

Chapter 6

Research on People who Lack Capacity

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Chapter 6 is in two sections:

- A. The problems encountered in New Zealand when health and disability research is intended to be carried out on people who lack capacity to consent (non-consensual studies) and the gap in the legal framework.
- B. International standards for research on people who lack capacity and the essential features of the statutory protections in ss 30 – 34 of the Mental Capacity Act.

Introduction

- 6.1 This chapter considers the statutory safeguards provided in the Mental Capacity Act (MCA) for adults who lack capacity to consent to research.⁷²⁰ While the discussion here aims to inform the proposed consultation by the Health and Disability Commissioner on Right 7(4) of the HDC Code (Right 7(4),⁷²¹ the recommendation is for legislative authority to be established rather than simply making changes to the HDC Code, to address “the clearly unsatisfactory but remediable situation”⁷²² that currently exists in New Zealand. The MCA provisions provide a useful legal framework which New Zealand could use to establish its own statutory protections where none currently exist.
- 6.2 Sections 30 – 34 of the MCA provide lawful authority to carry out research on participants who lack capacity, where approved by a research ethics committee, as long as various safeguards are complied with.⁷²³ These safeguards relate both to the characteristics of the research and to the participation of individuals in it. Among the numerous patient protections, the MCA provides that the research must have the potential to benefit the patient without imposing a burden that is disproportionate to that potential benefit, or the research must be of wider benefit for persons affected by the same or similar condition, and impose no more than negligible risk to the patient.
- 6.3 In New Zealand, it has been reported that since 2006 there have been 40 medical studies approved by ethics committees, in which some or all participants may not have had capacity to provide informed consent.⁷²⁴ Right 7(4) of the HDC Code,⁷²⁵ based on the common law doctrine of necessity, and the outdated provisions in the PPPR Act, substantially restrict the ability of researchers (investigators) to provide treatment without consent in the context of

⁷²⁰ Sections 30-34 of the MCA are set out in Appendix C. “Research” is intended to refer to health and disability research which falls under the current ethical review framework in New Zealand.

⁷²¹ In March 2015, Commissioner Hill announced that he would consult on whether Right 7(4) of the HDC Code should be amended in respect of research where participants lack capacity to consent. See A Hill (Commissioner) “20 Years Strong – The Commissioner, the Code and Informed Consumers” (A presentation at the Conference: “Improving the Consumer Experience”, Wellington, March 2015).

⁷²² J Manning “Non-consensual Clinical Research in New Zealand: Law Reform Urgently Needed” (2016) 23 JLM 516.

⁷²³ Mental Capacity Act 2005, s 31.

⁷²⁴ B Heather “Drugs Tested on Mentally Disabled” *Sunday Star Times* (13 July 2014) www.stuff.co.nz/national/health/10261601/Drugs-tested-on-mentally-disabled. Manning, above n 722 cites a number of examples at footnote 15.

⁷²⁵ Right 7(4) of the HDC Code is colloquially referred to as “right seven-four”. See discussion of Right 7(4) in Chapter 5A Best Interests in New Zealand Law.

research (for non-consensual studies).⁷²⁶ Deciding the legality of enrolling adults who lack capacity to consent in research that cannot reasonably be expected to provide benefit to them has been problematic and the current state of the law is a “legal near-vacuum”.⁷²⁷

6.4 Any changes made to the law in this sphere will need to be considered in conjunction with the governance arrangements for ethics committees and the standards they adhere to. In New Zealand, there is no overarching legal framework that expressly recognises the role and function of ethics committees to protect human participants in research and innovative practice.⁷²⁸ Ethics committees have a dual function in this respect: not only to protect the interests of research participants, but also to allow ethically sound research that will secure benefits.

6.5 The problems that exist for non-consensual studies are, in part, indicative of the changes made to ethics committees in 2012 and the undermining of the ethics review system.⁷²⁹ Although the government inquiry aimed to make New Zealand a more attractive place for innovative clinical trials,⁷³⁰ the downgrading of protection for research participants and restructuring of ethics committees is not in line with international standards,⁷³¹ and the current ethics review system is “ad hoc, and fragmented and difficult to navigate”.⁷³²

6A: THE GAP IN NEW ZEALAND’S LEGAL FRAMEWORK

Securing the benefits of research for people who lack capacity

6.6 There are three categories of adults who may lack capacity to consent to their participation in research: firstly, individuals whose diminished capacity is enduring due to a mental or physical

⁷²⁶ The National Ethics Advisory Committee has issued guidelines for researchers on the ethical review of both intervention studies (clinical trials and medical experimentation which may or may not have therapeutic benefit to individuals participating), as well as “observational studies” (observational research which is not a “clinical trial”). National Ethics Advisory Committee (NEAC) *Ethical Guidelines for Intervention Studies: Revised edition* (Ministry of Health, Wellington, 2012).

⁷²⁷ As described by the Scottish Law Commission who were reporting on the same problem over 20 years ago, prior to the enactment of the Adults with Incapacity (Scotland) Act 2000: Scottish Law Commission Report, 1995 [5.65], cited in Ward, above n 128.

⁷²⁸ Health and Disability Ethics Committees are established under s 11 of the New Zealand Public Health and Disability Act 2000. The Act empowers the Minister of Health to create ministerial committees with functions as determined by the Minister of Health. Section 16 of the Act mandates the appointment of a national ethics advisory committee for health and disability services, including health research. Ironically, New Zealand has had specific legislation for the protection of animals in research since 1983 but not humans: Animals Protection Act (NZ), subsequently repealed and replaced with the Animal Welfare Act 1999. G Gillett, A Douglass “Ethics Committees in New Zealand” (2012) 20 JLM 266.

⁷²⁹ The impact of the changes and gradual undermining of the independence of ethics review in New Zealand since the Cartwright Report in 1988 is discussed in: M Tolich and B Smith *The Politicisation of Ethics Review in New Zealand* (Dunmore Publishing Ltd, Auckland, 2015).

⁷³⁰ New Zealand Health Committee *Inquiry into improving New Zealand’s environment to support innovation through clinical trials* (House of Representatives 49th Parliament, Wellington, June 2011).

⁷³¹ The WHO Standards and Operational Guidance for Ethics Review of Health-related Research on Human Participants (2011) include: establishing a research ethics review system with an “adequate legal framework”, presumptive oversight of *all* research by ethics committees to avoid gaps, and scientific design and the conduct of the study as part of ethical review.

⁷³² NEAC “Cross-sectorial ethics arrangements for health and disability research: Submission summary” (14 July 2015) www.neac.health.govt.nz; see also New Zealand Law Society submission (26 February 2015) [www.lawsociety.org.nz/ data/assets/pdf file/0009/87597/I-NEAC-HD-Research-Ethics-26-2-15.pdf](http://www.lawsociety.org.nz/data/assets/pdf_file/0009/87597/I-NEAC-HD-Research-Ethics-26-2-15.pdf).

impairment; secondly, individuals who temporarily lack capacity, but whose capacity will return; and, thirdly, those with progressively deteriorating capacity.

- 6.7 Historically, people with intellectual disabilities have experienced disadvantage, over-protection and abuse where their right to give informed consent has been ignored.⁷³³ Additionally, research involving temporarily unconscious patients may involve the use of an innovative practice or the evaluation of an established therapeutic treatment in emergency situations where it is not possible to obtain informed consent from the individual concerned.
- 6.8 As the New Zealand population ages, research on the aging process, and conditions and diseases that disproportionately affect older persons has become increasingly important. Social science research is essential for understanding the social phenomena of aging, such as the increase in residential care for older adults,⁷³⁴ and through observation and understanding the experiences of adults who lack capacity and those who support them.⁷³⁵
- 6.9 Research participation can be direct, where the person is actively involved in a study and may receive a new treatment, or indirect, where the person's information or DNA samples are collected and analysed to better understand underlying causes of a particular disorder. This is especially true in biobanks where genetic research is focused on complex impairments such as psychiatric disorders or dementia.⁷³⁶
- 6.10 Research involving adults who lack capacity to consent can lead to innovations in healthcare that can substantially improve their health and quality of life and that of others with similar conditions. It is therefore important that these adults are given the opportunity to participate in such research.⁷³⁷ To exclude them from any research would be discriminatory and would diminish their ability to participate as fully as possible in society.⁷³⁸

Right 7(4) and legal justification for research without consent

- 6.11 Research involving unconscious patients or those with diminished capacity to consent or refuse participation in the research differs from standard research because participants are unable to give informed consent.
- 6.12 In general terms, an individual's ability to give valid consent or to refuse to participate in research will depend on the person's ability to understand what the research entails, provided they have been given sufficient information to make an informed decision. The degree of

⁷³³ A Bray *Research Involving People with Intellectual Disabilities: Issues of Informed Consent and Participation* (Donald Beasley Institute, Dunedin, 1998).

⁷³⁴ There is growing literature internationally about ageing, death and dying. For example, Atul Gwande in his book, *Being Mortal: Medicine and What Matters in the End* (Henry Holt/Profile Books, New York and London, 2014) calls for a change in the philosophy of healthcare, explores the different models of social housing and care for older adults, recognising the process of older people losing their independence and ways to improve their well-being.

⁷³⁵ In a qualitative assessment of how support workers caring for adults with intellectual disability perceived substitute decision-making under the MCA, Dunn and others found that the MCA extended this to all areas of personal care, not just to invasive and controversial medical treatment decisions. M Dunn, I Clare and A Holland "Living a Life Like Ours': Support Workers' Accounts of Substitute Decision-Making in Residential Care Homes for Adults with Intellectual Disabilities" (2010) 54 JIDR 144.

⁷³⁶ E Togni, K Dierickx, C Porteri "Participation in biobanks for research by incapacitated adults: review and discussion of current guidelines" (2014) 29 Int J Geriatr Psychiatry 670.

⁷³⁷ See for example, A Murray "The Mental Capacity Act Dementia Research" (2013) 25(3) Nurs Older People 14.

⁷³⁸ Human Rights Act 1993, s 21(1)(h); United Nations Convention on the Rights of Persons with Disabilities, (CRPD) art 5.

detail required will vary according to the needs of the individual patient and the complexity of the procedures involved. In particular, assessment of risk (an important part of decision-making in all forms of healthcare) takes on greater significance in this sphere, since research can involve a degree of uncertainty of the risk involved.⁷³⁹

6.13 In New Zealand, the requirement of informed consent to any health research is codified in the HDC Code, and is affirmed in human rights instruments.⁷⁴⁰ The Cartwright Report also intended that research participants should have access to the Health and Disability Commissioner process, to protect their rights.⁷⁴¹

6.14 The rights in the HDC Code extend to health and disability research, although the extent to which the HDC Code protects the interests of research participants is unclear because “health research” or “disability research” are not defined in the HDC Code or Act.⁷⁴² Research in which participants are unable to consent is not expressly contemplated under Right 7(4). Right 9 states:

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

6.15 In addition, the HDC Code applies only to research involving provision of healthcare, so it does not apply to all relevant research, for example observational research, or non-therapeutic health and disability research carried out by people other than healthcare practitioners.⁷⁴³

6.16 Right 7(4) sets out the legal position concerning research involving the treatment of patients who do not have capacity to consent, where there is no legally authorised person available to give consent: it provides an exception to the usual requirement for informed consent and gives decision-making powers to the clinician-investigator so long as they have taken the steps set out in Right 7(4), to reach the conclusion that participation in the research will be in the patient’s “best interests”.⁷⁴⁴ Right 7(4) can therefore be interpreted as authorising a decision

⁷³⁹ Letts, above n 282 at 142.

⁷⁴⁰ HDC Code, Right 5 (right to effective communication), Right 6 (right to be fully informed) and Right 7 (right to make an informed choice and give informed consent). Section 10 of the New Zealand Bill of Rights Act 1990 also provides for the right not to be subject to medical or scientific experimentation without consent. Article 15 of the CRPD requires State Parties to have effective measures to prevent persons with disabilities, on an equal basis as others, from being subjected to torture or cruel or inhuman or degrading treatment or punishment and, in particular, “no one should be subjected without his or her free consent to medical or scientific experimentation.”

⁷⁴¹ S Cartwright *The Report of the Committee of Inquiry into allegations concerning the treatment of Cervical Cancer at National Women’s Hospital and into other related matters* (Government Printing Office, Auckland, 1988).

⁷⁴² Health research “administered to or carried out in respect of any person” by a “healthcare provider” comes within the applicable definition of “healthcare procedure” and within the Code’s definition of “services”. Right 7(6) of the HDC Code, and the requirement that informed consent to a healthcare procedure (including participation in any research) must be in writing, contains important qualifications which reduce its impact in this context. Right 7(6) only applies to situations where consent “is required”. Therefore, written consent from those patients who are unable to consent (sometimes referred to as unconsentable) will not be required so long as the ethics committee is satisfied that the criteria in Right 7(4) are met.

⁷⁴³ L Wadsworth “Rights and Research: An Examination of Research under New Zealand’s Code of Health and Disability Services Consumers’ Rights” (2013) 21 JLM 187.

⁷⁴⁴ Right 7(4) requires either, reasonable steps have been taken to ascertain the views of the consumer, and if those views have been ascertained, the provider believes, on reasonable grounds, that the provision of services is consistent with the informed choice the consumer would make if he or she were competent: Right 7(4) (b) and (c)(i); or, if the consumer’s views have not been ascertained, the provider

to enrol a patient in research involving treatment, even though the consent of the patient or a substitute decision-maker has not been obtained. It provides a legal justification for research without consent, but only in some limited situations.

The problems with Right 7(4) of the HDC Code

- 6.17 Right 7(4) sits within a list of protections for patients in Right 7, but it largely provides a defence to Code liability for researchers, rather than a safeguard for participants based on the common law doctrine of necessity.⁷⁴⁵ There will be situations where it cannot be said that the research is in the individual's best interests, as often the point of research is not to benefit them but to benefit others in future who may be suffering from a similar condition.⁷⁴⁶
- 6.18 The National Ethics Advisory Committee Guidelines for Intervention Studies (NEAC Guidelines) place legal responsibility for non-consensual studies under Right 7(4) with the investigator, not the ethics committee, reflecting the position that ethics committees have no power to rule on the law.⁷⁴⁷ The NEAC Guidelines stop short of stating that the law prohibits non-consensual studies.⁷⁴⁸ Moreover, the status of the NEAC Guidelines and their interface with the Standard Operating Procedures (referred to as procedural, not ethical guidance), to which ethics committees are to adhere, is unclear, as is how they assist ethics committees when considering research that might be justified under Right 7(4).⁷⁴⁹
- 6.19 The problems with relying on Right 7(4) in the context of non-consensual health research came to a head in 2014. In a letter to ethics committees, the Chief Legal Advisor to the Ministry of Health advised that the NEAC Guidelines for non-consensual studies "are intended for application only to studies that are 'lawful'".⁷⁵⁰ The effect of this directive has been to halt the process of ethics committees reviewing the ethics of a study, including risks and benefits, if participants are not able to give informed consent. Researchers are left in the invidious position of having to confirm the legality of the research based on their own assessment of what is in a person's individual best interests (and implicitly of the risks) under Right 7(4). As Manning says, "researchers are being forced to run the gauntlet of the law."⁷⁵¹

takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider: Right 7(4)(c)(ii).

⁷⁴⁵ *Re F*, above n 124. Clause 3 of the HDC Code states that a provider is not in breach of the Code if the provider "has taken reasonable actions in the circumstances" to give effect to the rights, and comply with the duties, in the Code. Clause 3 specifically provides that in this context "the circumstances" means all the relevant circumstances, "including the consumer's clinical circumstances".

⁷⁴⁶ Ashton, above n 25 at 272.

⁷⁴⁷ NEAC *Guidelines*, above n 726 at 24 [6.27]. The NEAC Guidelines do not presume that participation in health research is limited to individuals who can give informed consent. They suggest that if there is a question as to the competence of a participant, the investigator should consider obtaining dual consent, from the participant and "the informed agreement of another person who is interested in, or has responsibilities for, that person's welfare".

⁷⁴⁸ NEAC Guidelines, above n 726 at 24 [6.24] – [6.29].

⁷⁴⁹ NEAC Guidelines are created under delegated legislation by the New Zealand Public Health and Disability Act 2000, ss 16(1) and (2). NEAC is charged with determining nationally consistent ethical standards and scrutinising health research and standards, for both interventional and observational health research studies. New Zealand Law Society submission to the National Ethics Advisory Committee (12 June 2012). http://www.lawsociety.org.nz/_data/assets/pdf_file/0020/53183/I-NEAC-ethical_guidelines_review-120612.pdf.

⁷⁵⁰ Letter from P Knipe, Chief Legal Advisor, Ministry of Health to Health and Disability Ethics Committees regarding informed consent for ethics approval for trials (7 April 2014). The committees were reminded that they do not have authority to consent on behalf of participants who do not have capacity to consent (implying that this was in fact happening), and that in terms of Right 7(4), investigators must satisfy the committee that the proposed research is "lawful".

⁷⁵¹ J Manning, above n 722 at 517.

The PPPR Act – limitation on powers of substitute decision-makers to consent

6.20 Where the person concerned is incapable of giving consent to healthcare, in the context of research, the first requirement of Right 7(4) is that a clinician-investigator attempt to obtain informed consent from someone entitled to give consent on the person's behalf, such as a welfare guardian appointed by the court or an attorney appointed under an EPOA, who has the authority to make health decisions on the person's behalf (a substitute decision-maker). The problem, however, is that section 18(1)(f) of the PPPR Act prevents such a substitute decision-maker from giving a legally effective consent to:⁷⁵²

any medical experiment other than one to be conducted for the purpose of saving that person's life or preventing serious damage to that person's health.

6.21 This rule prevents the substitute decision-maker consenting to research participation on behalf of the person for whom they act, except in very limited situations. The paramount consideration of a welfare guardian is the promotion and protection of the welfare and best interests of the person for whom they are acting.⁷⁵³ It is not to authorise enrolment of the person in research for the purpose of benefiting other people in future. But Right 7(4) may permit them to give substitute consent to research on a person that is carried out in an emergency department or ICU within a hospital where the treatment or new drug being studied is considered the best treatment or option available.⁷⁵⁴ This is because the treatment being trialled might save that person's life or prevent serious damage to their health, so providing substitute consent would not be prevented by section 18(1)(f).

6.22 These provisions on substitute consent to research under the PPPR Act are outdated. They do not take into account the broad range of health and disability research conducted beyond the clinical environment of emergency treatment, and they substantially limit the powers of others to consent to the inclusion in research of a person who lacks capacity to consent, in situations where their participation would be ethically justified. In the emergency setting, where the patient may be unconscious, there may also be difficulty in identifying whether the person has an appointed substitute decision-maker or not.⁷⁵⁵

Individual best interests and societal benefit

6.23 If no substitute decision-maker is available, Right 7(4)(a) requires the clinician-investigator, having taken the steps to ascertain the views of the person or others required by Right 7(4), to reach the conclusion that participation in the research will be in the person's "best interests". This includes a clinical assessment by the clinician-investigator that there is a need for treatment to proceed, and, in the case of research, confirmation that the research is in the best interests of the individual concerned.

⁷⁵² The same limitation of powers that apply to welfare guardians under s 18(1)(f) applies to attorneys appointed in relation to personal care and welfare (EPOAs) under s 98(4).

⁷⁵³ Protection of Personal and Property Rights Act 1988, ss 18(3) and 98A(2).

⁷⁵⁴ For a fuller discussion see Skegg, above n 580 at 227. Skegg states that if s 18(1)(f) precludes a welfare guardian from giving legally effective consent in such circumstances, the common law justification or "additionally or alternatively, for the purpose of Code liability under Right 7(4) of the Code of Rights", would suffice.

⁷⁵⁵ An electronic register of EPOAs and court orders would potentially solve this particular problem. There are similar problems with identifying whether a person has a legally valid advance directive under Right 7(5) of the HDC Code.

- 6.24 The dual roles of the clinician-investigator can divert attention from the ethical conflict involved in both caring for the patient and potentially enrolling them in a study that may expose them to unacceptable risks.⁷⁵⁶ Other than applying the “best interests” test to the proposed treatment, Right 7(4) does not give the investigator any guidance on how to address this conflict of roles and requires the investigator to make the decision whether or not to enrol the patient in the research in the absence of independent advice or oversight.
- 6.25 More often than not, it is not known in advance whether research will be in the best interests of the person, even though the research may subsequently prove to be beneficial and is not known to be harmful. In some research, there may be “clinical equipoise”, where there is genuine uncertainty in the expert medical community over whether a treatment will be beneficial.⁷⁵⁷ An argument can also be made that there is an “inclusion benefit” in clinical trials: by simply participating in a trial, the participants get more attention and monitoring than similar patients being treated in the same institution who are not involved in research.⁷⁵⁸
- 6.26 There is an important distinction between research that is undertaken in a situation where a therapeutic intervention is needed (and the most promising treatment available is provided),⁷⁵⁹ compared to research where the alternative treatment is less likely to benefit the patient (for example, receiving a placebo in a randomised clinical trial),⁷⁶⁰ or where the new treatment being trialled is no more than equivalent to the standard treatment (“non-inferiority clinical trials”).⁷⁶¹ In the former situation, there is likelihood of direct benefit to the individual, whereas in the latter situations there may only be societal benefits resulting from the research. Such research may still be ethically justified, but it may not be in the best interests of the individual participating in the research, as required under Right 7(4).

Some examples

RE-VERSE-AD: Right 7(4) applied where the treatment being researched was in the individual's best interests, even though the investigator had both clinical and research roles

- 6.27 This multi-centre clinical study was testing the efficacy and safety of a drug designed to reverse the blood-thinning effects of an anticoagulant drug to reduce the risk of bleeding. It received ethical approval on the basis that the research could be lawfully justified under Right

⁷⁵⁶ TL Beauchamp and JF Childress *Principles of Biomedical Ethics* (5th ed, Oxford University Press, New York, 2001) at 319; A Jonsen, M Siegler and M Winslade *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine* (3rd ed, McGraw Hill, New York, 1992) at 147; F G Miller and D L Rosenstein, “The Therapeutic Orientation of Clinical Trials” (2003) 348 NEJM 1383 at 1384.

⁷⁵⁷ B Freedman “Equipoise and the Ethics of Clinical Research” (1987) 317 NEJM 141. The “equipoise standard” is referred to in the NEAC Guidelines as the balancing of risks and benefits where there is a comparison of two or more interventions designed to meet the equipoise standard and there is usually use of a placebo or no intervention as a control.

⁷⁵⁸ J Lantos “The Inclusion Benefit in Clinical Trials” (1999) 134 J Paeds 30 at 31; Miller and Rosenstein, above n 756 at 1383.

⁷⁵⁹ For an example of a Phase 3 single arm study where the treatment was the best available see the RE-VERSE-AD study discussed below.

⁷⁶⁰ For an example of a Phase 2 randomised controlled trial, see the CLEMATIS study discussed below.

⁷⁶¹ A non-inferiority clinical trial is one where the treatment or drug is said to be “as good as” or “not inferior to” standard treatment. For example, ASPECT: A double-blind study to assess the safety and efficacy of intravenous Ceftolozane/Tazobactam with that of Meropenem in ventilated nosocomial pneumonia. This was a Phase 3 trial to see whether a new antibiotic was as effective as an existing antibiotic, rather than superior. Conditional approval was granted on the basis that the researcher provide information that participation in the research would be in the patients’ best interests. (Northern A Health and Disability Ethics Committee Minutes, 11 March 2014, www.ethics.health.govt.nz). For a fuller discussion of this study, considered at the same time as the CLEMATIS study, see Manning, above n 722 at 518.

7(4).⁷⁶² Prior to the study, patients on the anticoagulant had limited options available to control bleeding. Some of these patients were in a life-threatening emergency situation and required immediate surgical or medical intervention to manage their bleeding.⁷⁶³ In the large majority of cases in this study, no substitute decision-maker was available for the investigator to consult under Right 7(4).⁷⁶⁴ As there was potential to reverse a serious, life-threatening condition with the best treatment available, the principal investigator was able to confirm to the ethics committee that the research was in the best interests of individual participants, and so to proceed would meet the criteria under Right 7(4).

6.28 The study has been successful, with a significant number of “unconsentable” patients enrolled who had positive medical outcomes. In this way, New Zealand researchers have played a major role in globally demonstrating that the study drug is effective and safe.⁷⁶⁵

6.29 At the outset of this study, the principal investigator initiated the practice of seeking a second opinion from another doctor not directly involved in the study (a “disinterested colleague”) on the enrolment of a patient, when this would be justified under Right 7(4). The investigator explains the ethical conflict as follows:⁷⁶⁶

In cases where the decision as to whether treatment is in the patient’s interests rests predominantly on the clinician, the clinician’s judgement can be coloured by the wish to recruit patients to the trial. Even in cases where no bias is present, the possibility of perception of bias leading to an error of medical judgement cannot be excluded.

CLEMATIS study: Randomised control trial, justified ethically by the societal benefit; exclusion of adults as research not in their best interests, but not children with parental consent

6.30 When the benefits to an individual are less clear, or there is no imminent risk to health or safety that can be mitigated by the intervention, research participation is unlikely to be justified in terms of Right 7(4). The CLEMATIS study was a multi-centred clinical trial investigating a drug intended to enhance cognition and learning in people with Down syndrome. Approval for the study was initially declined, based on legal advice that it was not clear that the proposed research would be in the best interests of the participants.⁷⁶⁷

6.31 The application was resubmitted in July 2014 and was given approval for children whose parents could give consent for participation and for adults who had the capacity to give informed consent.⁷⁶⁸ Ethical approval was declined for adults with Down syndrome who

⁷⁶² Central Health and Disability Ethics Committee Minutes “Reversal of the Anticoagulant Effect of Dabigatran Using Idarucizumab” ethics ref. 14/CEN/58/AM03 (22 April 2014) www.ethics.health.govt.nz at 8. The writer subsequently provided one of two legal opinions submitted to the ethics committee when amendments were made to the consent forms: (Central HDEC approval letter dated 1 May 2015).

⁷⁶³ This is a Phase 3 single arm study and all patients enrolled in the study receive the study drug.

⁷⁶⁴ Email communication from Dr Gordon Royle, Haematologist, Middlemore Hospital, New Zealand principal investigator for the RE-VERSE-AD study to Alison Douglass (29 February 2016).

⁷⁶⁵ Email communication from Dr Gordon Royle, Haematologist, Middlemore Hospital, New Zealand principal investigator for the RE-VERSE-AD study to Alison Douglass (2 March 2016).

⁷⁶⁶ Royle, above n 764. The ethics committee did not initially require a second opinion but subsequently approved the process for unconsentable participants as set out in the “Form for participants who are not able to give written informed consent”. The form also has a procedure should the patient subsequently regain capacity post-treatment.

⁷⁶⁷ Northern A Health and Disability Ethics Committee “A Study of RG1662 in Adults and Adolescents with Down syndrome (CLEMATIS)” (8 April 2014) www.ethics.health.govt.nz at 3. The study was a Phase 2 randomised clinical trial of the safety, efficacy and tolerability of a cognitive enhancing drug in people with Down Syndrome between the ages of 12 and 30.

⁷⁶⁸ The Care of Children Act 2004 allows parents of children under 16 to give proxy consent for medical treatment.⁷⁶⁸ Guidelines have extended this to include participation in research, N Peart and D

lacked capacity to consent, even though the drug could not effectively be tested in persons without Down syndrome.

- 6.32 The ‘necessity’ principle in research, as it applies to children, is that research should only be carried out on children if comparable research with adults could not answer the same question.⁷⁶⁹ The decision to allow for substituted consent in one vulnerable population (children), but not to extend it to adults who lack capacity undermines this ethical principle and discriminates between two vulnerable groups.⁷⁷⁰ Under Right 7(4) no account can be taken of wider societal benefits of the research, or of the fact that this particular study drug was aimed at providing treatment for people affected by Down syndrome, even though the study had been approved for adults in eight countries,⁷⁷¹ including meeting the standards of the Clinical Trial Regulations in the United Kingdom.⁷⁷²

Proposal to amend Right 7(4) of the HDC Code

- 6.33 In the absence of clear legislative direction, these examples highlight the problematic terms of Right 7(4) when applied to research with participants unable to consent. Accordingly, in 2009, Commissioner Paterson recommended a change to Right 7(4) that might permit more research on unconscious or incompetent patients, provided the research was approved by an ethics committee.⁷⁷³ The recommendation was that Right 7(4)(a) should be amended so as to justify healthcare proceeding where:

It is in the best interests of the consumer, or in the case of research, is not known to be contrary to the best interests of the consumer and has received the approval of an ethics committee.

- 6.34 This proposed amendment (introducing the “not known to be contrary to” formula) in effect sets a lower threshold for establishing what is in a patient’s best interests. The double negative formulation used does not guide ethics committees as to what factors they should take into account, however, in deciding what is not harmful (and not contrary) to the interests of research participants, or whether the assessment of best interests can consider benefits over and above direct benefits to an individual. It also continues to confuse the role of Right

Holdaway “Legal and Ethical Issues of Health Research with Children” (1998) 2 Children’s Issues Centre 42 (www.hrc.govt.nz). The recently released report by the Nuffield Council on Bioethics *Children and Clinical Research: Ethical Issues* (2015) states that an understanding of a child’s longer-term welfare can include contributing to wider social goods, and parental consent to research should consider whether participation in the proposed research is *compatible* with their child’s immediate and longer-term interests (Chapter 4).

⁷⁶⁹ See, for example the HRC’s *Guidelines for Health Research with Children* www.hrc.govt.nz/sites/default/files/HRC%20Guidelines%20for%20Health%20Research%20with%20Children.pdf. The Guidelines are derived from the Guidelines of the Royal College of Paediatrics and Child Health 1999 and the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 1996. The ‘necessity principle’ is discussed below under the MCA.

⁷⁷⁰ J Lenagh-Glue “Resolving the Irreconcilable: Informed Consent and Participation in Medical Research for Adults with Intellectual Disability” (LLB (Hons) Dissertation, University of Otago, 2014).

⁷⁷¹ LuMind “Clinical Trials UPDATE: Roche Initiates RG1662 Phase II Clinical Trials for Individuals with Down syndrome” (19 May 2014) www.plus15campaign.wordpress.com.

⁷⁷² *Clinical Trials Regulation* (UK) <http://www.ukctg.nihr.ac.uk/trials/trial-details/trial-details?trialNumber=NCT02024789>.

⁷⁷³ In an earlier review of the HDC Code in 2004, Commissioner Paterson recommended the specific provision relating to research on unconscious or incompetent patients with appropriate safeguards rather than wholesale change to Right 7(4) to cover treatment of incompetent patients generally (not just research). See Health and Disability Commissioner *Report to the Minister of Health* (June 2009) at 14. <http://www.hdc.org.nz/media/21835/theact-review2004.pdf>.

7(4), a justification for proceeding with treatment in limited circumstances, with the need to have adequate safeguards in place for research participants.

- 6.35 In the 2014 review of the HDC Code, Commissioner Hill did not revisit the 2009 recommendation for changes to Right 7(4).⁷⁷⁴ What is required is separate legislation that would provide similar protections for research participants who lack capacity as are found in the MCA, and in the Adults with Incapacity (Scotland) Act 2000.

6B: INTERNATIONAL STANDARDS AND THE MENTAL CAPACITY ACT

International ethical standards for non-consensual studies

- 6.36 International ethical standards recognise that medical research involving subjects incapable of giving informed consent may be justified, such as research with unconscious patients, if the condition that prevents them from giving informed consent is a “necessary characteristic” of the research population. The World Medical Association’s Declaration of Helsinki⁷⁷⁵ sets recognised ethical standards for the conduct of research. Its basic principles in relation to the involvement of an incapacitated adult include:

- Incompetent adults should not be included in research that is unlikely to benefit them personally, unless the research is necessary to promote the health of the population represented by the potential research subjects; this research cannot instead be performed on legally competent persons; and it involves only minimal risk and minimal burden to participants.
- Where an adult is incapable of giving consent, the responsible researcher must obtain informed consent from any legally authorised representative.
- Where an incompetent adult is capable of assenting to decisions about participation in research, this assent must be obtained, in addition to the consent of a legally authorised representative. Any dissent by the person should be respected.
- The research must be intended to provide knowledge relating to the condition or conditions that have contributed to the impairment of the individual’s incapacity.

- 6.37 The World Health Organisation (WHO), in collaboration with the Council for International Organizations of Medical Sciences (CIOMS), has issued international guidelines for ethical clinical research with human subjects.⁷⁷⁶ Guideline 9 sets a “low-risk standard” for research involving individuals incapable of giving informed consent. This states:⁷⁷⁷

⁷⁷⁴ New Zealand Law Society submission on the Review of the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Consumers’ Rights (17 February 2014)

⁷⁷⁵ World Medical Association (1964) *Declaration of Helsinki*, Ethical Principles for Medical Research Involving Human Subjects, as subsequently amended most recently in 2008: see www.wma.net.

⁷⁷⁶ CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, Geneva, 2002).

⁷⁷⁷ CIOMS, above n 776 at 49.

The risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them.

- 6.38 Both the Declaration of Helsinki and the CIOMS guidelines affirm the need to have a legally authorised person, other than the investigator of the research, to give legally effective consent where a person lacks capacity to consent to research. If a participant with diminished capacity is capable of “assent” and there is no “dissent”, such assent is not legally effective on its own. The level of acceptable risk must be negligible or minimal even if there may be societal benefit over and above individual benefit, and an ethics committee must approve all research. None of these criteria in international standards are expressly articulated in New Zealand law.

Mental Capacity Act – law reform and research governance

- 6.39 In 1995, the English Law Commission found a “striking degree of consensus over the factors which make non-therapeutic research ethical” and these are largely reflected in the MCA’s scheme.⁷⁷⁸
- 6.40 The initial draft Mental Incapacity Bill presented to the UK Parliament in June 2003 did not contain any provisions on research. The Joint Committee on the Bill concluded that there should be provision in the Bill to enable strictly controlled medical research to explore the causes and consequences of mental incapacity and to develop effective treatment for such conditions. It further recommended that these clauses should set out the key principles governing such research and the protections against exploitation or harm enshrined in the Helsinki Declaration of the World Medical Association of 1964.⁷⁷⁹ Consideration was also given to the framework for research set out in s 51 of the Adults with Incapacity Act (Scotland) 2000.
- 6.41 The report acknowledged that if legal mechanisms prevented or deterred research for such people, then the development of treatments and the undertaking of treatment trials for disorders such as Alzheimer’s disease would be very problematic. The Joint Committee said:⁷⁸⁰

The range of medical research involving people with possible mental incapacity was considerable. Other examples include investigating why people with Down Syndrome are at such high risk for Alzheimer’s Disease, how best to treat the effects of acute brain injury, how to understand and manage problems such as self-injurious behaviour affecting people with autism, the causes of potentially very debilitating mental illness such as schizophrenia, or the best treatment of severe brain disorders such as in variant CJD. Research goes beyond the medical field and includes investigating factors influencing the quality of life of people with incapacitating disorders, or how they can be best helped to make decisions for themselves. In all of these examples, some of people involved will have the capacity to consent to research but others may not.

- 6.42 Medical research in England and Wales is governed by two distinct governance regimes. Clinical trials of investigational medicinal products are regulated under an EU Directive,⁷⁸¹

⁷⁷⁸ Hale, above n 194 at 220, citing Law Commission, above n 124 at [6.3(1)].

⁷⁷⁹ Joint Committee on the draft Mental Incapacity Bill First Report, Chapter 15 www.publications.parliament.uk/pa/jt200203/jtselect/jtdmi/189/18918.htm.

⁷⁸⁰ Mental Incapacity Bill, above n 779 at [279].

⁷⁸¹ European Union “Regulation of 16 April 2014” No. 536/2014 (2014) Official Eur Union. The Clinical Trials Regulations 2004 were updated in 2015. After almost two years of discussions, the EU Parliament

implemented by the Medicines for Human Use (Clinical Trials) Regulations 2004 (CT Regulations), with further amendments to come into effect in 2016.⁷⁸² All other medical research involving people who lack capacity (“intrusive research”), including clinical trials that do not relate to investigational medicinal products, falls under the MCA.

- 6.43 The Health Research Authority (like its predecessors prior to 2011) provides research and ethics committee governance in England and Wales, including an independent advisory panel available to assist ethics committees.⁷⁸³

Mental Capacity Act – sections 30–34

- 6.44 Sections 30 – 34 of the MCA⁷⁸⁴ provide lawful authority for “intrusive research” involving people without capacity where the research has been approved by an appropriate body.⁷⁸⁵ Research is “intrusive” if it would legally require consent if it involved people with capacity.⁷⁸⁶
- 6.45 A broad approach has been taken to what constitutes “intrusive research” under the MCA. This concept is not limited to medical or biomedical research that is physically invasive. As a result, it can be difficult to decide whether some social science research, such as qualitative and observational studies, comes under the MCA, for example observational studies in care homes.⁷⁸⁷

Loss of capacity during the research project

- 6.46 Some people who consent to long-term research studies may lose capacity before the study ends or experience diminishing and fluctuating capacity. The MCA follows the common law position that consent to participate in research does not survive the loss of capacity. This means that if a person has already consented to participate in research then loses capacity in the course of research, their continued participation would be unlawful unless the procedures applying to incapacitated participants were then followed.

in April 2014 adopted a new regulation on clinical trials, which would replace the currently applicable 2001 Clinical Trials Directive in 2016.

⁷⁸² C Gennet, R Andorno and B Elgar “Does the New EU Regulation on Clinical Trials Protect Vulnerable Participants?” (2015) Health Policy <http://dx.doi.org/10.1016/j.healthpol.2015.04.007>.

⁷⁸³ The Health Research Authority is an “arms-length” Non-Departmental Public Body (NDPB) that provides research governance for the National Health Service as well as social care research under the Care Act 2014. (Interview with Clive Collett, HRA Ethics Guidance and Strategy Manager, 5 June 2015, London) www.hra.nhs.uk.

⁷⁸⁴ Mental Capacity Act 2005, ss 30 – 34 are set out in full in Appendix C.

⁷⁸⁵ Section 34 is a transitional provision relating to the loss of capacity in research that started before 1 October 2007 but has limited application under regulations: Mental Capacity Act 2005 (Loss of Capacity During Research Project) (England) Regulations 2007. The Regulations only apply to tissue and data collected before the loss of capacity from a person who gave consent and do not cover research involving direct intervention, for example, taking a further blood pressure reading or the taking of further tissue after loss of capacity. Where the Regulations do apply, research can only continue if the project has procedures to deal with people who lose capacity during the project and that has been approved by an ethics committee.

⁷⁸⁶ Research may be unlawful for several different reasons, not only because it involves what would otherwise be an assault: for example, where use of the data or samples collected would breach confidentiality or data protection laws or the Human Tissue Act 2004. See *MCA Code of Practice*, above n 285 at Chapter 11.

⁷⁸⁷ Interview with Martin Stevens, Chair of the Social Care Research Ethics (SCREC) (London, 10 June 2015).

6.47 A key difference under the CT Regulations is that consent survives the loss of capacity. If the person loses capacity during the research then a legal representative (who may be a professional) can consent on the person's behalf.⁷⁸⁸

Ethics committee approval: key requirements

6.48 Under the MCA, an ethics committee, established as the "appropriate body", must approve any medical research project,⁷⁸⁹ and can only approve a project that involves a person who lacks the capacity to consent to involvement if the following requirements are met:⁷⁹⁰

1. The research must be connected to an *impairing condition* affecting the person or his treatment.
2. There must be reasonable grounds for believing that *research of comparable effectiveness cannot be carried out* if the project has to be confined to, or only relate to, people who have capacity to consent to taking part.
3. The research must:
 - (a) have the *potential to benefit the person without imposing a burden that is disproportionate to the benefit*, or
 - (b) be intended to provide knowledge about the *causes of the impairing condition*, its treatment or about the care of people affected by the same or a similar condition, provided the research involves *negligible risk*.
4. Arrangements must be in place to comply with s 32 (*consultees*) and s 33 (*additional safeguards*).

Impairing condition

6.49 An ethics committee may not approve a project unless it is connected with an "impairing condition" or its treatment.⁷⁹¹ Ensuring the research is related to the person's condition is described by Lewis as the "subject condition" requirement.⁷⁹²

⁷⁸⁸ The legal representative under the CT Regulations has legal authority to give consent or refusal. The differences between the two regimes regarding consultees can be confusing to researchers. In 2010 the NRES released an on-line toolkit offering practical advice on the confusing legal requirements and is explained in a video: <https://connect.le.ac.uk/alctoolkit/>

⁷⁸⁹ Mental Capacity Act 2005, s 30(4).

⁷⁹⁰ Mental Capacity Act 2005, ss 31(2)–(5).

⁷⁹¹ Mental Capacity Act 2005, ss 31(2) and 31(3). An impairing condition is one which is, or may be, either the cause or the effect of an impairment or disturbance in the functioning of the mind or brain or which contributes to it.

⁷⁹² Interview with Professor Penney Lewis, King's College London, London, 7 May 2015. See also P Lewis "Procedures that are Against the Medical Interests of Incompetent Adults" (2002) OJLS 575 at 602. This was also originally contemplated by the Law Commission, above n 125 at 98-100.

- 6.50 It is important that impairing conditions are linked to the condition that is being researched. For example, research that considers the increased incidence of falls in the elderly may justify enrolling people with dementia. However, enrolling people with dementia in genetic research to examine the genomes of a rare cancer unrelated to dementia should not, and did not, gain ethical approval.⁷⁹³

The necessity condition

- 6.51 Section 31(4) of the MCA requires reasonable grounds for believing that if research were to be confined only to people who lacked capacity to consent, it would not be as effective. This condition is described by Lewis as the “necessity” requirement, because research of equal effectiveness could not be carried out if confined to participants with capacity.⁷⁹⁴

Example: Observational study in an acute psychiatric-care setting where the necessity condition was not satisfied

- 6.52 The Social Care Research Ethics Committee declined to approve a proposed study of acute psychiatric care in respect of people who lacked capacity. The researcher wanted to observe the mental health assessment process, including both the mental health practitioner and the service user.⁷⁹⁵ The study raised the issue of the consent mechanism at a time when people lack capacity to consent because of a critical illness, but may regain capacity. The necessity condition was not met because research could have been carried out equally well by only including assessments of psychiatric patients who had the capacity to consent to taking part. The ethics committee noted that the research was of no personal benefit to the individuals and there were “non-negligible” risks involved given the intrusive nature of the assessment process. In addition, having a personal consultee,⁷⁹⁶ such as a family member, give consent could potentially cause a conflict of interest and would place more stress on the participants.
- 6.53 A similar study was approved which aimed to include participants who had sufficient capacity to agree to the researcher being present at the assessment (assent and no dissent). Consent for the data collected at the time of the assessment to be included in the research was sought if and when the person regained capacity. If the person did not regain capacity, or refused to allow their data to be used in the research, it would be discarded.⁷⁹⁷

⁷⁹³ As was the case in a large longitudinal study, the “100,000 Genomes” project. Interview with Nigel Wellman, Chair of the Oxford C Ethics Committee, (Oxford, 2 June 2015). The project will sequence 100,000 genomes from around 70,000 people. Participants are NHS patients with a rare disease, plus their families, and patients with cancer www.genomicsengland.co.uk/the-100000-genomes-project.

⁷⁹⁴ Lewis (2002), above n 792.

⁷⁹⁵ “Exploring AMHP decision-making during mental health assessments”, Extracts of anonymised minutes released by the National Social Care Research Ethics Committee, 12 June 2015.

⁷⁹⁶ Personal consultees are discussed below.

⁷⁹⁷ Stevens, above n 787.

Balancing the benefit and burden of research

- 6.54 Where the research meets the requirement of being connected to the person's impairing condition but does not have the potential to benefit the person without imposing a burden that is disproportionate to that benefit,⁷⁹⁸ the MCA imposes a number of additional requirements. There must be reasonable grounds for believing that:⁷⁹⁹
- The risk to the research subject is likely to be negligible [minimal];⁸⁰⁰
 - Anything done to, or in relation to, the research subject will not interfere with the person's privacy or freedom of action in a significant way;
 - Anything done, to or in relation to, the research subject will not be unduly invasive or restrictive.
- 6.55 The research should have the potential to benefit the person without imposing a burden that is disproportionate to that benefit. Therefore, if participants stand to benefit personally from the research, a greater level of risk or inconvenience may be acceptable.⁸⁰¹
- 6.56 The Scottish and English legal frameworks adopt similar approaches to the benefit and risk thresholds, but with nuanced differences. The Scottish legislation says that where the research entails "no foreseeable risk, or only a minimal foreseeable risk",⁸⁰² the research must be "likely to produce real and direct benefit" to the adult.⁸⁰³
- 6.57 Manning argues that the Scottish model is clearer and more protective of subjects because it only allows minimal risk, regardless of the potential to benefit the adult, whereas the MCA does not define what an acceptable risk might be.⁸⁰⁴ At the time the MCA Bill was before the UK Parliament there was a misapprehension that the Scottish wording "real and direct benefit" was too restrictive and that it meant that there would *definitely* have to be benefit to the individual research participant.⁸⁰⁵ The approach taken in the MCA was also justified as

⁷⁹⁸ Mental Capacity Act 2005, s 31(4). Examples of possible benefits to participants include developing more effective ways of treating them or managing their condition, improving the quality of their care, discovering the cause of this would be helpful to them, and reducing the risk of harm or disadvantage. *MCA Code of Practice*, above n 285 at [11.14]. Examples of useful general knowledge might be to see whether a particular way of helping people with congenital learning disabilities might also help people with disabilities caused by head injuries *MCA Code of Practice* at [11.17].

⁷⁹⁹ Mental Capacity Act 2005, s 31(6).

⁸⁰⁰ The Government committee considering the MCA Bill considered that "negligible" was synonymous with "minimal". Joint Committee On Human Rights Fourth Report_(on HL Bill 13) (24 January 2005) <http://www.parliament.the-stationery-office.co.uk/pa/jt200405/jtselect/jtrights/26/2607.htm>, at [4.67].

⁸⁰¹ This kind of research is sometimes referred to as "therapeutic" research. However the distinction between therapeutic and non-therapeutic research can be difficult. Under the NEAC guidelines, "intervention studies" refers to research that includes therapeutic interventions as well as preventative and diagnostic interventions, above n 726.

⁸⁰² Adults with Incapacity (Scotland) Act 2000, s 51(3)(d).

⁸⁰³ Adults with Incapacity (Scotland) Act 2000, s 51(3)(a). If it is not of real and direct benefit, it must be likely to benefit others with the same incapacity through 'significant improvement in the scientific understanding of the adult's incapacity to the attainment of real and direct benefit to the adult or to other persons having the same incapacity', s 51(4). Therefore, the necessity and condition requirements of both laws are similar.

⁸⁰⁴ Manning, above n 722 at 527.

⁸⁰⁵ Joint Committee On Human Rights Fourth Report, above n 779 at [4.63].

covering the broad range of research possible under the Bill (“intrusive research”), rather than only direct medical interventions.⁸⁰⁶

- 6.58 The Scottish model does not address the principle of proportionality when taking into account the relative risks and benefits of participating in research.⁸⁰⁷ By comparison, the MCA recognises a greater risk (burden) is justified where there is potential to benefit the individual concerned.⁸⁰⁸

Consultees

- 6.59 Section 32 of the MCA requires researchers to have adequate arrangements in place for consulting designated persons (“consultees”) about whether a person lacking capacity should take part in the research. Reasonable steps must be taken to identify a “personal consultee”. This should be someone who knows the individual who lacks capacity in a personal capacity and is able to advise the researcher about the person’s wishes and feelings in relation to the research.⁸⁰⁹ This will ordinarily be a family member or someone close to the person, or it could be someone acting under a lasting power of attorney (LPA) or appointed by the court.
- 6.60 If no appropriate person can be identified who is willing to act as a personal consultee, the researcher may consult a “nominated consultee”, that is, someone appointed by the researcher who has some connection with the participant (often a paid care worker or professional) and is independent of the research. Researchers have sometimes shown a reluctance to have a nominated consultee where a personal consultee is not available, or more rarely, where there is a conflict of interest.⁸¹⁰
- 6.61 The consultee gives advice rather than consent.⁸¹¹ They must be given information about the project and advise on what the participant’s wishes and feelings would be about taking part, similar to the approach taken when assessing a person’s best interests under s 4 of the MCA. A key difference in the CT Regulations is that it gives the legal authority to enrol a person in research to someone else (other than the researcher),⁸¹² whereas, under the MCA, it is the researcher who makes the decision about participation, provided the process has been approved by an ethics committee.

⁸⁰⁶ Joint Committee On Human Rights Fourth Report, above n 779 at [4.55].

⁸⁰⁷ Mental Capacity Act 2005, s 31(5)(a).

⁸⁰⁸ The omission of the principle of proportionality in the Scottish legislation in respect of research was noted by the Joint Committee on Human Rights, above n 779. The general principles in Part I of the Scottish legislation include the “least restrictive” principle and that there should be “no intervention in the affairs of an adult unless the person responsible for authorising or effecting the intervention is satisfied that the intervention will benefit the adult and that such benefit cannot reasonably be achieved without intervention,” s 1(2).

⁸⁰⁹ Mental Capacity Act 2005, s 32(2).

⁸¹⁰ Stevens, above n 786. For example, Independent Mental Capacity Advocates (IMCAs) appointed under the MCA could be a nominated consultee, but are not currently appointed for this purpose (Interview with Dr Michael Dunn, Ethox Centre, Oxford University and member of the Social Care Research Ethics Committee, Oxford, June 2015).

⁸¹¹ Mental Capacity Act 2005, s 32(4). Guidance on nominating a consultee for research involving adults who lack capacity to consent issued under s 32(3) of the MCA, Department of Health, 2008.

⁸¹² The legal representative can either be personal or professional and the latter can include the patient’s own doctor unless connected to the research study: Clinical Trials regulations, above n 772 at Part 5.

- 6.62 The consultee provisions in the MCA are stronger than the steps required under Right 7(4) in New Zealand and are tantamount to a power of veto over participation in the research. The researcher must take heed of any advice from the consultee that enrolment or continued involvement in the study would be contrary to the wishes of the person who lacks capacity.⁸¹³ Even if a person with capacity had originally consented to join the research project, if they later lose their capacity they must be withdrawn if this approval process has not been completed, unless withdrawal of the treatment would involve significant risk to their health.⁸¹⁴

Additional safeguards

- 6.63 The consultee provisions in s 32 also need to be read in light of additional safeguards in s 33 which include “dissent” during the course of the research.⁸¹⁵ These provisions mean that the research cannot proceed if the person appears to object, unless it would protect them from harm or reduce their pain or discomfort.⁸¹⁶ Nor can anything be done which is contrary to an advance decision, or any other form of statement by the participant, of which the researcher is aware.⁸¹⁷

Emergency care research

- 6.64 Where treatment is to be provided urgently, the MCA allows by exception for a person lacking capacity to be entered into research prior to a consultee being consulted, subject to strict conditions. The researcher must either have the agreement of a doctor who is not involved in the research, or, if this is not practicable, comply with some other procedure laid down by the ethics committee when the research was approved.⁸¹⁸ Once the urgency has passed, the research must not continue on this basis.⁸¹⁹
- 6.65 The CT Regulations were amended in 2006 to allow unconscious patients in emergency situations to be enrolled in clinical trials without prior consent, provided an appropriate research ethics committee has approved the research.⁸²⁰

Example: PARAMEDIC-2: The adrenaline trial

- 6.66 The PARAMEDIC-2 study is a large clinical trial that will involve 8000 patients and is looking at whether the use of adrenaline is safe and effective in the treatment of cardiac arrest.⁸²¹ The ethics committee approved the study under the CT emergency regulations. As all

⁸¹³ Mental Capacity Act 2005, ss 32(4) and 32(5).

⁸¹⁴ The consultee provisions are similar in some respects to human tissue legislation in England (Human Tissue Act 2004) and New Zealand (Human Tissue Act 2008) but there is no hierarchy of persons who can consent or object. See an explanation of the informed consent and objection provisions in the Human Tissue Act: A Douglass “The New Human Tissue Act” (2008) NZLJ 377.

⁸¹⁵ There is also a curious and slightly contradictory provision in s 33(3) of the MCA which states: “In conducting the research, the interests of the participant must always be assumed to outweigh those of science and society.” This principle is in compliance with international standards (Declaration of Helsinki, General Principle 8).

⁸¹⁶ Mental Capacity Act 2005, s 33(2)(a).

⁸¹⁷ Mental Capacity Act 2005, s 33(2)(b).

⁸¹⁸ Mental Capacity Act 2005, ss 32(8) and (9).

⁸¹⁹ Mental Capacity Act 2005, s 32(10).

⁸²⁰ Medicines for Human Use (Clinical Trials) Amendment (No 2) Regulations 2006.

⁸²¹ The PARAMEDIC-2 trial was reviewed and approved by the South Central Oxford C Research Ethics Committee [14/SC/0137]. This clinical trial is a double blind, randomised placebo controlled trial of the use of adrenaline in cardiac arrest in hospital, commenced in December 2014 and runs to 2018. As at 11 February 2016, 2000 paramedics are now trained in the trial procedures and 1500 patients were recruited. <http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/critical/paramedic2/>

patients undergoing treatment for cardiac arrest will lack capacity to consent to their participation, there was an agreed procedure for the investigators to recruit participants to the study.

- 6.67 Adrenaline is routinely used to treat a cardiac arrest. Analysis of international evidence available has shown that while use of adrenaline may improve the return of spontaneous circulation and short-term survival, there is insufficient evidence to suggest that it improves long-term survival and neurological outcome.⁸²² International consensus demonstrated the need for a randomised, placebo-controlled trial of adrenaline. Therefore there is genuine clinical equipoise concerning the two treatment approaches involved in this study.
- 6.68 The ethics committee had to consider two main ethical issues; firstly, whether to deny patients adrenaline, which has been standard care for 50 years despite the growing evidence against its use; and, secondly, whether relatives of participants who die should be told that their family member was in the study, in view of the low (1 in 10) survival rates in out-of-hospital cardiac arrests.⁸²³
- 6.69 Following a public information campaign and consultation about the study, the ethics committee agreed to an “opt out” process for consent. Members of the public who do not wish to take part, in the event that they have a cardiac event, can request a steel “no study” bracelet. In respect of whether to inform families, it was decided the burden of actively informing the family outweighed the potential benefit, unless families initiated contact; then they can meet with the ambulance team. Although there was some public opposition,⁸²⁴ the ethics review process allowed this large and important study to proceed.

Innovative treatment

- 6.70 Although the MCA covers the involvement of incapacitated adults in research, it does not make specific mention of innovative treatment, which is sometimes difficult to distinguish from research. Innovative treatment is often an extension of usual treatment but may expose the patient to a greater degree of risk than established procedures.
- 6.71 In *Simms v Simms*,⁸²⁵ use of an experimental treatment, not provided during research, was authorised by the Family Division of the High Court when it had not been tested on human beings. Its use was approved for two young patients (16-and18-years-old) who were thought to be suffering from variant Creutzfeldt Jakob disease (vCJD).⁸²⁶ Dame Elizabeth Butler-

⁸²² The International Liaison Committee for Resuscitation synthesised available evidence in 2010 with a re-assessment in 2012 (see the Adrenaline Trial Protocol, 3 March 2014, Oxford C REC: 14/SC/0157). The circumstances are similar to those of the CRASH trial (corticosteroid randomisation after significant head injury): steroids that had for years been given in head injury were actually doing harm. P Edwards, M Arango, L Balica and others “Final results of MRC CRASH, a randomised placebo controlled trial of intravenous corticosteroid in adults with head injury—outcomes at 6 months” (2005) 365 *Lancet* 1957. Interview with Nigel Wellman, Chair of the Oxford C Ethics Committee (Oxford, 2 June 2014).

⁸²³ M McCartney “Adrenaline in cardiac arrest: it’s unethical for patients not to know” (2014) 349 *BMJ* g5258 (22 August 2014). In the news media it was reported that, for people to be able to opt out, “there needs to be an information storm so that all potential participants will see some information about the trial. [Only] then is it legitimate to say that anyone who has not opted out has consented to participate.” The author of the *BMJ* article then asked, “But where is the consent from the thousands of other people who have cardiac arrests but do not know that the adrenaline that they receive may harm them?”

⁸²⁵ *Simms v Simms*, *PA v JA* [2003] 1 All ER 669, [2002] EWHC 2734 (FAM).

⁸²⁶ There are no reported cases regarding research in the Court of Protection under the MCA. Although this decision was made before the MCA came into force, it is likely that the Court of Protection would reach a similar decision, given that the innovative treatment was deemed to have been in the best interests of the person lacking capacity to consent: Letts, above n 282 at 149.

Sloss accepted that, although the patients would not recover, the treatment offered the only hope for them in slowing down the decline in their condition. The concept of “benefit” in this context would encompass:⁸²⁷

An improvement from the present state of illness, or a continuation of the existing state of illness without deterioration for a longer period than might otherwise have occurred, or for the prolongation of life for a longer period that might otherwise have occurred.

- 6.72 The current standards in New Zealand⁸²⁸ have reduced the scope of ethical review, which no longer covers “innovative practice”, or what was referred to as “innovative treatment” in earlier standards,⁸²⁹ and as “new or unorthodox treatment” in the Cartwright Report.⁸³⁰ People receiving such treatments who are unable to consent through their incapacity are just as vulnerable, however, as patients involved in research. They may be just as unaware that they may be exposed to unnecessary or unacceptable risks. This was the case with the patients whose treatment was investigated in the Cartwright inquiry. Any review of the regulatory framework for ethics review should therefore put innovative treatment back into the scope of ethical review, as originally recommended by the Cartwright Report.⁸³¹

Summary

- 6.73 There is a wide range of circumstances in which people who lack capacity to consent to research could, and should, share in the benefits and burdens of research. The key question is how to protect vulnerable research participants from harm and exploitation without excluding the populations to which they belong from the benefits of research.
- 6.74 Right 7(4) of the HDC Code is an inadequate legal basis for allowing participation in research by adults incapable of giving informed consent. In addition, the outdated provisions of the PPPR Act do not allow their participation in a sufficient range of research, or support people with diminished capacity to participate in worthwhile research that may benefit them.
- 6.75 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 statutory safeguards to protect the interests of such vulnerable research participants.

⁸²⁷ *Simms v Simms*, above n 825 at [57].

⁸²⁸ Ministry of Health *Standard Operating Procedures for Health and Disability Ethics Committees* (MOH, Wellington, 2014) www.ethics.health.govt.nz.

⁸²⁹ Ministry of Health *Operation Standards for Ethics Committees* (Updated ed, MOH, Wellington, 2006).

⁸³⁰ The “unfortunate experiment” was concerned with a situation where withholding of standard treatment of the time from women with pre-invasive cervical cancer was not thought by the researcher to expose them to harm. The women concerned did not give informed consent to participation in research and were unaware they were participating in medical experimentation. Cartwright report, above n 740.

⁸³¹ New Zealand Law Society submission to NEAC (16 February 2012).

RECOMMENDATIONS FOR RESEARCH ON PEOPLE WHO LACK CAPACITY

1. The recommendation is to adopt the main features of sections 30 – 34 of the MCA so that research may only be undertaken on people who lack capacity provided the following conditions are satisfied:
 - a) The research is approved by an *ethics committee*.
 - b) *An Impairing condition*: the research must be connected with the cause or treatment of the condition affecting the potential research participant.⁸³²
 - c) The *necessity condition*: research of a similar nature cannot be carried out with comparable effectiveness on an adult who is capable of consenting to participate.⁸³³
 - d) *Balancing the benefits and burdens of research*: the research must have either (a) the potential to benefit the person without imposing a disproportionate burden, or (b) is intended to provide knowledge of the causes or treatment of, or care of persons affected by, the same or similar conditions.⁸³⁴
 - e) There is *minimal risk*: If the research falls into category (b) above, there must be reasonable grounds for believing that both the risks to the person from taking part in the project are likely to be negligible, and it will be minimally invasive or restrictive.⁸³⁵
 - f) *Consultees*: researchers must take reasonable steps to identify an appropriate person who is interested in the participant's welfare and can advise the researcher of the participant's likely wishes and feelings – if they had capacity – about taking part, and their continued involvement in the research; as well as the ability to appoint independent advocates.⁸³⁶
 - g) *Additional safeguards for "dissent"*: nothing may be done to the person in relation to research to which the person appears to object, or which is contrary to any effective prior statement.
 - h) *Emergency care research*: an opinion from an independent doctor, or, if this is not practicable, following an agreed process with an ethics committee.
 - i) *Innovative treatment and practice*: is included within the scope of ethical review.

⁸³² Mental Capacity Act 2005, s 31(2).

⁸³³ Mental Capacity Act 2005, s 31(4).

⁸³⁴ Mental Capacity Act 2005, s 31(5).

⁸³⁵ Mental Capacity Act 2005, s 31(6).

⁸³⁶ Mental Capacity Act 2005, ss 32(2) and (4).