad issues identified in the consultation document that include:

- Whether the current criteria that limits research on a person who is unable to give consent to that which is in the person's best interest is sufficient;
- If the current limit is too restrictive and prohibits studies that could lead to significant improvements in health and disability services.
- The balance between the rights of the individual (best interests) and benefits to wider society.

The consultation document leads the reader to consider a series of case studies and how these may be considered in the light of potential new criteria or limits around research with a person who is unable to give consent.

The nature of this pathway means that reaching a consensus on the most appropriate limits among a small group of people such as within the OCNO is unlikely.

From a wider perspective, the OCNO has discussed the following points:

- Research that benefits a wider population group that may not necessarily benefit the individual is important but strict parameters regarding this would have to be in place for people who are unable to give consent. Such research should always be undertaken on people who can give consent in the first instance. Any risks would have to be minimal.
- Any research with people who are unable to give consent must go through a substantial ethical review process.
- Expectations around delegating to next of kin or Enduring Power of Attorney (EPA) if agreed upon must be very clear.
- Any recommendation for change would need to consider any system or legislative changes needed, including changes to the PPPRA Act.
- Any change would also require improved access to information on whether a person has activated an EPA or welfare guardian (e.g. improved access to data through shared electronic health records).

The OCNO hope these points contribute to the ongoing discussion on the topic. Staff at the OCNO may make individual submissions.

13/4/2017

PA

HDC Consultation

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

Consultation response form

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights (the Code). The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient. However, it is more complex to decide whether it is appropriate to include a person who cannot give consent to be a subject of research. At present in New Zealand, 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**.

Currently, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

This consultation will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended? Please note that this consultation is limited to research involving **adult** consumers.

To provide us with your comments, either:

a) complete the form online; or

b) print the form, record your answers on the form and return it to PO Box 11934, Wellington 6142. Add additional pages if you wish to do so.

You do not need to answer all of the questions for your responses to be considered by the Commissioner. Leave blank any questions that you do not wish to answer.

PB

Thank you for your contribution to this consultation.

HDC, with the assistance of the Expert Advisory Group, will review all of the submissions received. The Commissioner will then consider those submissions and decide whether to recommend any changes to the current law. If any change to the Code is recommended, further consultation will be conducted.

Please state your

Name:

Organisation:

HDC will publish a report after the consultation period has ended. All submissions that you make on this consultation are subject to the Official Information Act 1982. If you consider that all or part of your submission should be treated as confidential, please state this clearly when making your submission and indicate which of the grounds within the Official Information Act for withholding information you believe apply. HDC will take your views into account when determining whether or not to release information. Please note that any decision by HDC to withhold information is able to be reviewed by the Ombudsman.

17 April 2017 p1

HDC Consultation

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

I'm making this submission in response to a public notice seen in the Dominion Post pA5, Mon April 3rd, 2017

I don't wish to speak to my submission at any future related hearing, but you may call me if you want, or summons me.

I'm making this submission as a concerned member of the public & as someone who has been committed (unjustly) under the Mental Health (Compulsory Treatment) Act — [redacted] & whom has experienced being forced to accept treatment(s) both as a child patient & during my life-course to recently, despite my protestations & belief I don't have any Mental Health problems.

I believe NZ Law is farcical, saying one thing in one place, but something different elsewhere, so almost anything can happen. That also applies to alot of Rules, regulations, & Policy(s) including Health

My submission is at the time of writing this as an interested person, a former consumer, & a non-clinical researcher.

I think this public consultation could be about a few different things ~ in addition to the core consultation question, namely:

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- Review of the treatment of Mental Health Patients by the High Court of Wellington ~Aug 2016 to ~ Oct 2016 Presided over by Judge Ellis & representing 3 Patients by Tony Ellis, ~~and~~ see Appendix 1, and
- Wrt changes in legislation around euthanasia see Appendix 2

I see the core question of the consultation is: "Are NZ's current laws regarding non-consensual research appropriate?"

My answer is: Along with all related Acts, Rules, Regulations, & Policy (including NZPHDAct, MHA + similar Acts, The Code, Human Rights Act, Privacy Act & University & Hospital agreements/contracts), etc I dont think they are appropriate.

I think there's too much of them, creating a form of evasion of accountability & responsibility because of overlaps & unclear & uncertain policies. Importantly I believe related complaints organisations such as the HDC itself the Ombudsmen, Privacy Commissioner & the Legal System help those in the health + research system get away with a lot of stuff. Together with the Police & their influence & the Courts, this all leaves participants/people & patients vulnerable. The law, rules, reg's + policy isn't much use unless they're actually enforced properly & adequately, & the complaints organisations need to have powers to impose fines + penalties for any breaches of Acts.

My experience is like being a consumer wrt what is the subject of this public consultation.

I feel the patient should or the people & participant of health & disability research should have the final say in the research. It's important to make it clear that people with mental health problems and mental health comes under the definition of a disability under the NZPHDAct.

It's important to keep perverted staff, liars, & corrupt staff out of the Health & Research systems.

The Police need to be better trained wrt Mental Health & land related matters. As time goes on, the Hospitals are moving services out of the Hospitals & into people's homes. I think Privacy & Access issues will require more focus in the future so that Police actions are proper & adequate, & the Police need to realise people who've been committed under the MHA aren't all bad & are often used as scapegoats by others to get over breaches of Acts by others.

Thank you for considering my submission. I think my appendices 1 & 2 may be the most useful for you & help answer your consultation document questions 6 to 9.

Problems around Health & Disability research extend to drugs, treatment, & care & I think even involve a person's housing & any experimentation around people & patients & participants housing & accomodation. Privacy laws need changing so that private information, mental health, & time, can't be used as "weapons" against people.

Scenarios spoken of in a recent Mental Health (MH) Review at the Wellington High Court seemed to have major problems surrounding the movement of patients concerned (too much moving them) as well as too much changing of their treatment, & keeping them away from the place they wanted to be & reside, giving too much weight to their family's wishes.

I noted that importantly, psychiatrists, psychologists & some carers were quite possessive & walking over some of their rights wrt time regarding their being put into seclusionrooms. I think the use of seclusion rooms should only be for periods less than 24hours, & only if absolutely necessary for a safety basis. That is to protect the safety of other staff + other patients who may be affected by an unruly patient, person, or participant in research. Locking people up in seclusion >24h is known to be harmful.

Changes in policy(s) can be interpreted as being experimentation often without a person's consent - this situation needs fixing.

There is a delay in issuing the Mental Health Review decision by Ms Ellis (as far as I'm aware still hasn't been given). The decision is held up by deciding which Act has precedence. I think it will come down to the Human Rights Act having precedence over the MHAct, but with a proviso that some of the provisions of the MHAct will be able to be carried out whenever, wherever, & to whoever, so long as the action or actions is proper & appropriate considering the circumstances & context of those actions at the relevant time + over a relevant time period.

The law does need amending as mentioned above, but I doubt there will be much significantly changed to any of the laws reg's + policy(s) currently in force. If that's the case, people in my situation (in the past) will continue to suffer & that's wrong, but that's how the world is + how hospitals & treatments have operated over a long & sustained period in NZ. It's very sad, but realistic. Any changes made should be done in a timely manner of say < 1year duration. Any complaints should be dealt with in a timely manner also as said by former HRC + Ombudsman Rose Patterson.

Especially for those perceived to have mental health issues (but who don't actually have MH issues) they'll continue to be abused & discriminated against by all the various work staff types mentioned in this submission, especially by the Police & Health staff (if not properly educated & trained as stated.) Penalties & fines for their incompetence & breaches needs to be enabled via relevant complaints organisations & via a change of power/jurisdiction to allow that.

Appendix 2

I think this consultation could be seen to be ~~relevant~~ relevant wrt incompetent people considering euthanasia & for the purposes of enabling experimentation & research for people in those dire circumstances in the near future.

the euthanasia topic. My solutions come under 2 groups of people of: a) those who have competency & b) those who don't. I summarise the process for each group below:

a) Those who have all their facultys with them still (& are competent) & can give consent

That individual/person should be able to do the following by law:

(1) Go to a GP who writes a "euthanasia script"

(2) Take that script to various experts as follows:

(2a) End of life/Pallitive care worker (such as a Hospice Pallitive Care Nurse who would discourage the patient/person & advise of the alternative health care options, & give their approval of euthanasia if unable to change that individual/person's mind.

(2b) Ethics person who could act similarly to (2a)

(2c) Psychiatrist worker who could act similarly to (2a) but the Psychiatrist experts option/opinion would not be compulsory nor necessary in any final approval for euthansia.

(2d) Lawyer who would make an application to a High Court on behalf of that individual/person, or they could make the application themself.

(3) Attend a High Court Hearing where the High Court Judge alone could make an order/decision approving euthanasia based on the evidence the individual/person makes. [Any evidence of family/relations & gardians may be considered, but given little weight c.f evidence of the individual/person, & wouldn't be compulsory]

(4) The individual/person (if allowed in the Judges order/decision) then go to a Pharmacist & arrange & carry out administering of a relevant euthanasia drug or treatment, perhaps via assistance of a relevant person.

b) Those who are unable to give their informed consent

The process for this group (the subject of this consultation) could be as follows:

(1) Any relevant person representing another could apply on behalf of someone unable to give their informed consent by going to a lawyer who would make an application to a High Court

(2) Attend a High Court hearing where the High Court Judge alone could make an order/decision approving euthanasia based on the evidence of all the experts of a Pallitive care worker, ethics person, & optionally of a psychiatrist. Any documents of the relevant individual/person while they had testimentary capacity should have a much greater weight, c.f Family wishes.

(3) Only the same relevant person representing another could arrange the collection of script + its administering as (4) above.

The above process could exchange euthanasia with research/experimentation.

Ombudsman

Fairness for all

Health and disability research involving adult participants who are unable to provide informed consent – Consultation on Right 7(4) (Code of Health and Disability Services Consumers' Rights)

19 April 2017

1. This submission is made by the Office of the Ombudsman.

2. The Office of the Ombudsman plays a significant role in New Zealand's disability sector, handling disability-related complaints and enquiries about the administrative acts and decisions of central and local government agencies, and through our monitoring role as part of the Independent Monitoring Mechanism (IMM) under the United Nations Convention on the Rights of Persons with Disabilities (the Disability Convention).

3. We understand that the effect of Right 7(4) (Code of Health and Disability Services Consumers' Rights) is that research can only proceed on participants who are unable to give informed consent if it is in their best interests. Frequently the outcome from research of this kind is uncertain so it is difficult to know whether the participants will be better off participating in the research, than not participating. However, such research might provide important information of benefit to others.

4. We have not received any complaints in this area nor has this issue come to the attention of the IMM, other than by way of this consultation. We therefore have no evidence that a law change regarding non-consensual research is necessary.

5. We do, however, see this issue in the wider context of supported decision making: that is enabling disabled people to have the greatest possible say in and control over their lives. Implementing Article 12 of the Disability Convention will require a thorough exploration of issues of legal capacity and decision making processes by and for disabled people. We hope that this consultation will add to the knowledge and understanding of issues of consent, capacity and decision making by and for disabled people.

The Royal Australian and New Zealand College of Radiologists®

27 April 2017

Health and Disability Commissioner
45 Queen St, Level 10, Tower Centre Building
PO Box 1791, Auckland 1140
NEW ZEALAND
0800 11 22 33
www.hdc.org.nz

Dear Commissioner

Public Consultation on Health and disability research involving adult participants who are unable to provide informed consent

Thank you for according The Royal Australian and New Zealand College of Radiologists the opportunity to comment on the document relating to health and disability research involving adult participants who are unable to provide informed consent to participate in research.

Research is one of the College's seven strategic pillars and is now promoted through a research strategy. Therefore, patient consent in research is an important issue for us and we welcome the initiative in promoting the discussion of considering those who are vulnerable and/or unable to provide consent.

As a College, we support the principles of the Health and Disability Commission review and applaud the formalisation of the consent for the adult participants who cannot/unable to give informed consent.

Yours sincerely,

Dr Lance Lawler
Chair
New Zealand Branch Committee

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MĀORI PUBLIC HEALTH

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27th April 2017

Tēnā koe,

We read with interest your consultation document regarding health and disability research involving adult participants who are unable to provide informed consent. We wish to provide some feedback which is outside the scope of the consultation process currently underway, and hope you will consider this letter as sufficient to register Hāpai Te Hauora's interest in this matter should the Commissioner decide to recommend that an amendment to New Zealand's current laws regarding non-consensual research be considered.

We are a Māori public health organisation that holds government contracts to deliver coordination, infrastructure and support services to all New Zealanders. We are the quality connection to the community, often called upon to partner with regional and national organisations to provide a Māori perspective with regards to service design and delivery, strategy development and evaluation.

A recent literature review of seeking consent for research with indigenous communities published by BMC Medical Ethics emphasizes the need for consultation with indigenous people to determine how consent should be sought, and how best to evaluate this process. Common themes around concerns held by indigenous communities internationally include the individualistic vs community-based decision making process in providing consent for research, which you allude to in the introductory section of your consultation document. In New Zealand and among our indigenous networks internationally there is also growing interest in issues of indigenous data sovereignty in research, particularly around retention of tissue samples and DNA.

If the Commission decides to proceed with recommending an amendment to the New Zealand legislation regarding non-consensual research we suggest Hāpai and other indigenous groups should be involved from the beginning of this process to ensure appropriate Māori representation.

We welcome any opportunities to engage with the Commission on this matter.

Naku noa, nā

Lance Norman
Chief Executive Officer
Hāpai Te Hauora

HĀPAI TE HAUORA
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About Hāpai Te Hauora

Hāpai are national leaders in Public Health, Policy and Advocacy, Research and Evaluation and Infrastructure services.

Hāpai provide a strategic focus that is underpinned by evidence based research for the advancement of health and wellbeing for communities.

The Mission of Hāpai is to increase opportunities for Māori, and all others to enjoy good health and to be sustained by healthy environments.

Website: www.hapai.co.nz Twitter: www.twitter.com/hapaitehauora Facebook: https://www.facebook.com/hapaitehauora

HĀPAI TE HAUORA
MĀORI PUBLIC HEALTH

The Royal Australian & New Zealand College of Psychiatrists
New Zealand National Office

Your Health in Mind

27 April 2017

Mr A Hill
Health and Disability Commissioner
Office of the Health and Disability Commissioner
PO Box 11934
Wellington 6142

By email to: hdc@hdc.org.nz

Dear Mr Hill

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

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) thanks you for the opportunity to comment on the Health and Disability Commissioner (HDC)'s consultation document regarding research involving adult participants who are unable to provide informed consent.

This submission has been developed by RANZCP's New Zealand Branch of the Faculty of Psychiatry of Old Age (FPOA) in consultation with the New Zealand National Committee/Tu Te Akaaka Roa.

Introduction

We understand that health research must be person-centred and that any research must consider the individual's circumstances and their ability to make decisions regarding their participation in proposed research (RANZCP, 2012). Psychiatrists work with patients with progressive dementia and intellectual disabilities whose capacity is unlikely to improve in the foreseeable future. We are therefore in a position to comment on how these people may be included in potential research projects. The focus of this submission is on this group of patients rather than those individuals whose capacity may fluctuate over time (such as patients with psychosis or schizophrenia).

The RANZCP accepts that people with diminished decision-making capacity need to be protected from potential harms of research including pain and discomfort but we hold the view that the pendulum has swung too far towards 'protection by exclusion' rather than 'protection by inclusion' (Shepherd, 2016). As a result, patients with dementia and intellectual disabilities are disadvantaged by not being included in research that has the potential to advance our knowledge of meeting their complex health needs and providing them with better health care services.

The RANZCP advocates for a review of the current legislation regarding research undertaken involving adults with diminished capacity and for greater opportunities for these individuals to participate in research, such as low risk observational research, that has a limited benefit on the individuals but may benefit the community and other patients with dementia and intellectual disabilities.

Psychiatrists are often asked by general practitioners and other medical specialists to provide an opinion regarding an individual's mental capacity. We emphasise that capacity is domain and

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context specific, and that people without full capacity to make decisions may still retain the capacity to choose to participate in research whether it benefits them personally or not (and sometimes just participating is beneficial because it provides an opportunity for people to talk about their experiences).

In our view the current processes involving people with diminished capacity in research are paternalistic and are based on the assumption that a person with dementia has no capacity to be involved in decision-making. This may be due to a public view of dementia which is often regarded as an advanced stage illness. In fact most people with dementia are still autonomous individuals who can make decisions for their everyday life. Therefore, we believe the main issue is to promote autonomy and involvement with decision-making about their participation in research, whilst also ensuring safeguards are in place to protect people with diminished capacity so they are not exploited.

People with dementia and intellectual disabilities have rights under the United Nations Convention of the Rights of Persons with Disabilities (UNCRPD, 2006). Article 12 in particular notes that people with disabilities have equal recognition before the law and therefore signatories to the UNCRPD '*shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity*'. We would like to see greater attention given to facilitating the person's involvement in decision-making despite having diminished capacity. Supported decision–making acknowledges the individual's autonomy and it can take many forms including advance directives to health care proxies to nominated representatives (Carney, 2015). Supported decision–making enables the individual to retain their legal capacity regardless of the level of support they require (Carney, 2015). Cognitive capacity may also differ with regards to the individual's medical presentation therefore legal, social and clinical issues need to be considered when assisting the individual to consent to participating in research. For example, people with intellectual disabilities will require a different level of support around assisted decision–making than those living with dementia. Dementia is usually a late life disorder (and therefore people have expressed a lifetime of preferences and wishes which should be taken into account); it is progressive and therefore the capacity to consent is initially intact but diminishes with time – both are different to intellectual impairment (IHC, undated; Carney, 2015; Victorian Government Department of Human Services, 2012).

We believe the current approach in New Zealand is not consistent with other countries. Therefore, we urge the HDC to align our legislation with the United Kingdom (UK). Guidelines published by the UK Department of Health outline a range of approaches allowing research to be undertaken with people with limited capacity (Department of Health, 2008). The British system places some emphasis on the interests of others when enlisting a person with diminished capacity into a research programme. This research is not undertaken without due consideration to the individual and particular thresholds are in place including the potential benefit to the participant without causing undue harm or if the knowledge would assist people affected by a similar condition and if the risks to the individual are negligible. In our view this seems a reasonable approach, we recommend that further investigations are undertaken by the HDC to see if similar legislation could be implemented in New Zealand.

In your consultation paper you note the international literature allows '*research involving participants who are unable to give consent to proceed in a broader range of circumstances than in New Zealand*'. This would indicate to us that in New Zealand, we could extend, in some circumstances, research projects involving these individuals, and not put them at undue risk of harm. Australia and UK have appropriate frameworks and policies that could help expedite the implementation of a less restrictive approach to researching patients with diminished capacity.

We will present our argument for extending the opportunities to undertake research when a person has diminished capacity to provide an informed consent. The current legislation only allows research to progress where there is an immediate benefit to the participant. The RANZCP contends that this approach is too restrictive with potentially a detrimental impact upon the very populations the law seeks to protect.

Undertaking Research With Adult Participants Who are Unable to Provide Consent

In our view the key tenet of good medical and research practice is based on the principle 'first do no harm'. This principle is central to the code of ethics that governs medical practitioners in New Zealand (Medical Council of New Zealand, 2013) and ensures patient safety is always at the core of a doctor's practice, including when they undertake research. Research that has a high risk of harm clearly does not have a place in this proposed legislative review as we are aware of 'historical ethical transgressions' that seriously impacted on vulnerable populations (Shepherd, 2016.) However, if upholding 'first do no harm' is the key tenet of research, it may be possible to move towards a greater inclusion of those people (who lack capacity to consent) into a much wider range of research projects where the focus is upon inclusion rather exclusion in research. In other words, we seek changes to turn the legislation on its head: whereby these individuals are included in research and only excluded when the risks outweigh the benefits.

In our experience, the current ethics approval process means involving people with dementia and intellectual disabilities in research and service development is difficult due to issues around informed consent and the individuals need to have direct benefit from these activities. Ongoing and comprehensive research programmes are required to understand and develop services, interventions and treatments to improve health outcomes for these individuals and the research populations they represent. Scientific research must be undertaken on target populations so the outcomes can be extrapolated to the wider populations thus improving their health status. For example, if we are interested in developing new therapies for patients with advanced dementia, we must have the opportunity to study a sample of people with advanced dementia as *'differences between populations such as physiology, pharmokientics and treatment responsiveness can be significant'* (Shepherd, 2016). In New Zealand this is particularly important with Māori and Pacific peoples who often present with genetic, biological and socio-cultural differences that require specific investigations that can only be understood with tailored research.

We argue that people lacking capacity require greater involvement in research as they generally receive poorer health care resulting in health inequities. Participating in research can provide them an opportunity to receive potentially therapeutic interventions in addition to their standard healthcare. For example, people with dementia have complex needs and often have 'heterogeneous disabilities' greatly increasing their needs across clinical and social services (Post, 2000). People with dementia already experience stigmatisation with a negative impact on the health services they receive (Centre for Policy on Ageing, 2009). We contend therefore that undertaking research into these populations' needs may contribute to improving their services and gaining new insights into their care (Shepherd, 2016). The RANZCP also notes that there will be an increasing burden of an ageing population that will shape health service delivery in the future e.g. there will be a growing number of people experiencing dementia and other associated comorbidities. We observe that this phenomenon will result in greater demands for more research to understand these conditions and therefore an increasing need for relevant research participants. Because of the changing demography we believe it is prudent to review the legislation now.

The current legislation is very narrow hindering new research findings that may benefit vulnerable patient groups. As noted earlier a core value in medical care is patient safety but the existing legislation goes well beyond keeping the patient safe when participating in research. In our view we suggest greater attention is given to the following principles:

- The person's prior wishes

Prior to losing their capacity to consent to research a patient could have made advanced directives or included in their advance care plan their wishes to participate in research that may not only benefit themselves but contribute to the health of other patients with similar presentations. This situation would be aligned with the circumstances when a person consents to being an organ donor.

- Altruism

People can have altruistic intentions and be content that by participating in research they contribute to the greater good of society. People with diminished capacity can often inform clinicians and researchers of their altruistic intentions, either directly or via their families.

- Benefit to the wider community.

Currently for an individual to participate in a research there must be some demonstrative tangible benefit to the individual but not necessarily a benefit to the wider community. Our experience from working directly with patients who lack the capacity to consent suggests it is not unusual to hear family/whānau and carers saying that the individual would have liked to contribute to the research if they knew other people in the community would benefit.

Undertaking research with people with dementia and/or with intellectual disabilities presents many legal and ethical challenges but it should not be a reason for excluding them from research that may benefit them and others with similar presentations. We believe the inequity gap that exists between these populations and other patients can only be addressed if there are greater opportunities for research within the dementia and intellectual disability populations.

We would also like to draw HDC's attention to the issue of the 'authorised representative' and the important role they play in decision-making around an individual's participation in research. We argue that the family/whānau need to be closely involved in working with the participant to support them with their decision making. We note it can be particularly difficult to work with Māori and Pacific people as very often they do not have an 'authorised representative' and therefore a court order may be required to progress research. There are difficulties in determining what is in the best interests of the consumer. In other countries (e.g. UK) this has been addressed by working with the research participant and their family to nominate a consultee who will represent the person who has diminished capacity to consent (Department of Health, 2008).

Often it is not possible to proceed with the research and this may place these populations at a disadvantage. The literature reports that Māori continue to experience significant barriers in accessing health services and this may be amplified for older Māori (Jansen, 2008). Therefore, particular attention needs to be given to understanding and researching their specific needs. We are not confident that the current legislation is able to address these concerns.

Conclusion

We argue that a patient with dementia or with an intellectual disability has the right to participate in research. Therefore, systems need to be put in place to enable their involvement in research. We contend that by not allowing their full involvement in research they face discrimination and their specific health care needs will go unanswered. The current law focuses on excluding rather than including them in research and protecting them above all else.

We have demonstrated that research needs to be considered within a wider health context – beyond benefits to the individual to include similar populations groups that could reap the future benefit of the research. We call for a full review of the legislation governing the participation in research for those individuals who lack the capacity to consent.

In addition we advocate that the following areas are given a priority by the HDC:

- Ethics Committees are better informed about researching patients with dementia. Supporting a specialised ethics committee to assess clinical research involving people with dementia. Assessing the mental capacity of people with dementia and obtaining consent can be challenging (Sherratt, 2007).
- The Health and Disability Commission seeks a clinical expert in dementia to provide guidance around issues including research involving patients lacking the capacity to make an informed decision or give consent.
- Developing good practice guidelines for researchers undertaking research with patients with dementia (Department of Health, 2008). These resources could include information on determining assent and talking with the patient's proxies.

Thank you for the opportunity to provide feedback on this critical ethical issue. The RANZCP is available to discuss our submission further if you wish.

If you require further information regarding this submission, please contact the RANZCP's New Zealand Manager, who supports the New Zealand National Committee. can be contacted on or by email

Ngā mihi

Dr Mark Lawrence FRANZCP
Chair, New Zealand National Committee - Tu Te Akaaka Roa

Dr Gary Cheung FRANZCP
Secretary, New Zealand Faculty of Old Age Psychiatry

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Blind Foundation Submission

Health and Disability Commission consultation on the law dealing with informed consent

30 April 2017

The Blind Foundation is the main provider of rehabilitative, support and advocacy services for blind and low vision New Zealanders. The Blind Foundation has approximately 12,000 clients throughout the country.

Our Purpose

To enable people who are blind or have low vision to be self-reliant and live the life they choose.

Our Vision

Life without limits

Kahore e Mutunga ki te Ora

Four Key Priorities

1. Independent living
2. Access for all
3. Reach more people
4. Building a foundation for the future

The Blind Foundation advises government, business and the community on inclusive standards to ensure that the people we represent can participate and contribute equally. We have four major contracts with government. We value our relationships

with officials and ministers. We seek to act as a trusted advisor and specialist on the blindness sector. We are a long-serving and expert provider of services to the sector.

Background to the Submission

The Blind Foundation wishes to make a general submission on the Commission's paper on health and disability research involving adult participants who are unable to provide informed consent.

From time to time, the Blind Foundation either commissions or conducts research aimed at improving its current service programmes or developing new programmes and delivery options. In many cases, the research uses Blind Foundation client records which fall under the jurisdiction of the Health Privacy Information Code.

The Blind Foundation's specific interest in the informed consent requirement in the consultation paper is that it does not address the issue of whether informed consent should be required in cases where the practical issue of requesting consent cannot be reasonably achieved by the researchers. This is especially the case where the research meets the requirements of the Heath Information Privacy Code Rule 10 Sec 1 (e)(i) and (ii), which permits the use of information for purposes other than applied to its original collection.

Law Change Issues

Our point in this submission is that any law changes for informed consent for research that involves intervention and observational studies should not make the situation with purely record-based retrospective and anonymous studies any more difficult than it is currently.

The first issue of concern is that the research may involve accessing hundreds, if not thousands of records. In many cases, the records will be decades old but still relevant, but contacting the original client may no longer be practical or even possible. Also, the volume of records and the cost of contacting past clients is prohibitive for an organisation that relies on public donations.

The second informed consent issue is the conundrum that records have to be accessed before they can be selected for inclusion in a study. It should be clear that accessing a record to assess its value to a research study is different than using the information.

In both of these cases, there is an issue that the record is being used without prior consent, even though the conditions are manifestly different than research that involves intervention and observational studies.

Exclusions

In research studies, the technical presence of a non-consent issue is sufficient to trigger the need for a Health and Disability Ethics Committee review and approval, even when the use of the data fully meets the requirements of the Health Information Privacy Code in all other respects. A review and approval by the HDEC itself is an

additional cost to the project which could be avoided if the qualifying conditions on what constitutes informed consent were clearer, so that some types of research could be excluded from HDEC review.

Recommendation

Our recommendation is that permissible exclusions from an informed consent requirement include research studies where:

- The data has been gathered as part of the client's care and exists in a record held by the researching organisation, and
- The researcher does not require having any contact with the client, and
- The data will be anonymised before use, and
- The research outputs will not identify any individual or contain any information that could lead to an individual being identified.

Note in addition to the type of research noted in the recommendation, from time to time, the Blind Foundation is involved in research where new data is gathered and where the participant does have contact with the researcher. In such cases, the participants do give informed consent and the appropriate ethics protocols are followed.

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Pharmaceutical Management Agency

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28 April 2017

Anthony Hill
Health and Disability Commissioner
PO Box 11932
Wellington 6142

Dear Anthony

HDC Consultation: Health and Disability research involving adult participants who are unable to provide informed consent

Thank you for the opportunity to provide comment on this consultation which intends to seek views on current legislation guiding health and disability research involving adult participants who are unable to provide informed consent.

PHARMAC's statutory objective is to 'secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.' One of our statutory functions to fulfil this objective is to engage in research as required. We support further exploration of how broadening the current restrictions could enable more research relating to health outcomes.

PHARMAC would emphasise the need to ensure Māori, Pacific and other cultural perspectives are thoroughly considered when consulting on any specific changes.

We look forward to hearing the outcome of this consultation.

Yours sincerely

Steffan Crausaz
Chief Executive
PHARMAC

NZOA
New Zealand
Orthopaedic Association

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28 April 2017

Health and Disability Commissioner
P O Box 1791
Auckland 1140

Sent by email to:

HDC Consultation Document: Health and Disability Research Involving Adult Participants who are Unable to Provide Informed Consent

We refer to and thank you for sending us a copy of the above-identified consultation document for our consideration and comment.

The New Zealand Orthopaedic Association (NZOA) regularly funds research applications. We are not aware of any previous NZOA research projects that would involve adult participants who are unable to provide informed consent.

The NZOA Research and Outcomes committee recently declined to fund a study which involved Pain Scores for a cohort of fractured neck of femur patients; one reason for this was concern that the presence of dementia might present methodological difficulties.

The NZOA always insists on Ethics Committee approval for all of our funded research involving patients. This provides another safety net.

We trust these comments are helpful and thank you for consulting with the NZOA.

Yours sincerely

Andrea Pettett
Chief Executive

MINISTRY OF HEALTH
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28 April 2017

Anthony Hill
Health and Disability Commissioner
PO Box 11934
Wellington 6142

Dear Anthony

Thank you for providing the Ministry with a copy of the consultation document *Health and disability research involving adult participants who are unable to provide informed consent.*

Thank you also to you and for being available to meet with the Clinical Leaders Forum and other interested Ministry staff on 4 April 2017. This was a useful opportunity to understand and discuss the issues and implications further.

In addition to the feedback provided through these sessions, please find attached a further response from the Ministry's Disability Policy team.

We hope that this feedback is useful and look forward to seeing the outcome of the consultation.

Yours sincerely

Dr Andrew Simpson
Chief Medical Officer

Disability policy response to HDC Consultation Health and disability research on adult participants who are unable to provide informed consent (April 2017)

General Comments

Disability Policy's[1] main concerns about non-consensual research apply to disabled people who have persistent, impaired decision-making capacity as a result of significant intellectual, cognitive or communication impairments. This group is among the most marginalised and disadvantaged groups in society. They can experience significantly poorer health and socioeconomic wellbeing that non-disabled people. They are at higher risk of and particularly vulnerable to violations of their human and civil rights. This includes non-consensual abuses, including removal of legal capacity on basis of diagnosis of mental disorder, intellectual or physical impairment; sexual violence, sterilisation, physical assault, financial exploitation, and exploitation for and harm from research participation.

People with impaired decision-making capacity are unable to make a particular decision at a particular time because they are incapable of:

- understanding any information that may be relevant to the decision; or
- retaining such information; or
- using such information in the course of making the decision; or
- communicating their decision in any manner; or
- by reason of being comatose or otherwise unconscious, is unable to make a particular decision about his or her medical treatment.

The Ministry of Health (MOH) and district health boards (DHBs) fund significant health care and disability supports to people with impaired decision-making ability:

- MOH funds national disability support services mainly for those with a physical, sensory and/or intellectual impairment, and certain neurological conditions under the age of 65. In September 2016, half of all DSS clients (33,084) had an intellectual disability as their principal disability.
- DHBs administer around three-quarters of the total health funding, including for people with severe stroke, dementia, serious mental health disorder (e.g. schizophrenia) and psychiatric disability (e.g. Korsakoff's Syndrome – a form of alcohol-induced dementia).

The strategic direction of the New Zealand disability sector is starting to focus more on respecting the person's legal capacity[2], recognising they are able to hold rights and exercise those rights, and have choice and control over their lives just like anyone else. Having legal capacity is the cornerstone of human rights and at the heart Article 12 of the Convention on the Rights of Persons with Disabilities.[3]

In the human rights approach, a person has decision-making capacity to make choices about consenting to medical treatment or research unless proven otherwise. In instances where a person's decision-making capacity is in doubt, the person's rights to make decisions and choices must be recognised and supported, including through a supported decision making process.[4] This includes respecting any refusal or reluctance or indication not to participate in research.

Of the two overseas frameworks cited in the consultation document, the Australian model is more closely matched to current human rights directions in New Zealand.

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[1] The Disability Policy team is part of the Population Outcomes group in the Strategy and Policy division of the Ministry of Health (MOH). The team provides advice to Health Ministers on issues specific to disabled people and disability support services, supporting the MOH's work across government and its international obligations related to those from the United Nations.

[2] Legal capacity implies an ability of a person to act under the law. Exercising legal capacity means making decisions about employment, medical or psychological treatment, property, finances.

[3] http://www.ohchr.org/EN/HRBodies/CRPD/Pages/ConventionRightsPersonsWithDisabilities.aspx

[4] Supported decision making recognises disabled people's rights to make decisions about their own lives but where a disabled person cannot make an independent decision, a supported decision-making process should be used.

Our primary concern is that disabled people are not used for research without their consent to prevent their exposure to inappropriate risks (of harm), or be exploited for research purposes. Non-consensual research cannot be justified on the basis of saving life or preventing serious harm – this is not research, it is emergency treatment that should not be withheld from the person. Nor can the research be justified on the likelihood, probability or speculation that it may or is intended to provide a benefit to the individual.

Our view is that a person's capacity to give informed consent is the critical component in whether they should participate in research. Research participation should be fully consensual. No research should be allowed to be carried on persons if they are unable to give free and fully informed consent.

In ensuring maximum protection of people who are unable to give fully informed and free consent, we favour a 'stricter protection' model rather than a 'greater access to research model'.[5] Stricter protections will have implications for the current consent framework, considering:

- **Bill of Rights Act 1990** – introducing mechanisms to enforce sections 10 and 11 that every person has the right not to be subjected to medical or scientific experimentation without that person's consent, and has the right to refuse to undergo medical treatment.

- **Protection of Personal and Property Rights Act 1998** – excluding explicitly under section 18 the powers of welfare guardians to consent to any form of non-consensual research on the person to whom they are acting.

- **Right 7(4) of the Code** – amending the code to exclude non-consensual research under any circumstances for people with impaired decision-making, requiring that research participation should only be permitted where free and fully informed consent can be obtained by the subject and not from an alternative decision maker.

- **Specific policy and guidelines on informed consent, decisional incapacity and non-consensual research** – these are to protect against risk of decisions about a person's life being made without their involvement or against their actual or anticipated wishes, and ensure clear direction to providers on legal requirements regarding non-consensual research.

- **Supported decision-making** – some people with impaired decision-making require a supported decision-making process that can assist them to make significant decisions in their lives and uphold their rights to 'legal capacity' as everyone else.

- **Independency advocacy mechanism** – exploring options for consumers to access independent advocacy for actions to be taken on their behalf, which operate below the level of formal complaint (i.e. Health and Disability Advocacy Service).

[5] https://bioethicsarchive.georgetown.edu/nbac/capacity/Informed.htm

Disability policy response to HDC Consultation Health and disability research on adult participants who are unable to provide informed consent (April 2017)

Response to HDC consultation questions

Questions on 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 People with intellectual disability, including Down Syndrome, are significantly more vulnerable to non-consensual enrolment in research due to limitations in thinking skills, including the ability to work things out and remember, difficulties with attention and organising information, trouble seeing how things or how events relate to each other, and may have limited ability to listen and talk.

If will and preference of people with intellectual impairment cannot be communicated or determined by a supported decision making process, then the person should be fully protected from / not included in the research.

E.3 Do you think the proposed consultation with family/whānau/caregivers gives sufficient protection for participants who are unable to give consent?
NO.

E.4 It cannot be automatically assumed that family caregivers:

- will have the necessary skills and are competent themselves to ascertain the will and preference of their disabled family
- can understand the risks and implications of participating in a drug trial
- can fully understand the concept of 'best interests', including that non-consensual participation can only ever be justified on the grounds there is a 'therapeutic benefit' to the person.

Consultation Question 1. General Comments

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent?

NO, special safeguards are required to obtain the informed consent of disabled people with impaired decision making. If the will and preference of the individual cannot be ascertained by supported decision making, the person should not be subjected to research.

There should be no exceptions to this to ensure maximum protection to vulnerable disabled people from non-consensual research.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:
1.2 N/A

1.3 **YES**, the same laws should apply to all health and disability related research?

1.4. See response to 1.1 above.

Consultation Question 2. Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

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?
YES.

2.2 In the **Bill of Rights Act 1990** under sections 10 and 11 every person has the right not to be subjected to medical or scientific experimentation without that person's consent, and has the right to refuse to undergo medical treatment.

In New Zealand, refusal to participate in research should be considered as a fundamental human right, no different to refusing to be subjected medical or scientific experimentation. The term 'research' needs to be included in the scope as '**medical, research, or scientific experimentation**'.

Consultation Question 3. Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

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?
NO, not under any circumstances.

3.2 It is illegal and should not ever be permitted under New Zealand law.

Consultation Question 4. Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

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 Disabled people are highly vulnerable to exploitation for the purposes of medical experimentation. 'Incompetent persons' should be fully protected from non-consensual research. Research should not be permitted on persons who lack competence to give informed consent.

Consultation Question 5. 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?
NO.

5.2 **Right 7(4) of the Code** should continue to apply, in which non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

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?
NO.

5.4 N/A

Consultation Question 6. Ethics committee approval
An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

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 It is insufficient to assume research investigators will ensure that all applicable standards are met. Legal regulation is required to ensure that disabled people with impaired decision-making are not ever subjected to non-therapeutic intervention studies and that research participation is only permitted with the disabled person's informed consent. No consent means no participation.

Consultation Question 7. 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?
NO.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 The problem with the best interests test is that it assumes that the affected person has no decision-making capacity and that other decision makers are ethical, are competent to decide what's best for the person who is unable to give consent, know their wishes, preferences and so on.

Disabled people with impaired decision-making should be given maximum protection from becoming the subject of non-consensual research if their will and preferences about research participation are unknown.

Consultation Question 8 . Who decides?
8.1 Do you think there should be any change made to New Zealand law regarding *who* decides whether an incompetent consumer will be enrolled in a study?
YES.

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

8.3 If you answered "Yes" to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making. Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

Person who could have a role in decision-making (X)	Should X ever have a part to play in deciding whether an incompetent consumer is enrolled in a study?	If yes, in what circumstances should X be involved in decision-making	What role should X have in decision-making?
EPOAs/ welfare guardians	YES	e. in all cases, regardless of circumstances, X must be consulted on all matters regarding the persons health, wellbeing and welfare	b. Must have right to VETO non-consensual research
Family/whanau	NO, generally and only if they are designated EPOs or welfare guardians	c. only if they are designated as back-ups for EPOAs or welfare guardians who are unavailable	b. Must have right to VETO non-consensual research
Provider	NO	Under no circumstances for research purposes	X should have no decision rights over an incompetent consumer for research purposes
Researcher	NO	Under no circumstances for research purposes	X should have no decision rights over an incompetent consumer for research purposes
Ethics committee	YES	e. must have power to not allow non-consensual research when consumers are unable to give informed consent	b. Must have right to VETO non-consensual research

8.4 Who should be the final decision-maker on enrolments of incompetent persons in a research project?

1. Other legal authority, assuming law is changed to not allow non-consensual research on decision impaired people.
2. EPOAs/Guardians, assuming they would not allow/ are not permitted to consent to non-consensual research
3. Family/guardian but only as a back up to EPOAs/ welfare guardians

Researchers and providers should not be allowed under any circumstances to enrol decision impaired people who are unable to consent to research.

END.

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

Submission to the Health and Disability Commissioner

Date: 28 April 2017

Contact

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NEW ZEALAND NURSES ORGANISATION | PO BOX 2128 | WELLINGTON 6140

About the New Zealand Nurses Organisation

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand. NZNO represents over 47,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment related matters. NZNO is affiliated to the International Council of Nurses and the New Zealand Council of Trade Unions.

NZNO promotes and advocates for professional excellence in nursing by providing leadership, research and education to inspire and progress the profession of nursing. NZNO represents members on employment and industrial matters and negotiates collective employment agreements.

NZNO embraces te Tiriti o Waitangi and contributes to the improvement of the health status and outcomes of all peoples of Aotearoa New Zealand through influencing health, employment and social policy development enabling quality nursing care provision. NZNO's vision is *Freed to care, Proud to nurse*.

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on health and disability research involving adult participants who are unable to provide informed consent.

2. NZNO has consulted its members and staff in the preparation of this submission, in particular members of NZNO's Nurses' Research section, Te Rūnanga and professional nursing, policy, legal, and research advisers.

3. There are many areas of nursing practice where nurses are responsible for, and provide, health care to adults who are temporarily or permanently incapacitated.

4. The discussion document describes "incompetent adults" ie those unable to make informed decisions for themselves, as 'vulnerable'. Vulnerability has been described as "a foundation of ethical sensibility in nursing", and is a construct that informs NZNO's Code of Ethics (2010) and guides nursing practice.

5. This is more fully explored in Megan-Jane Johnstone's *Bioethics: a nursing perspective (2016,* 6th ed., Elsevier: Melbourne); in particular the sections on vulnerability in chapter 6, and informed consent in chapter 7 may be useful in the context of this discussion.

6. Although we didn't receive a lot of feedback, it was marked by strong concurrence and unanimity from nurses working with adults unable to give informed consent, that current New Zealand law limiting the circumstances in which research can involve these consumers is satisfactory.

7. We haven't been aware of a particular call for or need to change consent regulations for this group of adults, and the consultation document does not clarify whether it is motivated by on actual or anticipated needs.

8. The rationale for change would have to be clarified if further action were to ensue. For instance, we would expect evidence to support the statement "research …. could lead to significant advances".

9. We also expect that potential risks as well as potential benefits arising from advances in science and technology would be spelled out, since consumers who are unable to make informed choices for themselves, and their families *are* particularly vulnerable.

10. Finally we welcome the limitation of the consultation to that affecting adults. Although it may appear that there are parallels between children assenting to be research participants because they don't have the capacity to consent and adults who can't consent because of lack of capacity, we regard them as quite distinct.

11. The case for children's voices to be heard and reflected in research data is well established; in general, children give assent rather than consent.

12. We acknowledge that there are challenges in getting research data from both groups, and that there is likely to be some value in addressing that lack of evidence. However, we think the onus rightly lies on the research community to find ways of getting valid data from children and incompetent adults that are consistent with their human rights.

PART IV: CASE STUDIES

Case Study A: Observational study measuring clearance of antibiotics during dialysis

Case Study A questions

A.1 If you were a patient with sepsis and unable to consent, would you want the research to go ahead with you as a participant?

No

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

The research could not benefit the patient, who would be subjected to extra testing which may be uncomfortable/painful, even risky. Treatment with antibiotics is standard best practice.

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

Case Study B questions

B.1 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.

There is no cost or risk to the patient who would have exactly the same treatment. The results may inform and potentially improve treatment for future patients.

B.3 What are your views about “delayed consent”?

Delayed consent is only supported in particular circumstances, which would generally include testing being non-invasive and/or not affecting normal treatment.

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

Case Study C questions

C.1 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.

Potential to benefit from development of a new model of care.

Case Study D: Clinical trial regarding use of adrenaline

Case Study D questions

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

No

D.2 Please state the reasons you formed this view.

Would expect current best practice to be followed on all patients.

Being unable to give informed consent in anticipation of a cardiac arrest is not the same as being an “incompetent adult”; few adults would be knowledgeable enough to make an “informed choice” about

alternative treatments for cardiac arrest either before or after the event.

D.3 What are your views about the proposed "opt out" process?

Do not support it for above reasons. There may be inadvertent pressure not to opt out; an "opt on" option may be preferable.

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

Case Study E questions

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.

It presents a risk and is unethical because there is no benefit to the person since the drugs will not be available.

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

No. It puts carers in a vulnerable position where they may be subject to pressure. We note a report in the Journal of Medical Ethics *Brief report on the experience of using proxy consent for incapacitated adults* in found that "consent decisions of legal representatives will not necessarily reflect those of patients themselves" (Mason et al, 2005 http://dx.doi.org/10.1136/jme.2005.012302)

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

As above.

CONSULTATION QUESTIONS

Consultation Question 1

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.

Generally no.

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

Only in limited, clearly identified circumstances where participation would clearly benefit the person. As indicated previously, we are not aware of any particular imperative for change ie that there is any really important research that is currently impeded by inadequate law.

The Code provisions relate to health and disability research conducted only by a health care or disability services provider. Research relating to health and disability issues is also conducted by non-providers, for example, some academic research. Given that such research is outside the jurisdiction of the Commissioner:

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

Yes

1.4 Please make any general comments you have about question 1.3.

The law should be consistent and ensure appropriate protection for vulnerable consumers in all circumstances.

Consultation Question 2

Dissent

Some people who are unable to make an informed choice to participate in research may be able to express dissent or refuse the procedures involved, for example, by way of facial expressions indicating pain or fear.

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?

Yes

2.2 Please give reasons for your answer.

Consumers who are unable to give informed consent in usual ways – eg nodding, saying yes –may nevertheless give some other indication of what they are feeling to a trained and skilled observer. They must be given that opportunity.

Consultation Question 3

Delayed consent

In some jurisdictions, researchers may be permitted to carry out research on a person who is temporarily unable to give informed consent provided that the researcher obtains delayed (retrospective) consent from the participants after they regain the ability to consent. Delayed consent is not permitted under New Zealand law.

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?

Unsure – only in very limited, non-intrusive circumstances

3.2 Please give reasons for your answer.

In general we would not support delayed consent. However, considering the potential capture of lifelong health data, (that can be anonymised) there may be some circumstances in which delayed consent to use it for research purposes *may* be appropriate.

Consultation Question 4

Alternative participants

The NEAC guidelines require that studies should not be performed with vulnerable groups if the studies can be performed adequately with other groups. However, this ethical standard is not a legal requirement.

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.

Consultation Question 5

Interests of others to be taken into account

There are different possible criteria about the people who might benefit from research conducted with other people as participants. Examples of such criteria are requirements that the research:

 be permitted only if it may benefit others who have the same or a similar condition to the participant

 be connected to the impairing condition that prevents the participants from being able to provide consent

 be intended to provide knowledge of the causes or treatment of the impairing condition that prevents the participants from being able to provide informed consent

 be intended to contribute to significant improvement in scientific understanding of the incapacity suffered by the participants.

Given that in most research on incompetent participants any benefits for participants are uncertain, but the outcomes may benefit others:

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?

Unsure

5.2 Please give reasons for your answer.

There would have to be a very clear indication not only of the potential to benefit others, but that the findings would be implemented. It would not be acceptable, for instance, to research models of care, therapies, medicines etc. that would not be made available to incompetent adults.

If the answer to question 5.1 is yes:

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.

1. Can't be conducted on adults able to give informed consent

2. No harm, minimal discomfort to participant

3. Benefit should be 'real' ie results will be acted on

4. Benefit should be significant

5. Any others?

Consultation Question 6

Ethics committee approval

An option for change would be to make ethics committee approval mandatory in all cases where the research involves adult consumers who are unable to provide informed consent. This requirement could be introduced independently, or in addition to other criteria.

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.

Because the participant are vulnerable and robust independent and transparent processes need to be in place to up hold their rights as human rights.

Consultation Question 7

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?

Yes

If you answered “No” to question 7.1, please answer question 7.2.

7.2 If research were to be permitted to proceed without the consent of adult incompetent participants, what criteria/tests do you believe should be used to assess the advantage and disadvantage to the participants?

7.3 Please state the reasons you formed this view.

Consultation Question 8

Who decides?

8.1 Do you think there should be any change made to New Zealand 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 New Zealand law?

Unsure

8.3 If you answered “Yes” to question 8.1 and/or 8.2, please complete the table below about possible decision-makers and the roles you believe they should play in decision-making. Please note that you may consider that a combination of decision-makers is appropriate (either to play different roles in the decision-making process or to make decisions in different circumstances).

See answer below

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.

Please rank the decision-makers you chose in order of preference from 1. being your most preferred to 5 being your least preferred. If you prefer a decision-maker other than those listed, please indicate the decision-maker.

1. Other –these decisions have important implications for society and this group of very vulnerable people needs expert protection. We suggest that eg an ethical committee should be assigned responsibility for the final decision. It should take into account the recommendations of EPOA or welfare guardian and family/whānau

2. EPOA or welfare guardian: Involved, but not make the final decision

3. Family/whānau Involved, but not make the final decision

4. Provider not involved in the research (e.g., the consumer’s responsible clinician or GP). It may be appropriate to seek *input* from the clinician directly involved in participant’s care, as s/he may have established other ways of understanding the person’s feelings. However, such a *decision* is neither the prerogative nor the responsibility of clinicians, but it is one that is often foistered them. A much broader social remit than an occupational one is necessary for decisions which are society’s responsibility.

5. Researcher – obvious conflict of interest

8.5 Please provide any other comments you wish to make about the decision-makers.

9. Please add any final comments or suggestions you wish to make.

Human Rights Commission
Te Kāhui Tika Tangata

Submission on the "Health and disability research involving adult participants who are unable to provide informed consent" Consultation Document

Contact Persons:

[redacted]
Human Rights Specialist
[redacted]

[redacted]
Senior Legal Adviser
[redacted]

Submission of the Human Rights Commission on the "health and disability research involving adult participants who are unable to provide informed consent" consultation document

1. The Human Rights Commission ("Commission") welcomes the opportunity to provide this submission to the Health and Disability Commissioner ("HDC") on his "Health and disability research involving adult participants who are unable to provide informed consent" Consultation Document ("Consultation Document").

2. The Consultation Document seeks views "on health and disability research involving consumers who are unable to consent to their participation in that research"[1] to assist the HDC to determine whether there is a need for a change to the current law. It focuses on two fundamental questions:

   - are New Zealand's current laws regarding non-consensual research appropriate?
   - if not, how should they be amended?

3. This submission sets out the applicable human rights obligations and considers their application to the current framework for conducting research on those who are unable to consent.

4. The Commission believes that New Zealand's current laws regarding non-consensual research are inadequate and need to be amended in a manner consistent with New Zealand's binding legal human rights obligations.

5. The Commission considers that the law should be amended so that research may only be undertaken on people who lack perceived mental capacity provided the following conditions are met:

   - all reasonable steps have been taken to provide support to enable them to express their will and preferences, and/or to identify and engage with a person who can speak for the research participant's welfare
   - it is in their best interests
   - the research is necessary
   - there is minimal risk

[1] HDC, *Health and disability research involving adult participants who are unable to provide informed consent,* Consultation Document (2017), at ii.

- the research is approved by an ethics committee. This approval must consider all the elements identified above
- nothing may be done which the person subject to the research appears to object to or which is contrary to their best interests
- a process is established for periodic review of the individual's participation in the research

1. Human Rights and Disability

6. New Zealand ratified the Convention on the Rights of Persons with Disabilities ("CRPD") in 2008. Article 12 of CRPD provides that "States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life." The Article recognises that some people will require support to exercise this legal capacity.

7. As the Consultation Document states, Article 12 of the CRPD and the shift from substituted to supported decision-making is relevant to this consultation because it "means that in all circumstances, people with disabilities should be supported to make their own decisions in respect of research rather than others making decisions for them".[2]

8. The United Nations Committee on the Rights of Disabled People ("CRPD Committee") has issued a General Comment on Article 12 which provides guidance for States on how to interpret the article.[3] The General Comment makes it clear that people with disabilities have a right to support in exercising of their legal capacity. This support must "respect the rights, will and preferences" of people with disabilities.[4] Support is a broad term which covers both informal and formal arrangements, ranging from peer support, to external advocacy. The General Comment recognises that the type and intensity of support will vary significantly from one person to the next as like everyone, people with disabilities are diverse.

9. Another key element of Article 12 is the requirement for States to create appropriate and effective safeguards for the exercise of legal capacity, the purpose of which is to "ensure

[2] Ibid at 57.
[3] Committee on the Rights of Persons with Disabilities, *General Comment No. 1,* (2014) Geneva, CRPD/C/GC/1: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRPD/C/GC/1&Lang=en
[4] Ibid at paragraph 17.

the respect of the person's rights, will and preferences"[5] by providing protection from abuse on an equal basis with others.

10. Article 17 of the CRPD states that "Every person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others." Read in conjunction with Article 12, the CRPD Committee considers medical treatment undertaken without someone's free and informed consent as a breach of their physical/mental integrity.

11. Article 15 of the CRPD provides that "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation." This article protects people from undergoing medical experimentation, including the testing of medicines, against their will.

12. In considering Article 15, the UN Special Rapporteur on Torture has stated that "the more intrusive and irreversible the treatment, the greater the obligation on States to ensure that health professionals provide care to persons with disabilities only on the basis of their free and informed consent".[6]

13. Domestically the New Zealand Bill of Rights Act 1990 ("BORA") provides that every person has the right not to be subjected to medical or scientific experimentation without that person's consent,[7] and that everyone has the right to refuse to undergo any medical treatment.[8]

2. Right 7(4) and research involving the treatment of patients who do not have mental capacity to consent

14. The requirement of informed consent for any treatment (including research by a health care or disability services provider) is set out in the Code of Health and Disability Services Consumers' Rights ("Code"):

    - Right 5 – Right to effective communication
    - Right 6 – Right to be fully informed

[5] Ibid at paragraph 20.
[6] Special Rapporteur on torture and other cruel, inhuman or degrading treatment, *Interim report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment*, (2008) at 59.
[7] New Zealand Bill of Rights Act 1990, s 10
[8] Ibid, s 11.

- Right 7 – Right to make an informed choice and give informed consent

15. Right 7(4) sets out the legal position concerning research involving the treatment of patients who do not have mental capacity to consent, where there is no legally authorised person available to give consent. Right 7(4) states:

> *Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -*
>
> *a) It is in the best interests of the consumer; and*
>
> *b) Reasonable steps have been taken to ascertain the views of the consumer; and*
>
> *c) Either, -*
>
> *i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or*
>
> *ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.*

16. Right 7(4) provides an exception to the requirement for informed consent. It gives decision-making powers to the researcher (clinical investigator) so long as they have taken steps to ascertain the patient's views (or the views of other suitable people) to reach the conclusion that the research will be in the "best interests" of the patient. In other words, it provides a legal justification for research without consent in some circumstances.

17. There are very few safeguards applicable to the clinical investigator's decision under Right 7(4). Research in New Zealand may be assessed by a Health and Disability Ethics Committee ("HDEC") but this is not always the case.

18. The investigator can in effect have two roles – that of researcher and that of decision maker as to what is in the best interests for the patient. Right 7(4) does not give any guidance on how to address any conflict of roles and the investigator could potentially decide whether to enrol the patient in the research in the absence of independent advice or oversight.

3. Adequacy of Right 7(4)

19. Right 7(4) anticipates supported decision making where the circumstances allow, making the provision consistent with the purpose of the CRPD. However, its application can be less consistent with the spirit and letter of the CRPD and other human rights obligations including those in BORA.

20. Article 12 of the CRPD expressly requires the establishment of effective safeguards for the exercise of legal capacity. The absence of such safeguards or any independent monitoring or oversight is concerning.

21. Alison Douglass has undertaken extensive analysis on New Zealand's legal framework relating to research on people who lack mental capacity. In this research, she traverses the nuances of applying right 7(4) in this context. Her case studies clearly illustrate the challenges in balancing the rights of patients without mental capacity with the undertaking of health and disability research which may be in their best interests.[9] The lines are not always clear and a case by case assessment needs to occur in light of all the circumstances and this assessment needs to include independent oversight and monitoring.

22. Ms Douglass concludes that:[10]

> *Right 7(4) of the HDC Code is an inadequate basis for allowing participation in research by adults incapable of giving informed consent.*
>
> *…*
>
> *Within a cohesive regulatory framework, where the risks are minimal, the law should permit research on people who lack capacity that has potential to benefit either them or other people with a similar condition provided there are clear*

[9] Alison Douglass, *Mental Capacity; Updating New Zealand's Law and Practice*, A Report of the New Zealand Law Foundation (2014), see in particular Chapter 6, *Research on People who lack capacity.*
[10] Ibid at 152.

statutory safeguards to protect the interests of such vulnerable research participants.

23. The Commission agrees with this conclusion. However, to ensure compliance with New Zealand's international obligations there needs to be a robust mechanism to enable supported decision making in as many circumstances as possible before resorting to a "best interests" assessment. Although Right 7(4) anticipates and requires supported decision-making, for this to happen in practice explicit and detailed operational guidelines should be developed and implemented to ensure that:

    (a) Supported decision-making is available to everyone regardless of their level of support needs, as far as possible in the circumstances;
    (b) Those designing and carrying out the research/trial are fully aware of the principles of supported decision-making and how this can be facilitated and achieved in practice.[11]
    (c) Support is based on the will and preferences of the person;
    (d) People have a right to be have support in communicating their will and preferences, even if this communication is unconventional;
    (e) People have the right to be supported in a range of ways, formally and informally. They also have a right to refuse support; and
    (f) Safeguards are set up, with the goal of ensuring the person's will and preferences are respected as far as possible in the circumstances.

4. Recommendations

24. The Commission believes that New Zealand's current laws regarding non-consensual research are inadequate and need to be amended in a manner consistent with New Zealand's binding legal human rights obligations. The Commission considers that the law should be amended so that research may only be undertaken on people who lack mental capacity provided the following conditions are met:

    - all reasonable steps have been taken to provide support to enable the individual to express their will and preferences
    - if the individual is unable to express their will and preferences with support, all

[11] More information on the principles and practice of supported decision-making can be found at: http://aucklanddisabilitylaw.org.nz/supported-decision-making-home/supported-decision-making-resources/

reasonable steps have been taken to identify and engage with a person who is best placed to understand what their will and preferences might be if they could be expressed ("best guess")

- the research is in the individual's best interests
- the research is necessary
- the overall material benefit to be gained significantly outweighs any potential risks
- the research is approved by an ethics committee. This approval must consider all the elements identified above
- nothing may be done which the person subject to the research appears to object to or which is contrary to their best interests.
- a process is established for periodic review of the individual's participation in the research

25. The Commission believes that the United Kingdom model - referenced in the Consultation Document - is a good starting point. The Commission encourages the HDC to consider how such a model may be applied in New Zealand.

30 April 2017

The Health and Disability Commissioner
PO Box 11934
Wellington 6142
New Zealand

Dear Commissioner

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

The Code and Act came about as a direct consequence of research without consent.

This was a major input to the drafting of the Code. With hundreds of meetings and thousands of submissions it remained a constant theme.

To now suggest that it's ok to allow a conscious capable person to deny research but as soon as you are unconscious it is ok does not seem credible. The most ridiculous suggestion has to be that the population should decide to wear a coloured band to deny research in case they have a heart attack and become unable to consent.

Do not misunderstand that I do not see the benefits of research as requested in the examples given. However consent is fundamental. Also, there are multiple other examples where research could be undertaken after the event. All medical procedures involve record keeping and samples of urine and blood are already kept for a limited time for quality control purposes. Those samples can later be used for research if the consumer agrees to this after emergence from the coma.

Importantly, I note that the Code is not a list of individual rights, it is a cohesive structure of inter-related rights, each co-dependant on others. To begin tinkering (as would be necessary to effect the proposition) could fundamentally damage these inter-relationships.

In closing, I note that the solution already exists within the Code - advance directives.

A capable individual has the right to give an advance directive that, in the event they are unable to consent, they give approval to any research currently being undertaken.

The education function of the Commissioner gives the power to promote this and the commissioners webpage could have a draft form that would enable consumers to choose to give the directive, with options
Options should include various issues including: With or without ethics approval; Inclusive or exclusive of "no treatment option"; Etc. Obviously it would also need a statement recommending advice be taken and the directive be witnessed etc.

Consumers should have the right to put such directives, including a directive on the donation of organs, on to a national health database. The constant problem that still exists, despite the Code is the lack of co-ordination of medical records between the service providers. How many times do consumers need to be asked if they are allergic to any medicines or asked what operations they have had or what medicines they are taking?

It is time the entire sector addressed such issues and at the same time this research issue could move forward.

I trust the submission, brief though it is, will be accepted.

Regards

PS
My husband had a major infection in which is exactly as presented in one of the case studies and was in A coma in ICU for over a week. As his wife, I know that he would have consented to the research as suggested in the case study and I would have given consent if I had been asked at the time. Such consent would have been limited to the taking of extra samples only. At the time there were 2 treatment options available, these were discussed with the family, the doctors gave their recommendation and we consented. It was undertaken entirely in accordance with the code and in terms of research my husband would have seen it in his best interests for the research to proceed as well.

Consultation on research in adult subjects who are unable to provide informed consent

Feedback provided by ADHB

1. researchers have undertaken many clinical trials in adult subjects who are unable to provide informed consent at the time of enrolment e.g. patients admitted to the ICU or emergency department. At all times the research is considered to either be in the patients' best interest or not harmful, in other words the setting of equipoise. Those studies have provided important research findings which in turn have influenced care for the better, with translation of the findings across international healthcare settings.
2. Those studies have applied retrospective consent in which the subject is informed and provided with the opportunity to provide consent or withdraw as soon as they are able to. At all times any family members present are advised and asked if they would know the participant's wishes, acknowledging that is not a surrogate for informed consent.
3. It is unethical to exclude subjects who cannot give informed consent from the opportunity to either participate in research or to have the opportunity for research to be undertaken in relation to their disease/disability simply because it is unlawful to participate without clear evidence of benefit. People with disability or serious illness are entitled to knowledge that can advance their care and their outcomes and should not be denied those opportunities that are realized by their participation in clinical research.
4. Many adult subjects participate in clinical research out of beneficence, knowing that there will be no direct benefit, indeed even some inconvenience or discomfort, to them but that others will benefit e.g. populations or other patients. There is no reason why subjects who cannot give informed consent would think any differently.
5. It cannot be presumed that treatment A might be better than treatment B and the very nature of hypothesis testing in scientific research means that subjects must be enrolled to either arm of a comparative study in order to determine which treatment is most efficacious. The answer cannot be known until the trial is completed so it might not be possible to know if there is a treatment benefit. As such, so long as the researcher can, to the best of their ability, determine that the 'experimental' treatment/intervention is not harmful, rather it is as good as or better than standard treatment, then in the opinion of this author, the subjects should be allowed to enter the trial.
6. Although there is debate about the true benefit of the Hawthorne effect in clinical research involving human subjects, it is none the less true that academic hospitals with sound frameworks for research governance offer high level care. Enrolment in clinical trials allows for rigorous and systematic data collection, recognition of and intervention in respect of adverse event and careful monitoring at all stages of the trial. Arguably such care is of benefit to enrolled subjects.
7. Having stated that it is ethical to enroll adult subjects unable to provide informed consent into clinical trials, it is necessary to have protections including independent advocacy for the wellbeing of the subject, such that, irrespective of the requirements of the research, the subject's interests are considered at all times. It is not clear what the best framework for such protection is. In respect of children, the parents as guardians perform that function. In adults there may not always be an adult who could accept that surrogacy. Where an EPO

exists then that is clearly adequate but it is not practicable to have the court determine that in each instance. Indeed, for some trials early enrolment is imperative e.g. emergency department studies.

8. It is suggested that for studies that enroll adult subjects unable to provide informed consent, that additional standards exist e.g. research can only be conducted in an institution with strong research governance, with clear reporting frameworks, where each researcher has current GCP certification and where there is transparency regarding research activities, protocols and outcomes. This sits within a wider ethical and regulatory framework.

To: Health and Disability Commissioner
From: Stephanie Clare,
Chief Executive
Age Concern New Zealand He Manaakitanga Kaumatua Aotearoa
Date: 28 April 2017

Submission: Informed Consent

Dear Anthony Hill

We are responding to your call for views on informed consent.

Please find our submission attached.

Kind Regards,

Stephanie Clare

Stephanie Clare

Contact person

Age Concern New Zealand He Manaakitanga Kaumātua Aotearoa
Serving the needs of older people

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Age Concern New Zealand supports the status quo and does not support a change in law that will reduce the protection of an individual's autonomy, nor the responsibilities of service providers. We would, however, welcome the increased protection of health consumers, particularly for those who are vulnerable on account of frailty, impairment or have reduced capacity to make decisions. Consideration should be given to expand inclusion of other health-related research that does not currently fall under the HDC Code.

We recognise that research plays a crucial part in the advancement of medicine, adds years to life and provides an improvement of the quality for those years. There is no doubt that research benefits individuals and the wider community, but the costs and risks are can be directly borne by the incapacitated, subject individual. The intention that the individual will provide insight for the treatment and good health of other members of the community is not reconcilable. As the rights of the individual are at odds with an imagined, collective rights to good health and treatment.

If legal protections were to be reduced, internal processes including ethics approval process will need to be strengthened to protect the most vulnerable and to ensure that there are appropriate checks on how this used, appropriately monitored, conflicts of interest managed, and rights of the incapacitated consumer upheld.

Supported decision-making process would need to be developed and strengthened so that meaningful consent can be provided, no pressure or withholding of the best available care. Care would need to be taken to ensure that the incapacitated person has an understanding of the scope of the research, benefits to themselves and the level of risk. The law should not be extended to include retrospective consent as the research process has already began.

Impact on Older People

Across the world, people are living longer and in New Zealand this is no different. The number of people in the +65 age are increasing but this includes the advanced age groups beyond 65 years old. Health science research has played a significant factor in understanding and treatment of disease, particular conditions and rehabilitation. Increased life span is one of the achievements of modern society supported by health sciences. But older people who are too frail or incapacitated to make decisions, can be subject to more unconsented research on account of their vulnerability.

Medical research is not with folly, risk and misadventure. The nature of research is that it is speculative and an enquiry on how the human-subject responds. Therefore, either by design or omission, the legacy of some health science research is that it is not person-centred.

The great awareness of rights of the vulnerable and how it applies to different population groups has resulted in a dramatic change in the human rights environment. Convention on the Rights of Persons with Disability has questioned the medical model of disability and has given recognition of the humanity of all peoples. Advanced age is not a disability but there are conditions that some older people experience that are disability related.

Best interests

When a person is unable to make decisions for themselves, the medical professional holds the right to make decisions on behalf of the incapacitated person. This obligates the medical professional to act in the best interests of the person in their care. The best interest doctrine is provided based on the assumption that the medical professional makes "best interest" decisions for the patient concerned, not the wider community. A medical professional who holds decision-making powers

over a vulnerable person has much power; this comes with responsibility and must be wielded carefully but in the interests of the person concerned.

Medical research has elements of risk and uncertainty. Even if the medical professional manages the risk with care, the individual person has not consented to be involved in this process. In this case the the incapacitated patient is not accorded respect and dignity; their rights are not being upheld. The wider benefits of research should not be the responsibility of the incapacitated person who is at their most vulnerable and has not given consent. In this case the “best interest” doctrine would be at odds with the “right to life”. Article 6 of International Covenant on Civil and Political Rights (ICCPR) which protects the "right to life" is a crucial element of the “best interests” doctrine and how it relates to that particular incapacitated person.

Conclusion

Age Concern New Zealand does not support any reduction in protection of an incapacitated person. When medical professionals have the right to make decisions on behalf of such people, this has to be exercised in the best interests of the person concerned. The best interest principles are closely related to ICCPR’s right to life.

Age Concern New Zealand is not in a position to answer the individual questions and provide responses to the case studies. We are of the view that a principled approach based on human rights should be adopted. Considerations related to the well-being of the human subject should take precedence over the interests of science and society.

NEW ZEALAND COLLEGE OF MIDWIVES (INC)

28 April 2017

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

Feedback from: New Zealand College of Midwives
PO Box 21-106
Edgeware
Christchurch 8143

Phone (03) 377 2732

The New Zealand College of Midwives is the professional organisation for midwifery. Members are employed and self-employed and collectively represent 90% of the practising midwives in this country. There are around 2,900 midwives who hold an Annual Practising Certificate (APC). These midwives provide maternity care to on average 60,000 women and babies each year. New Zealand has a unique and efficient maternity service model which centres care around the needs of the woman and her baby. It provides women with the opportunity to have continuity of care from a chosen maternity carer (known as a Lead Maternity Carer or LMC) throughout pregnancy and for up to 6 weeks after the birth of the baby, and 92% of women choose a midwife to be their LMC. Primary maternity services provided by LMC midwives are integrated within the wider primary care and maternity services of their region or locality. The College offers information, education and advice to women, midwives, district health boards, health and social service agencies and the Ministry of Health regarding midwifery and maternity issues. Midwives interface with a multitude of other health professionals and agencies to support women to achieve the optimum outcome for their pregnancies, health and well-being.

NEW ZEALAND COLLEGE OF MIDWIVES (INC)

28 April 2017

Health and Disability Commissioner
PO Box 1791
Auckland 1140

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

The opportunity to make a submission was welcomed by the New Zealand College of Midwives (the College).

Midwives work in partnership with women and it is the midwife's professional responsibility to uphold each woman's right to informed decision making throughout the childbirth experience. It is respect for the woman's autonomy that underpins the requirement for informed consent, and informed decision-making emphasises the autonomy of the individual. The College considers that informed decision-making involves the exchange and understanding of relevant information. It respects the rights of individuals to make decisions about actions, which affect them. Making an informed decision is part of a process, which results in either informed consent or refusal.

Feedback from the College is below.

1. Midwives are evidence-based practitioners and the College recognises that because knowledge needs to increase, research is necessary. However, we do have significant concerns about non-consensual research and clinical trials.

2. As described by Ledward in 2011, because research is not treatment it should always be seen as distinct from clinical care, and therefore the ethical justification for research will be different. Ledward comments that assuming that a research study will always offer potential benefit to research participants represents a narrow interpretation. She goes on to say "There may sometimes be elements of direct benefit to participants (therapeutic research), or the research may offer a degree of benefit to both participants and future patients. However, research most frequently has the objective of benefiting others in the future (non-therapeutic research)."[1]

3. The College considers that as a general rule research should not be carried out in non-consensual situations.

[1] Ledward, A. (2011). *Informed consent: Ethical issues for midwife research*. Evidence-based midwifery, Royal College of Midwives. https://www.rcm.org.uk/learning-and-career/learning-and-research/ebm-articles/informed-consent-ethical-issues-for-midwife

4. The College also considers that enrolling adults in research when there is an inability to consent, and where the research is not expected to provide benefit to them, is ethically troubling. Taking advantage of people who are unable to protect their own interests is a breach of human rights.

5. Ledward points out that "competence should not be seen as an 'all or nothing' concept, but might be dependent on the type of decision to be made." What this means is that there may be competency to decide on some issues and not others, and this may also occur within varying time-frames. The College recommends this concept be recognised, and we emphasise the ethical obligations to ensure that all avenues to information provision are explored.

6. The College considers that research on people who cannot give informed consent should not proceed unless the research is deemed to be in the best interests of the person. We also consider that family and whānau, or authorised surrogate, need to be intimately involved in all decision making.

7. The College also consider informed consent as a dynamic process. As described by Johnson & Keenan, consent is not as a single act, but a process which involves open and honest communication.[2] If new evidence or information emerges, there should be a right for family/whānau to change their minds at any time.

8. The College considers that an appropriately qualified, diverse and independent ethics committee should be involved in all the decision making processes involving non-consensual research. This ethics committee should protect the interests of all research participants, but particularly those in situations of great vulnerability, where persons cannot protect their own interests and wellbeing.

9. The WHO, Standard 4: Independence of research ethics committees (REC) states, *"Policies governing the REC include mechanisms to ensure independence of the REC's operations, in order to protect decision making from influence by any individual or entity that sponsors, conducts, or hosts the research it reviews. Such policies provide at a minimum that REC members (including the Chair) remove themselves from the review of any research in which they or close family members have a conflicting interest."*[3]

10. The College understands that there have been forty medical studies in New Zealand since 2006 that included non-consenting 'participants' and that these studies were approved by ethics committees.[4] We recommend that ethics committees should be required to prioritise the role of protection of human participants in research, and the ethics involved in non-consensual 'participation'.

11. The College notes the argument in support on non-consensual research by Aspen New Zealand, who are a pharmaceutical company. We consider research on unconscious patients, without their prior consent, to be a major breach of their human rights, and we would like to express our alarm at suggestions made in the Aspen article, that excluding adults unable to consent from research, is some form of discrimination. Using language such as 'opportunity to participate' and 'diminishing their ability to participate as fully as possible in society' is frankly abhorrent in situations where the research is of no value to the person's current, or future, health situation, and they are unable to consent or refuse.

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[2] Johnson, S., & Keenan, R. (2010*) Consent*. In R Keenan, ed. Health Care and the Law, Chapter six, Brookers: Wellington.

[3] World Health Organisation. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

[4] Aspen New Zealand. Undated. *Research on people who lack capacity*. http://www.aspenltd.co.nz/mc/assets/Ch-6.pdf

12. International guidelines from the World Health Organisation cover ethics and clinical research, and state that it is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants.[5] The College supports this statement.

13. Whilst carrying out background research for this submission the College was disturbed to find that entering 'non-consensual' into the search engine on the National Ethics Advisory Committee yielded zero results.

14. The College did find a statement within the National Ethics Advisory Committee's 2012, 'Ethical Guidelines for Intervention Studies: Revised edition' which states in 6.28 that "*Intervention studies with no therapeutic intent should be undertaken only with the prior informed consent of the competent individual, unless a legal proxy can consent for an incompetent individual."* [6] The College would not like to see this statement reduced in any way, and we support New Zealand law that substantially limits the powers of health practitioners to offer treatment without consent in the context of research.

15. In situations where there is an inability to provide informed consent by the person, the College considers that the tenets of informed consent remain and that the family/whānau, or authorised surrogate, should be afforded all information necessary.

16. If the person is unable to participate in decision making, and has temporarily lost autonomy, the College considers that information should still be provided to the family/whānau in a way that is easy to understand and engage with.

17. The information provided must still be accurate, objective, relevant and culturally appropriate.

18. Information to family/ whānau should include details of the proposed research, and a clear benefits and risks analysis.

19. Alternatives to the research proposed, and the risks and benefits, should be provided to family/ whānau, and this will include information about what will likely occur if consent is refused.

20. The information provided to family/whanau should remain free from coercion

21. Wherever possible a designated and reasonable amount of time should be given for family/whānau to discuss, consider, and seek further information to assist in their decision making.

Thank you for the opportunity to provide feedback on this document

CBartle

Carol Bartle
Policy Analyst

[5] World Health Organisation. (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.* Geneva, WHO.
[6] The National Ethics Advisory Committee. (2012). *Ethical Guidelines for Intervention Studies: Revised edition.* Wellington, MOH.

From:
To: Rose Wall < >,
Date: 29/04/2017 01:17 p.m.
Subject: individual submission on Right 7(4) consultation

Thank you, Rose, for the opportunity to read the HDC discussion document and express my individual view on it. For the avoidance of any doubt, this is an individual, subjective, personal opinion.

I am deeply conflicted about the citizen responsibilities that are raised in this document. I personally believe in my duty to participate in research that might build a better future for all.

However, my experience teaches me that supported decision making is still in a primitive state in New Zealand. As a totally blind person

I am reasonably equipped to digest information provided to me in accessible electronic formats. Forms can be made accessible so that I can read them and fill them in with the assurance that I know what I wrote and can file a copy if I wish. In practice experience teaches me that this is not the case, in particular in the health sector. Too often I have to rely on someone to read information to me, then complete the informed consent form, and I must hope they wrote my details correctly.

How much worse it must be for anyone for whom English is a second language, or who might have a learning disability. I cannot take responsibility for others in the community. However since my experience teaches me the situation regarding equal access to information is so patchy it amounts to discrimination, I cannot support any liberalisation of the legislation and/or The Code of Rights at this time. I deeply regret holding this view.

Thank you again for the opportunity to comment. I do realise that if the Commissioner decides to recommend any change, there will be a further round of consultation on any proposed changes.

Turning to an entirely different issue, I have been most surprised at how uneven the knowledge about this very important consultation has been in the sectors I move in.

Several people knew nothing about the consultation

In my own case I will bee more responsible and look out for an HDC email list to join so I am not reliant on your generously remembering to let me know in the future.

Kind regards

26 April 2017

Health & Disability Commissioner
PO Box 11934
Wellington 6142

By Email: hdc@hdc.org.nz

Re: Public consultation regarding research involving adult participants who are unable to provide informed consent to participate in the research

Thank you for the opportunity to make a submission on this important subject. I am a neurologist . I ask that the Code is changed to enable the enrolment of clearly defined groups of people who are unable to provide full informed consent into research studies.

I'd like to use stroke, to demonstrate why this should be. Stroke affects approximately 8000 New Zealanders every year of whom approximately half will be left dead or dependent on others for help with activities of daily living. Most (85%) strokes are due to an occlusion of an artery, usually due to a blood clot, supplying blood to part of the brain. Brain downstream from the occlusion will cease to function within seconds to minutes, and will begin to die within minutes to hours. Depending on the artery that has been occluded, a person may develop weakness, sensory loss, visual disturbance or impaired language with inability to comprehend verbal or written communication, or to express their wishes. This means that most people with large and potentially devastating strokes do not have the capacity to provide full informed consent to take part in research studies. Brain cells do not regenerate and so this tissue is lost forever. Many people consider being left severely disabled and dependent on others for help with activities of daily living following a stroke as being as bad as or worse than death.

An example of acute stroke studies where participants may not have been able to provide full informed consent were a series of five large randomised-controlled trials of endovascular clot retrieval published in 2015. Clot retrieval aims to physically remove the occluding blood clot and restore blood flow and salvage as much brain as possible from dying. Each of the five studies showed that clot retrieval provided a significant clinical benefit compared to standard therapy. A meta-analysis of these five studies (giving greater confidence of the degree benefit) showed a clinically significant improvement in function for every 2.6 people treated, and one more normal or near normal person for every five treated. These studies have resulted in changes in clinical practice so that endovascular clot retrieval is now considered standard care. They had clear hypotheses and rationale and had

the potential to benefit people with stroke although this wasn't known for sure at the outset - if it was then there would have been no need to do the studies in the first place. It was conceivable that clot retrieval could have even been harmful. This was thought unlikely but the researchers couldn't guarantee this. It is only by doing studies like this that new treatments are developed.

Acute stroke studies require very rapid intervention. The clot retrieval studies enrolled patients 6-8 hours from symptom onset. This meant that a person or their family/whanau needed to recognise they were having a stroke, get them to hospital, have brain imaging and then be enrolled in a study and be treated within 6-8 hours of the symptoms coming on. There was simply not enough time to wait to see if a person was going to improve sufficiently to have the capacity to provide full informed consent. Furthermore, it was people with the greatest deficit (making the capacity to provide consent unlikely) who had the most to benefit from clot retrieval and who were the targets of these studies. To have excluded such people would have defeated the purpose of these studies.

My own view as a clinician, researcher and citizen that it is wrong to exclude people with life-threatening illnesses, who by the nature of the illness may not have the capacity to provide informed consent, from the opportunity to take part in research. This is as long as the study has clear hypotheses, sound rationale, has been approved by an independent ethics committee and at least has the potential to be of benefit for that individual, or the study involves the collection of specimens or clinical information that doesn't harm the individual but has the potential to benefit others in the future.

Please don't hesitate to contact me if you require any further information.

Yours sincerely

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HDC Consultation - Health and disability research involving adult participants who are unable to provide informed consent

Response from the Chairs of the four national Health and Disability Ethics Committees (HDECs)

Introduction

Thank you for inviting submissions on this important topic. The four national Health and Disability Ethics Committees review over 600 new research ethics applications per annum. HDEC members are appointed by the Minister of Health and comprise both lay and non-lay members with interest and experience in ethical issues and the conduct of safe research that contributes to improvements in health and disability care in New Zealand. Our role carries with it a great responsibility for the conduct of research and the safety of participants in studies. We review research across a full health research spectrum, from observational studies through to first-in-human clinical drug and device trials. This submission is the position of the Chairs of the HDECs.

We would welcome the opportunity to meet with you to discuss our submission and also the options that emerge from the feedback to the review.

General Position

We support the Commissioner's comments which affirm that the rights of participants are at the heart of ethics in New Zealand and echo the findings of the Cartwright report on the autonomy of the individual, the avoidance of harm and informed consent[1]. Therefore, if the law in New Zealand governing consent is to be amended, then it must be done with the utmost caution, and in ways which do not diminish respect for autonomy, or cause people harm. To do any less would severely undermine public trust in the research endeavour, and tarnish New Zealand's reputation on the world stage.

The right to make an informed choice and give informed consent before participating in research is the first and foremost ethical standard that HDECs expect researchers to meet. Our response to the HDC Consultation Document is based upon the pivotal importance of individual consent, as well as the recognition that research ethics is an essential component

[1] We acknowledge that individual consent is a Western concept. Indigenous peoples may be more comfortable working within a framework of collective consent. While there is yet to be a fully worked-out pathway for collective consent in the New Zealand context for Maori-specific research, HDECs expect evidence that researchers have undertaken a fulsome consultation with Maori prior to commencing the research. However, having the support of the community or the family does not outweigh an individual's rights concerning withdrawal or refusal, especially in cases where the research involves tissue, genetic material or end-of-life decisions.

in the continuum of high-quality health care delivery. Research must proceed in ways that meet or exceed the recognised ethical standards of beneficence, non-maleficence, justice and respect. In addition to these principles we acknowledge the essential principles of participation, protection and partnership in the Treaty of Waitangi. Further, we approach our response to the HDC Consultation from the perspective of the ethical principle of respect for the particular vulnerabilities of some participants. All four HDEC committees share an interest in facilitating high quality health research that adds to knowledge of health and/or disability, that protects the rights and well-being of all participants, and preventing studies that pose an unacceptable risk of harm.

Alongside autonomy rights, we recognise New Zealanders' other rights, including the right to receive high quality healthcare services that are inter-connected with high quality scientific investigations, and to have a fair opportunity to participate in research and to access its benefits.

The Code

We are concerned about the apparent confusion that exists amongst researchers about the law regarding research with adults who cannot consent, and therefore commend the Commissioner's attempt to bring greater clarity and strengthen the regulatory pathways and disciplinary mechanisms. Any campaign which promotes awareness of the law and the protections provided by the HDC Code with respect to research participants amongst researchers, the Health and Disability Advocacy Service, and the public would have our full support.

Our view is that the Code serves at least three purposes:

1. to inform consumers about their rights and how they are protected in their interactions with health professionals, and
2. to provide procedural guidelines for these professionals, and
3. to set the benchmark against which the conduct of practitioners (and researchers) might be judged.

We believe that the conflation of research with therapeutic practice in the Code is not aiding clarity, particularly with respect to the questions about 'incompetent' participants. It would be useful to consumers, researchers, (and us) if research per se and treatment (which may include audit, clinical evaluation and quality assurance practices as part of good care and treatment) were distinguished within the Code. While there is always an incremental risk in being part of research, this is sometimes negligible, perhaps no more than inconvenience, and it is inequitable to treat all research as though it was high risk clinical research.

In recent years, we have heard from many researchers, particularly those working in Intensive Care, Intellectual Disability and Psychogeriatric settings who report that the current legal environment is preventing good research from occurring within populations who cannot provide their own informed consent. They argue that Right 7(4) effectively excludes such persons from research, and unjustly means that healthcare does not develop for these groups. They also assert their desire for an appeals process against HDEC decisions that is better than the one at present.

Despite these views, HDECs receive quality applications from researchers and clinicians working with patients who cannot provide consent which meet the current ethical and legal requirements, by prioritising and safeguarding the rights and welfare of very vulnerable or gravely unwell participants. Where health intervention protocols meet both aspects of Right

7(4), i.e. “best interests” and “reasonable steps”, HDEC approval may be (and is) given. Key factors in our deliberations about these protocols are: the research cannot be performed with consenting persons; there is a benefit of inclusion which is not available to non-participants; that individuals are receiving best care according to the current standard; and that the assent of those persons who are interested in the welfare of the persons who cannot consent regarding the consistency of the study with that individual’s own views about research participation in general (as well as the specific study under consideration) are taken into account.

Researchers who successfully argue best interest do so in a variety of ways. These include both physical and psycho-social measures of wellbeing, increased monitoring and advanced alerts of issues of health concern. We always ask researchers to provide us with evidence of the claimed best interest, and do not accept outright the argument that participants in health research are always better off. The onus is on the researcher to prove legality of the trial as well as the benefit to participants.

HDECs may be satisfied of the lawfulness of a study involving persons who cannot consent where, for instance, different standards-of-care are being compared with each other in a randomised way in an intensive care setting. Where there is genuine uncertainty about which intervention is most suitable for this class of patient, then the study may meet best interest where the increased monitoring provides information to inform treatment in a real-time way. Where there is an inclusion benefit, we require that as much information as possible about the study is given to participants and their families, and that only a minimum number of least vulnerable participants are included in the study. If capacity to consent is restored we require that full information is given to the individual participants, and that consent is obtained both for the use of previously collected health information, and any prospective follow-up in the study. In comparative effectiveness studies in settings such as intensive care, where there is already a very high level of monitoring, and where there is no additional inclusion benefit, the lawfulness of the study will not be proved.

The very high threshold of best interest is therefore preventing the advancement of knowledge in some cases: a more moderate best-equal threshold would not only ensure that all participants were receiving best available care, but would also allow knowledge to progress, safely.

Consent, Assent, “Proxy” Consent

Where a trial involves an unproven (experimental) medicine, innovative practice or new device compared against standard-of-care or placebo, Right 7(4) prevents us from approving the research with adults who cannot consent; in these circumstances it is highly unlikely that an investigator could provide sufficient evidence to us of best interest. Nor would these cases be likely to meet a best-equal interest threshold. However, so long as the study did not pose an unacceptable risk of harm the study which is not allowable for persons over the age of 16 may be lawful for children.

We feel that it is important to stress the consequence of what the inconsistency in the law surrounding consent-on-behalf is doing. Currently in New Zealand no other adult, even those who hold EPOA’s (Welfare) is legally authorised to provide consent on behalf of another adult for the purposes of non-life-saving research: it is precluded under the PPPR Act (1988). However, even where the study does not meet best interest, it is lawful when conducted on children whose legal guardians/ parents have given consent and where the child has lawfully provided assent to the level that is appropriate to them (as in Gillick competency). We

observe that this is potentially pushing higher risk research in the direction of children, who are arguably more vulnerable than adults.

Adding to this is the confusion arising within the research sector (especially for new and emerging researchers) from the currently unlawful suggestion regarding the use of "proxy" consent within NEAC's Guidelines for Intervention Studies. Overseas researchers who are familiar with the use of proxy consent in other jurisdictions are baffled by the plethora of rules and competing legal requirements in this country.

The importance of clear and readily understandable terminology by applicants of who can give informed consent to research within the NZ environment is vital as different jurisdictions apply various meanings and uses across international clinical trial sites. Whilst strict compatibility is not required, it is beneficial if use of authorised persons or assent rules are synergistic with like jurisdictions, or where NZ departs from other countries, for example on the use of proxy consent, that the NZ rationale is consistently applied, communicated and understood. Sponsors accommodate jurisdictional differences if they understand the cultural reason for individual autonomous adult consent.

We note the reliance on legally authorised individuals in the Declaration of Helsinki where the research is not intended to benefit the individual "unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden". While Helsinki does not have legal bearing in New Zealand, it is widely accepted as the best available ethical standard, and we would support amendments to the law which bring New Zealand research regulations into line with it.

Without any change to the law with respect to whether another person is legally entitled to consent for research on behalf of another adult who lacks capacity, we believe that if the Code's 'best interests' were to be amended, any deviation from the best interests standard (e.g. to best-equal-interest) should be very small, and only be applied where:

- the proposed health intervention entails only minimal risk and burden; and
- the research is entirely impractical on consenting subjects; and
- the research question is important to the population of persons like those being considered for inclusion; and
- the numbers of incompetent persons enrolled are at the minimum level needed to answer the question; and
- a reasonable person would not object to enrolment; and
- participants' interests are protected and promoted equal to non-participants
- effective assent has been obtained from reasonably nominated representatives of the individual, involving the transmission of information to the level that would be required for consent; and
- the research has a social value involving real world relevancy, is likely to generate real world answers and where there is a likelihood of direct uptake by health services.[2]

[2] Habets, M. G. J. L., van Delden, J. J. M., & Bredenoord, A. L. (2014). The social value of clinical research. BMC Medical Ethics, 15(1), 66. doi:10.1186/1472-6939-15-66

Aside from these criteria we do not regard there to be any further potential justifications for including persons who cannot consent in studies. Including the determinants of social value in the criteria for judging the acceptability of non-consent studies will likely exclude protocols which are student-led studies conducted primarily for the purposes of attaining a qualification, and which are unlikely to have any direct uptake.

Whatever the outcome of the consultation and review, our members will continue to put the rights and welfare of individual participants first: protocols which expose vulnerable participants to experimental therapies which carry either unknown or more-than-minimal risks without consent fail to meet the recognised ethical standards of beneficence, non-maleficence, justice and respect. However, if the law were to accommodate protocols of minimal risk and burden (without a legal proxy consent), and which did not necessarily offer a benefit to the individual concerned, certain types of important research which are currently disallowed could proceed. These would include, for example, a routine intervention within observational research, such as an extra blood draw or assessment in a comparative effectiveness study. Applying a minimal risk threshold in the consideration of lower risk interventional and evaluation research, such as the evaluation of a modification to a rest-home environment or music therapy for residents with dementia would allow such research to meet both ethical and legal standards, so long as all other safeguards with respect to privacy, dignity and confidentiality were in place. In these circumstances, we believe that there is a strong public and scientific interest in permitting research where the burdens born by vulnerable non-consenting persons are not above minimal. Such a threshold of minimal risk is routinely applied in international ethical jurisdictions, and clear guidance about what constitutes minimal risk research is available.

We believe that the current law rightly prevents research from occurring where persons are enrolled into protocols without consent as a matter of them being a convenience sample, or where researchers wish to discharge themselves from their vital obligations concerning informed consent. While some New Zealand researchers demonstrate a high level of sophistication with respect to ethically reflective practice, unfortunately many do not. We continually have to remind researchers of their ethical obligations, both in interventional and observational research. Ethical conduct is as much part of research integrity as study justification, protocol, independent peer review, recruitment practices, and data safety monitoring.

We have responded to Case Studies A-E below. Rather than directly answering the questions posed we have instead responded by summarising what would be the key factors and conditions of approval in reaching a committee's decision as per current law and our Standard Operating Procedures, should these be real cases presented to us. Where we think current law might benefit from amendment, we have noted this. We hope you find this approach useful.

We note the Commissioner's own commentary on each of the cases suggesting that *none* of them meet the Best Interest test. However, in our practice we draw a distinction between interventional research and observational/evaluation research using only routinely collected health information. We do not believe that evaluative or information-only research needs to meet Right 7(4) as it does not entail the 'provision of a service'. However the use of health information does need to meet the Health Information Privacy Code, and in the case where its use is without consent we apply Clause 6.43 of NEAC's Observation Guidelines and Rule 11 of the HIP Code.

HDC Jurisdiction

We also note the Consultation documents' advice that health research conducted by non-providers (e.g. academics) is outside the jurisdiction of the Commissioner. We advise that in practice we do not draw an ethical line between research conducted by a physician and that conducted by a university researcher (staff or student), or a manufacturer of a device: where persons who cannot consent are considered for a health intervention study, the study has to meet best interest since research and treatment are interwoven, especially where the individuals concerned are vulnerable and have complex and multi-disciplinary health needs. Where any participant faces risks which are of clinical concern these must be managed clinically. The conduct of a study and safety of participants is a core ethical issue. It would concern us very greatly if health consumers in interventional research were protected unevenly, dependent on whether the researcher was also a health provider, or not. We reiterate that if a consumer is enrolled as a subject in a health or disability study the rights and protections of the Codes are theirs, regardless of who is conducting the study.

Further Points

Before concluding we would like to respond to the other questions raised in the Consultation. Firstly, the question of 'deferred or delayed' consent: we find this terminology problematic as it implies that consent for the intervention may be given retro-actively. We note Helsinki's use of the phrase "consent to remain in the study" in Article 30: this is not consent to have been previously randomised, but rather an agreement obtained after the acute phrase of treatment when persons are well enough to understand that they have a choice of whether or not to allow their health information to be used for research, and to take part in any on-going follow up.

We are extremely cautious in providing approval for research involving opt-out consent processes, and are not persuaded by arguments based on the cost effectiveness and efficiencies provided to researchers by these. We do not believe that doing nothing represents an act of truly informed consent, unless there has been a very comprehensive awareness campaign directed at the persons who are likely to meet a study's inclusion criteria.

Similarly, *any* expression or act of dissent by persons who cannot provide a legal consent must be regarded by an investigator as refusal or withdrawal. This acceptance of dissent is standard practice amongst researchers working in early childhood, and we see no reason to accept a variation of this for adults who cannot consent.

We are not familiar with studies where investigators are relying on a blanket advance directive concerning health research. Our view is that the decision to take part in research must be made on a case-by-case basis, and following the provision of full information about the risks of the particular study. We do not foresee a situation wherein a person could give blanket consent to any future research of any nature in the event that they should become unable to provide consent.

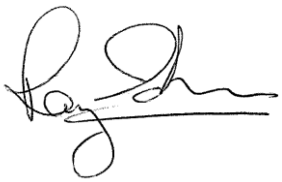
As HDECs and other accredited institutional ethics committees are essential to the protection of the human subjects, prior ethics committee approval should be mandatory. While we have confidence in strong DHB and University policies regarding ethics review, and *hope* that the entirety of health research receives prior review by an ethics committee, we are very keen to see any remaining gaps closed. The mandatory review by an Ethics Committee should be included within primary legislation, and we suggest that the Therapeutic Products Bill may present a good opportunity to insert this into the Regulations.

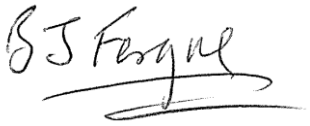
Conclusion

In conclusion, HDECs are very mindful of achieving the proper ethical and legal balance between achieving better health outcomes across populations, including for our most vulnerable peoples, whilst maintaining a very high level of protection for every individual involved in research. The intent of Right 7(4) is absolutely correct in that it ensures that very vulnerable persons are provided with the highest level of protection. However, we suggest that extra clarity could be provided by inserting a research specific clause within the Code which, for example, drawing out elements which contribute to optimising the trade-off between protection in minimal risk research and health-care advancement. Further, adjustments might be made within legislation concerning the provision of consent to research by legally authorised persons, and mandatory ethics review.

We look forward to the outcome of this Consultation. We would appreciate the opportunity to meet with you to discuss “Next Steps” and any emerging trends from the consultation.

Yours Sincerely,





APPENDIX I

Case Study A: Observational study measuring clearance of antibiotics during dialysis

Research Aim: to determine the rate at which routinely administered antibiotics are cleared during dialysis in order to be able to know which antibiotics which are removed less rapidly, and that therefore may remain in the body longer for therapeutic effect.

Acutely unwell patients (who may not be able to give consent) will receive antibiotics and dialysis as per routine clinical treatment plans. Participants will be observed during dialysis. This involves extra measures (urine, blood) taken to determine anti-biotic concentrations as the dialysis proceeds. However minimal the risks, these extra tests cannot currently be deemed as in the individual's "best interest" – i.e. the participants are not better off by being in the study, although future patients are likely to benefit from the knowledge gained. Therefore, under current law an HDEC could approve the study only with consenting adults. However it is probable that only a very few consenting adults could be enrolled due to the serious nature of the condition, even if reasonable steps were taken to ascertain the views of persons interested in the patient's welfare. The resulting sampling bias would significantly undermine the power of the study to produce meaningful results.

We consider that in this case the research with non-consenting patients is ethically justifiable; it is n important research that matters to the population of persons with sepsis and which is designed to improve standard-of-care; the extra testing involves no-more-than minimal extra risk of harm than treatment, and the overall weighting of benefit over risk is favourable. It is research that we expect a competent and informed person to consent to. In this research we believe that once patients are well enough to receive information about the study, it would be necessary to attain their agreement for any on-going follow-up and for their health information to be used for this research, or provide them with the opportunity to withdraw their information from the study.

Is the current law appropriate? No

The argument of additional blood draws and/or monitoring is sometimes used persuasively as a benefit for the individual research participant because of the resulting closer monitoring. In real time studies these extra tests may inform practice in stages. In general terms however, increased monitoring is not supported by evidence as a benefit to participants over non-participants[3]. We note that hospitals that embed research into clinical practice and have research facilities do have better quality outcomes overall.

How should current law be amended? To allow interventions that carry no-more-than-minimal extra risk of harm, which are part of an observational / evaluation study about of standard-of-practice, and which are accompanied by sufficient safeguards (including review by an ethics committee).

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

Research aim: this is a comparative effectiveness study of two products, currently used as standard of care by surgeons to close membranes after brain surgery. As there is genuine uncertainty about which of the two products produces better/safer results, current treatment is subject to randomisation by surgeon's choice. The proposal involves removing this aspect

[3] Vist GE, Bryant D, Somerville L, Birminghem T, Oxman AD. Outcomes of patients who participate in randomized controlled trials compared to similar patients receiving similar interventions who do not participate. Cochrane Database of Systematic Reviews 2008, Issue 3. Art. No.: MR000009. DOI: 10.1002/14651858.MR000009.pub4

of clinical judgement, and generating random assignments for surgeons involved in the study. Research participation also involves routinely collected post-surgical outcome data. While a few subjects may have capacity for prior consent it is likely that many are incompetent due to the nature of the condition. The researcher has argued that it is important to include both categories of participants in order to generate meaningful results.

We consider that this case is at the margins of best interest, and is typical of cases that challenge our committees with respect to their lawfulness. The researcher's claims that both products are standard of care, the degree of randomisation to the products was essentially the same as surgeon's choice, and there is genuine equipoise between them are insufficient to meet best interest. The researcher would need to supply HDECs with evidence that participants were made better off by inclusion, perhaps by closer monitoring. If such evidence were supplied, HDEC approval for the trial in incompetent adults would be based on

- Independent peer review - including from a surgeon not involved in the study – unequivocally confirming the investigator's uncertainty about the relative safety and effectiveness of the study products, and justification of incompetent persons; additionally, bio-statistical evidence regarding the minimum number of inclusions to generate a reliable result that was not confounded by the random element of different surgeons;
- Reasonable steps would be taken to ascertain the views of persons interested in the welfare of incompetent persons; enrolment into the study would proceed only if it were consistent with those views;
- The provision of details of the constitution of the independent data safety group;
- If this study were presented as a RCT of a new product it would not meet the best-interests test for incompetent persons. Nor is it likely to meet any minimal-risk or best-equal interests thresholds applied.

Arguing best interest convincingly in this case is not easy. Without diminishing the investigators (or the surgeons') responsibility to provide best care for persons who are acutely unwell, it is important to acknowledge that without a properly conducted scientific trial these physicians remain uninformed about what best care actually is. A learning health system is one in which care and research are in a continuous and two-way loop with each other. We believe that if HDECs were unable to approve this study in accordance with Right 7(4), the Right needs minor revision, perhaps to a 'best equal interest' level. Any trials that were to be approved under this test must also be subject to close scrutiny and review.

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

Research aim: To compare conventional care with interactive / psychosocial care in a rest home setting in patients with severe dementia, using psychiatric and QoL measures. Both arms of the study will receive additional study related (non-interventional) qualitative assessments. The balance of benefit over risk of these assessments is declared as unknown: there is a risk that participants will find the extra interaction with researchers distressing. While a few participants will have capacity, it is intended to include incompetent persons.

> Note: The Case fails to describe whether participants in the interactive arm would receive conventional physical care *plus* the psycho-social care, or whether the physical care would be withheld. In this discussion we assume the study compares standard of care vs. standard of care plus intervention (i.e. physical vs. physical plus psychosocial).

We believe that under current law HDECs would have difficulty approving this study for incompetent persons given the investigator's expressed doubt about incremental risks for those receiving the intervention. We would certainly probe this uncertainty, as given sufficient information upon which to base a decision, our members would be inclined to agree that interventions involving more person-centred care, which allowed for a greater quantum of quality human interaction designed to combat loneliness and to optimise personhood would meet "best interest" when compared with standard of care alone. Any approval would be based on sufficient evidence that any residual risk of distress during study assessments would be no greater that the risk of distress in residents during routine interaction with rest-home staff, and would also be subject to the following provisions:

- Provision of further detail to satisfy the committee that the benefits of person-centred care outweigh the risks. We would expect peer reviewed evidence of the demonstrable benefit of the intervention in an equivalent setting with competent (e.g. mild dementia) participants.
- Demonstration of the reflective practice of the CI, and provision of evidence of their suitability to undertake the study; as part of this we would expect that all potential participants would be informed of their involvement in the study as much as possible, that their decision making was supported, and that any indication of dissent was taken as a refusal to participate;
- Scrutiny of the programme manual for the intervention arm, provision of all assessment measures, and evidence of independent peer review of their appropriateness in this setting;
- The establishment of a data safety monitoring body who could assess the study data on a regular basis and who could advise study termination at the point at which it was clear that one arm of the study was clearly doing worse than the other.
- We would suggest that an additional assessment point be inserted mid-way through the trial period, and that this data is given to the study monitor;
- Provision of assurance of how any indications of distress in the assessments would be managed (including recording / reporting as an adverse event), and that consideration of withdrawing these participants from further assessments would be given; for those randomised to the intervention arm, withdrawing participation would mean that the individual was returned to standard-of-care without additional study assessments;

- That study co-ordinator would take all reasonable steps to ascertain the views of persons interested in the welfare of the potential participants, and obtaining their informed agreement for participants if enrolment in the study is in line with these.

Is the current law appropriate? No. Until such time as the investigator could provide evidence of best interest (perhaps as a result of closer monitoring, or best care plus proven beneficial intervention) this study would not be approvable, despite our members' agreement that the application of psycho-social care is highly likely to be valuable to the individual. In this case it is clear that best interest is too high a bar, and might lowered to allow research with minimal risk or best-equal interest, so long as all other appropriate safeguards (including ethics committee review) were in place.

We additionally note that this is the kind of study that would be presented to HDECs as being led by a non-provider, e.g. a PhD student. While the provision of the locality authorisation of the rest-home provides a measure of security, we would assume that the potential participants were entitled to the kinds of protection ensured by the Code, regardless of who was leading the study.

How should current law be amended? In this case it would be helpful if a legally authorised representative was allowed to provide consent on behalf, and if a minimal risk threshold (i.e. does not involve devices or new or inappropriate drugs) were applied. We would support the adoption of reasonable proxy consent in the New Zealand context, as allowed by law.

Case Study D: Clinical trial regarding use of adrenaline

This study involves withdrawal of standard of care (adrenaline following cardiac arrests) using an opt-out consent process.

HDECS would not approve this study for persons who cannot consent under current law regarding best interest: the withdrawal of standard of care cannot be proven as best interest. Nor might it meet any future best-equal interest or minimal risk threshold.

The attempt at consent in this study does not meet our standards of informed consent, either. We do not consider the opt-in consent protocol (indicated by not wearing a study issued 'opt-out' bracelet) to be sufficiently robust evidence that consent is informed. Even after a very large (and expensive) public information programme delivered in multiple first languages and in a wide variety of settings, there could be absolutely no guarantee that a patient presenting with a heart attack and not wearing a bracelet had given a fully informed consent to be part of a study whereby s/he would be randomised to standard of care vs. withdrawal of the standard. We would expect that those who had gone to the effort to receive a bracelet had the opportunity to obtain full information about the study and weigh up the risks and benefits for themselves. Even in the unlikely event that opt-out were approved, and given that the nature of the study involves long-term follow-up, we would expect those randomised to be informed about the study once the emergency was over, and be given the opportunity to withdraw from long-term follow up.

Is the current law appropriate? Yes. Best interest is the appropriate standard where risks are more than minimal, such as where standard of care is withdrawn from non-consenting people until such time as there was genuine equipoise between the arms of the study e.g. by using small scale studies with consenting patients (e.g. those at very high risk of cardiac

arrest who had received sufficient information about the study from their general practitioner and had the opportunity to provide a prior consent to the randomisation)

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

A new drug therapy being tested to see if it impacts cognitive ability in persons with Down syndrome. Risks may include suicidality. Regular long assessments.

This Case is an excellent example of one in which would not be given approval for incompetent adults even if the best interest law were moderated by including a minimal risk threshold. When this Case was presented at HDECs it was made clear by the applicant that Down adults would be very unlikely to have capacity to consent. Incidentally, we were also advised that very few primary caregivers of adult Down had progressed to formally obtain an EPOA.

This Case exposes the anomaly in current law discussed previously, since HDECs could approve this study for children with parental consent, but not for adults with Down syndrome. It strikes us as potentially unfair that the current law with respect to consent-on-behalf pushes this type of research, (which clearly has more-than-minimal risk) onto children who are arguably more vulnerable than adults. It is important to note that the research with children is permitted only in so far as it meets our requirements with respect to managing the risks adequately, including by an i*ndependent* data and safety committee, and conducting the trial according to GCP standards.

The consultation with family/ whanau/ caregivers is certainly necessary, but does not provide sufficient protections for incompetent participants, given the very complex science involved, and the difficulties in presenting information about risks in a way that lay person can easily understand.

Is the current law appropriate? Yes and No, the current law protects adults who cannot give consent for research where they may face serious risks of harm. However as noted, the current law does allow higher risk research on children, with parental consent: it seems strange to us that a parent / legal guardian of a 15 year old can choose to enrol their child in this study, but a parent of a 17 year old cannot.

If allowed by law, we would be satisfied with the proxy consent by a legally authorised representative of an adult Down participant, if they had sufficient information presented in lay language for making an informed decision. Assent of the Down participant is of course also required.

APPENDIX II – Summary of General Consultation Questions

Consultation Question 1

1.1 Do you believe research should ever be allowed to proceed with adult participants who are unable to provide informed consent?

YES, persons who cannot consent are also likely to face complex health problems that are specific to them. There is an imperative to continually improve health-care by applying the findings of high quality and safe research.

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

YES, regardless of who is conducting the research, the rights of safety and protection apply equally. However, research occupies a very wide spectrum of risks, utility, and importance. This multi-facetedness requires laws that are flexible enough to account for a variety of contexts, and not be too blunt to be of insufficient use in all circumstances. There is no question that all research has to be ethical. Our current experience is that some low-risk and potentially quite useful interventional research is, while ethical, disallowed by current law.

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?

Yes - respect for any individual's wishes is fundamental to ethical research.

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?

No – a person cannot provide consent retrospectively; however, consent may be obtained to remain in the study and for the use of previously collected information.

Similarly we have concerns about the use of opt-out consent protocols except in very exceptional circumstances where doing nothing can be reasonably regarded as an informed and voluntary choice of the individual.

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 – It is up to the investigator to provide sufficient evidence to an ethics committee, that the research question may not be answered adequately by persons with capacity.

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 and No - while the potential for the research to provide wider benefit may be taken into account, these interests cannot override the interests, rights and welfare of an individual participant. The Declaration of Helsinki permits minimal risk research where the research benefit is not applicable to the individual and the additional blood draw, for example, imposes little real risk for the individual.

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?

Ethics Committees are an essential component of a suite of measures designed to safeguard the rights and welfare of research participants. Therefore, and as a first step, all health and disability related research must be subject to prior ethics committee review.

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

7.1 Do you think the current best interest's 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?

Yes and No – in cases where the risks of participation are more than minimal, respect for the autonomy of competent consumers means that they can weigh up the risks of participation for themselves. However, in persons who lack this capacity additional protection mechanisms must be in place. As previously described, best interest may be argued for in a variety of ways. However we remain concerned at Right 7(4) setting the highest standard for research which carries a minimal risk of harm. In such research we would be satisfied to apply a law which allowed research in which participants are not made worse off by participation compared with non-participants, where the research is important to people like the ones being considered for participation, and is carried out properly. In addition to the criteria for ethicality and integrity applied to research in general, we suggest that the following criteria be included in the criteria for the permissibility of non-consensual research:

- the proposed health intervention entails only minimal risk and burden; and
- the research is entirely impractical on a consenting subjects; and
- the research question is important to the population of persons like those being considered for inclusion; and
- the numbers of incompetent persons enrolled are at the minimum level needed to answer the question;
- a reasonable person would not object to enrolment; and
- effective assent has been obtained from reasonably nominated representatives of the individual, involving the transmission of information to the level that would be required for consent; and
- the research has a social value involving real world relevancy, is likely to generate real world answers and where there is a likelihood of direct uptake by health services.

Response to HDC Consultation

"Health & disability research involving adult participants who are unable to provide informed consent"

from

mental health client with Post Traumatic Stress Disorder.

Dear Sir

I was very keen to respond to your consultation but the questions did not fit the feedback I want to give you.

In 1990, I went into the Pain Clinic at Auckland Hospital for treatment for an intractable headache (daily for 18 months).

At this time I was a successful teacher.

I was told the Pain Clinic programme was a one month inpatient treatment.

I was very keen to get rid of my headache. In my naievity, I believed this was a bona fide treatment for pain.
At no time was I told my pain was considered a mental illness, or that I was about to enter the psychiatric system. I did not give informed consent.

As soon as I was admitted, I began to be treated less than respectfully, and was bewildered and confused.

The pain management programme was full of new age experimental "treatments". I had

P.T.O

(2) not given consent for this. I was an intelligent adult. In the absence of information to the contrary, I had the right to expect standard medical treatment, not to be subjected to an experimental programme.

I was pressured to participate in sessions involving meditation, hypnotherapy, biofeedback, reflexology etc. When I tried to withdraw consent for hypnotherapy, I was banished from the group; sent back to my bed like a naughty child.

We were made to participate in physical exercise every day. One activity was a speed walk. One day I had cystitis & said I would not take part. I was told participation was compulsory! ("Non-negotiable!") It was definitely experimental research without consent.

Every day the group was made to fill out feed-back forms & were expected to say they were getting better.

At the end of a month, we were given diplomas (tied with a red ribbon) indicating our success. The group met (independent of the hospital) for a long period after, and no-one was better. We had effectively been told our pain was all in our heads and if we were prepared to "give it up", we would get better.

After I was discharged I had a headache, was traumatised by my experience and was now suicidal. What had begun as a physical/medical problem was now very much a mental health issue. I was referred to Claybury House at Kingseat Hospital.

③ At Claybury House, I was asked to sign a form, not for participation in the Claybury programme as such, but for psychodrama. No-one who has no experience of psychodrama could possibly understand the ramifications of participating. And by now I was mentally unwell (as were all Claybury patients), so on two counts, my consent could never be considered informed.

I spent 5 months in Claybury House. I stuck it out because I was told if I gave it my all I would get well. I was told I would be back at work in 3 months and that they had a 90% cure rate.

Claybury House did not conform to any standard medical or psychological standard. It was again an experimental programme using mental health patients who could not give consent, informed consent, because they had no way of knowing how the programme would impact on them.

Four of the 21 women in my group later committed suicide. Far from a 90% success rate, there was not even a 90% survival rate.

Throughout the programme, patients attempted to withdraw consent. They were forced to participate under threat of expulsion. We were told if we "voluntarily" withdrew from Claybury, no other branch of the mental health services would be allowed to treat us. We would be referred straight back to Claybury.

PTO

(4) A number of patients tried to run away, or overdosed. One tried to hang herself.

After discharge I made a complaint to the District Inspector, and this led to the Claybury Inquiry. Despite expert after expert testifying Claybury practices were appalling, it was all swept under the mat.

I was sent to Ashburn Hall for 9 months at the DHB's expense.

When I got out I made an ACC claim and medical negligence was accepted. I was found to have a 70% permanent disability. I was on ACC until I reached 65 years of age. I was never able to return to my profession.

We sought a review of the Inquiry, and the all-female panel recommended compensation, which the DHB refused to pay.

Three patients brought a case against the health board and we were given an out of court, confidential settlement.

I have an open apology from the Director General of Health.

My mental health was destroyed by these two programmes – in effect research without authorisation. The issue of informed consent is very important to me.

⑤ In regard to research in mental health, I don't feel any patient should be required to give consent. When you are unwell and desperate, you're not in a good place to weigh up your options.

No patient should be co-erced into participating into something they don't feel comfortable about. The "research" programme must not be presented as their only option.

Mental health patients should be allowed to withdraw consent at any stage. And should be provided with alternatives.

At Claybury, patients were told we were not allowed to tell anyone outside what was happening. Concerned family members did complain, and this led to the patients involved getting publicly humiliated and threatened with expulsion.

You couldn't just leave. What could you do if you were mentally unwell, suicidal, and had been told you couldn't access any other services?

Family members / friends must be allowed to be involved in decision making if a patient is too unwell to give informed consent.

The other thing I was terrified about while "in the system" was being committed. After I made my complaint I was terrified of being committed, and being rendered unable to tell my story, by compulsory

PTO

(b) drugs or ECT.

At one stage, when I was suing the psychiatrist at Claybury House, a diagnosis (Factitious Disorder) was given as a punishment, to destroy my credibility. It was a thoroughly fictitious diagnosis, but made me realise how powerless a mental health patient can be. (Twelve months later, it was quietly withdrawn.)

We need the protection of very robust systems so we are not experimented on, as I was. "First do no harm."

Kind regards

NZMA
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

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[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

Point of View

Intensive care unit research ethics and trials on unconscious patients

G. R. Gillett*

Summary
There are widely acknowledged ethical issues in enrolling unconscious patients in research trials, particularly in intensive care unit (ICU) settings. An analysis of those issues shows that, by and large, 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 of accessing 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 (according to international evidence-based treatment guidelines). Given that we have discovered a number of 'best practice' regimens of care that do not optimise outcomes in ICU settings, it is of great benefit to all patients (including those participating in research) that we are constantly updating and evaluating what we do. Therefore, the practice of ICU-based clinical research on patients, many of whom cannot give prospective informed consent, ticks all the ethical boxes and ought to be encouraged in our health system. It is very important that the evaluation of protocols for ICU research should not overlook obvious (albeit probabilistic) benefits to patients and the acceptability of responsible clinicians entering patients into well-designed trials, even though the ICU setting does not and cannot conform to typical informed consent procedures and requirements.

Key Words: clinical research, consent, incompetent patients, ethics

An increasingly difficult situation is arising in many jurisdictions in Australasia in conducting clinical research on incompetent patients (e.g. emergency department, stroke and dementia patients and critically ill patients in intensive care), including trials that compare different existing (or non-experimental) medical therapies that are not well-established in their effectiveness. These are often investigator-initiated, pragmatic, phase III or phase IV effectiveness trials (versus the commercial efficacy phase III trials). While guardian tribunals exist in some states in Australia and may grant permission for the next of kin to give informed consent for clinical research, many states still do not have any legal provisions to allow the next of kin to give informed consent for clinical research, although they can give informed consent for medical treatment including organ donation after cardiac death. In the past, many ethics committees used next of kin acknowledgement to allow incompetent individuals to be enrolled in clinical trials and with subsequent patient informed consent when they regained competence. This practice is, however, questionable and indeed the rules have been changed recently so that such a practice is only allowed in negligible or low-risk research when any adverse events associated with a trial cannot be more than just mild discomfort. Arguably, this conservative position reflects the relative (or absolute) ignorance that patients, families and policymakers have about the extent and quality of evidence to support much of the care provided in intensive care units (ICUs). Would attitudes to research be different if it was clearly understood that so little of what is done on a daily basis is based on high-quality evidence and, moreover, that when we do test things that we think are going to work we not uncommonly find the opposite? The issue is compounded by the problem that for many clinical trials on sick and incompetent patients, we cannot clearly determine whether any potential adverse events that occur during the course of ICU treatment are truly related to the trial intervention itself or the underlying disease process that causes patients to be critically unwell. Because of the conservative shift in practice by many ethics committees in Australasia, many investigator-initiated (or non-commercial) clinical trials have not been able to get through the ethics committees and, hence, are not able to be started, even when they are funded by the National Health and Medical Research

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Council (equivalent to the National Institute of Health in the United States or the Health Research Council in New Zealand).

But the divergence in perceived permissibility prompts certain questions. Is it acceptable that Australasian hospitals are condemned to treating their patients in increasingly outdated ways and yet are forbidden to contribute to the development of new methodologies of care? Is it ethical to the ethics committees if we treat all our patients in a certain way in one hospital and a completely different way in another hospital, when both ways of treating the patients are considered clinically acceptable but with uncertain relative effectiveness? Conversely, would it be unethical if patients in both hospitals are randomised to be managed by one of these two acceptable ways and would that change if any potential associated adverse events of the clinical interventions were more than mild discomfort? Should we go on rigidly adhering to established practices and disallowing innovation even if shortcomings in those established regimens are suspected?

In intensive care, there are standard practices which, as is the case throughout medicine, either outstrip the best evidence for their efficacy in the conditions they are used to treat or are being constantly improved to increase their safety and/or efficacy. ICU specialists are activists (and therefore, in one important respect, like surgeons) and experimentalists because they deal with a constantly evolving range of conditions that shift from the category of 'fatal' to the category of 'seriously life-threatening' or 'potentially rescuable'. ICUs also require rapid definitive intervention, often under extreme time pressure and despite considerable uncertainties about the clinical situation or the best way to treat it. Therefore, it is not surprising that many of our treatments, as in crisis medicine in general and in surgery, are based on current theories about the human body and its workings and things that have been found to work in some cases but not definitely proven as effective and safe interventions. In intensive care, we have near total control over what goes on in the body; we have drugs to manipulate bodily physiology, we regulate breathing patterns, we induce unconsciousness and so on. Importantly, however, we are working by guesswork as much as, and no more than, in any other complex area of science but the complexities of holistic human function can sometimes confound the 'knowledge' that our theories endorse (as we see in the case of alternative healing methods and things like the placebo effect). It is also clinically and ethically significant that many ICU interventions, applied in good faith in managing critically ill patients, can turn out to be harmful. What follows are some examples help to illustrate this point.

It is reasonable to believe that because blood carries oxygen and nutrients around the body and nature has designed the human blood system to work with a certain level of haemoglobin, then maintaining a level close to that would provide optimal conditions for healing and recovery from major trauma or illness. Not so. An important study found that patients maintained at a haemoglobin level of 100 to 120 g/l (close to the normal values of 120 to 180 g/l) fared worse than those who were only transfused when they dropped below 70 g/l[1].

It is plausible that patients who have cardiac arrhythmias after heart attacks are at greater risk of death than others and therefore, that antiarrhythmic drugs would be of benefit to such patients in terms of mitigating that risk. Indeed, it seems almost unethical not to give such drugs to patients after heart attacks. Not so. A prospective randomised controlled clinical trial of antiarrhythmics against placebos showed a totally unexpected increased death rate in the actively treated group[2].

Decompressive craniectomy is becoming a valuable tool in the management of patients with severe traumatic brain injury on the basis that a number of studies have demonstrated that, in the context of intractable intracranial hypertension, either a bilateral or unilateral decompression can achieve the 'physiological' goal of lowering the intracranial pressure[3]. However, while raised intracranial pressure following traumatic brain injury is highly predictive of mortality, surgical intervention may not necessarily provide clinical benefit because the procedure is associated with a number of complications, many of which can have a significant effect on outcome. A recent Discovery Early Career Researcher Award study compared early bifrontal decompression with standard medical therapy for patients with severe traumatic brain injury and raised intracranial pressure (>20 mmHg for more than 15 minutes)[4]. It found that, although the intracranial pressure was lower in patients who had decompression, their outcome was worse than in those patients who received standard medical therapy[5]. It is therefore important that even something as compelling as an urgent life-saving surgical intervention should be thoroughly investigated by appropriate clinical trials.

In each of these cases, we see that plausible theories about the human body and how it works, apparently well-reasoned clinical practice and even felt demands to rescue patients[6] can mislead us about whether this or that intervention is beneficial so that we need careful clinical trials to tell us whether our beliefs about the right way of treating certain serious conditions actually are correct. Thus, there is a real need in intensive care (as there is in surgery) to perform the trials that will show us what should be done in a given clinical situation, but there is also a need to protect patients from unilateral decision-making that may put them at risk (as we saw in the Cartwright inquiry that led to a reformation in New Zealand medical ethics).

But this immediately provokes a set of questions about the need for informed consent to medical research. This need should be discussed in light of the facts already mentioned, which ground a number of substantial conclusions about research on those who cannot give consent. In fact, those conclusions are predictable from i) a rational preference for the best treatment, ii) an informed discussion of clinical decision-making, iii) the need for clinical trials in modern medicine so that we all benefit from evolving and improved medical care and iv) the best interests of patients who cannot speak for themselves. Six arguments for ICU research even on unconscious patients flow from these considerations.

Firstly, any person making choices about treatment should opt for the treatment that stands the best chance of returning him or her to health. There may, however, be specific reasons why some particular intervention is not acceptable to a person, for instance a Jehovah's Witness patient may, on the strength of their interpretation of the Old Testament, refuse a blood transfusion. We could also imagine a person with extreme racist views not wanting an organ transplant from someone of a different race—a decision which might be abandoned when the patient is in extremis. On balance, however, a treatment decision for any individual in accordance with the majority view is most likely to coincide with the view of the patient (absenting clear reasons to think otherwise).

Secondly, it is most rational for any patient to accept the best available treatment according to the current state of knowledge at the time of their illness and contemporary clinical care, particularly in academic hospitals, recognises that this is the prevailing standard of treatment. But it is quite possible that an ideally informed clinician would be unable to decide between a currently accepted standard treatment and a suggested modification or innovation. In such a case, the doctor does not know whether the treatment proposed for a given patient at a given time *is* the best thing to do or whether what is being trialled may be significantly better (given that safety assessments have been completed). Therefore, from the patient's point of view, the patient has no reason to opt for the standard treatment rather than the other possibility being considered. In fact, the patient, given that they and others like them may require further treatment at a later date, has a definite interest in doctors getting to know as much as possible about their condition and its treatment, so as to make well-considered judgements about ongoing management. This is most likely to happen in the context of a well-designed scientific trial where rigorous monitoring is the rule (and where the patient is guaranteed to get treatment equal to the currently accepted standard of care).

Now, given that a treatment in an ICU is only trialled if it is unclear whether a new treatment actually offers more benefit to patients than existing options, it follows that it should be a matter of indifference, ethically speaking, which of the two arms of a clinical trial (the treatment arm, where something new is tried, or the control arm, where standard treatment is used) any given patient is assigned to. For this reason it is best, on the grounds of self-interest or optimal care of the patient, for an ICU patient to be enrolled in a trial of treatment where a sensible question can be asked about how they ought to be treated.

Thirdly, it would be in accordance with good care and the best interests of patients, more broadly conceived of, for people to want to contribute to medical knowledge in conditions of uncertainty. This is almost self-evident because it is always good for a healthcare system to be extending and using knowledge about a patient and their problem and there are real benefits to a patient in being cared for by a medical system in which active clinical research is going on. Indeed, given that there is a certain amount of community feeling in all of us, we should all want the members of our community to benefit from lessons learnt when misfortune befalls any of us if we can be sure that gaining that knowledge will not increase the risks of our own clinical treatment. In retrospect, of course, it may turn out that patients enrolled in one or other arm of a study (sometimes the opposite one to that expected) have been disadvantaged by the clinical trial but that fact cannot be known at the time of enrolment and the dangers continue to exist until the relevant facts are discovered.

Therefore, we should conclude that clinical research trials of treatment in ICUs expose no patient to any extra risk over and above those that exist for them by virtue of their eligibility for the trial and that the cessation of that research means that they and their fellow citizens will probably be exposed to unnecessary risks in the future.

Fourthly, it is reasonable to assume that everybody has a degree of altruism, however limited, and that it should be encouraged by ethicists for the following reasons:

1. Most people have a positive interest in the wellbeing of the fellow members of their community and in the best treatment being used in the care of the community.
2. Where someone stands to gain by a community practice—such as best ICU treatment and the research that underpins it—we should support and participate in it.
3. We all recognise that altruism is something to which, in our best moments, we aspire so it does no harm to assume that people should be treated in a way that reflects that value (unless that decision runs counter to one's own objective best interests). Therefore, we should be prepared to be enrolled in properly conducted trials of ICU research even when we cannot consent.

Fifthly, relatives are often badly placed to make life-and-death decisions as has been objectively demonstrated and is easy to understand[7]. All the uncertainties associated with life-and-death decisions cluster around every conversation between an ICU team and relatives. In addition to the informational turmoil, there is an emotional cauldron—some

feel shocked, others guilty and yet others protective. So a mortal decision must be made in a context that is heavily overlaid by issues of technology, urgency and the power of the medical establishment; and there are often conflicted feelings so that it is unrealistic to believe that anything like informed consent can prevail. In reality, we can only hope for a sensitive and supportive partnership between the clinical team and the patient's *whānau* (extended family) and a climate in which a duty of care has been clearly thought through.

Sixthly, clinical staff have a duty to make the best decisions for any given patient, to be suitably sensitive to the realistic interests, concerns, fears and expectations of ordinary folk (and not be influenced by distorting factors such as extreme right-to-life or euthanasia views, the fear of litigation or financial gain). That implies that the best chance of getting soundly researched clinical care in an area of medicine where intuitions and theory-based reasoning can both mislead even the best of well-intentioned clinicians is if we continue to enrol unconscious patients in clinical trials. The invariant duty for a doctor or medical team to practice according to a good standard of care is universal and it sometimes means that the wishes of relatives, when they are not in accordance with a careful and informed assessment of the best interests of the patient, must be set aside. That implies that where there is an objective chance of better treatment within the context of a clinical trial than there is if we follow current established practice, we could be considered to have a duty to participate in and give our patients access to such trials. That duty and the decision that is made is the only rational expression of our professional duty to care for each patient and to make their wellbeing our primary concern.

So what is the ethically defensible alternative to the status quo? We should trust ICU clinicians to grasp instances of true equipoise and the need for further research and to carry it out in well-designed physician-initiated trials of treatment. Such regimens of care are held to, and the standards of accountability, professional scrutiny and clinical policy need to reflect that fact and be more clearly outlined to staff and patients. Society requires of us a high degree of professionalism and that should include i) 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 patient wellbeing, ii) external scientific review to ensure that what is being proposed in such a trial will see that appropriate existing standards of care are upheld for all trial participants, iii) solid pre-clinical data to exclude any known harm and support a real prospect of benefit for a new experimental therapy and iv) a commitment to trialling new treatments against best-standard regimens.

In reaching such a conclusion, any review body will need to consider not only the absolute risk of harm but also the additional (marginal) risk over and above the condition and its usual treatment. If two alternative treatments are in widespread use, but their relative effectiveness is not known, then a clinical trial to compare them and the relative indications for each is not merely desirable but, one could plausibly argue, the only ethical way to proceed.

It is always best for the clinical team looking after any patient to make an evidence-based plan for that patient's management, especially when the patient is incompetent and their life is in danger. It is clear that in ethical terms, this should be the default position and the plan should reflect best current practice (as practical in the context) with disputed cases being arbitrated by some suitably impartial body such as an ethics committee and with the courts being used only when, here as elsewhere in medical care, things cannot be managed in a better way. In any event, it seems that, in ethical terms, the general practice of doing ICU research should be commended under the condition that the clinical team, acting in good conscience, can enter their patients into well-designed trials, even where informed consent prior to entry into the trial cannot be obtained.

Editor's Note

Some of the issues discussed in this article have been published and discussed on the Internet through science blogs (http://sciblogs.co.nz/guestwork/2014/05/19/research-ethics-and-trials-on-unconscious-patients/>sciblogs.co.nz/.../research-ethics-and-trials-on-unconscious-patients; http://blogs.otago.ac.nz/bioethicscentre/>blogs.otago.ac.nz/bioethicscentre) and are elaborated in this article for further debate and discussion.

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HDC Consultation on research involving adult participants who are unable to give informed consent

Staff of The Nathaniel Centre

Introduction:

This submission is made on behalf of *The Nathaniel Centre – the New Zealand Catholic Bioethics Centre*. *The Nathaniel Centre* is an agency of the New Zealand Catholic Bishops Conference. Its role is to address bioethical and biotechnology issues on behalf of the Catholic Church in New Zealand.

General Discussion:

We note and endorse the idea that "The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of New Zealand's Code of Health and Disability Services Consumers' Rights", (HDC Consultation Document, p. 1). In a similar vein, we have previously written about the critical importance of informed consent, advocating that all people have a right not to be experimented on without their knowledge or consent, whatever the nature of the research.[1]

It is broadly accepted that the history of 'informed consent' in human research goes back to the Nuremberg Code of 1947. This Code was developed after the Nuremberg trials at the end of the Second World War which exposed the unethical nature of research carried out by many Nazi researchers. The lesson learnt from this and other well-known instances of unethical research, such as Tuskegee and Willowbrook, is *that justifying research on the basis of its potential benefits or outcomes alone, and without reference to the inalienable rights and dignity of human participants, all too easily leads to human exploitation and harm*. Upholding informed consent is one of the key ways in which the rights and dignity of research participants can be protected.

In New Zealand, current thinking and practices around ethical review and the centrality of informed consent have been informed by our own instances of unethical research, including the removal and retention of organs from deceased babies without parental consent and the 'unfortunate experiment' on patients with cervical cancer carried out at National Women's Hospital.

The current Code of Health and Disability Services Consumers' Rights allows research on a person who is unable to give consent to take place only if participation in the research is in the person's best interests. It thus reflects a strong commitment to the principle of informed consent. It also reflects a commitment to *ensuring that the interests of the person must not be subsumed to those of society*. In other words, it embodies a rejection of the main premise underpinning utilitarianism, the idea that 'the greatest good for the greatest number' is a sufficient measure of what is ethically acceptable.

If there are to be changes to the parameters which currently proscribe non-consensual research on adults, *it is critical that our society's commitment to the notion that the best interests of the person must ultimately always outweigh those of society* (Consultation Document, p. 44, n.3) *be upheld and not eroded in any way*.

We have previously argued that there can be legitimate exceptions to the requirement that informed consent be obtained from research participants, in certain exceptional circumstances. Thus, in 2015 we

[1] Kleinsman, J, and S. Buckley. "Facebook Study: A Little Bit Unethical but Worth It?" *Bioethical Inquiry* 12, no. 2 (2015): 179 - 82.

wrote that the "only exceptions to this are in circumstances where (i) the research is strictly observational or (ii) participants are, for various reasons, unable to give consent, in which case consent must be sought from someone legally entitled to provide consent for them." In the same article we also stated: "In exceptional circumstances, limited disclosure may be justified or consent might be obtained retrospectively, for example because of the need to avoid a biased response. It is also possible to seek a waiver of consent where the risk is low and where there are strong reasons why it would not be practical or possible to obtain consent." We then added: "… in these situations, the ethical rider is that such research must always be held up to close scrutiny by an appropriately accredited and independent review body."[2]

We note that current practice in New Zealand, by allowing consent to be waived in circumstances when it is deemed to be in the person's best interests, already constitutes an *exception* to the principle of informed consent, albeit a very narrow one. This debate, therefore, is about the scope of such exceptions in New Zealand and, more specifically, whether they might now be broadened to include some situations where research on a person unable to give consent is justified on grounds other than being in their personal best interests.

Our overall position is that *we are not in principle opposed to broadening the parameters which regulate non-consensual research on adult participants*.

Ethical Discussion:

Our response to the two fundamental questions posed in the Consultation document ("Are New Zealand's current laws regarding non-consensual research [involving adult participants] appropriate and, if not, how should they be amended?" (Consultation document, p.2)) reflects our belief that it is, *in theory,* both possible and ethical, in certain prescribed circumstances with adequate scrutiny and safeguards, to broaden the parameters that apply to non-consenting- adult participants in research.

We add the qualifier "in theory" because we believe that any moves to broaden the parameters around non-consensual research would be acceptable only within a system of robust, accredited and independent ethical overview. Given the experience of two of the writers of this submission who have previously served as members of an HDEC Ethics Committee for a combined period of 11 years, our concern is that *some of the more recent restructures of New Zealand's HDEC ethical review system have contributed to a less comprehensive and less robust system than was previously the case* – fewer committees and fewer members as well as a significantly narrower set of criteria for determining when research requires full HDEC review.

Any moves, therefore, to change the current law must, in our mind, first be considered against the current effectiveness of ethical review committees in New Zealand. In which case, a decision in principle to broaden the criteria for non-consensual research (which, as already noted above, we would support) *might be considered unworkable or unsafe in the current context of ethical review*. *The decision might, therefore, be made not to proceed with any changes for pragmatic reasons* even while it was otherwise considered ethically acceptable in theory.

In the event it was deemed practically acceptable to broaden the parameters, it is our firm belief that, because of the inherent risks in non-consensual research, such applications should require *an additional layer of scrutiny to what is already currently available* by a group under the auspices of the Health and Disability Commissioner's Office that includes *representatives of, or people able to speak on behalf of or advocate for, the group of persons on whom the research will be carried out*.

[2] Ibid.

When reflecting on why it might be ethically acceptable to allow non-consensual research on a person when it is not in their best interests and when it will introduce an element of risk, the obvious answer is that there will be benefits for others, whether persons in similar circumstances or, perhaps, society in general. Herein lies the greatest danger in broadening the parameters of non-consensual research because any such move inevitably opens the door to the sorts of utilitarian arguments and premises that have characterised unethical trials such as Tuskegee and Willowbrook.

This danger reinforces for us the need to de-lineate three other parameters when evaluating non-consensual protocols: (i) 'the interests of the person must always be assumed to outweigh those of society'; (ii) in situations where this is not clear for a specific person, the 'precautionary principle' must be automatically invoked which dictates that the person not be included and (iii) *any expression of dissent* ("whether by showing signs of resistance or otherwise" – Mental Capacity Act 2005 (England and Wales) as quoted in Consultation Document, p. 43) from a potential participant incapable of giving consent should be regarded as sufficient reason for them not to be included (see also Declaration of Helsinki, as quoted in Consultation Document, p. 58).

In addition, as we highlighted in our submission to the National Ethics Advisory Committee (NEAC) on Cross-sectoral Ethics Arrangements for Health and Disability Research (February 2015), we see that it is a significant weakness of the current system of ethical review in New Zealand that there is no mechanism for checking that a particular study is carried out according to the agreed ethical protocols. We believe that such follow up should be mandatory for all non-consensual research projects, something that will require a specific mechanism to be created and funded. This requirement, we note, is stipulated in Paragraph 24 of the Declaration of Helsinki under the heading of Research Ethics Committees: "The committee must have the right to monitor ongoing studies."

Whereas some might see such requirements as creating unnecessary barriers for researchers, we see that they will ensure that non-consensual research proceeds only when it is absolutely required, and that it will be characterised by a strong focus on ethical practice.

An Adjusted Framework for Non-consensual Research on Adult Participants:

Our suggestion is that an adjusted New Zealand Code follow and reflect the relevant sections of the Declaration of Helsinki which address the question of non-consensual research:[3]

> 28. *For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to* ***promote the health of the group represented by the potential subject****, the research* ***cannot instead be performed with persons capable of providing informed consent****, and the research* ***entails only minimal risk and minimal burden****.*
>
> *29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative.* ***The potential subject's dissent should be respected****.*
>
> *30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients,* ***may be done only if the physical or mental condition that***

[3] Declaration of Helsinki. 64th WMA General Assembly, Fortaleza, Brazil, October 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (emphasis added)

***prevents giving informed consent is a necessary characteristic of the research group**. In such circumstances the physician must **seek informed consent from the legally authorised representative**. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been **approved by a research ethics committee**. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.*

In summary, we argue that the key points of an adjusted Code which would broaden the parameters within which non-consensual research could be carried out in New Zealand are:

- The research cannot otherwise be carried out using participants capable of providing informed consent and …
- The research will directly promote the health of the group represented by the potential subject and …
- The research entails only minimal risk and minimal burden and …
- The potential subjects dissent, however it is expressed, is respected absolutely and …
- The research may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group and …
- Informed consent is sought from a legally authorised representative and …
- The research is given a full review by the appropriate accredited HDEC Committee and …
- The research is subject to an additional layer of scrutiny by a group that is overseen by the Office of the Health and Disability Commissioner, a group which includes representatives of, or people able to speak on behalf of or advocate for, the group of persons on whom the research will be carried out and …
- There is ongoing, independent, effective and active monitoring of the research project while it is being carried out and …
- The participants' confidentiality is absolutely respected and …
- In cases where a participant regains consciousness after having been included in a trial, they are given the option of having their data withdrawn where that is possible and …
- Any data that is retained after a study is only be able to be used for further research in an aggregated or totally anonymous form unless separate independent ethical consent is sought.

Conclusion:

We are in principle open to the parameters of non-consensual research being broadened within New Zealand in line with the World Medical Association Declaration of Helsinki that we have outlined above. What we are proposing would involve moving from the "best interests framework" that characterises current practice in New Zealand to one that takes account of and permits a degree of minimal risk and minimal burden to participants.

The key questions in moving to an approach that tolerates a degree of risk are 'Who decides?' and 'How will assessments about "minimal risk" and "minimal burden" be made?' For this reason we have argued that there must first be a degree of confidence in the current system of ethical review in New Zealand. That is, a determination must be made that the HDEC review committees are adequately resourced and adequately trained to foresee and prevent the sort of excesses that have characterised research on vulnerable persons throughout the 20th Century in numerous places around the world including New Zealand.

While broadening the parameters of non-consensual carries inherent attitudinal risks because it can dispose society to the dangerous excesses of utilitarian thinking and make certain actions which undermine the inherent dignity of persons seem morally acceptable, we think this risk can be safely managed by the introduction of an additional layer of ethical scrutiny that is carried out under the auspices of the Office of the Health and Disability Commissioner.

John Kleinsman (PhD) is director of The Nathaniel Centre and a former member and Deputy Chair of the Central Region Health and Disability Ethics Committee. He is a current member of two Institutional Research Ethics Committees.

Sue Buckley (MA(Applied) Soc.Sc.Res) has been involved in social and health research over the last 16 years in both government and university contexts.

Associate Professor John France (PhD, DSc, FAACB) is a reproductive scientist (now retired). He is a former member of the Auckland Health and Disability Ethics Committee and former member and Deputy Chair of the Northern Regional Health and Disability Ethics Committee.

FILE NOTE

DATE: 4 May 2017

CLIENT: HDC - RESEARCH

Focus Group Tauranga 4 May 2017 9.30 am – 1pm

People First –

worked through the Easy Read version of the consultation document with 8 members of the Bay of Plenty branch of People First ( ) and three assistants (.

The comments captured below are individual responses except where noted as a collective view.

1. General discussion about involvement in health and disability services:
    a. Importance of talking directly to the Person, not their parent or support person when in hospital.
    b. Importance of "nothing about us without us".
    c. Importance of the Code of Rights. Good awareness of existence and relevance of Code (general theme).
    d. Want things explained, not dropped "in at the deep end". Want to be informed about things that happen to me.
    e. What if a Person lives with their parents? Do they have to ask their parents?
    f. Importance of information being provided in a way I understand.

2. Importance of feeding back to this group the results of the consultation process when released by the HDC.

3. Case Study 1

    a. "No" because of risks of possible changes in treatment.
    b. 50:50 yes: no because might be beneficial but then again might not. Not clear enough benefit for me. My parents would help me make that decision.
    c. I'd like to make the decision but sometimes information can be confusing. I would like someone to help me make the decision. I get given conflicting information sometimes.
    d. I was in an residence for a long time and do not have any family. I live independently now but if I have to go to hospital I take someone from I have known for a long time and knows me really well and we have become really good friends. She isn't a welfare guardian or an EPOA but a friend.
    e. My brother helps me with some decisions like spending a lot of money on something. If I could not understand a decision [like research] I would not want someone else making a decision to enroll me even though my brother helps me on other things.

f. Is there a way of checking someone's wishes about things like research if they can't communicate? [discussed advance directives – general agreement that a central register would be useful to record wishes regarding research, organ donation and donation of body for medical research. Not in favour of families being able to override an individual's instructions as sometimes happens with organ donation.]
g. No one else should be able to enroll me in research or make that decision for me. I would worry about the effects on my medicines.

4. Case Study 2
    a. I would like to be able to write out my rule about my participation in research.
    b. Some doctors are better than other doctors; they are not all the same. [Discussion around it sometimes being difficult to say "no" to a doctor].
    c. Discussion around involvement in decision making in health care – I chose to have treatment to my teeth. I could tell the doctor about my eye jumping. My support staff made the decision to call the ambulance but once I was in hospital it was my decision to tell the doctor and the doctor talked to me and I was involved in that discussion.
    d. Delayed consent is never OK – general theme.
    e. Comments from assistant – I would participate in any research if it helped others. Note that this comment did not prompt any agreement from the PF members.
    f. The doctor is the expert on the operation.

5. Case study 3
    a. I'd say "no".
    b. It's a tricky question so I'd say "no".
    c. [assistant] I'd definitely agree.
    d. You could sign something before you got dementia and before you got worse. If you got dementia it would be good to be able to record your wishes before you got worse.
    e. There's no cure for dementia at the moment so I would want to be part of the research.
    f. I would want to make sure that the researchers/staff were safe and didn't have a criminal record.

6. Case study 4
    a. If I knew what the medicine was and the doctor could explain it to me then I would agree.
    b. If I go to the doctor I want to know the side effects of the medicine.
    c. I think this is risky.
    d. Sometimes medicine doesn't work.
    e. "No" because there is no information.
    f. I don't like the opt-out bracelet idea.

7. Case study 5
    a. I wouldn't think it's right to get consent from support people. It's better to have family to help. In my house some people have no family so a social worker should be involved.
    b. Not everyone has family.
    c. If people can't give consent they should not be involved.
    d. Should ask family to help with decision making or support workers if there is no family.
    e. General agreement – don't participate at all if can't consent.
    f. Staff can look at files to help make a decision if a person's wishes are recorded. But confidentiality is important.

g. All sorts of people are on the staff. Not just one staff member should make the decision. Senior staff should be involved too. I would not want to take part if there was any risk to me.
h. A range of people should be involved in helping me to make the decision.

8. General discussion
    a. If risks are unknown I don't want to participate.
    b. If someone can't speak and they don't have an advance directive then they should not be enrolled in research.
    c. If someone looks like they are in pain or are anxious they should not have to continue in the research.
    d. If the research is of benefit to others but not to me? - - it would depend on what the research is. Can't make a general comment.
    e. Even if the research was of benefit to others I still wouldn't agree.
    f. All research should go through ethics committees.
    g. Who else could be consulted? –
        i. only the Person themselves, not a legal representative.
        ii. Only someone the Person has agreed to make that decision for them.
        iii. Family.
        iv. Not GP or any other doctor.
        v. My family GP.
        vi. Not a researcher.
        vii. Social worker.

thanked the group.

9 May 2017

Submission *to the*
Health and Disability Commissioner *on the*
Consultation on health and disability research involving adult participants who are unable to give informed consent.

> ***Since I was diagnosed, I have been asking to be in a research project. I want to be a research subject but I haven't had the chance.***
> Alzheimers NZ Consumer advisory group member with dementia
>
> ***I would have preferred a process that meant I was better informed before giving consent. It's a big responsibility to make a mistake on behalf of someone else.***
> Alzheimers NZ Consumer advisory group member – carer/partner of person with dementia

1. Alzheimers NZ welcomes the opportunity to comment on the consultation on research involving adult participants unable to give informed consent.

2. We recognise the importance of having a rigorous human rights and ethical approach to the question of consent for research. Abuses where consent has not been sought are well documented and outlined in the consultation document, and have resulted in the current safeguards. As noted by the HDC consultation document, people who lack the capacity to make informed choices are particularly vulnerable to abuses of their rights and interests.

3. However, Alzheimers NZ is concerned that a narrow interpretation of consent, or the capacity to give consent, can lead to situations in which people with dementia can be excluded from participation in research that they wish to be part of and wish to see take place.

4. There needs to be more research undertaken into dementia. People at different stages of the dementia journey wish to see this happen and wish to be participants in it. Members of our Consumer Advisory Group and others in the dementia community say they want to be participants in research which will provide insights into the condition and the best care and support options which will be of benefit to others with the disease. They know they themselves may not personally benefit from this research, but they want the community to benefit in the long run. We see validity in extending the boundaries of research beyond the current standard that it should only take place when it is assessed as being of direct benefit to the participant.

5. The UN Convention on the Rights of People with Disabilities (UNCRPD) recognises **provision**, **protection** and **participation** rights. The inclusion of Article 15 specifically covers the right of people with disabilities to be protected from being subject to medical or scientific experimentation without their consent. However, it is important not to read this Article in isolation from those covering participation rights, such as Articles 5, 12 and 19. A key element of ensuring that both protection rights and participation rights are met is ensuring that communication and other processes are appropriately modified for target communities.

6. As the Consultation document notes, the UNCRPD notes the importance of a mental shift from **substituted decision-making**, where decisions are made by others on behalf of the relevant individual, to **supported decision-making,** where the individual receives support that allows them to make the decision themselves. Alzheimers NZ strongly supports this approach, which requires more than a simple assessment in the abstract of whether a particular individual is cognitively capable of making a decision. It also involves more complex assessments about whether a person is able to make a decision to participate in research in the specific context and specific conditions at the time, including their own state of wellbeing.

7. Jan Dewing[1] and other researchers working in the area of research with dementia patients argue that a narrow focus on cognitively biased informed consent and to consent taking place at the beginning of projects is exclusionary for people with dementia. She outlines a method for consent which enables people with dementia to take part in research projects, and on consent as a process that runs through the whole of a research project. We would like to see more serious examination of these options in New Zealand research, and attach a copy of her paper with this submission.

8. Obtaining consent at the start of a research project alone will not protect a person from abusive or intrusive research if no other safeguards exist. We believe there are other ways to ensure that people with dementia are safely and appropriately included in research.

9. While obtaining consent from another person with legal capacity to make decisions for people with dementia should not be overlooked, Dewing focuses on asking family members/carers rather on **permission for access** to a person with dementia. Her process may include carers in the conversation to further enhance the communication with the person with dementia and to confirm assumptions or conclusions being made about whether consent is given and continues to be given in a research context.

10. Family members in our Consumers Advisory Group recognise there are situations in which carers can be conservative and over-protective about giving permission for their family members to take place in research, out of concern about not knowing what their loved person really would like to happen. Some carers wish to see an independent advocate appointed to

[1] Dewing J (2007). Participatory research: A method for process consent with persons who have dementia. *Dementia: The International Journal of Social Research and Practice.* 6 (1) 11-25

assist the assessment of participation of a person with dementia in a research project was appropriate. This included an acknowledgement that there are times that they are too close to, and the researcher too distant from, the person with dementia to properly assess what they want and what will be of benefit to them and the wider community.

11. It is essential that there is enhanced oversight of research involving people who have reduced capacity to give consent, and not just by ethics committees at the start of research. There needs to be ongoing monitoring and assessment of whether the research was undertaken in the way originally proposed.

12. Members of the Alzheimers NZ Consumer Advisory Group wish to see the Code of Health and Disability Rights Services and Consumers' Rights coverage extend to all research undertaken with people with dementia. One example given of research involving a family member with dementia appeared to be a University design school study into design elements of dementia care facilities, which the researchers understood to be outside the Code. However, our CAG group member was surprised to find the questions covered a much wider range of issues, including how the person with dementia felt about being put into care and attitudes about the care she was receiving. He felt the researcher did not have the competence to understand and appropriate respond to the emotions being generated by the questions, and it was a traumatic experience for both the person with dementia and their family and institutional carers. This project appeared to depart significantly from the stated purpose for the research, and to have inadequate sign off and oversight by an Ethics Committee. We believe that this particular situation did fall within the Code, and this also should have been assessed as such by the Ethics Committee.

13. It is important to note that this negative experience is not an argument for not undertaking research including participants who have dementia; rather it is an argument for ensuring that the highest standards of ethical behaviour are required for research of this kind.

14. In conclusion:
    - It is important to provide ways that people with dementia can be included in research projects.
    - We believe the current guidelines can and should be extended to include:
        - Research that may not benefit directly the person with dementia but is of long term benefit to others with the same conditions and to the wider community;
        - A wider range of forms of consent, including participatory processes such as those outlined by Dewing and other researchers working on these issues;
        - Priority given to supported decision making over substituted decision making.
    - Protection of people with dementia in research projects is important and the highest standards of research and oversight by Ethics Committees need to be in place.
    - However, there also needs to be a balance of protection and participation rights. Issues around reduced cognitive capacity should not stop research projects into dementia from proceeding, or people with dementia from participating in them.

Submission to the Health and Disability Commissioner's consultation

People First New Zealand Ngā Tāngata Tuatahi is pleased to make this submission to the consultation by the Health and Disability Commissioner's Office.

1. About People First New Zealand

People First NZ Inc. Ngā Tāngata Tuatahi is a Disabled Persons Organisation and a national self-advocacy organisation run by and for people with learning disability.

People First NZ uses the term "learning disability" rather than "intellectual disability", as members think it is more respectful.

People First NZ was set up in New Zealand in the 1980's and has been an independent Incorporated Society for over 13 years. There are more than 28 local groups around New Zealand where members meet monthly to learn about their rights and how to speak up for them.

To be a member of People First NZ you must be a person with learning disability, over 18 years of age.

People First NZ members speak up on issues that are important to them such as:

- having the same rights as all other New Zealanders;
- being a member of the community;
- being a citizen of New Zealand.

People First NZ works in a human rights framework and works to implement the United Nations Convention on the Rights of Persons with Disabilities to make sure people with learning disability have a good life. People First NZ is also a member of the New Zealand UN Convention Coalition Monitoring Group that monitors the rights of disabled people against the UN Convention.

People First NZ runs a translation service called **Make It Easy**, which translates information into Easy Read – everyday words and pictures. Easy Read is a format that is more accessible for people with learning disability, low-literacy or English as a second language.

People First NZ also provides information and advice about rights and supports for people with learning disability. We run courses for people with learning disability and deliver educational presentations to the wider community.

People First New Zealand is part of the Disabled Persons Coalition that works in partnership with the Government, making Article 4.3 real.

2. Why People First New Zealand wants to make this submission.

People First NZ members are concerned with the human rights of all people and want to have their say about important issues.

Members believe it is particularly important to speak up on issues for disabled people and in particular the rights of people with learning disability.

Members believe the rights in the CRPD are the minimum standard for disabled people and it is important that New Zealand puts in place policies and practices that make these rights real.

People First New Zealand thinks the 'Code of Health and Disability Rights' is very important.

3. What People First NZ New Zealand thinks:

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Question 1

1.1 Yes.

Research that is **low risk, does no harm, has ethics committee approval and gains consent through a supported decision-making model** could proceed.

Supported decision-making is a model where others are involved in decision-making, alongside a person who requires support to make decisions. In supported decision-making, decisions are also made based on the person's **will and preference**. Supported decision-making is in-line with the UNCRPD (Article 2, General Comment No.1). Supported decision-making rejects substitute decision-making and the concept of 'best interests'. In New Zealand, supported decision-making is still an emerging practice and requires more work and understanding - alongside legislation review and amendment.

Supported decision-making models could assist with people (who cannot give informed consent) being involved in research where their “supporters”, who make decisions based on the persons will and preference, could potentially give consent on their behalf. Ideally as a safeguard, there should be at least 2 people involved as “supporters” and these people know the person well.

1.2 Any research would need to use a supported decision-making process and be low risk, do no harm and have ethics committee approval.

1.3 Yes

1.4 The same laws should apply to all research. However, People First NZ is aware that currently the Code of Health and Disability Rights does not apply to all research organisations. People First NZ would not want any change to stop these organisations from doing research that would improve the lives of people with learning disability.

Question 2

2.1 Yes.

2.2 If a person shows through any form of communication (verbal or nonverbal) that they do not want to continue to be part of the research, then the researcher should stop. This should be in the law.

Researchers need to be trained to be aware that communication takes many forms, including facial expression. All communication needs to be respected and taken seriously.

Question 3

3.1 No.

3.2 Delayed consent should not happen. Delayed consent takes away any consent process.

Question 4

4.1 Yes.

4.2 This would provide additional safeguards for people who are able to give informed consent but may take part through a supported decision-making process**.**

Question 5

5.1 Yes.

5.2 Only if the research is low-risk, does no harm and consent is given through a supported decision making process which is based on the persons will and preference.

5.3 Yes.

5.4 People First NZ is not a research organisation. We have outlined some criteria throughout this submission such as low-risk, do no harm and using supported decision-making models. There may be other criteria we are not aware of.

People First NZ would welcome the opportunity to work with HDC and researchers to make a set of criteria that would be used for research which may include people with learning disability through a supported decision-making process.

Question 6

6.1 Yes.

6.2 All research should go through an independent, accredited ethics committee as a safeguard to make sure the research will be safe and respectful and focused on making life better.

Question 7

7.1 No.

7.2 There is a paradigm shift away from substitute decision-making and 'best interests' to supported decision-making using the will and preference of the person. In New Zealand, this paradigm shift is just beginning and laws need to change to reflect the shift.

Additional information

Informed consent

To assist more people with learning disability to be able to give informed consent:

- all research information should be made accessible, for example made into Easy Read (a way of writing information using everyday words and images, to assist with meaning) and/ or film. Providing accessible information in these formats also assists others with low-literacy and English as a second language.

- informed consent is a process and people with learning disability require all information in an accessible format, time to process and someone to discuss the decision with.

- more people with learning disability would be able to give **advanced consent** if information was available in accessible formats.

People First NZ thanks you for the opportunity to have a say.

For anything further please contact on: