

MINA RASSAM

PROTECTING THE VULNERABLE OR ADVANCING
MEDICINE?
Evaluating New Zealand's legal framework on non-
consensual clinical research

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I Introduction

In New Zealand, a significant tension exists between a person's right not to be subjected to clinical research without their informed consent, and society's interest in the advancement of medical knowledge.¹

The impetus for this paper was the recent release of a consultation document by the Health and Disability Commissioner, Anthony Hill. The consultation paper sought the public's views on health and disability research involving adult participants who are incompetent and cannot provide informed consent.² Two questions were asked: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended?³

This paper addresses these questions and traverses New Zealand's legal framework in a bid to identify legal gaps in the area of non-consensual research. At present, the law greatly restricts and renders uncertain the circumstances in which clinical research can lawfully be carried out. The identified legal issues are summarised as follows: First, the NZBORA prohibits all research on individuals who cannot give consent. It is unclear whether the benefit of medical knowledge is a reasonably justified limit to the NZBORA. Second, legal representatives can never consent to any form of research on incompetent adults. A lower standard is needed for substitute decision-making to give effect to the wishes of incompetent adults. Third, where no legal representative is available, the best interests test is the only other option available for research to be lawfully carried out on incompetent adults. The research must prove a direct benefit before the best interests test can be satisfied. Research is inherently uncertain. A benefit to the participant cannot be guaranteed in order to meet the test. Fourth, the law needs to be clearer for ethics committees to ensure research is lawfully approved. Fifth, while the accident compensation scheme adequately compensates

¹ Joanna Manning *Non-consensual clinical research in New Zealand: Law Reform Urgently Needed* (2016) 23 JLM 516 at 522.

² Anthony Hill *HDC Consultation Document: Health and Disability Research Involving Adult Participants Who Are Unable to Provide Informed Consent* (Health and Disability Commissioner, 24 February 2017).

³ Sonia Scott "Health and Disability Commissioner Research Consultation" (1 March 2017) Health and Disability Commissioner <<http://nzccss.org.nz/news/2017/03/16310/>>.

publically-funded clinical trials resulting in harm, industry trials remain excluded from cover. This paper will address these issues and concerns as follows:

The next part addresses the general scope of the paper. Part III analyses the gaps in New Zealand's legal framework. Part IV briefly examines the way research on incompetent adults has been approved by ethics committees under the current law. Part V assesses New Zealand's compensation regime and identifies areas where it could better cater for participants who assume the risks of research. Part VI reviews the legal framework in England and Wales, and Scotland and identifies effective areas which can be implemented in New Zealand's framework in Part VII.

II Scope of the paper

This paper refers to incompetent *adults* who participate in clinical research. This group cannot provide any level of informed consent because they belong to one of three categories: Firstly, individuals are so cognitively impaired that they lack decisional capacity despite receiving special assistance. The incapacitating condition is usually present from birth. Secondly, individuals whose loss of capacity is temporary and will return. Their condition usually arises suddenly, sometime during their lifetime and can be severe, such as a heart attack, seizure or drug overdose. Thirdly, there are those with progressively deteriorating capacity. This state of incapacity is usually slow and progressive such as in Alzheimer's dementia.⁴

1 Terminology

It is noted that this paper uses the terms "participants," "subjects" and "consumers" interchangeably to refer to the class of adults who cannot consent to their own participation in research. This paper deliberately does not refer to this class as "patients" in order to distinguish research activity from treatment.

2 Impetus for change

⁴ At 5.

The HDC Consultation document arose out of several reports revealing that since 2006, more than 40 medical studies have been approved by ethics committees in which some or all participants could not consent to clinical trials.⁵ This is concerning because the lawfulness of such research remains uncertain in New Zealand.

3 *Vulnerability of incompetent subjects*

Incompetent adults are prone to exploitation and require special protection in the research setting. It is widely understood that clinical trials inherently have unknown risks. Most research trials are stopped before the treatment reaches the pharmacy shelf. It has been shown that 70% of phase II trials ended because of toxicity or lack of efficacy and only 20% of trialed drugs actually become marketable.⁶ The potential for harm is compounded by the fact that unobservable adverse reactions cannot be communicated by the subject.⁷

Moreover, certain patients may have difficulty coping with minor procedures that would seem standard for healthy patients. For dementia patients, a small change to their routine can “constitute real threats to needed order and stability, contribute to already high levels of frustration and confusion, or result in a variety of health complications.”⁸

4 *Why research on incompetent adults should be lawful*

If legal mechanisms excluded incompetent adults entirely from research studies, it may adversely affect the development of medical treatment for those people. It would otherwise be difficult to increase knowledge and understanding of the underlying causes of their incompetence without researching on them.⁹ Understanding the

⁵ Ben Heather “Drugs Tested on Mentally Disabled” stuff (13 July 2014) <<http://www.stuff.co.nz/national/health/10261601/Drugs-tested-on-mentally-disabled>>.

⁶ US Food and Drug Administration “Testing in Humans. (2003) <www.fda.gov/fdac/special/newdrug/testtabl.html>.

⁷ Oonagh Corrigan and Bryn Williams-Jones “Consent is not enough-putting incompetent patients first” (2003) 361*The Lancet* 2096 at 2096.

⁸ Edward Keyserlingk and others “Proposed guidelines for the Participation of Persons with Dementia as Research Subjects (1995) 38(2) *Perspectives in Biology & Medicine* 319 at

⁹ David Scales and others “Patients’ Preferences for Enrolment into Critical-Care Trials (2009) 35(10) *ICM* 1703 at 1704.

condition that led to the condition causing their incompetence may not be well advanced by studying people who are competent. The appropriate test population is required so that research is scientifically sound.¹⁰

Another basis for reforming the law is the concept of social inclusion. It should not be assumed that incompetent adults “would wish to be free-riders, nor that they be excluded from discharging an obligation of good citizenship which we all share.”¹¹ It challenges the notion that vulnerable groups are a drain on society. On the other hand, it is difficult to assume incompetent adults have altruistic motives, particularly since a presumption as such can neither be affirmed or denied during their state of incompetence.

A balance needs to be struck so that vulnerable adults are not exploited while at the same time ensuring that these same people are not excluded from the opportunities derived from research that are beneficial to them.¹²

5 *Therapeutic and Non-therapeutic research*

Medical research on human participants is traditionally divided into two categories: therapeutic and non-therapeutic research. Therapeutic research trial various methods to determine the method most beneficial for the research subject.¹³ Phase II and III clinical trials, the later stages of research, usually fall under this heading. In contrast, non-therapeutic studies do not have the prospect of “diagnostic, therapeutic or preventative benefit” to the individual study participant.¹⁴ Phase I studies are an example. These trials involve the initial intervention into humans of innovative therapy and are inherently more risky with no possibility of personal benefit from participation.¹⁵ However, these terms have received criticism for creating artificial

¹⁰ UK Parliament “Joint Committee on the draft Mental Incapacity Bill First Report, Chapter 15: Medical Research” <www.publications.parliament.uk/pa/jt200203/jtselect/jtdmi/189/18918.htm>.

¹¹ John Harris “The Ethics of clinical research with cognitively impaired subjects” (1997) 5 *Italian Journal of Neurological Science* 9.

¹² Aurora Plomer “Protecting the Rights of Human Subject in Emergency Research” (2001) 8 *EJHL* 333 at 334.

¹³ Lydia Wadsworth “Rights and Research: An Examination of Research Under New Zealand’s Code of Health and Disability Services Consumers’ Rights” (2013) 21 *JLM* 187 at 187.

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¹⁵ **Ethical Guidelines for Intervention Studies at 40.**

categories. In reality, research is more aptly described as falling along a spectrum.¹⁶ Research on incompetent adults should not hinge around the therapeutic/non-therapeutic schism for several reasons that will be outlined below.

Although related, medical research and treatment are distinct activities and should be regarded as such by the law.¹⁷ It is important to categorise the nature of the activity accurately. Therapeutic benefit must not be used to disguise the true nature of research intervention.¹⁸ This way, the duties and responsibilities of a researcher and doctor will be clearly defined. Describing a clinical study as “therapeutic” or research as “treatment” may be misleading. It may allow the researcher to assume the role of physician thereby creating an impression of an expectation of benefit, which does not actually exist. The researcher can only hope a benefit will arise but cannot guarantee it. Moreover, ethics Committees may be more permissive in allowing a therapeutic study to go ahead because the levels of risks and burdens may be regarded as more acceptable so that it is more likely to proceed as opposed to research that does not derive a direct benefit for the participant.¹⁹

These concerns are heightened by the potential conflict of interest that may arise in the research setting where the health professional also acts as the researcher.²⁰ Health professionals are expected to act in the best interests of their patients.²¹ However, in the context of medical research, the doctor-researcher is also interested in collating information for future patients as well as personal motives, including; professional recognition; pursuing a medical breakthrough; intellectual curiosity and satisfaction; and obtaining research grants.²²

¹⁶ R Gillon “Medical Treatment, Medical Research and Informed Consent” (1989) 15 JME 3 at 4.

¹⁷ M Cherriff Bassiouni, Thomas G Baffes, John T Evrard “An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation” (1981) 72(4) JCLC 1597 at 1605.

¹⁸ George Tomossy and David Weisstub “The Reform of Adult Guardianship Laws: The Case of Non-Therapeutic Experimentation” (1997) 20(1) IJLP 113 at 114.

¹⁹ Anna Westra and Inez de Beaufort “Improving the Helsinki Declaration’s Guidance on Research in Incompetent Subjects” (2015) 41 JME 278 at 279.

²⁰ Philip Bein “Surrogate Consent and the Incompetent Experimental Subject” (1991) 46 Food Drug Cosm LJ 739 at 757.

²¹ Right 7(4).

²² Bein, above n 20, at 757.

Moreover, a doctor may justify medical research on the grounds of therapeutic treatment, thereby bypassing legal safeguards that may have otherwise precluded the activity. Regarding particular research as quasi-therapeutic may diminish the importance of safeguards as compared to non-therapeutic research. Medical research justified on the grounds of therapeutic benefit may pose significant risks that must be considered.²³ As the incompetent participants cannot display their disapproval or question the researcher's methods, the risks to the participant are increased. The law must clearly set out how to distinguish between research and treatment and provide legal safeguards accordingly.

²³ Tomossy and Weisstub, above n 18, at 114.

III Current Legal Framework in New Zealand

This part critically analyses the relevant legal framework regulating research on people who cannot otherwise give consent so that any gaps can be identified and addressed.

A Informed Consent

The Code of Health and Disability Services Consumer's Rights (the Code or Code of Rights) provides a framework for informed consent in New Zealand. Right 7(1) of the Code provides:²⁴

Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

Self-determination and autonomy derived from the process of informed consent is near impossible in the context of incompetent adults. Research on unconscious or cognitively impaired adults differs markedly from standard research. Individuals lack the requisite capacity to decide how much risk they are willing to assume, particularly where there is no prospect of a benefit to the participants.²⁵ Therefore, it is important that New Zealand's legislative framework protects the research subject so they are not left worse off than their pre-research condition.²⁶

B New Zealand Bill of Rights Act 1990 (NZBORA)

Non-consensual research raises constitutional issues concerning the right to be free from experimentation without consent. Section 10 of the NZBORA appears to prohibit all forms of research on incompetent adults:²⁷

10 Right not to be subjected to medical or scientific experimentation

Every person has the right not to be subjected to medical or scientific experimentation without that person's consent.

²⁴ Right 7(1).

²⁵ Corrigan and Williams-Jones, above n 7, at 2096.

²⁶ Dangata Yohanna Yanshiyi "The Role of Consent in Medical Research: Breaking or Building Walls? – A Call for Legislative Reform" (2011) 30 Med Law 477.

²⁷ New Zealand Bill of Rights Act 1990, s 10.

However, the parameters of its application are not entirely clear and its prohibition limited by other variables. If a wide interpretation of “medical experimentation” is taken, all interventionist research would be unlawful for the purpose of s 10. On the other hand, a narrow approach so that a prohibition is only applicable to non-therapeutic research. Johnston and Godlovitch argue that the NZBORA excludes therapeutic research from its scope unless s 10 is interpreted narrowly so it would not qualify Right 7(1).²⁸ They argue that the researcher would not infringe s 10 if he or she could show that the research is at least potentially therapeutic to the participants.²⁹ Purely scientific research would be caught within the provision’s prohibition. The latter is the more plausible approach, since the NZBORA refers to medical “experimentation” rather than “research.” This could be viewed as a deliberate attempt to distinguish between the terms thereby defining the scope of s 10. However, as explained earlier, making distinctions based on therapeutic benefit is unhelpful. In any case, the term “experimentation” not “research” is used across the PPPRA and Code of Rights. Under the Ethical Guidelines for Intervention Studies, an intervention study may either be a “medical or scientific experiment.”³⁰ Clarifying the interpretation of “experimentation” in the NZBORA is pertinent so that the scope of the prohibition under the NZBORA can be clarified.

The effect of s 10 may also be limited by the application of section 3. The NZBORA acts as a mechanism to protect against the conduct of the legislative, executive, or judicial branches of government.³¹ This is essential where the State has an active role in the advancement of medical knowledge in relation to funding projects and policies. The majority of research is conducted in public hospitals, owned and funded by District Health Boards (DHBs), which are Crown Entities. The NZBORA may also apply to acts done by Health and Disability Ethics Committees (HDECs). Approval

²⁸ Sue Johnson and Glenys Godlovitch “Clinical Research in Unconscious Patients: Legal Uncertainty and the Need for Consistency” (2000) 8 JLM 207 at 213.

²⁹ at 212.

³⁰ Ethical Guidelines for Intervention Studies July 2012 at 1.

³¹ New Zealand Bill of Rights Act, s 3.

given to research that breaches the NZBORA may result in the decision being challenged legally challenged and found unlawful.

In saying that, there is debate whether the actions of DHBs and Ethics Committees would fall within the scope of s 3(b). The NZBORA applies to acts done by “any person or body in their performance of a public function.”³² It follows that a health service provider, acting as a researcher, will be covered by the NZBORA only if their research was endorsed by the public health system’s policies and funding. Private hospitals and commercially-funded researchers are unlikely to fall within the ambit of s 3(b) due to the private nature of their activities.

1 Justified Limitations

The apparently wide prohibition of s 10 may further be limited by section 5 of the NZBORA. Any attempt to override the right not to be subject to medical experimentation needs to be considered with regard to the justified limitations of s 5.³³ It is arguable that medical research on incompetent adults is reasonably justified in terms of s 5 of the NZBORA. The justifications can be premised on the potential benefits derived from the development of medicine and the anticipated treatments that may result. The proportionality test in s 5 can be satisfied in ensuring medical researchers possess powers that are not excessive and no more than necessary in a democratic society to achieve the legitimate purpose of advancing science. This requires robust legislative safeguards in order to justify the derogation from the consent requirement in s 10.

However, to preserve the aim of protecting personal bodily integrity from coercive medical procedures, express statutory authority is necessary to override the NZBORA rights. As will be evident in the forthcoming discussion, the position in New Zealand is far from clear on the lawfulness of research on incompetent adults.

³² New Zealand Bill of Rights Act, section 3(b).

³³ Section 5.

C *Legal Representatives*

The Protection of Personal and Property Rights Act 1988 (PPPRA) is the main statute dealing with proxy decision-making for people suffering from incapacity that affects their decision-making. The participants in this category usually suffer from longer term impairment where there is time to appoint a legal guardian.

In New Zealand, only two circumstances exist where a valid consent can be provided by another person: when a person is not competent to give consent, a court-appointed welfare guardian is entitled to grant consent on their behalf under the PPPRA; or before a person becomes incompetent, they can execute an enduring power of attorney (EPOA), so that another person can make such decisions on their behalf.³⁴ The person's spouse, next of kin, or other family member cannot by virtue of their relationship with the participant give consent on behalf of his or her incompetent relative.³⁵

These circumstances are further limited to research that has the purpose of saving the person's life or preventing serious damage to their health. Section 18 provides:³⁶

18 Powers and duties of welfare guardian

(1) No court shall empower a welfare guardian, and no welfare guardian shall have power,—

...

(f) to consent to that person's taking part in any medical experiment other than one to be conducted for the purpose of saving that person's life or of preventing serious damage to that person's health.

On a close reading of the PPPRA, s 18(1)(f) can never be satisfied.³⁷ Research on persons under the authority of a court-appointed welfare guardian or EPOA can never

³⁴ Protection of Personal and Property Rights Act 1988 (NZ), s 98.

³⁵ R Freebairn "Informed Consent and the Incompetent Adult Patient in Intensive Care – a New Zealand Perspective" (2002) 4 Critical Care and Resuscitation 61 at 61.

³⁶ Protection of Personal and Property Rights Act, section 18.

³⁷ Manning, above n 1, at 519.

proceed because consent can never be lawfully given on behalf of the incompetent participant. Clinical research is never carried out to save a person's life or prevent serious damage to their health. The sole purpose of clinical research is to generate knowledge that can benefit *future* patients.³⁸ Only treatment can satisfy that goal for *that person*.

On this basis, the PPPRA appears to conflate the definitions of treatment and research thereby excluding the incompetent group from the possibility participating in research. The law should be refined to clearly and accurately reflect this distinction.³⁹

It is acknowledged that the autonomy-based rationale of consent is weakened by imposing one person's personal choice over another person in appointing a legal representative. However, incompetent people should not be excluded entirely from the ambit of research based on researchers' inability to obtain first party consent. A study sought the views of 240 ICU survivors found that most survivors (78%) preferred the involvement of a proxy-decision maker in their enrolment in a clinical trial, even when the study involved higher risks of complications.⁴⁰ The study was not without its limits. The survivors were not given an option of choosing "no research to be conducted on incapable participants".⁴¹ Moreover, the survivors were not asked their reasons for preferring a substitute decision-maker. Participants had survived ICU, so their views towards their ICU experience may generally be more positive.⁴² Nonetheless, the views of research participants should be considered by consulting a representative. In doing so, the high threshold in the PPPRA needs be lowered to allow a representative to consent or refuse consent to research. The representative should be the person's nearest relative or someone known to the person to accurately represent their views.⁴³

1 *Application of the NZBORA*

³⁸ At 520.

³⁹ Bassiouni and others, above n 17, at 1597.

⁴⁰ Scales and others, above n 9, at 1703.

⁴¹ 1710.

⁴² 1710.

⁴³ Tomossy and Weisstub, above n 18, at 18.

The Code defines “Consumer” as someone who is entitled to consent on behalf of the person receiving the services. This is qualified by Right 7(1) where “any enactment... provides otherwise.” Section 10 of the NZBORA seems to “provide otherwise.” Where s 10 refers to “that person,” it is clearly the participant of the research who can consent, not their legal representative, further contributing to the uncertainty.

2 *Community consultation*

Western notions of informed consent and the individualistic nature of the Code may not accurately reflect the views of a subset of New Zealand’s population. Therefore, undertaking research on critically-ill patients has the potential to infringe on established values. This rings particularly true for Maori and Polynesian communities who are disproportionately represented in New Zealand’s intensive care units.⁴⁴ More specifically, care must be taken to ensure the Guidelines for Researchers on Health Research Involving Maori are actively implemented, specifically in recognising tikanga.⁴⁵ Researchers and ethics committees are responsible for ensuring that Māori (and, where relevant, other population groups) are consulted in the development and conduct of research, in their needs and concerns, the Treaty of Waitangi and its appropriate application. Any legal framework must accommodate the diversity of views in New Zealand’s pluralistic society.

Moreover, patient groups identified as “vulnerable” due to their socioeconomic position or cultural background may be more at risk of the social pressures arising from medical research carried out by doctors and other health professionals. Some groups may not be used to questioning the medical expertise of their unconscious relative’s doctor who is advocating medical research. Anna Freud points out that a subject remains “in a state of submission, admiration [and] obedience to the doctor.”⁴⁶ Trusting the technical judgment of the investigator may be more likely to result in the

⁴⁴ JP Gardiner, JA Judson, GS Smith, R Jackson and RN Norton “A Decade of Intensive Care Unit Trauma Admissions in Auckland” (2000) 113 NZ Med J 327.

⁴⁵ Health Research Council of New Zealand “Guidelines for Researchers on Health Research Involving Maori” (2010)

⁴⁶ Anna Freud Unpublished Manuscript Based on a Lecture to Students at Western Reserve Medical School (1964).

enrolment of the patient.⁴⁷

Some may argue that research on incompetent participants should proceed on the basis that informed consent is not needed or valued to the same extent in certain communities because autonomy and individual rights are inherently Western notions. Denying research based on the absence of informed consent may typify a sort of “medical-ethical imperialism” on the incompetent adult who belongs to an ethnic minority.⁴⁸ However, this approach is flawed for several reasons. First, research is not a basic right. Ethnic communities in New Zealand are not denied its benefits as compared to the rest of the population. They too have equal access to medical care under the public health system and their views on research should be determined. More importantly, informed consent is based on the universal human right to self-determination which applies globally and from which derogation is not permitted.⁴⁹ There is no evidence to suggest that vulnerable adults from non-western cultures prefer not to make autonomous decision with regards to their health.

We should be slow to completely exclude incompetent adults from medical research on identity-based acuties. Rather, the law should provide an opportunity to understand the cultural, religious and other specific nuances of the person before undertaking medical research study. Disabled communities and other vulnerable groups should also be considered. To do this, law reform should consider implementing mandatory consultation with the wider community group as a prerequisite to ethics committee approval. It is acknowledged that the Code affords an express right to respect the cultural, religious and ethnic needs, values and beliefs of individuals.⁵⁰ However, a more sophisticated, broader legislative model of consultative decision-making is needed to fully comprehend the subject’s wishes when they are unable to make it themselves. The law should view consultation as

⁴⁷ Benjamin Meier “International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent” (2002) 20 Berkeley J Int’L 513 at 539.

⁴⁸ at 545-546.

⁴⁹ Meier, above n 47, at 547. M Angell “Ethic Imperialism? Ethic in International Collaborative Clinical Research (1988) 319 new Eng J Med 1801 at 1802.

⁵⁰ Code of Rights, Right 1(3).

another way to give effect to the autonomy of the person by gaining a better understanding of the patient's views from others, rather than paternalistically making the decision for them in outright prohibition.

C Advance Directives

Adults in New Zealand have a right to use an advance directive for research to be carried out on them in the future in accordance with the common law.⁵¹ These directives are considered "expressions of autonomy"⁵² as they allow a person to make a decision about whether or not they wish to receive health services in the future. A consumer can make a choice while they are competent regarding a health care procedure which becomes effective only when he or she is not competent.⁵³ Health care procedures include health research administered or carried out by a health care provider.⁵⁴ Advance directives are relevant upon diagnosis of a progressive disease, such as Parkinson's or Huntington's, that eventually renders a person incompetent. To fully respect the patient's autonomy, medical researchers should give effect to advance authorisation and the law should encourage its use in research.

Historically, however, there has been a low up-take of advance directives in this context for several reasons.⁵⁵ Unlike deciding whether to refuse treatment in the future, such as turning off a ventilator, participation in medical research remains largely unanticipated. There is little public awareness of the possibility of executing these types of directives in the context of research. Even if future participation is anticipated, there is a low personal motive in executing an advance directive purely for altruistic reasons.⁵⁶ Moreover, if an advance directive is executed, it cannot adequately capture the patient's wishes across a variety of hypothetical research scenarios. Advance care documents use imprecise language to cover a range of

⁵¹ Right 7(5).

⁵² N Cantor "Prospective autonomy: on the Limits of Shaping One's Post-Competence Medical Fate" (1992) 8 JCHLP 13.

⁵³ The Health and Disability Commissioner (Code of Health and Disability Services Consumer Rights) Regulations 1996, Regulation 4.

⁵⁴ Regulation 2, Right 7(4). Regulation 4. Health and Disability Commissioner Act 1994, s 2.

⁵⁵ K Stern "Advance Directives" (1994) 2 Med L Rev 57 at 75.

⁵⁶ Meier, above n 47, at 746.

potential scenarios which are unlikely to accurately correspond with the situation encountered by the patient.⁵⁷ The advance directive should at least address the possibility of a conflict arising between a person's exercise of their future autonomy and their welfare as an incompetent person.

Moreover, their use is limited in situations where the person has lost capacity suddenly as in cardiac arrest. The research must be applied before the patient stabilises but the patient does not have advance or present decisional capacity to write a directive.⁵⁸ However, advance directives are important as they give an opportunity for the incompetent adult to exercise their right to make autonomous decisions about participating in research which continues after competence has been lost. Arguably, decisions are autonomous if they can be changed, which is not the case here. However, the directive may at least capture the patient's cultural values and religious beliefs which could indirectly inform the researcher of the incompetent adult's views on research. These devices also generate an opportunity for subjects to preserve the patient's dignity by ensuring their wishes are respected.

D Code of Health and Disability Services Consumer's Rights

Where a welfare guardian has not been appointed, or EPOA established, the wishes of the incompetent patient cannot be known. The researcher must rely on Right 7(4) of the Code for research to proceed lawfully.⁵⁹ Right 7(4) provides:⁶⁰

Right 7

(4) 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

⁵⁷ Richard Saver "Critical Care Research and Informed Consent" (1996) 75 NCL Rev 205 at 247.

⁵⁸ At 207.

⁵⁹ The Health and Disability Commissioner (Code of Health and Disability Services Consumer Rights) Regulations 1996, Regulation 2, Right 7(4).

⁶⁰ Regulation 4.

(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.

A health professional may provide services without obtaining informed consent only where it "is in the best interests of the consumer" and only where the steps specified in Right 7(4) have been followed."⁶¹ In the Code, services include medical research.⁶² However, there are difficulties in relying on Right 7(4)(a).

1 *Proving benefit*

The researcher's fundamental problem is in affirmatively demonstrating that the proposed research *is* in the best interests of the patient. This means that Phase I trials are automatically ruled due to the uncertainty in their outcomes. However, it cannot be said with certainty that even research labelled "therapeutic" will derive a benefit for the patient. In Phase II and III randomised control trials, the placebo control group cannot be said to receive a clinical benefit and therefore it is not in their best interests to proceed.⁶³ Research trials are primarily designed to understand whether the particular therapy will benefit *future* patients suffering from a condition. The researcher generally cannot guarantee that the therapy is in each participant's best interests.⁶⁴ It is the very point of research to find out.⁶⁵

2 *Inclusion benefit*

Arguably, the best interests standard can be satisfied through an "inclusion benefit."⁶⁶

⁶¹ Right 7(4)(a).

⁶² Regulation 4.

⁶³ Sheldon Magder and Annette Lfebvre "Obtaining Consent for Research Studies on Incompetent Subjects: The Quebec Experience" (2003) 29 Intensive Care Med 496 at 497.

⁶⁴ Corrigan and Williams-Jones, above n 7, at 2096.

⁶⁵ Joanna Manning "Review of New Zealand's Health and Disability Commissioner Act and Code of Rights" (2009) 17 JLM 314 at 323.

⁶⁶ A Moore, K Hall and K Hickling "Critical Care Research Ethics: Making the Case for Non-Consensual

Individuals enrolled in research get better care because they are better monitored so that conditions they may develop are picked up more quickly.⁶⁷ However, the inclusion benefit is only a secondary benefit to the purpose of the research. Any benefit that actually eventuates is merely fortuitous and incidental. Moreover, it is difficult to prove that inclusion benefit outweighs the risks for the research to be justified.⁶⁸

3 *Population benefit*

It is acknowledged that research on incompetent adults raises ethical challenges that are difficult to justify when there is no direct benefit to the research participant. The utilitarian approach deems that society should accept medical investigation on the premise that individuals must sacrifice for the public good.⁶⁹ The best interests test could only be reasonably justified on utilitarian grounds. Individuals who receive the benefits of previous studies should be included in research as a “pay-it-forward” for future patients.⁷⁰ However, Right 7(4) requires that research is in the best interests “of the consumer” - not for any other person. The best interests tests can only be satisfied unless if the research directly benefits the participant.

Something more achievable is needed to carry out valuable research to be carried lawfully on participants who cannot consent.

Research in ICU” (2004) 6 Crit Care Resusc 218 at 224.

⁶⁷ Auckland Women’s Health Council Newsletter “Enrolling unconscious patients in clinical trials” May 2014 at 4.

⁶⁸ Manning, above n 1, at 521.

⁶⁹ Bassiouni and others, above n 17, at 1607.

⁷⁰ At 1605.

IV *Ethics Bodies*

Ethics committees are another strand of New Zealand's regulatory framework that demands legislative attention in the context of research. Ethics committees are important as they ensure public involvement and transparency in clinical research.⁷¹ This part analyses the extent to which ethics committees in New Zealand protect vulnerable adults who participate in research.

New Zealand has four geographically-spread Health and Disability Committees (HDECs) established under s 11 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act). HDECs have the responsibility of ensuring health and disability research meets established ethical standards set out in the guidelines of the National Ethics Advisory Committee (NEAC).⁷² However, the NEAC guidelines place the legal obligations of Right 7(4) on the investigator, not ethics committees. In effect, ethics committees do not have legal teeth to rule on the law.⁷³ Moreover, ethics committee approval is only a condition of funding and is not otherwise mandatory.⁷⁴

A *Medical trials in New Zealand*

As already mentioned, the current law is restrictive in allowing research on incompetent participants to proceed lawfully. However, in New Zealand, clinical research on non-consenting adults continues to receive ethics committee approval. One such example is a study brought before the Northern A Ethics Committee (NAEC). This involved a non-inferiority trial that was designed to test whether an antibiotic drug is not less effective than the standard treatment in use.⁷⁵ The trial is clearly important in light of the rise of antibiotic resistance.

However, the participants suffered from a severe infection that rendered them unable

⁷¹ Jade Du Preez "Cross-Examination: Unconscious Decisions – Who Should be Able to Say Yes to Clinical Trials?" Equal Justice Project <<http://equaljusticeproject.co.nz/2016/08/cross-examination-unconscious-decisions-who-should-be-able-to-say-yes-to-clinical-trials/>>.

⁷² Ministry of Health - National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised Edition* (2012) at 9. "About the Committees" Health and Disability Ethics Committees <<http://ethics.health.govt.nz/about-committees/>>.

⁷³ At 24.

⁷⁴ Don Chalmers "Research Involving Humans: A Time for Change?" (2004) 32 J Med Ethics 583 at 586.

⁷⁵ Seokyung Hahn "Understanding Non-Inferiority Trials" (2012) 55(11) Korean J Pediatr 403 at 403.

to give consent and ethics approval could not be granted. Researchers could not show that the antibiotic was the better treatment so as to satisfy the best interests test. Nor was there any prospect of gaining consent through the PPPRA. Problematically, the NAEC were focused on circumventing clear advice from Crown Law and the Ministry of Health in order to grant approval.⁷⁶ The law must be clear so as to ensure incompetent participants are not unlawfully enrolled in clinical trials without adequate safeguards.

Recent legislative changes have significantly altered ethics committees which saw a decline in lay person membership. Ethics committees should be representative. The membership should return to post-Cartwright Inquiry of 50% lay members and 50 % health professionals and scientists.⁷⁷

⁷⁶ Auckland Women's Health Council Newsletter, above n 67, at 4.

⁷⁷ "Enrolling Unconscious Patients in Clinical Trials" (May 2014) <www.womenshealthcouncil.org.nz>.

V *Compensation for Research-Related Injury*

In this section, I look at whether New Zealand's accident compensation scheme adequately compensates research participants who experience injury from a clinical trial. The compensation scheme should be amended in two ways. First, personal injury should be appropriately categorised as a "research injury" rather than a "treatment injury" so the law clearly makes a distinction between the activities. More significantly, New Zealand should extend its no-fault compensation scheme to injury resulting from commercially funded clinical trials.

The Accident Compensation Act 2001 (the Act) provides no-fault access to compensation for participants injured as a result of publicly-funded clinical trials under the head of "treatment injury." The Act provides:⁷⁸

32 Treatment Injury

...

- (4) Treatment injury includes personal injury suffered by a person as a result of treatment given as part of a clinical trial, in the trial.

The claimant must meet the statutory criteria under the Act in order to recover the compensatory and rehabilitative benefits. The trial must have received ethics committee approval. The barrier to recovery is in establishing proof of a causal link between the clinical trial and personal injury. The claimant must bear the financial cost of injury if it is "a necessary part, or ordinary consequence, of the treatment." This high threshold is even more difficult to prove when a patient is unconscious in an ICU ward or suffering from severe dementia and cannot advocate for themselves.

The issue is that clinical trials are identified as "treatment" for the purpose of the Act. This is another instance in New Zealand's legislation where research is regarded as tantamount to treatment. If the Act intended to cover personal injury resulting from Phase II or III trials, or trials where the risks are minimal, it should explicitly state this.

⁷⁸ Accident Compensation Act 2001, s 32(4).

The main barrier to recovery is in establishing proof of a causal link between the clinical trial and personal injury.⁷⁹ The claimant must bear the financial cost of injury if it is “a necessary part, or ordinary consequence, of the treatment.”⁸⁰ The logic behind this is that a claimant should bear the risk if it is an expected consequence of treatment. However, in the context of research, the risks are uncertain even to the researcher. The researcher would need to inform the participant of the risks in the trial that can be described as “an ordinary consequence” of the trial product. Unconscious participants in an ICU ward or people suffering from severe dementia could not be informed of the likely risks. This may be relevant where a legal representative represents the participant and has been informed of the risks. In any case, the alternative ground provides cover for non-consensual research so incompetent patients can receive compensation.

Another issue is the Act excludes cover for injuries suffered from participation in commercially-sponsored clinical trials.⁸¹ Subjects injured from industry trials must initiate a tort action, which is obviously expensive, slow and onerous in proving its legal elements. The key legal hurdle lies in proving fault on the part of the researcher, usually in negligence. Since the very purpose of undertaking research is to understand the risks, any injury that may eventuate during the clinical trial would arise from unforeseen risks and cannot be considered fault under the Act. Research subjects will find it difficult to show that harm was reasonably foreseeable.⁸²

The CRYSTIAL trial is one example of the difficulty experienced by injured participants in receiving compensation from commercially funded research. The sponsors initially argued that the injuries were not caused by the trial drug.⁸³ The sponsor’s insurance company managed the claim in a strictly commercial manner and the parties only arrived in a settlement after three years. In another trial (Insulin

⁷⁹ Accident Compensation Act, Section 32(2)(a).

⁸⁰ s 32(1)(c).

⁸¹ Section 32(6)(a)(ii).

⁸² At 5.

⁸³ Joanna Manning “Does the Law on Compensation for Research-related Injury in the UK, Australia, and New Zealand Meet Ethical Requirements?” (2017) 1 at 19.

variant trial), the injured subject has yet to receive any compensation despite ministerial pressure to reach a settlement.⁸⁴

New Zealand's compensation scheme falls short of the ethical requirements of no-fault cover for vulnerable people. By treating participants in publically funded trials differently to those in industry trials, the Act is discriminatory and unethical.⁸⁵ The source of funding for the trial is immaterial once the subject is injured. The concern is that New Zealander levy-payers would have to bear the cost while commercial industries enjoy the profits. Moreover, it may mean overseas research companies would target New Zealand, so that New Zealanders would bear the burden of questionable trials.⁸⁶

The law is unsatisfactory at present. All subjects should be compensated under the no-fault scheme because they are ultimately assuming the risk for society's benefit. The Act should ensure treat participants who participate in commercially funded research as it does publically funded research. Moreover, Ethics Committees should withhold their approval of clinical trials unless the risk of injury is minimal or negligible and that compensation is available in case of injury and where ACC cover is not available. Similarly, private health insurers should remove the barriers to compensation for injury from clinical trials. Commercially-sponsored health research is beneficial to New Zealand. We should engage with research companies to build a stronger industry rather than disincentives medical research based on its funding source.

⁸⁴ Letter dated 1 October 2015 Minister for ACC to [name withheld under s 9(2)(a) of Official Information Act 1982].

⁸⁵ Manning, above n 80 at 17.

⁸⁶ At 17.

VI *Overseas Legal Frameworks*

This part addresses the law in England and Wales, and Scotland to provide a useful framework which New Zealand can use to establish its own framework. Three distinct legal frameworks govern this area: the Mental Capacity Act 2005 (MCA); the Adults with Incapacity (Scotland) Act 2000 (AISA); and the Medicines for Human Use (Clinical Trial) Regulations 2004 (CT Regulations). Their most significant features are analysed in the forthcoming discussion.

A *Features*

Several distinguishing features in the MCA and AISA immediately stand out in comparison with New Zealand's legislative model. First, the legislation provides a specific framework for research, rather than elusively and confusingly regulating research through the law directed to treatment. Second, the legislation generally promotes, rather than hampers research on incompetent people, so long as safeguards are met. Enrolment in research progresses on a finely attuned measure of risks and benefits according to the type of research, rather than by applying an unattainable best interests standard. The following features are notable:

1 *Impairing condition criterion*

In the MCA, an ethics committee may approve research if it is connected with an "impairing condition" or its treatment (the condition causing the incapacity).⁸⁷ Similarly, the AISA requires the study to relate to the "causes, diagnosis, treatment or care of the adult's incapacity."⁸⁸ This means that the study cannot continue if it is completely unrelated to the condition underlying the person's incapacity. For example, researching people with Huntington's disease to relieve its symptoms can proceed. Enrolling people with Huntington's to research a cancer drug will not (and should not) gain ethics approval. This requirement limits the amount of research carried out on incompetent people while recognising that incompetent people are necessary subjects of research so that we can better understand their condition.

⁸⁷ Mental Capacity Act 2005, section 31(2).

⁸⁸ Adults with Incapacity (Scotland) Act 2000, s 51(1)(a)(i).

2 *Necessity criterion*

Both the AISA and MCA require that research of a “similar nature” or “equal effectiveness” could not be carried out on participants who can give consent.⁸⁹ This ensures that exposing incompetent people to the risks of research is a last resort.

3 *Advance decisions*

It is also a condition of research in the AISA that the “adult does not indicate an unwillingness to participate.”⁹⁰ The MCA provides a clearly mandate framework in which advance directives can prevail.⁹¹ It is a model which New Zealand should adopt and implement.

4 *Ethics committee approval*

Both the AISA and MCA require that all research must be approved by an ethics committee before proceeding.⁹²

5 *Risk and benefit*

In the MCA, the research must have the “potential to benefit P without imposing on P a burden that is disproportionate to that potential benefit to P.”⁹³ A greater level of risk is justified where a person stands to directly benefit from the research. This test does not specify the extent of benefit required and the minimum level of harm acceptable in the research design, which can be problematic in its application.⁹⁴ By comparison, the AISA does not adopt a proportionality principle in weighing the benefits to justify the risks.

The AISA does not differentiate between the research that may potentially benefit participants and research of no benefit. All research must impose “no foreseeable risk,

⁸⁹ Mental Capacity Act, s 31(4). Adults with Incapacity (Scotland) Act, s 51(1)(a).

⁹⁰ Adults with Incapacity (Scotland) Act, s 51(3)(b).

⁹¹ Mental Capacity Act, section 33(2).

⁹² Adults with Incapacity (Scotland) Act, S 51(3)(c). Mental Capacity Act, s 30(4).

⁹³ Mental Capacity Act, s 31(5)(a).

⁹⁴ Manning, above n 1, at 524.

or only a minimal foreseeable risk”⁹⁵ and minimal or no discomfort to the adult.⁹⁶

First, the test acknowledges that benefit cannot be guaranteed in research. Although, it may be argued that requiring the research to produce a “real and direct benefit” is arguably too definitive, the word “likely” softens this requirement. Second, the test stipulates an acceptable level of risk. Only minimal risk is allowed in research, whereas the MCA does not specify the allowable level of harm. Manning prefers the AISA as it is more protective of subjects.⁹⁷ The Scottish test is a better measure for New Zealand as avoiding unacceptable risk is more likely to protect the participant’s interests. It may be difficult to measure risk in Phase I trials however, which may exclude participation in some early phase trials. Where the research is not likely to produce real and direct benefit to the adult, it can still proceed under the AISA, provided more stringent safeguards are met.⁹⁸

6 *Legal representative*

Unlike the highly restrictive requirements in the PPPRA, the AISA and MCA ensure that designated persons can be consulted depending on availability. The MCA makes consultation mandatory and comprehensively sets out a hierarchy of people that the researcher can consult according to availability.⁹⁹ Researchers need to have adequate arrangements in place to identify and consult the person’s representatives. Unlike the PPPRA, Family members or others can be appointed to give the researcher advice on the person’s wishes and feelings.¹⁰⁰ If no personal consultees are identified or willing to act, the research can appoint someone who has some connection with the participant. However, the consultee does not have powers under the MCA to consent to a person’s enrollment in research –the researcher decides. Conversely, the CT Regulations give the consultee legal authority to consent to participation.¹⁰¹ The AISA

⁹⁵ Adults with Incapacity (Scotland) Act, s 51(3)(d).

⁹⁶ s 51(3)(e).

⁹⁷ Manning, above n 1, at 527.

⁹⁸ Adults with Incapacity (Scotland) Act, s 51(4).

⁹⁹ Mental Capacity Act, s 32

¹⁰⁰ Section 32(2).

¹⁰¹ Medicines for Human Use (Clinical Trial) Regulations 2004 (CT Regulations), Part 5.

allows consent to be obtained from any guardian or welfare attorney with the power to consent. If no such representative exists, consent needs to be obtained from the adult's nearest relative.¹⁰² Consent of any guardian or welfare attorney or nearest adult is not required in situations where it is not practicable to get that consent, such as in emergency.¹⁰³ New Zealand needs to consider whether leaving the decision to consent is better in the hands of the researcher or a relative.

¹⁰² Adults with Incapacity (Scotland) Act, s 51(3)(f)

¹⁰³ At s 51(3A)(c).

VII Proposed Framework for New Zealand

Any uncertainty about the lawfulness of medical research on incompetent adults in New Zealand needs clarifying for researchers, patients and the wider public. In doing so, New Zealand should strike a balance in favour of increased research on incompetent adults.

Amending Right 7(4) through executive Order in Council is the most efficient method of achieving this outcome. However, this is innately short-sited and doesn't aptly address the issues. This paper recommends that a wholesale legislative reform is needed to govern research so that it cohesively addresses existing gaps in the law. Legislative design should place the relevant provisions regulating research in the same statute, much the same as in the MCA and AISA, so that the relevant law can easily be identified.

Significantly, the framework should clearly implement laws specifically on research rather than continue to rely on the treatment framework. Research participants are better protected when the law is clear and applied appropriately. Indeed, it is often unclear when research activity crosses the rubicon to treatment. Establishing reliable indicators based on risk is far superior than broadly relying on an elusive distinction between therapeutic and non-therapeutic research. For example, Phase I trials may carry a high risk indicator to show that more restrictive safeguards are needed or the research should not be conducted at all on incompetent participants. The following discussion will outline the areas of the law that require closer scrutiny in future review.

A NZBORA

Most of the uncertainty in the NZBORA could only be clarified through the court process. However, ministerial guidelines are required to help clarify the definition of "experimentation" and ensure consistency in our interpretation of the NZBORA.

B Reforming the PPPRA

Individuals who are assigned a welfare guardian could never lawfully participate in research. Professor Joanna Manning advances that “the key barrier to the lawfulness of such studies is s 18(1)(f) of the PPPRA.¹⁰⁴ A consent framework is needed to adequately address the legal void left by the prohibitive wording of s 18(1)(f).

It follows that a review of the substitute-decision making regime in the PPPRA is needed. Researchers should be able to consult a prioritised hierarchy of consultees as found in the MCA. This would allow a continuum of available options where individuals interested in the person’s welfare are consulted. Non-consensual research should only proceed if all representatives are unavailable.¹⁰⁵

Moreover, legislative reform must be geared towards respecting the wishes of the individual in a broader sense. That means the views of family, relatives and community are consulted under the law - rather than assuming a purely individualistic model.

C Best Interests Standard

In New Zealand, if research takes place where a person is unable to consent to participation, that research would effectively breach the Code of Rights by virtue of the uncertainty inherent in such research.¹⁰⁶ Joanna Manning argues that a lower standard than “best interests” is needed. A change to Right 7(4) is needed to provide for the inherent uncertainty in clinical research thereby allowing more research to proceed. A new legal standard is required that clearly recognises that the activities in medical research are distinct from treatment.¹⁰⁷

The Health and Disability Commissioner in his 2009 Report recommended “not known to be contrary to the best interests” as an alternative test.¹⁰⁸ Professor Manning

¹⁰⁴ Manning, above n 1, at 530.

¹⁰⁵ Saver, above n 57, at 213.

¹⁰⁶ Johnson and Godlovitch, above n 28, at 213.

¹⁰⁷ Manning, above n 64, at 324.

¹⁰⁸ Ron Paterson “A Review of the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Services Consumer’s Rights: Report to the Minister” (Health and Disability Commission,

submits that although the test establishes a lower threshold, the double negative is confusing. The formulation does not assist ethics committees and investigators decide what factors they should consider in establishing what would be harmful to the participant and where the benefits should outweigh the risks involved. The standard of minimal risk in the Scottish legislation provides the best option for New Zealand. People generally want to be assured that they will not be subject to harm. The necessity criterion and the impairing condition criterion should also be incorporated in this framework. Research with no potential benefits to the participant should be subject to stricter conditions.

The approach to advance directives in the MCA should be emulated so that a formal indication of the participant's views can be upheld. A provision applicable to all non-consensual research should be included so that informal indications of refusal are respected, particularly if we allow non-beneficial research to proceed.

D Mandatory ethics approval

Ethics approval should be a mandatory pre-requisite for enrolling non-consensual participants in medical research. This approach ensures that a two-tier layer of protection is affixed in the law: a legal representative authorises the research activity; and in the governance framework of ethical bodies that ensure medical researchers engage with their subjects in accordance with their legal and ethical obligations.

E Compensation

New Zealand should not exclude participants of commercially-driven drug trials entirely from the compensation scheme. If we decide to take a utilitarian position on research, the entire legislative framework should recognise that all research participants are benefiting society. In saying that, mechanisms should ensure cost-recovery from companies and more rigorous approval requirements by ethics committees so New Zealand levy-payers are not overly-burdened.

Wellington, August 2009) (the Paterson Report) at 13.

VI Conclusion

Research should be carried out on incompetent adults without compromising their interests so we can better understand the cause of their condition. A comprehensive legislative framework is required that cohesively regulates research on individuals who cannot give consent. Appropriate safeguards should be implemented to protect vulnerable participants.

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