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SECTION 10 OF THE NEW ZEALAND BILL OF RIGHTS ACT: ITS IMPLICATIONS FOR EXPERIMENTS ON PERSONS WITHOUT CAPACITY

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ABSTRACT

The New Zealand Bill of Rights Act ("NZBORA") was enactedto affirm and protect human rights in New Zealand and to affirm New Zealand's commitment to the International Covenant on Civil and Political Rights ("ICCPR"). Section 10 of NZBORA appears to reflect the second part of article 7 of ICCPR and, by stating that every person has the right not to be experimented upon without his or her consent, appears to preclude all experiments on persons who have not consented including where consent has not been obtained because the subject lacks capacity. Experiments on such persons are continuing in any event.

This paper discusses why medical experimentation on persons who lack capacity is a human rights issue but concludes that a degree of experimentation should be allowed on persons who do not have the capacity to consent.

NZBORA is subject to common law and legislated limits but these only allow such experiments where they are in the subjects' best interests. Thus the effect of NZBORA is to prevent all other experiments even where the risks involved for the subject are small. If such experiments are not allowed persons without capacity will become "research orphans" who are precluded from obtaining the benefits of medical advance. The law needs to be changed to allow a degree of experimentation but the implications need to be thought through carefully.

This paper is 19,000 words more or less, excluding footnotes and bibliography.

I INTRODUCTION

A *Overview*

The New Zealand Bill of Rights Act 1990 ("NZBORA") was enacted to affirm and protect human rights in New Zealand and to affirm New Zealand's commitment to the International Covenant on Civil and Political Rights ("ICCPR"). Section 10 of NZBORA appears to reflect the second part of article 7 of ICCPR and, by stating that every person has the right not to be experimented upon without his or her consent appears to preclude all experiments on persons who have not consented including where consent has not been obtained because the subject lacks capacity. Experiments on such persons are continuing nonetheless and those responsible do not appear to have appreciated the potential implications of s 10.[1] This is surprising given that the writers of at least two Medical Law text-books well known in New Zealand[2] have suggested that its effect is to preclude almost all research on those incapable of consenting.[3]

In this paper I discuss why medical experimentation on persons who have not consented (by reasons of incapacity or otherwise) is a human rights issue and consider the arguments for allowing a degree of such experimentation on persons without capacity. I then endeavour to ascertain what is now the law in New Zealand concerning experiments on those without capacity. Finally I set out my conclusions on the scope of permissible experiments and the consequences which flow therefrom.

B *Structure*

Part II of this paper is preliminary and sets the scene for the discussion which follows. In it I discuss the nature of medical experiments and the basic elements of a "lack of capacity"; I also comment on the extent of medical experimentation in New Zealand at present.

Part III is an explanation of why medical experimentation has come to be a human rights issue. I discuss, by reference to abuses following World War II, why it remains an important issue. It will be seen that it is frequently those who are for some reason disempowered in our society who are the subjects of such abuses generally by "well-meaning" scientists who for various reasons lose sight of the best interests of the particular patient subject.

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1 It is mentioned in some of the Guidelines referred to in this paper. However, its implications are discussed in none of them.

2 I Kennedy and A Grubb *Medical Law: Text with Materials* (3 ed, Butterworths,1994); DB Collins *Medical Law in New Zealand* (1 ed, Brooker and Friend, 1992).

3 Above n 2: Kennedy and Grubb,1067: "The clear and intended effect of section 10 is to outlaw medical research on those not competent to consent for themselves"; Collins,140: "[section 10] creates a general right not to be the subject of medical and scientific experiments without consent. Such a requirement effectively renders impossible medical research on the unconscious and others unable to consent in their own capacity unless that experiment was designed to save the subject's life or prevent serious damage to their health."

I move on in part IV to discuss the ethical perspective on human experimentation and why codes of ethics have sought to justify a level of experimentation on persons unable to consent. I consider the competing moral claims and conclude that some level of experimentation on subjects without capacity should be allowed.

Parts V to IX of the paper investigate the scope of experimentation permitted in New Zealand following the passage of NZBORA. In part V I discuss the approach of the New Zealand Courts to NZBORA and suggest a framework for analysing s 10. Applying this framework involves first, (in part VI) a consideration of the content of s 10 which, in turn, necessitates a consideration of the meaning of art 7 of ICCPR (from which s 10 is derived) and the extent to which the meaning of art 7 assists in determining the meaning of s 10. Secondly, it requires determining whether the existing limits on the right of persons without capacity not to be experimented are effective to restrict or override the prima facie right set out in s 10. The existing limits on the right are: the regulation of medical research (including experiments) primarily through a system of state-endorsed independent ethical review (part VII); New Zealand legislation (part VIII); and the Common Law (part IX). At the end of my discussion of each of these limits I reach a conclusion on whether the limit restricts or overrides the prima facie right. In part X of this paper I set out my conclusions and briefly consider the implications for medical experiments and those involved in them.

II PRELIMINARY

A Definitions

1 *Medical experiments*

Section 10 of NZBORA concerns medical or scientific experiments. The scope of this paper is restricted to medical experiments but it is well to note that the concept of scientific experimentation is very wide indeed and would cover, for example, psychological experiments.[4] An experiment is "medical" when it relates to the practice of medicine which is defined in the Shorter Oxford Dictionary ("OD") as: "the science or practice of the diagnosis of and treatment of illness and injury and the preservation of health".

The OD describes an experiment in two ways which could be relevant: "An action or procedure undertaken to to make a discovery, test a hypothesis, or demonstrate a known fact"; and "A procedure or course of action tentatively adopted without being sure that it will achieve its purpose". Generally, "experiment" is used in the medical context in the first sense and describes medical research involving subjects.[5] Research is, however, a much broader

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4 For example, it would extend to the famous experiments conducted by Milgram discussed in TL Beauchamp & JF Childress *Principles of Biomedical Ethics* (4 ed, Oxford University Press) 155.

5 Doctors will tell you that any medical procedure is an experiment in the second sense. Another expression , "innovative therapy" is generally used to refer to a category of procedures which fit within the second definition. These are new or non-standard procedures which are performed to

concept extending to the study and analysis of information which has already been gathered for general purposes; and the collection of information for subsequent analysis.

A person is subjected to an experiment when the experimenter intervenes in some way in order to gain scientific knowledge. The difficulties arise when the experimenter manages the subject in a manner which is different to the manner which that person would have been managed if he or she were not the subject of the experiment.

Experiments are frequently referred to in medical literature as "studies" or "clinical trials". They are often described as "randomised" which means that the subjects are randomly divided into groups which are managed in different ways. For example, one group may act as a control and be given no treatment and another may be given a new therapy; or there may be a range of therapies available and different groups will each be given a different one. The trials may be "blinded" so that the subjects (or their carers) do not know which form of management has been adopted; or "double-blinded" which means that those gathering the data are also kept from knowing into which group a subject falls.[6]

2 *Capacity*

This paper is principally concerned with experiments on subjects without capacity.

Whether someone has the capacity to consent is a question of law and much has been written on this topic.[7] Detailed examination of this question is beyond the scope of this paper. Briefly, someone lacks capacity if he or she has insufficient understanding of the matters to which the consent relates. This may be due to youth, disease or as a result of a temporary state such as unconsciousness or acute mental illness. Sometimes such persons are referred to as lacking competence.

B The Extent of Medical Experimentation in New Zealand

A substantial amount of medical research (including medical experiments) takes place in New Zealand. Draft figures for the 1992-1993 period for "known direct expenditure on health research in New Zealand" show a total expenditure of $46,751,941 which can be broken down as follows:[8]

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treat a patient and not for the purpose of gathering knowledge. See Kennedy & Grubb above n 2, 1031.

6 The purpose is to ensure objectivity. Randomised trials are the most scientifically rigorous way of testing new therapies. See the discussion in the Report of the Cervical Cancer Inquiry below n x, 62.

7 See eg Kennedy & Grubb above n 2, 106.

8 Health Research Council of New Zealand *Summary of Known Direct Expenditure on Health Research in New Zealand (1992-1993).* The document ,which was obtained by me from the Researched Medicines Industry Association of New Zealand Inc, is stamped "draft". I have been unable to obtain final or more up to date figures from the Health Research Council.

Health Research Council of New Zealand[9]	14,976,000	
Other Government Expenditure	9,151,083	
Total Government Expenditure		24,127,083
General Purpose Foundations etc	1,473,991	
Banks	109,450	
Other Bodies	148,369	
Special Purpose Foundations etc	5,993,048	
Members of the Researched Medicines Industry Association of New Zealand Inc[10]		14,900,000
Total Non-Government Expenditure		22,624,858
Total Expenditure		46,751,941

Current figures for health research are likely to be higher: For example, the Health Research Council ("HRC") Statement of Cash Flows for the year ended 30 June 1995 shows income of $18,258,000 and expenditure of $19,819,000.[11] Members of the Researched Medicines Industry Association of New Zealand Inc ("RMI") invested approximately $13,800,000 in 1995 on clinical trials but the budgeted expenditure on such trials for the three years 1996 to 1998 is $55,400,000 (about $18,500,000 per annum).[12]

Clinical trials are experiments and those performed by members of the RMI will relate to newly developed drugs and medical appliances. The remainder of the expenditure referred to above relates to research which, as we have seen, is a wider concept than experimentation. However, it is likely that a significant portion of this research is experimental. For example, at least 11 of about 170 new research projects funded by the HRC for the period ended 30 June 1995 clearly appear from their brief descriptions in the Report of the HRC for the year ended 30 June 1995 to be experiments as they involve interventions to test the efficacy of treatments.[13] Furthermore, others of the research projects described appear likely to involve interventions for the purpose of gaining information which would not otherwise have occurred either at all or in the

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9 See text below at n 133.

10 This body represents 33 international research-based pharmaceutical companies working in the health sector in New Zealand.

11 HRC *Report of the Health Research Council for the Year ended 30 June 1995.*

12 Researched Medicines Industry *Annual Review 1995-96,* 13.

13 Above n 11, 57 ("The effect of anti-platelet therapy..."), 59 ("A randomised trial of blood pressure reduction..." and "Clinical, randomised, prospective, double-blinded, controlled trial of lignocaine..."), 60 ("Venous ulceration - prediction prevention & evaluation of treatment"), 61 ("A study of the role of Doppler and low dose aspirin in small-for- gestational-age fetuses ..."), 72 ("An experimental evaluation of adjunctive therapy in bacterial meningitis."), 73 ("Gene and protein studies of secreted enzymes of *Candida albicans"*), 85 ("Bulimia nervosa: Cognitive and exposure based treatment.") 86 ("Temperament, character and depression."), 91 ("Determination of safety and immunogenicity of *Haemophilus* influenzae vaccine to Papua New Guinean children"), ("Randomised controlled trial of active management of labour").

course of the management of the particular patient.[14] They should also, therefore, be classed as experiments.

Details of the number of subjects of experiments in New Zealand are unavailable. However, the numbers must be in the order at least of tens of thousands given that one randomised trial can have 6,000 participants.[15]

This paper is primarily concerned with experiments on people without capacity to consent to treatment. They include young children and elderly people sufferring from dementias of various sorts. It is clear that such experiments are performed in New Zealand at the present time. For example, the following experiments are referred to in the Report of the HRC for the Year ended 30 June 1994 and clearly relate to children who would not have capacity.[16]

Neonatal screening for deafness using otoacoustic emissions
A preliminary evaluation of click evoked-otoacoustic emissions (OAE) has provided reliable data on auditory function ... n very young infants and it is fast and non-invasive compared to other techniques. This research will continue past work on establishing norms with well babies and extend it to test high risk and intensive care infants, as well as examining new advances ...

The influence of selenium supplementation on clinical outcome in New Zealand very low birthweight infants: A nationwide blinded randomised controlled trial
This study focuses on investigating a possible relationship between low blood selenium levels and respiratory difficulties in the premature infant. The study will determine whether selenium supplementation of very low birth weight infants improves their clinical outcome by reducing chronic lung disease. A national blinded randomised control trial involving all regional level III neonatal intensive care units in New Zealand is being conducted ...

Further examples may be: the controversial gene therapy performed by Professor Matt During on children suferring from Canavan's disease and aged two years and eighteen months;[17] and a recently reported experiment to find out if the cooling of babies heads after asphyxiation at birth can reduce brain damage.[18]

As regards adults without capacity, members of the RMI are currently conducting clinical trials to develop treatments for Alzheimer's disease and strokes which, given the nature of these conditions, appear likely to involve patients without the capacity to consent.[19]

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14 See, for example, above n 11, 57 "Left ventricular performance following surgical repair of tetralogy of fallot and ventricular septal defect": although the summary of this experiment states that a new non-invasive method will be used to investigate left ventricular heart muscle function of adults who have had heart surgery in childhood, the research must involve some form of testing which obviously would not have occurred had the subjects not participated in the experiment.

15 See above n 11, 59 ("A randomised trial of blood pressure reduction for the secondary prevention of cerebrovascular disease").

16 Health Research Council of New Zealand *Report of the Health Research Council of New Zealand for the year ended 30 June 1994*, 50 & 70.

17 See:"Genetic Jeopardy" *The Listener*, New Zealand, June 15 1996, 18; "Ethical questions raised over youngsters' gene therapy" *The New Zealand Herald* Auckland, New Zealand, 13 June 1996, 1.

18 "Study to see if cooling stops damage" *The Sunday Star Times* New Zealand, 30 June 1996, A4.

19 Above n 12, 13.

There are no figures indicating the number of New Zealand subjects of experiments without capacity. It seems likely, however, that the numbers are significant. Furthermore, given that health research on children is a priority for the HRC[20] and the projected increases in HRC funding,[21] the numbers of such subjects will no doubt increase.

III MEDICAL EXPERIMENTATION AND HUMAN RIGHTS

A Introduction

Medical treatment has a very significant human rights dimension.[22] This is particularly so where treatment (used in its widest sense) is imposed upon or denied to someone who has not consented. Kennedy[23] expresses this well when he states that: "consent is ... the legal and ethical expression of the human right to respect for autonomy and self-determination". The human right to self-determination is not, however, an absolute right and is, therefore, abrogated where good reason for doing so exists. An obvious example in the medical context is where medical treatment is urgently required to save the life of an unconscious accident victim.

B The Nazi Doctors

The implications for human rights of improper medical experimentation were brought into stark relief by the medical experiments performed by the Nazi doctors before and during World War II. The experiments performed by Dr Josef Mengeles are the most infamous[24] and have no doubt lead to the generally held impression that the experiments were perpetrated by "mad nazi scientists". In fact, two of the 20 physicians involved, and who were tried and convicted in the doctors' trial before the Nuremburg military tribunal were described by the prosecutor as: "[o]utstanding men of science, distinguished for their scientific ability in Germany and abroad"; two others were described as: "outstanding medical administrators"; and five other younger men as:"the possessors of considerable scientific ability, or capacity in medical administration".[25]

Most of the experiments that were the subject of the trial were related to Germany's war effort or to epidemics of disease which had broken out due to the disruption caused by the war. For example, non-consenting prisoners were

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20 Above n 11, 11.

21 The Government intends to increase HRC funding to $25,156,000 in 1996/1997 and $26,776,000 in 1997/1998. See Hon Jenny Shipley *Policy Guidelines for the Health Research Council of New Zealand 1996/97.*

22 See I Kennedy "Patients, doctors and human rights" in R Blackburn and J Taylor (eds) *Human Rights for the 1990s Legal Political and Ethical Issues* (Mansell Publishing Ltd, 1991) 81.

23 Above, 84.

24 For a moving account by one of the survivors of Mengeles' experiments see: E Mozes-Kor "The Mengele Twins and Human Experimentation: A Personal Account" in GJ Annas and MJ Grodin (eds) *The Nazi Doctors and the Nuremburg Code (Oxford University Press,1992)* 53.

25 See the opening statement by the prosecution December 9, 1946, reproduced in *The Nazi Doctors*, above n 24, 67 at 87.

deliberately subjected to freezing temperatures and simulated high altitude to understand better the effect of these conditions on soldiers and thereby devise means of assisting them. Prisoners were also infected with malaria, epidemic jaundice and typhus so that the efficacy of various innoculations could be tested. The defence justified these experiments on the basis, inter alia, that it was reasonable to sacrifice the lives and health of a few for the benefit of the majority.[26]

Of course the individuals subjected to the experiments did not consent and: "experienced extreme pain or torture, and in most of them they suffered permanent injury, mutilation or death...".[27]

C *The Nuremburg Code*

Fifteen of the 23 tried in the doctors' trial were found guilty, seven were hanged and the remainder sentenced to life or long terms of imprisonment. In giving its judgment the tribunal set out 10 basic principles concerning the conduct of medical experiments on human beings. These 10 principles are generally known as the Nuremburg Code.[28] Not suprisingly, the Code is concerned with the rights of subjects of experiments. Clause 1 of the Code begins:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force ... and should have sufficient knowledge and comprehension of the subject matter involved as to enable him to make an understanding and enlightened decision....

The code was based on the testimony of two United States physicians who gave expert evidence for the prosecution, Drs Leo Alexander and Andrew Ivy,[29] and was the first international code to set out principles governing human experimentation.[30]

Perley, Fluss, Bankowski and Simon state that art 7 of the International Covenant on Civil and Political Rights ("ICCPR") was influenced by the Nuremburg Code.[31] They trace that influence up until the adoption of ICCPR by the United Nations General Assembly in 1966.

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26 See AL Caplan "The Doctor's Trial and Analogies to the Holocaust in Contemporary Bioethical Debates" in *The Nazi Doctors* above n 24 , 258 at 266-268.

27 See the extract from the judgment of the militatry tribunal reproduced in *The Nazi Doctors* above n 24, 94 at 104.

28 The Nuremburg Code is part of the judgment in *United States v Karl Brandt* and is reproduced in above n 24, 2 and in Collins above n 2. The part of the judgment immediately preceding the Code states: "The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts".

29 S Perley, SS Fluss, Z Bankowski, F Simon "The Nuremburg Code: an International Overview" in *The Nazi Doctors*, above n 24, 149 at 152.

30 Above, 150. There had been a number of quite enlightened national codes prior to this including, ironically, Guidelines on Innovative Therapy and Scientific Experimentation established by a Circular of February 28,1931 of the (German) Reich Minister of the Interior.

31 Above,153.

D *The International Covenant on Civil and Political Rights*

The International Covenant on Civil and Political Rights is one of the four components of the International Bill of Rights.[32] New Zealand signed ICCPR on 12 November 1968 and ratified it on 28 December 1978.[33] New Zealand ratified the First Optional Protocol to ICCPR in 1989.[34] The Protocol establishes a complaints procedure and enables New Zealanders to to bring alleged breaches of ICCPR before the Human Rights Committee.[35] The New Zealand Court of Appeal has described the Human Rights Committee as "in substance a judicial body of high standing" which is in a sense part ot this country's judicial structure".[36]

Article 7 of ICCPR provides:

> No one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. In particular, no one shall be subjected without his consent to medical or scientific experimentation.

The New Zealand Bill of Rights was passed, in part, to affirm New Zealand's commitment to ICCPR and ss9[37] and 10 of NZBORA clearly have their genesis in art 7 of ICCPR.

E *Continuing Abuses of the Rights of Subjects*

The horror of the Nazi experiments and the wide ratification of the ICCPR and other human rights treaties have, sadly, not prevented the occurrence of many experiments on humans which undoubtedly amounted to serious violations of the rights of the subjects concerned. Some examples follow.

1 *The Tuskagee syphilis experiment*

From 1932 until 1972 an experiment was conducted by the United States Public Health Service ("PHS") on a group of about 600 black men in in Macon County, Alabamba, around Tuskagee.[38] About 400 of the men suffered from syphilis and about 200 were free from the disease and acted as controls. The purpose of the experiment was to study the untreated late-stage complications of the disease,[39] particularly as they manifested themselves in black men. From 1932

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32 See G Huscroft & P Rishworth (eds) *Rights and Freedoms: The New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993* (Brooker's Ltd, Wellington, 1995) 44. The other three components are the Universal Declaration on Human Rights, the International Covenant on Economic, Social and Cultural Rights and the First Optional Protocal to ICCPR.

33 P Sieghart *The International Law of Human Rights* (Clarendon Press, Oxford,1983) 448.

34 See UN Doc CCPR/64/c/64/Add.10, below n 124, 2.

35 See above n 32, 44.

36 *Tavita v Minister of Immigration* (1993) 1 HRNZ 30, 40.

37 Section 9 of the Bill of Rights provides: " Everyone has the Right not to be subjected to torture or to cruel, degrading, or disproportionately severe treatment or punishment".

38 JH Jones *Bad Blood The Tuskagee Syphilis Experiment* (The Free Press, New York, 1981) 1.

39 Syphilis is a highly contagious sexually transmitted disease caused by a microscopic organism. Three stages mark its development with the tertiary stage being the most serious: the organisms

to about 1953 the generally available treatment for syphilis was with arsenicals and mercury.[40] This treatment had severe side-effects but was still regarded by the medical profession at the time as preferable to leaving the disease untreated. By 1953 penicillin was both widely available and an appropriate and effective treatment for syphilis.[41] The subjects of the experiment received minimal or no treatment for syphilis. They were ill-educated and poor and were not told either that they were participating in an experiment or that their underlying disease was not being treated.

One of the doctors involved regarded the Nazi experiments as "horrendous" but was unable to see that there were parallels between those experiments and the experiment in which he was involved.[42] It seems that the experiment was never assessed against the Nuremburg Code[43] and the 1964 Declaration of Helsinki,[44] which was endorsed by most leading medical institutions in the United States, does not seem to have been considered.[45] The experiment was, furthermore, contrary to Alabamba's public health statutes which required public reporting and treatment of venereal disease; from 1943 it contravened the Henderson Act which required state and local health authorities to test everyone in the state aged between 14 and 50 years and to treat those infected.[46]

Details of the experiment were widely known. Because of its duration, a large number of PHS doctors and other officials were involved. The co-operation of local doctors was enlisted at an early stage: they were informed about the experiment in mini-seminars.[47] The advent of penicillin was seen by the PHS as increasing the value of the study rather than a reason for halting it and treating the subjects.[48] A full scale review of the study in 1951 resulted in major re-organisation but no questioning of its propriety.[49] The experiment spawned some 13 articles published in professional journals between 1936 and 1973.[50]

In 1948 the ethics and legality of the experiment were questioned by a statistician at the PHS. But no action was taken.[51] The first member of the

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(spirochetes) concentrate in the body's tissues and destroy them. Different parts of the body may be attacked: the skin, bone, liver, brain and heart to name a few. Paralysis, insanity and death may result depending on the part of the body attacked. See above, 2-4.

40 Aboven 38, 211.

41 Above. The PHS had, in fact, started administering penicillin to syphlitic patients in 1943 (above, 178). Above, 164: "Within a few years of its discovery in the early 1940s, penicillin was hailed a wonder drug by medical authorities around the globe. Relatively inexpensive, safe for most patients, fast-acting and incredibly effective, penicillin gave physicians the best treatment for syphilis the world had ever known".

42 Above, 179-180.

43 Above text at n 28.

44 Discussed below. See text at n 78.

45 Above n 38, 189.

46 Above, 178.

47 Above, 144.

48 Above, 179.

49 Above, 181-184.

50 Above, 257-258.

51 Above, 181.

medical profession openly to criticise the experiment did so in 1956 after reading one of the published articles.[52] His letter was ignored. It was the persistence of the second open critic of the experiment, a social worker employed by the PHS in 1965 as a venereal disease interviewer, which caused the study to stop. The worker, Peter Buxton, resigned from the PHS in 1967 after raising his concerns that the experiment was immoral.[53] In 1972 he approached a journalist and the story of the experiment was published.[54]

The American public was outraged and a citizens' panel was set up to investigate. The panel concluded that the experiment was unethical from its inception[55] and recommended that it be terminated immediately and the surviving men treated. Senate committee hearings were arranged by Senator Edward Kennedy and following these the government moved to locate and treat the remaining subjects. A class action was filed on behalf of the subjects and settled by the government for US$10 million.[56]

2 Abuses discussed in Dr Beecher's article

In 1966 an article written by Dr Henry K Beecher, a research professor at Harvard Medical School, was published in the New England Medical Journal.[57] Dr Beecher reviewed the very substantial increase in research in human subjects following World War II. He considered studies published in medical journals and concluded that: "unethical or questionably ethical procedures are not uncommon".[58] In the article, reference was made to 50 apparently unethical experiments and 22 were discussed in detail. The experiments included: (a) withholding known effective treatments from selected groups of patients so that the progress of their diseases could be compared with that of the treated group;[59] (b) studies where drugs were given to, or procedures performed upon, patients which were unrelated to their conditions the purpose being to study the physiological effects.[60]

In an example of the former category, penicillin was withheld from a control group of 109 service-men suffering from streptococcal respiratory infections: three of them developed serious complications from their untreated infections.[61]

An example of the latter category was an experiment to test the survival of skin grafts on small children following the removal of the thymus gland, thought to play a role in initiating an immune response and hence the rejection of skin

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52 Above, 190.
53 Above, 192.
54 Above, 204.
55 Above, 210-211.
56 Above, 206-219.
57 J Katz *Experimentation with Human Beings* (Russell Sage Foundation , New York 1972) 306.
58 Above, 307. For example, he found 12 of 100 consecutive human studies published in 1964 in "an excellent journal" appeared to be unethical.
59 Above, 307.
60 Above, 308.
61 Above, 307.

grafts. The children selected did not require skin grafts and were in hospital for heart surgery during the course of which the thymus could easily be removed. After surgery skin grafts from an unrelated adult donor were sutured in place and then removed for biopsy when signs of rejection appeared.[62] It seems that none of the children suffered adverse effects from the skin grafts although there were associated risks including the contraction of serum hepatitus. The children had, however, permanently, and in many cases unnecessarily,[63] lost what one scientist writing to the New England Journal of Medicine in 1964 clearly regarded as an important defence against future infection.[64]

In some of the studies discussed by Dr Beecher the researchers openly acknowledged that consent had not been obtained from the subjects. In others, no reference was made to consent having been obtained and the nature and risks associated with the experiments were such that it is hard to imagine that consent would have been given had proper information been supplied. In one study[65] a mother consented to the transplantation of melanoma from her daughter who was dying of the disease. It seems the mother was lead to believe that this would enable the researchers to gain knowledge about this cancer which might benefit the daughter. The daughter died the day following the transplant and appears, therefore, to have been beyond help. The mother's implant was not, however, removed for some three further weeks. Less than 18 months later the mother died of melanoma found to have developed from the transplanted tissue. It seems very unlikely that the mother was properly informed firstly, as to the extreme unlikelihood of any benefit accruing to the daughter and secondly, as to the risks associated with not removing the transplanted tissue immediately.

3 *The "Unfortunate Experiment" at National Women's Hospital*

From 1966 until at least 1982 a research trial was conducted at National Women's Hospital in Auckland.[66] Its aim was to prove that carcinoma-in-situ of the cervix is not a disease which proceeds to invasive cancer of the cervix. This was the belief of Dr Herbert Green who proposed the research and conducted it until his retirement in 1982. It was not the view generally held by the world-wide medical profession at the time which was that CIS was a precursor to cervical cancer.

In line with the world-wide view, the standard treatment for CIS in 1966 was hysterectomy[67] although the less radical procedure of "coninization" (removal

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62 Above, 308. Extracts from the text of the 1964 New England Journal of Medicine Article where the results of the experiment were published are above 959.

63 It was only sometimes necessary to remove the thymus for the purposes of the type of heart surgery undergone by the children.

64 See J Katz above n 57, 960.

65 See J Katz above n 57, 309.

66 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, July 1988).

67 Surgical removal of the uterus.

of a cone shaped wedge of the cervix encompassing all the diseased tissue) was gaining acceptance where appropriate. Both these treatments aimed to remove entirely the tissue affected by CIS. The women in Dr Green's trial were not so treated; they were monitored (which in many cases included taking tissue samples) but given conventional treatment only if they developed invasive cancer. In 1984, after Dr Green's retirement, Dr McIndoe, a colposcopist who had worked with Dr Green and become critical of his approach to the treatment of cervical cancer, wrote up the results of the research trial.[68] He reviewed the case histories of 1028 women diagnosed as having CIS. Most had been treated by conventional techniques; a small number had received the conservative "treatment" advocated by Dr Green. Dr McIndoe concluded that patients who continued to have abnormal smears following initial treatment (131 patients) were 24.8 times more likely to develop invasive carcinoma of the cervix than those who had normal smears following treatment. Furthermore, as at the review date, four of the "normal smear" women had died from invasive carcinoma (.5%); whereas eight of the "abnormal smear" women had died (8%).

Thus the research trial confirmed the orthodox view that CIS is a precursor to invasive cancer of the cervix. The majority of the women involved were unaware that they were not being treated in the conventional way or that they were participating in a research trial.[69] For a minority of women treated for CIS at National Women's their unknowing participation in the trial resulted in: "persisting disease, the development of invasive cancer and, in some cases, death".[70]

The trial had many critics.[71] Dr McIndoe had repeatedly voiced and recorded his concerns about the consequences of conservative treatment of CIS. The concerns were raised with Dr Green and, when they were ignored, raised in 1973 with the medical superintendant at NWH who consulted the superintendant in chief of the Auckland Hospital Board. Dr McLean, a pathologist, also expressed concerns. Dr Green's response was obtained and the matter was referred to the NWH Medical Committee and then, in December 1974, to a working party. The working party comprised three specialists and reported back in October 1975. It failed to respond to the concerns raised by Drs McIndoe and McLean and did not question the ethics of the trial.

In 1984 Dr McIndoe's paper[72] was published in a prestigious medical journal and its conclusions were widely disseminated. No steps were taken, however, officially to halt the trial or to ensure that women included in it were recalled and given proper treatment.

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68 It was subsequently published in the journal of the American College of Obstetricians and Gynecologists ('Obstetrics and Gynecology' 64, No.4, October 1984). It is reproduced above n 66, 247-257.

69 Above n 66, 211.

70 Above, 210.

71 Above, 70-102.

72 Above n 68.

A journalist, Sandra Coney, obtained a copy of Dr McIndoe's paper. The article written by Sandra Coney and Phillida Bunkle appeared in the June 1987 issue of *Metro Magazine*. The public concern following the appearance of the article resulted in a public inquiry under the Hospitals Act and Judge Cartwright's Report of the Inquiry was published in July 1988.

Evidence was also given in the course of the inquiry that a research trial had commenced in 1963 which required taking swabs from the cervices of newborn baby girls. The consent of the parents was not obtained and, although Dr Green decided not to pursue the trial after 200 babies had been swabbed, this was not communicated to the nursing staff so that a further 2000 or so babies were unnecessarily subjected to the procedure.[73]

F Conclusions

The experiments discussed above share certain common features. In each case the doctors involved appear to have had little insight into either the questionable ethics of their conduct or the consequences for their subjects. The experiments were, in most cases, known of by other doctors both through contacts and through published articles. In relation to the Tuskagee and National Women's experiments it was not doctors but outsiders who ultimately brought the situation to the attention of the public so that steps could be taken to treat those who had been neglected and ensure that measures be taken to ensure that similar situations did not arise. In many cases the experiments involve people who are disadvanteged or disempowered (poor, ill-educated, black men, children, service-men, women).

One can speculate as to why these situations arose. An explanation may be the conflict of interest which arises as soon as a doctor combines care of his or her patient with the conduct of an experiment. That is the doctor loses sight of the one when he or she embarks on the other. Whatever the reasons, and notwithstanding that measures have been taken in New Zealand to protect the rights of the subjects of experiments (see part VII), it is clear that experimentation on human subjects remains an important human rights issue in New Zealand. This is particularly so in relation to those without capacity who are, by definition, a group vulnerable to exploitation.

IV THE ETHICAL DEBATE

A Ethics and Human Rights

I have discussed the human rights perspective on human experimentation and set out examples of breaches of those rights which have occurred since the Nuremburg Code.

The Nuremburg Code prohibits experimentation on those incapable of consenting. It sets out a human right in unqualified terms. An ethical debate is concerned with the rights of individuals. But it is also concerned with society

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73 Above n 66, 140.

as a whole. It seeks to balance competing rights, and in relation to medical experimentation, this means taking some account of the benefits which accrue to society from medical experimentation.

B How Much does Society Benefit?

The extent of these benefits is often assumed. They should not, however, be overstated. Nor should it be forgotten that there is much important health research which can be done which does not involve subjecting people to experiments. For example, Professor R Beaglehole from Auckland Medical School produced a discussion paper for a Medical Research symposium[74] in 1987 which included the following:[75]

> It is important to remember that the determinants of health are largely outside the medical care system, and that the medical profession does not have a pre-eminent role in health. There have been major changes in the pattern of diseases in New Zealand over the last 100 years. Despite the continuing importance of some infectious diseases and the emergence of others, the chronic diseases and unintentional injuries are now the most important causes of premature death and disability in New Zealand. The major factors responsible for the decline in infectious disease have been nutritional, environmental and behavioural. The most important determinants of future disease trends will probably be behavioural, environmental and nutritional ...
>
> There has always been a tendency to overestimate the effectiveness of medical interventions (and to underestimate their risk) ...
>
> We must also be aware of the risks of encouraging the belief that medical research can perform miracles. Encouragement of faith in the ability of medical research to deliver more magic bullets ... may foster this unfortunate trend ....
>
> The recognition that improvements in health are are likely to come in the future, as in the past, from modification of the conditions which lead to disease, rather from intervention in the mechanism of disease after it has occurred, has important implications for research. Although basic and applied research are complementary, there is a need to shift the balance of effort from laboratory-based research to public health research.

Professor DCG Skegg of Otago Medical School made the same point at the symposium although he was slightly more positive about the potential benefits of clinical and laboratory research.[76]

It is, nonetheless, clear that the advances which medical experimentation brings about can be of great benefit to society both in human and economic terms. An example is the study conducted at National Women's Hospital in the 1960s which resulted in the development of antenatal cortico steroid therapy which has reduced mortality, respiratory distress syndrome and haemorrhage in pre-

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74 Medical Research Council of New Zealand Golden Jubilee Symposium. *Challenges for medical research* (23-24 November 1987 Dunedin). The proceedings of the Symposium are reproduced in NZMJ 1988; 101, 683.

75 Professor R Beaglehole, Department of Community Health, University of Auckland School of Medicine, Auckland "Discussion" NZMJ, above n 74, 713.

76 Professor DCG Skegg, Department of Preventative Medicine, University of Otago Medical School, Dunedin, "The changing patterns of disease" NZMJ above n 74, 707.

term infants. This and other cortico-steroid treatments are estimated to save the USA alone in excess of US$150 million per year.[77]

C Balancing the Rights of the Individual and the Benefits to Society

I have already discussed principle one of the Nuremburg Code which relates to consent. The remaining eight principles comprise further important safeguards as well as ensuring scientific integrity. Thus, the information sought must be unprocurable by other means, the anticipated results must be such as to justify the experiment, all possible tests on animals must have been performed and so on.

These principles have not been seriously questioned. But the absolute requirement of consent and the prohibition of experiments on those without capacity has been.

The argument for allowing experiments on those unable to consent is that unless this occurs, they will become "research orphans" that is, members of a class whose general health is unable to benefit from research. Take the following example. Most people with Alzheimer's disease will not have the capacity to consent to participating in a trial to test a new drug to treat Alzheimer's disease. Until the drug has been so tested, it will not be possible to assess either its benefits or its side-effects and hence whether it should be made generally available. If it is a beneficial drug, then the class, people suffering from Alzeimer's disease, will be unable to benefit. This is the basis for the argument that research on those unable to consent should be permitted as long as all other safeguards have been complied with. It can be applied to treatments for other illness which causes incapacity. It also applies to other groups of persons without the capacity to consent where their physiological differences from "normal" adults require testing on group members; For example, babies and young children.

However, allowing such experiments means that the interests of a few (those experimented upon) are subverted to the interests of the majority (the group who will ultimately benefit from a therapy once it is developed). This is because every experiment carries with it a risk. That is why the experiment is being conducted. That is why the drug or therapy is not already generally available. However, in circumstances where the risk is very small and, for example, where there also a possible benefit to the subject, the arguments for allowing the experiment to proceed become more powerful.

D The Declaration of Helsinki

No doubt it was these sorts of considerations which lead to the World Medical Association Declaration of Helsinki which abrogates the first principle of the Nuremburg Code in several respects. The current declaration was adopted by

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77 Dr Robert Chambers QC, Chair of the Health Research Council of New Zealand in Report of the Health Research Council of New Zealand for the Year Ended 30 June 1995, above n 11.

the 41st Medical Assembly, Hong Kong in September 1989.[78] The declaration seeks to resolve competing ethical principles rather than to set out the rights of those subjected to human experimentation.

Thus it emphasises the benefits which accrue to humanity from research. Where the proposed subject lacks the capacity to consent proxy consent "in accordance with national legislation" is sufficient save that a minor child's consent must be obtained in addition to that of the guardian.[79]

The Declaration states to be fundamental the distinction between therapeutic research (where the aim is essentially diagnostic or therapeutic) and non-therapeutic research (where the aim is essentially scientific and without implying direct diagnostic or therapeutic benefit).[80] This distinction is problematic. First, almost all experiments, even where the aim is diagnostic or therapeutic, carry some degree of risk over and above the risks of standard therapy. Secondly, many experiments fall between the two categories. That is, they have mixed therapeutic and scientific aims.

The distinction thus seems to obscure the real issue which is whether the subject is being given the treatment which he or she would have been given had he or she received treatment in his or her best interests and not been the subject of a medical experiment.

This problem is further highlighted by other parts of the Declaration. Clause I(5) states that: "concern for the interests of the subject must always outweigh the interests of science and society". Yet the greater interests of society (as a whole) is the justification for allowing experiments which may carry risks for the individual.

These difficulties are of less moment where the person experimented upon is a properly informed adult who has freely consented to participating in the experiment. They assume more importance in relation to persons without capacity.

E Conclusions

In my opinion, experimentation on incompetent persons should be allowed only in limited circumtances. Those circumstances may be where, in addition to compliance with the usual safeguards, the experiments: are essential for the purpose of advancing the interests of a particular group (of which the subject is a member) incapable of giving consent; and subject those involved to minimal risk. They may also be justified where participation in an experiment treatment offers the only hope of saving life or preventing serious injury to health. This is tantamount to saying that the experiment is in the best interests of the patient.

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78 A copy is reproduced in The Interim Guidelines for Good Research Practice, Ministry of Health, Therapeutics Section (September 1996).

79 See above, cl I(11).

80 See above, introduction.

For the reasons discussed the Declaration of Helsinki does not contain clear, logical guidelines for medical experiments on persons without capacity. The International Ethical Guidelines for Biomedical Research Involving Human Subjects[81] do achieve this. For example, guideline 5 which relates to research involving one group that will generally not have capacity, children, acknowledges that risks are involved and states that such research should only proceed where its purpose is to obtain knowledge relevant to the health needs of children and the risk is both low and proportionate to the knowledge to be gained.

V NZBORA: DEVELOPING AN ANALYTICAL FRAMEWORK

A Introduction

Section 10 of NZBORA provides:

> **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.

On the face of it s 10 precludes all experiments (whether humane, inhumane, involving negligible or significant risk, or where involvement in the experiment offers the only hope of preventing serious illness or death) on subjects who have not consented. This must include those that have not done so due to lack of capacity. However, the rights set out in NZBORA do not exist in a vacuum and the following factors are critical to understanding the effect of a right. First, it is in the nature of bills of rights that they are expressed in general terms which leaves scope for the interpretation of the content of a particular right.[82] Secondly, the rights set out in NZBORA do not have absolute effect and must be read in the light of ss 3, 4, 5 and 6 of NZBORA. The purpose of this part of the paper is to ascertain the analytical process to be applied to determining the content of a right and the restrictions on it.

B Determining Content

The long title to NZBORA is as follows.

> An Act-
> (a) To affirm, protect, and promote human rights and fundamental freedoms in New Zealand; and
> (b) To affirm New Zealand's commitment to the International Covenant on Civil and Political Rights

The New Zealand Court of Appeal has emphasised the importance of the long title as a guide to the manner in which NZBORA should be interpreted. It requires first, that NZBORA should not simply be interpreted to preserve the status quo and will, therefore, require development of the law where necessary

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81 The Council for International Organisations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva 1993).

82 See *A Bill of Rights for New Zealand A White Paper* (Government Printer, Wellington, 1995) 45.

and secondly, that ICCPR is critical to any interpretation of NZBORA.[83] The influence of ICCPR, furthermore, extends beyond assisting the Court to interpret individual sections of NZBORA which have parallel provisions in ICCPR: in *Baigent's Case*[84] the fact that, by art 2(3) of ICCPR, New Zealand had undertaken to ensure an effective remedy for violation of the rights contained in ICCPR was a factor which influenced the Court of Appeal in concluding that compensation for a breach of NZBORA would, in principle, be available notwithstanding that NZBORA itself contained no such provision. There is further scope for such use of ICCPR: the effect of art 4 of ICCPR is that certain articles of ICCPR (including art 7) are absolute and cannot be derogated from. It has been asserted that, notwithstanding the general application of s 5 of NZBORA (justified limitations), the New Zealand Courts will undoubtedly take into account that such rights are non-derogable under ICCPR.[85]

Because parallel provisions of ICCPR are relevant, any guides to the interpretation of those provisions are of significance. Such guides include the *travaux preparatoires* (working papers) of the Commission on Human Rights and the Third Committee of the General Assembly of the United Nations which were responsible for settling the final form of ICCPR. The decisions of the Human Rights Commitee are guides as are the General Comments of the Human Rights Committee on the reports of States parties which arise under art 40 of ICCPR. [86]

Of considerable assistance (and certainly most frequently referred to in New Zealand cases) are the decisions of overseas national courts (particularly Canada) relating to parallel constitutional provisions and of the European Court of Human Rights under the European Convention for the Protection of Human Rights and Fundamental Freedoms.

These aids to interpretation can only go so far. NZBORA is a very significant piece of New Zealand legislation but it is still an ordinary statute and not entrenched like constitutional statutes in other parts of the world. Furthermore, reasoning by analogy with interpretations of the provisions of ICCPR, the European Covenant, the Canadian Charter and other similar international or constitutional documents only assists if the provisions are truly analagous to those contained in NZBORA. For example, there is no other document which contains a provision equivalent to s 11 of NZBORA (the right to refuse medical treatment) and the New Zealand courts will have to work out the content of and limitations to this right themselves.[87] Another example is the splitting of art 7 of ICCPR into two parts, sections 9 and 10 of NZBORA. The significance of this is critical to this paper and will be discussed in due course.

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83 *Ministry of Transport v Noort. Police v Curran* [1992] NZLR 260, 268.

84 *Simpson v Attorney General [Baigent's Case]* [1994] 3 NZLR 667.

85 See the Report of the Department of Justice in Justice and Law Reform Select Committee (1987) *Interim Report of the Justice and Law Reform Select Committee Inquiry into the White Paper - A Bill of Rights for New Zealand*, 30.

86 For example, both are referred to by Heron J in *R v B* 1 HRNZ 12.

87 *R v B* above is the only case so far to consider this section.

C *Sections 3, 4, 5 and 6 of NZBORA*

The rights set out in NZBORA are not entrenched and nor are they absolute. Their impact is determined by ss 3, 4, 5 and 6 of NZBORA.

Section 3 of NZBORA provides that it only applies to acts done :

> (a) By the legislative executive, or judicial branches of the government of New Zealand; or
> (b) By any person or body in the performance of any public function, power, or duty conferred or imposed on that person or body by or pursuant to law.

Sections 4, 5 and 6 need to be interpreted together and are set out in full below.

> **4. Other enactments not affected -** No court shall, in relation to any enactment (whether passed or made before or after the commencement of this Bill or Rights), -
> (a) Hold any provision of the enactment to be impliedly repealed or revoked, or to be in any way invalid or ineffective; or
> (b) Decline to apply any provision of the enactment
> - by reason only that it is inconsistent with any provision of this Bill of Rights.
>
> **5. Justified limitations** - Subject to section 4 of this Bill of Rights, the rights and freedoms contained in this Bill of Rights may be subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.
>
> **6. Interpretation consistent with Bill of Rights to be preferred** - Wherever an enactment can be given a meaning that is consistent with the rights and freedoms contained in this Bill of Rights, that meaning shall be preferred to any other meaning.

Where an act constitutes a prima facie breach of NZBORA and there is legislation which may permit the act in question there are two possible approaches. The first is that adopted by Cooke P (as he then was) in *Noort* [88] and is as follows. Section 5 of NZBORA has no role in determining whether the act in question is an actionable breach. It is only relevant: (1) to the Attorney General's s 7 report to parliament on the compliance with NZBORA of newly introduced bills; and (2) where a common law rule infringes a prima facie right. The analysis, therefore, involves a two-stage inquiry. First, an interpretation of the legislation which is consistent with the particular right (if possible) and second, a determination of whether the legislation so interpreted is consistent with NZBORA. If the legislation is inconsistent then must be given effect to under s 4.

The second approach is that preferred by Richardson J[89] (as he then was) and Hardie Boys J[90] in *Noort*. It is as follows. The first enquiry is whether the legislation (including its operating requirements) comprises such reasonable limits prescribed by law as can be justified in a free and democratic society. If it does, then there will be no need to consider ss 4 and 6. If the legislation does

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88 Above n 83, 272.

89 Above, 282. Note, however, that Richardson J found that the operating requirements of the legislative provision is question were such reasonable limits etc so that he did not express a "concluded view" on the effect of s 6.

90 Above, 286.

not comprise reasonable limits etc it will then be necessary to consider whether it can be interpreted in a manner which is consistent with the right *as abridged by any reasonable limitations.* Only if no such interpretation is possible should the enactment be found to be inconsistent with NZBORA and, therefore, to override it.

In my analysis I will adopt the approach of the majority of the Court of Appeal.[91] The approach of the majority places great importance on the meaning of the expression "such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society". I will, therefore now discuss the meaning of this expression. It has been well analysed in other jurisdictions and that analysis has been adopted by the New Zealand Court of Appeal in *Noort*.

1 *Prescribed by law*

The expression "prescribed by law" requires first, that the law must be adequately accessible and secondly, that the law must be formulated with sufficient precision to enable the affected citizen to regulate his or her conduct and, if need be, to foresee to a reasonable degree the consequences which a given action may entail.[92] The "law" may be prescribed by legislation or the common law.[93] However, unpublished orders and instructions used to guide a state authority will not be sufficient unless those affected by them have been made aware of their contents and in which case they could then be taken into account but only for the purposes of assessing foreseeability in relation to the application of rules made under an act of parliament.[94]

Furthermore, where the law confers a discretion on state authorities the scope of that discretion must be clear although the detailed procedures and conditions to be observed do not necessarily have to be incorporated.[95] The degree to which the criteria for the exercise of the discretion should be set out will depend on the particular subject matter. For example, in the case of secret surveillance of individuals closed to scrutiny from both the public and the particuar individuals, it would be contrary to the rule of law for the executive's discretion to be expressed in unfettered terms.[96] Similarly, a statute authorising film censorship which gave the censor unfettered discretion to ban or cut films proposed for public exhibition failed the "prescribed by law" test under s 1 of the Canadian Charter[97] even although the censor board had developed its own rules which were available to the public.[98] In a case with a medical flavour, the

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91 McKay J concurred with Richardson J.

92 See *Sunday Times v UK* (1979) 2 EHRR 245 and *Noort* above n 83, 272 (per Cooke P) and 283 (per Richardson J).

93 Above *Sunday Times.*

94 *Silver v UK* (1983) 5 EHRR 347.

95 See above and *Malone v UK* (1984) 7 EHRR 14.

96 See above *Malone.*

97 The Canadian Charter of Rights and Freedoms is part of the Constitution Act, 1982 (Canada). Art 1 states that the Charter "guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society."

98 *Re Ontario Film and Video Appreciation Society* (1984) 45 OR (2d) 80 (CA).

European Court of Human Rights found that legislation which said that persons contained in a mental hospital: "may be subjected to restrictions ... as to their contact with the outside world" failed the test as there was no indication of the criteria or procedure to be observed: this was unacceptable particularly when the legislation authorised far reaching restrictions on fundamental rights.[99]

2 *Demonstrably justified in a free and democratic society*

The onus of establishing this element rests on those seeking to rely on it. Deciding whether these criteria are met involves the courts in public policy analysis and value judgements. However, considerable assistance can be got from decisions made in other jurisdictions which set out a principled basis on which to proceed, although these need to be modified to reflect the unentrenched status of the rights under the New Zealand statute.[100] The essential elements of the enquiry to be gleaned from other jurisdictions are as follows:[101]

(a) The legislative objective, in pursuit of which the measures have been implemented, must be sufficiently significant to warrant overriding the right. That is, it must be related to concerns which are pressing and substantial in a free and democratic society.

(b) The means chosen must be reasonable and and demonstrably justified in a free and democratic society. That is they must be proportional which requires that: first, there must be a rational connection between the measures and the objective they are to serve; secondly, the measures should impair the right as little as possible; and thirdly, the negative effects of the measures must be justifiable in light of the objective which they are to serve.

Having taken account of these principles and the different status of NZBORA the Court of Appeal stated:[102]

> It is worth emphasising to that in principle an abridging enquiry under s 5 will properly involve consideration of all economic, administrative and social implications. In the end it is a matter of weighing:
> (1) the significance in the particular case of the values underlying the Bill of Rights Act;
> (2) the importance in the public interest of the intrusion on the particular right protected by the Bill of Rights Act;
> (3) the limits sought to be placed on the application ot the Act provision in the particular case; and
> (4) the effectiveness of the intrusion in protecting the interests put forward to justify those limits

D An Analytical Framework

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99 See below n 129, 472.

100 See *Noort* above n 83, 283 (per Richardson J).

101 Above, paraphrasing Richardson J's quote from *Re A Reference re Public Service Employee Relations Act* [1987] 1 SCR 313, 373

102 See *Noort* above n 83, 283.

The discussion above suggests the following as the framework for an analysis of the implications of s 10 for medical experiments on those who do not have the capacity to consent.

(1) What is the content of s 10 of NZBORA? Is it a principle which cannot be derogated from by analogy with art 7 of ICCPR?
(2) Certain de facto or potential limits to the right not to be experimented upon without consent can be identified. They are as follows: (a) The system of regulation of medical experimentation which allows the decision of an ethics committee combined with the ethical obligations of individual doctors to determine whether experiments on subjects without capacity can proceed. (b) New Zealand legislation which appears to allow a person to consent to participating in an experiment on behalf of a person without capacity (proxy consent). (c) Common law principles which appear to allow proxy consent. In respect of each of these, is it such a reasonable limit prescribed by law as can be demonstrably justified in a free and democratic society?
(3) In relation to the legislation, if it can be read in a way which does not prescribe such reasonable limits, is there another interpretion that is consistent with s 10 subject to reasonable limitations?
(4) If the legislation cannot be so read then its provisions will override s 10.

It may not be necessary to go through each step of this analysis to reach a conclusion. For example, if the conclusion at stage 1 is that s 10 is non-derogable that will mean that no limits can be imposed on the right and the next inquiry will be at stage 3 (save that there will be no reasonable limits to take into account).

In the next part of this paper I discuss the content of NZBORA. In the three parts which follow I consider each of the de facto or potential limits on the right not to be experimented upon without consent and, by adopting the above analysis, consider whether experiments performed in accordance with them are still permissible in New Zealand.

VI THE CONTENT OF SECTION 10

A Article 7 of ICCPR

1 *Introduction*

The starting point for this discussion must be a determination of the content of the second sentence of art 7 of ICCPR. This is critical for two reasons. First, any interpretations of and comments upon the second sentence of art 7 will only be relevant to an interpretion of s 10 in the event that the two provisions are equivalent. Secondly, art 7 of ICCPR cannot be derogated from in any circumstances: however, it is only if the second part is equivalent to s 10 that it can be argued that s 10 must also be non-derogable (that is a right subject to no limitations).

2 *The United Nations Commission on Human Rights*

In 1947 the draft Covenants on Human Rights were referred to the UN Commision on Human Rights for consideration.[103] In their discussions of the second clause of art 7 of ICCPR (and its earlier incarnations) a number of themes emerge. One is that art 7 was regarded as an essential ingredient of ICCPR the purpose of which was to ensure that the experiments performed by the Nazis during World War II should never again occur.[104] Another is that the article should not be drafted so as to prevent legitimate medical experiments or prevent experiments which constitute the treatment of a sick person. [105]

The form of the relevant part of the draft article eventually agreed upon by the UN Commission on Human Rights read as follows.[106]

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation involving risk, where such is not required by his state of physical or mental health.

The article clearly covers all medical experimentation involving risk and not required by the subject's state of health. That is, the article is saying that such experiments are a kind of cruel, inhuman or degrading treatment. The article quite clearly does not mean that only experiments involving risk, required by the subject's health *and* which are also cruel, inhuman or degrading are prohibited. The consequence of this latter interpretation would be that all experiments involving risk but required by the subject's health were cruel, inhuman and degrading but nonetheless permitted. The former interpretion is the only one which makes sense and was clearly also the one intended by the Commission, as is clear from the following extract from a summary of the Commission's deliberations.[107]

> It was clear that experiments involving risk should not, in principle, be carried out without the free consent of the person concerned. However, it was said that there might be exceptions to this principle where the interests of the health of the individual or the community were involved. The extent of such exceptions gave rise to some discussion. On the one hand it was thought that it should not be left entirely to national laws to define them. On the other hand it was realised that it would be difficult to draw up a complete list of criteria for permitting experimentation without the free consent of the individual concerned. There was general agreement that failure to obtain the consent of a sick, sometimes unconscious, person should not make any experimentation illegal where "such was required by his state of physical or mental health". A proposal that

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103 See Sieghart above n 33, 25.

104 See United Nations Economic and Social Council Commission on Human Rights Fifth Session *Summary Record of the 91st Meeting*, UN Doc E/CN.4/SR 91 31 May 1949. United Nations Economic and Social Council Commission on Human Rights Eighth Session, *Summary Record of the 312th Meeting* UN Doc E/CN.4/SR.312 12 June 1952 ; United Nations General Assembly ("UNGA") Tenth Session *Draft International Covenants on Human Rights Annotation prepared by the Secretary-General*, UN Doc A/2929, 87.

105 See above. See eg the statement made by the UK delegate at p 4.of UN Doc E/CN.4/SR.312.

106 See above n 104, UN Doc E/CN 4/SR 312, 12 where the form of the draft article was agreed to and UNGA Thirteenth Session *Draft International Covenants on Human Rights Report of the Third Committee* UN Doc A/4045 9 December 1958, 2 (Also in UNGA Official Records Annexes (XIII) 32). This document summarises the discussions leading from the draft to the final version.

107 See above n 104, UN Doc A2929, 88.

compulsory measures might be taken "in the interest of community health" was rejected on the grounds that it may lead to abuse.

3 *The Third Committee*

The draft article was then referred to the Third Committee on Social, Humanitarian and Cultural Questions which debated it at length during meetings held in New York in 1958.[108] Almost the entire debate related to the second part of art 7.

It is well to set out again here the text of art 7.

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

The article is thus in the form settled by the Commission on Human Rights except that the words: "involving risk, where such is not required by his state of his physical or mental health" have been deleted. This deletion was an amendment proposed by the Netherlands[109] which was adopted by a majority of the Third Committee[110] following extensive debate.

Given the clear meaning of the second part of the draft article, it would seem at first glance that the Third Committee had concluded that all experiments without the consent of the subject were cruel, inhuman or degrading treatment which should be prohibited. However, a consideration of the discussions which took place suggests that the majority sought to prohibit only such experiments which were also cruel, inhuman or degrading. I explain below.

The members of the Committee, like the members of the Commission before them, were clear that the purpose of art 7 was the prohibition of the types of experiments carried out by the Nazis.[111] Some (including a New Zealand delegate)[112] suggested that the second part of art 7 was redundant because such experiments were clearly caught by the first part of art 7. Most wanted it retained but there was considerable confusion regarding whether the second part of the article expanded the first part or was illustrative of it; and whether the first part of the article qualified the second part so that only cruel, inhuman or degrading experiments of the type described were prohibited. This of course implies a judgment that there are some kinds of experiments involving risk and not required by a person's health which should be allowed even although the person has not consented. The Commission had clearly not intended that the second part of the draft article be qualified by the first part and attempts were made by a United Kingdom delegate and former member of the Commission,

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108 See UNGA Thirteenth Session Official Records Third Committee Social, Humanitarian and Cultural Questions *Summary Records of Meetings 16 September to 8 December 1958 New York,* 67 - 107 (848th to 856th meetings).

109 See above n x, UN Doc A/4045, 2.

110 Above n 106, 102.

111 The discussion is littered with such references.

112 Above n 106, 68.

Sir Samuel Hoare, to put the Third Committee right.[113] However, it was this interpretation (with the deletion of references to risk and the requirements of health) which eventually held sway.

The Netherlands delegate, Mr Beaufort, explained the basis for the Netherlands amendment in the following terms:[114]

> The [draft] article expressed two different intentions ... . On the one hand, the Commission had wished the individual to be protected against cruel and inhuman treatment in general, and against criminal medical or scientific experiments in particular; on the other hand it had sought at the same time not to hinder the progress of medical science. The attempt to combine the two ideas in one short text had been the cause of the ambiguity of the article. Accordingly, all references to normal and legitimate medical practices should be deleted, in particular the expression "required by his state of physical or mental health". The phrase "involving risk" should also be eliminated, since a criminal experiment, even if it did not endanger life or health, violated the dignity of the individual.

It is unclear from this what Mr Beaufort means by "criminal" experiments. Later he makes his position a little clearer.[115]

> .... the purpose of the Netherlands amendment ... was to ensure , on the one hand, that all forms of torture or cruel or degrading treatment, including criminal medical and scientific experimentation, should be prohibited, and on the other hand, that no obstacles should be placed in the way of normal and legitimate medical practices. While he felt that the text proposed by his delegation achieved that end, it was by no means perfect, and the Australian amendment might well serve the purpose better.

The Australian amendment was for art 7 to be one clause with the second part reading: "and in particular no one shall be subjected to such treatment in the form of medical or scientific experimentation".[116] It is thus quite clear that Mr Beaufort intended that only medical experiments which were also cruel, degrading and inhuman treatment should be prohibited.

Sir Samuel Hoare noted that this was the intention of the Netherlands amendment but observed that an ambiguity still remained.[117]

> .... the first part of the second sentence, up to the word "experimentation", would not necessarily be taken to be limited to experiments such as those carried out in Nazi Germany unless the Committee's records made that intention unequivocally clear.

The records of the Committee do not, unfortunately, make the position unequivocally clear. The discussion which follows the extracts above reveals some concern that a narrow interpretation of the Netherlands amendment could prevent certain types of medical treatment.[118] However, those speaking

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113 Above n 106, 84. See also at p 83 where Sir Samuel explains at length the reasons for the form of the second part of the draft article.
114 Aboven 106, 77.
115 Above, 82.
116 Above, 3.
117 Above, 83.
118 Above, 85 (France).

in favour of the Netherlands amendment appear generally to understand it only to prohibit cruel, inhuman and degrading experiments performed on subjects who have not consented.[119] Furthermore, some who spoke against it did so because they thought it would allow cruel experiments to be performed on persons who had consented, which presupposes an understanding that the Netherlands amendment only related to such experiments.[120]

In the end the majority appear to have accepted that free consent was an essential part of the second part of the article. Mr Beaufort's reasoning on this point was as follows:[121]

> ....certain kinds of treatment became cruel, inhuman or degrading only in so far as they were administered without the victim's consent. The notion of free consent was therefore an independent and positive element and could not be abandoned without reducing the scope of the article.

4 *Conclusions*

The discussions of the Third Committee are sometimes rambling and confused. This makes it difficult to form a definite view on what the Committee as a whole intended when it voted in favour of the Netherlands amendment which resulted in the final form of art 7. On balance, and for the reasons set out above, it appears that their intention was to prohibit cruel inhuman or degrading experiments on subjects who had not consented and not to prohibit "normal", "legitimate" experiments which may be sanctioned by medical ethical rules. The draft art 7 tried to set out the attributes of experiments which are cruel, inhuman or degrading. However, the final form of art 7, when given the meaning intended by the committee, leaves this unclear save that any which are comparable to those performed by the Nazi scientists are clearly prohibited.

B General Comments and Decisions of the Human Rights Committee

The General Comments of the Human Rights Committee ("UNHRC") on the second part of art 7 of ICCPR are of some assistance. In 1992 the UNHRC stated in relation to the second part of art 7:[122]

> The Committee notes that the reports of States parties generally contain little information on this point. More attention should be given to the needs and means to to ensure observance of this provision. The Commitee also observes that special protection in regard to such experiments is necessary in the case of persons not capable of giving valid consent, and in particular those under any form of detention or imprisonment. Such persons should not be subjected to any medical or scientific experimentation that may be detrimental to their health.

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119 Above, 85 (Turkey), 85 (Bulgaria), 86 (Poland), 87 (Yugoslavia), 88 (Australia - not speaking in favour but clearly understanding it this way), 97 (Ireland), 100 (Israel).

120 Above,87 (United Kingdom), 91 (Panama)

121 Above, 100.

122 United Nations Human Rights Committee Forty-fourth session *General Comments Adopted by the Human Rights Committee under Article 40, Paragraph 4, of the International Covenant on Civil and Political Rights* UN Doc CCPR/C/21/Rev.1/Add.3 7 April 1992, 2.

In 1994 the UNHRC stated:[123]

> The Committee notes that the reports of States parties have generally given little or no information on this point.[124] It takes the view that at least in countries where science and medicine are highly developed, and even for peoples and areas outside their borders if affected by their experiments, more attention should be given to the possible need and means to ensure the observance of this provision. Special protection in regard to such experiments is necessary in the case of persons not capable of giving their consent.

The UNHRC thus clearly envisages some experimentation on subjects without capacity who, therefore, cannot have consented. That is, the UNHRC clearly does not interpret the second part of the article as precluding all medical experiments on those who have not consented which suggests that, in line with the *travaux preparatoires* discussed above, it sees the second sentence of art 7 as qualified by the first. The Comments also suggest that States parties must be vigilant to ensure that experiments on persons without capacity do not constitute cruel, inhuman or degrading treatment.

I am unaware of any decisions of the Human Rights Committee which clarify further what might comprise the types of experiments prohibited by art 7.[125]

C Overseas National Courts and the European Court of Human Rights

As far as I am aware, there is no other international or constitutional document which contains an express reference to the right not to be experimented upon without consent. However, since art 7 (as understood by the Third Commitee and probably also by the HRC) is largely a category of cruel, inhuman or degrading treatment it is relevant to consider how this type of provision has been interpreted. Such provisions are contained in the European Convention (art 3) and the Canadian Charter (s 12). The bulk of the case law under these provisions relates to cases of imprisonment and I have been unable to find any relating to experiments. There are, however, a few cases which discuss medical treatment and are, therefore, of some assistance.

In Canada a Provincial Court found that an order granting custody of a handicapped child to a state agency so that a malfunctioning brain shunt could be replaced was cruel and unusual treatment of the child because the surgical

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123 United Nations International Human Rights Instruments *Compilation of General Comments and General Recommendations Adopted by the Human Rights Treaty Bodies* UN Doc HRI/Gen/1Rev 1 29 July 1994, 7.

124 The reports from New Zealand are no exception. New Zealand's report submitted in 1994 is notable for its failure to refer to s 10 of NZBORA in its discussion of the implementation of art 7: it discusses s 9 of NZBORA and in relation to the second part of art 7 refers only to the Health Information Privacy Code issued under the Privacy Act 1993 which is really beside the point. See The Third Report of the New Zealand Government in United Nations Human Rights Committee *Consideration of Reports Submitted by States Parties Under Article 40 of the Covenant.* UN Doc CCPR/C/64/Add.10, 30 May 1994, 10.

125 I located none in either: United Nations Human Rights Committee *Selected Decisions under the Optional Protocol (Second to Sixteenth Sessions)* (United Nations, New York, 1985), or United Nations Human Rights Committee *Selected Decisions of the Human Rights Committee under the Optional Protocol Seventeeth to thiry-second sessions (October 1982-April 1988)* United Nations, New York, 1990.

intervention was not necessary. But the order was granted on appeal where the judge thought that no charter issue was involved.[126] In another Canadian case, involving an order to enable a child to have a blood transfusion against the parents' wishes, the court found that s 12 was was not intended to extend to medical treatment.[127] But in a later case it was said that treatment would be cruel and unusual treatment if it was administered against a person's will and for the benefit of a government agency rather than the person involved.[128]

The European Commission has found that compulsory medical treatment does not violate art 3 of the Convention provided that it is medically necessary and carried out in conformity with standards accepted by medical science. However, forced feeding and medical treatment going beyond this would constitute cruel, inhuman or degrading treatment.[129]

D Is the Second Part of Article 7 Analogous to s 10 of NZBORA?

The New Zealand Bill of Rights Act is an Act to affirm New Zealand's commitment to ICCPR. At first blush ss 9 and 10 of NZBORA simply enact as New Zealand law the first and second sentences of art 7. However, the only reason for interpreting the second sentence of art 7 on the basis that it is qualified by the first is that the two parts are contained in the one article and linked by the expression "in particular". Even then the article is ambiguous and the qualification is only clear from a careful reading of the *travaux.*

Section 10 stands alone and there is no basis for any ambiguity. It unequivocally expresses a right not to be subjected to experimentation without consent. There is no basis for reading into this that experiments which are not cruel or degrading are excluded; or that experiments on persons without the capacity to consent are not come under the aegis of s 10.

I have mentioned that art 7 is an article of ICCPR which cannot be derogated from. It follows from this that the right contained in s 10 should be found to be non-derogable to the extent that it relates to the types of experiments envisaged by art 7. However, s 10 clearly goes beyond art 7 and to that extent it must surely be subject to justified limitations under s 5 of NZBORA.

The views set out in the two preceding paragraphs are, futhermore, clearly those of the drafters of NZBORA. The White paper commentary on the first draft of NZBORA had the following to say about clause 20(2) of the draft which was in identical form to s 10.[130]

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126 *Re S D* [1983] 3 WWR 597; [1993] 3 WWR 618 discussed in DC McDonald *Legal Rights in the Canadian Charter of Rights and Freedoms* (2 ed, Carswell, Canada, 1989), 570.

127 *REDM v Alberta (Director of Child Welfare)* [1987] 1 WWR 327.

128 *Howlett v Karunaratne* 1988 64 OR (2d) 418, 434.

129 *Herczegfalvy v Austria* (1993)15 EHRR 437, 468.

130 See above n x 108. Note that the whole of the original s 20 read ":**No torture or cruel treatment** (1) Everyone has the right not to be sujected to cruel, degrading or diproportionately severe treatment or punishment. (2) Every person has the right not to be subjected to medical or scientific experimentation without that person's consent". So the fact that s 10 is a completely separate provision further reinforces this point.

> Article 7 of the International Covenant includes this right as a component of the larger right to freedom from cruel, inhuman or degrading treatment or punishment, and it has been pointed out that this linkage was designed to make it clear that only experiments which come within the range of inhuman treatment are forbidden whereas legitimate scientific or medical practices are not hindered. There seems no good reason to limit in this way the principle that all medical and scientific experiments require the subject's consent and Article 20(2) does not do so.
>
> The question of consent given on behalf of minors and others incapable of giving their consent could arise in this context. Any challenge to a law which permitted consent to be given on behalf of another to medical or scientific experimentation would certainly see the courts exercising the utmost vigilance to protect the rights of those on whose behalf that consent was sought to be given.

There can be no challenges to legislation under NZBORA. However, the statement above holds good in relation to the common law or any form of regulation not incorporated in legislation. Given the clear indication that the right prima facie excludes non-consensual experiments, the reference in the second paragraph is clearly to the court's role in deciding whether there are justified limitations prescribed by law.

E Conclusions

The second part of art 7 of ICCPR precludes all experiments on subjects without the capacity to consent but only where they are cruel, inhuman or degrading. At one extreme it is clear that the sorts of experiments carried out by the Nazis which had no therapeutic purpose and often resulted in suffering and death for the subjects were cruel, inhuman or degrading. At the other end of the spectrum, experiments performed on persons without capacity which involve minimal risk to the subjects and offer them and the group of which they are members possible benefits are probably the very sorts of experiments which the members of the Third Committee wanted to ensure would not be prohibited by the article. Where the line would be drawn within these two extremes is unclear. One would hope that experiments on children described in Beecher's article[131] would be prohibited by art 7 and that the New Zealand courts would find that, accordingly, we have a non-derogable right not to be subjected to them.

Section 10 clearly goes further than art 7 and precludes all experiments on persons without capacity. However, to the extent it goes beyond the content of art 7 it is subject to such reasonable limits prescribed by law as can be justified in a free and democratic society; and to any inconsistent legislative provisions. I now turn to discuss these limits which operate to restrict the right of a person without capacity not to be experimented upon. The first of these is the system of regulation of medical research which is based on the ideas of ethical committee approval and the ethical obligations of each individual doctor.

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131 See above n x57 One would hope that the other experiments described would be caught because of the failure to obtain fully informed consent from persons with capacity.

VII NEW ZEALAND REGULATION OF MEDICAL EXPERIMENTS ON HUMAN SUBJECTS

A *Introduction*

Medical research in New Zealand is not subject to direct, comprehensive regulation by the state. A combination of statutory requirements and initiatives from the Department of Health make up the state regulation of the ethical aspects of health research. First, all research funded by the HRC must have ethical approval from either the HRC Ethics Committee or a committee approved by that committee Secondly, any pharmaceutical company wishing have a new medicine trialed in New Zealand must have both the trial and the investigating scientists approved in advance by the Director General of Health on the recommendation of the HRC. Thirdly, the Minister of Health has used a variety of devices to ensure that any research funded by the crown or performed in Crown institutions is subject to ethical approval. I elaborate on these controls below.

B *The Health Research Council*

The HRC replaced the Medical Research Council[132] and was established by the Health Research Council Act 1990 ("HRCA") which came into force on 1 October of that year.[133] The purpose of the HRCA is to :"improve human health by promoting and funding health research".[134]

The HRC is given certain functions and powers by the HRCA.[135] In relation to both it must: "have regard to the general policy of the government in relation to health research."[136] The HRC's functions relate to funding and other matters. In relation to funding, it is to negotiate every three years its bulk funding by the Government and to administer those funds for the purpose of implementing national research policy.[137] Other functions include: advising the Minister of Health on health research policy; supporting and encouraging health research; promoting and disseminating the results of health research; and appointing members of various committees established under ss 13 to 26 of the HRCA.

Under s 7 of the HRCA the HRC is given all powers reasonably necessary to carry out its functions and further powers which relate to the administration of its funds. In particular, it is given the power: "To make, subject to section 31.. , grants to any person, institution, or body of persons ... for the purpose of health research".[138]

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132 Established in 1937 as a committee of the Department of Health and incorporated as an autonomous body by the Medical Research Council Act 1950. It was the national coordinating body for medical research and was responsible for administering government grants for medical research. See Collins above n 2, 134.

133 HRCA, ss 1 & 5.

134 HRCA, s 4.

135 HRCA, ss 6 & 7.

136 HRCA, s 6(2) and s 7 (3).

137 HRCA, s 6(1)(b) and s 6(1)(c).

138 HRCA, s 7(2)(b).

Section 31 of the HRCA sets out the procedure which the HRC must follow where an application is made for health research funding. The HRC must refer it to a research committee for scientific assessment and to the HRC Ethics Committee for the purpose of an independent ethical assessment.[139] Under s 31(2) the HRC can approve the application only if the HRC: "considers, after having regard to the scientific assessment ... and to the independent ethical assessment ... " that the scientific design is sound, the study is relevant and feasible given the available resources, and the research is ethically acceptable.[140]

The HRC Ethics Committee is established by s 24 of HRCA. Its functions under s 25 include advising the HRC on ethical issues and the provision and review of ethical guidelines.[141] It also obliged to ensure that, in respect of each application submitted to the HRC, an independent ethical assessment is made either by the HRC Ethics Committee or by: "a committee approved by the Ethics Committee".[142] Another function is giving advice to ethics committees established by other bodies in relation to membership, procedures and standards.[143]

The HRC Guidelines on Ethics in Health Research ("HRC Ethics Guidelines")[144] and HRC Guidelines for Ethics Committee Accreditation ("HRC Accreditation Guidelines")[145] indicate how the system works in practice. It seems that most ethical approvals are provided by ethics committees approved (termed "accredited" and "having delegated authority") by the HRC rather than by the HRC Ethics Committee itself. It also appears that HRC funding is released on receipt of evidence of ethical approval from an approved ethics committee which suggests that the HRC does not regard itself as able to override a decision made by an approved committee.[146]

The composition of the HRC Ethics Committee is prescribed by the HRCA: it comprises the chairperson of the HRC (or his or her nominee), two scientifically qualified appointees (one of whom is to be a member of the HRC) and four other persons. In making its appointments the HRC is to have regard to the need for a diversity of knowledge and experience in relation to ethics, philosophy, law, theology, nursing, women's health, patient advocacy and tikanga maori.[147] The HRCA does not, however, prescribe the composition of ethics committees which can be approved by the HRC or the ethical standards which must be observed by those committees or by the HRC Ethics Committee.

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139 HRCA s 31(1).

140 HRCA s 31(2).

141 HRCA, s 25(1)(a) &(b).

142 HRCA, s 25(1)(c).

143 HRCA, s 25(1)(f).

144 HRC *Guidelines on Ethics in Health Research: Guidelines and Requirements for Researchers* (4 April 1996)

145 HRC *HRC Guidelines for Ethics Committee Accreditation* (1996)

146 See above n 144, 5.This approach appears to ignore s 31(2) of the HRCA which expressly states that the HRC makes the final decision after having regard to, inter alia, the independent ethical approval. Arguably this should be more than a "rubber stamping" exercise.

147 HRCA, s 26.

The HRC Ethics Guidelines aim to set certain basic requirements for medical research involving human subjects:[148]

> It is a basic tenet of research with human participants that their interests, whether individual or collective, must always take precedence over the interests of others. Where conflict may arise, particularly concerning the larger public good, open discussion with the community should be invited.

The guidelines refer to the need for freely given and informed consent. In relation to participants unable to give their consent due to age, mental incapacity or lack of consciousness it is stated that: "it may be appropriate to seek proxy consent from family, guardians, persons with power of attorney or others". Reference is also made to the "National Standard" which will be discussed further below.

Those involved in experiments specifically are directed to the CIOMS guidelines[149] and the Declaration of Helsinki: the provisions of the latter are summarised in the HRC Ethics Guidelines.

C *The National Standard*

The HRC Accreditation Guidelines explain what is necessary for an ethics committee to be approved under s 25 of the HRCA.[150] The basis for approval is stated to be the compliance of the committee seeking accreditation with the National Standard. The most recent version of the National Standard is dated July 1996 and was issued by the National Advisory Committee on Health and Disability Services Ethics ("NACHDSE").[151] NACHDSE is a committee appointed under ss 7 and 46 of the Health and Disablity Services Act 1993 to: "advise the Minister of Health on ethical issues of national significance in relation to such matters as the Minister specifies by notice to the committee." One of its roles is the periodic review of the National Standard.[152]

The purpose of the current National Standard is stated to be to provide guidelines on the: "constitution and operation of health and disability sector Ethics Committees".[153] An Ethics Committee must comprise at least seven members at least half of whom must be "lay" and at least two of whom must be Maori.[154] It is stated that "it is desirable" that meetings of Ethics Committees be held in public but closed meetings may take place where necessary "to

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148 Above n 144, 8.

149 See above.

150 Above n 145, 5.

151 National Advisory Committee on Health and Disability Services Ethics *National Standard for Ethics Committees July 1996*. The first National Standard was published in 1988 by the Minstry of Health following the Cervical Cancer Inquiry.

152 Above, 4. It is also now responsible for the accreditation and monitoring of Regional Ethics Committees although for the 1996/97 financial year the Ministry of Health has contracted with the HRC Ethics Committee to perform this activity on NACHDSE's behalf: See National Standard above n 151, 41.

153 Above, the National Standard, 5.

154 Above, 8 & 26. A person is not "lay" if he or she is a registered health professional, is involved in research or would be seen as having some kind of professional bias.

ensure the privacy and confidentiality of of participants involved in research or innovative treatments.[155] Six of the National Standard's 49 pages deal with the ethical principles to be applied by Ethics Committees in considering a research proposal.[156] The requirement of informed consent where the subject has capacity is stressed.[157] The following extracts offer the only guidance in relation to the approach to be adopted where the subject does not have capacity.[158]

> In assessing protocols for treatment, service delivery , or research, an Ethics Committee must be satisfied that the potential good outweighs any potential harm. This requires the Committee to look at safety and efficacy data .... . The safety of and benefit to the individual must take precedence and where there is not likely to be any direct benefit to the participant then the risks to the individual ought to be heavily outweighed by the potential good to society or future individuals with relevant needs.

The need for informed consent is discussed and the difficulties posed by lack of or doubtful competence.[159]

> In cases where competence is in doubt ... every effort should be made to gain the consent of the participant. In cases where participation has no direct benefit for participants and may carry an element of risk, proxy decisions should not overrule clear objections from research participants.

A section on "vulnerable participants" states that special care should be taken in relation to participants at particular risk or those who are disadvantaged by their condition:[160]

> for example, patients under duress, children, people with physical or mental disabilities, and unconscious patients, to ensure that their agreement to participate is freely given. In each of these cases an arrangement should be in place to ensure that the best interests of of the patient should be safeguarded and their wishes, as far as they can be ascertained, respected.
>
> In the case of research involving children, the researcher may be required to seek informed consent. If the child withholds consent, this should take precedence over any valid proxy consent ...

It is also stated in relation to vulnerable participants that the Ethics Committee shall ensure that prior knowledge has been obtained through research with adults and animals and that no valid alternative to the use of children in the research is available. The Ethics Committee must also ensure:[161]

> a valid proxy consent (where children consent to participate in the research) must have been obtained ... Note: Proxy consent cannot authorise research which carries

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155 Above n 151, 31.
156 Above, 17 - 22.
157 Above, 18.
158 Above, 17. Clearly the National Standard does not purport to be the last word on ethics. International guidelines are listed at above n x, 7 and include the CIOMS guidelines.
159 Above, 18.
160 Above, 19.
161 Above, 20.

> significantly greater risk to the research participant than nomal clinical treatment would pose.

A section on "cultural appropriateness" refers to: "certain cultural aspects of research and service delivery which need attention in ethical review". It is said that:[162]

> consent processes may need to be modified in some settings so as not to assume Western individualism as the normal state of being for humankind. It may be appropriate to have consent given by a suitable authoritative body within the culture or, at an individual level, only in the presence of family or support persons ....

Even putting aside the poor drafting, the National Standard does not clearly set out when experiments on persons without capacity are ethically acceptable. On the one hand it is suggested that such experiments may proceed with proxy consent where there is no direct benefit to the subject and an element of risk; on the other that the best interests of such a subject should always prevail.

D Clinical Trials of Pharmaceuticals

The Medicines Act 1981 ("the MA") regulates the manufacture, sale and supply of medical products in New Zealand.

Anyone who wishes to sell or supply a new medicine in New Zealand must first apply for and obtain the consent of the Minister of Health.[163] This requirement is subject to certain exceptions including where the sole purpose of the distribution of the medicine is the obtaining of clinical and scientific information as to its safety and efficacy, referred to as a "clinical trial". But in order for the exception to apply both the clinical trial and the persons conducting the trial (the investigators) must have been approved by the Director General of Health on the Recommendation of the HRC.[164]

The HRC has formed a committee under s 29 of the HRCA to carry out this function : it is the Standing Committee on Therapeutic Trials, generally referred to as the SCOTT Committee. The SCOTT Committee has a contract with the Department of Health and the majority of the applications received by it are for clinical trials sponsored by pharmaceutical companies.[165]

The HRC Ethics Guidelines contain a brief discussion of ethical issues involving clinical trials but these go no further than the statements in the guidelines concerning research generally. [166]

E Regulation through the Ministry of Health

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162 Above, 22.
163 MA, s 20.
164 MA, s 30.
165 Above n 144, 9.
166 Above n 144, 10.

Since 1993 the health sector has undergone significant structural reform. The old Area Health Boards ceased to exist and the Health and Disability Services Act 1993 ("the HDSA") provided for the establishment of Regional Health Authorities ("RHAs")[167] and Crown Health Enterprises (CHEs)[168]. RHAs are designated "purchasers" under the HDSA and are funded by the Crown in return for their purchasing, or arranging the purchase of, health services, disability services or both.[169] CHEs are designated providers of health services etc.[170]

Under s 19 of the HDSA, RHAs are required to purchase services only from persons who maintain standards (including ethical standards) that the RHA "considers appropriate for those services". Pursuant to s 11(1)(d) of the HDSA an objective of a CHE is to: "uphold the ethical standards generally expected of providers of health services...".

RHAs are given certain broad functions under the HDSA[171] and are subject to Government direction and control in various respects including the Minister's written notices of objectives,[172] the requirement that they make decisions in accordance with their Statement of Intent,[173] and their contractual obligations under the funding agreements between them and the Crown.[174] These documents can all be obtained by members of the public: the objectives must be published in the *New Zealand Gazette*, the Statements of Intent are tabled before parliament and will be supplied on request by each of the RHAs and the Ministry of Health will make a copy of the funding agreement available on request (with financially sensitive information deleted).

The RHA can exercise control over the CHEs by means of the terms of the purchase agreement. Under s 40 of the HDSA a CHE may be required by notice to provide specified health or disablility services.[175] The only relevant notices issued to either RHAs or CHEs are as follows: those notifying the RHAs in 1993 that one of the Crown's then objectives was the development of processes for dealing with ethical issues including those relating to research;[176] and in 1994, 1995 and 1996 those notifying RHAs that they should purchase

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167 HDSA, s 32.The RHAs are created by Order in Council and are constituted as body corporates with the powers, rights and privileges of a natural person.

168 CHEs are companies formed in the usual way but all the voting shares in them must be held by the shareholding ministers (ss 37 and 38 of the HDSA).

169 HDSA, ss 20 and 21.

170 HDSA, s 11. The RHAs purchase health services from other providers as well, including in the private sector.

171 HDSA, s 33.

172 HDSA, s 8.

173 HDSA, s 35(1).

174 HDSA, s 21.

175 The notice must be published in the Gazette and laid before the House of Representatives.

176 Notice to the Northern RHA (1993) New Zealand Gazette 1949, 1951. Notice to the Midland RHA (1993) New Zealand Gazette 1952, 1954. Notice to the Central RHA (1993) New Zealand Gazette 1954, 1956. Notice to the Southern RHA 1957, 1958. In each case the objective is at Part II(ii)(f)(viii).

services through contracts which require providers to comply with legal and ethical standards.[177]

Each of the RHAs has tabled a Statement of Intent in parliament[178] which states that the RHA will use its best endeavours to purchase services which comply with or exceed legal and ethical standards and that it will ensure that providers who conduct research or innovative treatments shall seek ethical review and advice from an accredited ethics committee in accordance with the National Standard.[179] The current funding agreement contains similar provisions.[180]

F Regulation of Professional Conduct

Every doctor involved in research is personally responsible for ensuring that the research is ethically acceptable. New Zealand Medical Association ("the NZMA") is a private organisation funded by contributions from members[181]. and without statutory foundation or support. It represents the interests of medical practitioners in New Zealand and issues a Code of Ethics which sets out the ethical standards expected of New Zealand practitioners. The Code refers to international ethical codes including, in relation to research, the Declarations of Helsinki which it has endorsed. The Code contains an "interpretation" of the international ethical codes and, in relation to research, summarises the Declaration of Helsinki: cl I(11),[182] which relates to persons without capacity is not reproduced.

If a Doctor commits any significant breach of the applicable ethical principles he or she can be disciplined by the Medical Practitioners Disciplinary Tribunal and may be subject to penalties which range from censure to being struck off the register of medical practitioners.[183]

G Reasonable Limits

1 *Introduction*

The right not to be subjected to experimentation without consent is limited by decisions of individual doctors and of Ethics Committees to allow experiments

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177 Notices to the Northern Midland, Central and Southern RHAs: (1994) New Zealand Gazette 1902; (1995) New Zealand Gazette 1905: (1996) New Zealand Gazette 1751.

178 Southern Regional Health Authority *Statement of Intent 1996/97.* Central Regional Health Authority *Statement of Intent 1996-99.* Midland Regional Health Authority *Statement of Intent 1996/97;* Northern Regional Health Authority *Statement of Intent 1996/97 to 1998/99.*

179 See above: eg Southern RHA, 50; Central RHA, 70.

180 Ministry of Health 1996/97 *Funding Agreement Between the Crown and the RHAs.*See also *Policy Guidelines for Regional Health Authorities 1996/97.* Note that the policy guidelines are stated to have no legal effect and that the reference in them to guidelines issued by the Minister of Health appear to be to the *Interim National Standard for Ethics Committees May 1994.* which was a discussion document superseded by the current national standard.

181 Telephone discussion with Jason Dowse, NZMA, 20 September 1996. It is a company.

182 See above n 78.

183 Medical Practitioners Act 1995, part VIII. A breach of an ethical obligation could be disgraceful conduct, professional misconduct or conduct unbecoming of a medical practitioner depending on the seriousness of the breach.

on persons without capacity. More particularly the right of persons without capacity not to be experimented upon is limited by decisions of ethics committees allowing such experiments to proceed on the basis that they are "ethical" notwithstanding the absence of consent.

2 *Prescribed by law*

We have seen that for a provision to be prescribed by law it must, inter alia, be contained in statute or other delegated legislation or in the common law. The requirement in the HRCA that independent ethical approval be obtained in relation to HRC funded experiments and that the HRC approve funding after considering, inter alia, ethical acceptability meet this test. So does the requirement in the MA that a clinical trial be approved by the Minister of Health on the recommendation of the HRC and the requirements in the HDSA that CHEs uphold ethical standards and RHAs purchase services from persons who maintain ethical standards. But all these provisions do is require or envisage ethical assessments that are the exercises of discretion. They do not set out at all the circumstances when a person without capacity can be experimented upon.

The HRC has issued guidelines and has endorsed the National Standard. The RHAs have tabled Statements of Intent which state that they are required to purchase services from providers who are obliged to comply with the current National Standard. The RHAs are, under the Objectives notified to them, to do this through contracts with the providers. The Statements of Intent and the Objectives are not statutes or delegated legislation, nor are the terms of the agreements between the Crown and the RHAs, or the RHAs and the providers (including CHEs). However, even if these provisions could be elevated to "law" for the purposes of the test, all they do is require compliance with the National Standard. The National Standard and the HRC Guidelines have official endorsement and provide some guidance as to when a person without capacity can be experimented upon. But they are not "law' for the purposes of the test. Even if they were, they do not set out with sufficient precision when an experiment can be performed on a subject without capacity. We have seen that this is also a requirement in order for a provision to be "prescribed by law".

The ethical rules which doctors are bound to observe are not contained in any statute or regulation. Nor are they part of the common law. They are simply an expression of the consensus of medical opinion regarding ethical conduct. They are not prescribed by law.

In conclusion, the system of regulation of medical experiments in New Zealand does not provide limits on the rights of subjects of experiments which are "prescribed by law" for the purposes of s 5 of NZBORA. There is no need, therefore, to proceed further and consider whether the limits prescribed by the regulatory system which does exist are "demonstrably justified in a free and democratic society".

VIII NEW ZEALAND LEGISLATION

A Introduction

In the following paragraphs I consider New Zealand legislation which might authorise subjecting persons to medical experimentation without their consent. The Health Code , the Guardianship Act, the Children Young Persons and their Families Act and the Protection of Personal and Property Rights all contain provisions which may be relevant to when one person (the proxy) can consent to participation in a medical experiment on behalf of a person without capacity. The other legislation referred to allows compulsory treatment of persons with or without capacity and could, therefore, result in a person without capacity being experimented upon.

B The Health Code

The legislation discussed all came in to force prior to the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 ("the Health Code Regulations"). Regulation 2 provides for the Code of Health and Disability Services Consumer's Rights ("the Health Code") which is the outcome of one of the recommendations made by Judge Cartwright in the Report of the Cervical Cancer Inquiry.[184] The Health Code sets out the rights of health consumers and the duties of health providers and contains certain provisions relating directly to health research. Right 6 is the right of a consumer to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive including being notified of any participation in research. This has no bearing on those without the capacity to be informed.

Right 7 is the right to make an informed choice and give informed consent. Consent must be in writing where the consumer is to participate in any research or if the procedure is experimental. Where, however, the consumer is not competent to give informed consent, and there is no person entitled to give consent on that person's behalf, the provider may provide services where all of the following requirements are met.

> (a) It is in the best interests of the consumer; and
> (b) Reasonable steps have been taken to ascertain the views of the consumer; and
> (c)Either,-
> (i)If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
> (ii)If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

Reg 5 is significant. It provides:

> Nothing in this code requires a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

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184 See above n 66.

C *Children*

1 *The Guardianship Act - guardians other than the court*

The Guardianship Act 1968, inter alia, defines and regulates the authority of parents and others as guardians of children. The Act recognises the following as the guardians or potential guardians of a child. The natural parents; on the death of a guardian, a person nominated by the deceased to become a guardian in that event; a guardian appointed by the court; or the High Court itself . For the purposes only of section 23(3) of the Act a person in whose home a child has been lawfully placed for the purpose of adoption is also a guardian. Pursuant to s 21(1) of the Act, guardianship of a child terminates when a child attains the age of 20 years or sooner marries.

Section 25(1) of the Guardianship Act 1968 provides that :

> the consent of a child of or over 16 years ... to any medical, surgical ,or dental procedure....to be carried out on him for his benefit ... shall have the same effect as if he were of full age.

Section 25(2) relates to a child who is or has been married and is in similar terms save that: (1) it refers to a refusal to consent as well as a consent to medical treatment; (2) there is no requirement that the procedure be for the benefit of the child.

These provisions do not say, however, that children under the age of 16 years (or never married) are deemed incapable of consenting to medical treatment so that the consent of a guardian must always be obtained.

Section 27(3) of the Act provides that: "Where the consent of any other person to [the medical procedures] to be carried out on a child is *necessary or sufficient*",[185] consent may be given by the child's guardian or where such person does not exist or cannot be found, a person who has been acting in the place of parent or, if necessary, a person appointed by the District Court or the Director General of Social Welfare. This provision does *not* say that the consent of the persons referred to *is* necessary or sufficient. The necessity for or sufficiency of consent by a proxy is something which must exist before the provision can apply.

Notwithstanding this, Hillyer J in *Re X*[186] stated that:[187]

> ... it is specifically provided in s 25(3) [of the Guardianship Act] that consent may be given by the guardian to any medical procedure if consent is necessary. Of course where a child is under the age of 16 or is intellectually handicapped, such consent is necessary.

The Judge does not set out the reasoning for his conclusion. However, his reasoning may have been as follows: The Age of Majority Act 1970 provides

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185 My emphasis.
186 (1990)7 FRNZ 216.
187 Above 225 (obiter).

that: "For all the purposes of the the law of New Zealand a person shall attain full age on attaining the age of 20 years.."[188] Without more this Act would preclude the giving of valid consent by anyone under the age of 20 years. However, the the Guardianship Act provides an exception to this general rule: once married children and those over 16 years can give effective consent in relation to medical treatment (although in respect of a never married person between 16 and 20 the treatment must be for that person's benefit). Where a child is under 16 (or between 16 and 20, never married and the treatment is not for his or her benefit) and, therefore, unable to consent (or is unable to consent for some other reason), a guardian is empowered to consent on his or her behalf.

With respect, this argument is wrong. Whether someone consents to any form of touching is a question of fact and, therefore, the Age of Majority Act does not come into play. Otherwise, no-one under the age of 20 could be touched without this constituting an assault. This point is made well by Professor Skegg:[189]

> The view that at common law all minors are incapable of consenting to medical procedures results from a fundamental misconception...Medical procedures are not in a different category from other bodily touchings. If minors are incapable by reason of their age alone of consenting to medical procedures, it would follow that they were incapable of consenting to other touchings ... anyone who embraced a girl who had not obtained her majority [would commit a battery]-unless on one view, the consent of one of her parents had been obtained. Furthermore, a minor would be unable to give a legally effective consent to a haircut.

The provisions of the Guardianship Act do not, therefore, permit parents to consent to their children being subjected to such medical experiments as fall within the ambit of a "medical surgical or dental procedure".

What is the position if I am wrong and the Guardianship Act does allow guardians to consent on behalf of children under the age of 16? Would a guardian then be able to consent on a child's behalf to treatment which does not benefit the particular child? Section 23(1) of the Act states that in proceedings where: "any matter relating to ... guardianship of a child .... is in question, the Court shall regard the welfare of the child as the first and paramount consideration." By inference, a guardian consenting under s 25 would also be obliged to consider only the best interests of the particular child. Furthermore, the Health Code only permits a health care provider to provide services to a consumer without the capacity to make an informed choice. which are in his or her best interests.

2 *The Guardianship Act - the court as guardian*

Section 9 of the Guardianship Act empowers the Court to order that any unmarried person under the age of 20 years be placed under the guardianship

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188 The Age of Majority Act 1970,s 4(1).

189 PDG Skegg *Law Ethics and Medicine Studies in Medical Law* (revised edition, Clarendon Press, Oxford, 1988) 51.

of the Court. The High Court has wide powers in relation to its guardians which include the authority to approve medical treatment.[190] The Court is subject to s 23(1) of the Guardianship Act and must, therefore, act in the best interests of the child or young person.

3 *The Children Young Persons and their Families Act*

The Children, Young Persons and Their Families Act 1989 ("the CYP Act") reformed the law relating to children and young persons in need of care or protection or who have committed offences.[191] Sections 139 to 149 of the Act provide that those caring for a child may enter into agreements with certain state or social agencies for the temporary or long term care of children[192] or young people.

Section 149 of the Act provides that such agreements may: "authorise [the agency] to consent to the carrying out , on that child or young person, of any medical, surgical or dental procedure .... and where any person is so authorised that person shall be deemed to be a guardian of the child or young person for the purposes of section 25(3) of the Guardianship Act 1968"

The fact that an agreement between an agency and the erstwhile guardian of a child authorises the agency to consent to medical treatment of the child or young person cannot give that agency the right to give effective consent on the child or young person's behalf. Section 149 only allows an agreement to confer on the agency those powers available to a guardian under s 25(3) of the Guardianship Act. Therefore, the CYP Act does not operate to confer on any agency the right to consent to any experiment on behalf of that child or young person.

Section 6 of the CYP Act states that the welfare of the child or young person is the first and paramount consideration in all matters relating to the administration or application of the Act apart from certain parts and provisions relating to offending. Therefore, if my conclusion is incorrect and the Act does confer substantive rights to consent to medical treatment on behalf of a child or young person such powers would have to be exercised accordingly. As discussed, the Health Code would, in any event impose this obligation on the health care provider.

4 *Other legislation applying to children*

Where a person under the age of 20 has no parent or guardian, the Protection of Personal and Property Rights 1988 may apply. Children under the age of 17 are subject to the provisions of the Mental Health Act 1992 subject to the limited exceptions set out in part VII of that Act.

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190 Collins above n 2, 107.

191 Preamble to the Children, Young persons, and Their Families Act 1989.

192 Above s2: a boy or girl under the age of 14 years is a child and one over 14 but younger than 17 is a young person (unless he or she has been married).

D Adults

1 *The Protection of Personal and Property Rights Act*

The preamble to the Protection of Personal and Property Rights Act 1988 ("the PPPR Act") states that it is: "to provide for the protection and promotion of the personal and property rights of persons who are not fully able to manage their own affairs".

In relation to personal rights, competence is presumed and the court has jurisdiction only where a person lacks capacity to understand the consequences of decisions, or, has such capacity, but is unable to communicate.[193] Jurisdiction is limited to those never married and more than 20 years of age unless no parent or guardian is living or in regular contact with the person.[194] Under s 12 of the PPPR Act the court may appoint a welfare guardian to deal with those aspects of a person's care which the person lacks the capacity to deal with him or herself.

Pursuant to s 18(3) of the Act a welfare guardian's first and paramount consideration in exercising his or her powers is: "the promotion and protection of the welfare and best interests" of the incapacitated person. In relation to medical experimentation the position is put beyond doubt: s 18(1)(f) provides that a welfare guardian does not have the power to "consent to [the incapacitated 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".

The scope for experimentation on persons unable to consent to it, and in respect of whom a welfare guardian has been appointed, is, therefore, very limited. Where no welfare guardian has been appointed, however, the health care provider would be entitled to incorporate an incapacitated person in an experiment if an experimental treatment was in the best interests of the patient and the other requirements of Right 7(4) of the Health Code were met.

2 *Other legislation*

Certain legislation permits compulsory treatment of persons whether with or without capacity. For example, those suffering from of venereal disease (s88(1) Health Act 1956) are obliged to submit to treatment of the disease. If treatment in this context includes an experimental treatment, then any such legislation might allow non-consensual experimentation on those both with and without the capacity to consent.

The most significant legislation of this type is the Mental Heath (Compulsory Assessment and Treatment) Act 1992. This Act provides, inter alia, for the compulsory assessment and treatment of mentally disordered people. A "mental disorder" is defined in s 2 of the Act as follows:

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193 PPPR Act s 6(a) & 6(b).

194 PPPR Act ss 6(2) & 12(3).

> .. an abnormal state of mind (whether of a continuous or an intermittent nature), characterised by delusions, or by disorders of mood or perception or volition or cognition, of such a degree that it-
> (a) Poses a serious danger to the health or safety of that person or of others; or
> (b) Seriously diminishes the capacity of that person to take care of himself or herself....

It is certainly conceivable that a mentally disordered person could retain legal capacity to make decisions about his or her treatment. This would depend on whether he or she remained able to understand the consequences of such decisions.

A mentally disordered person (with or without capacity) is required by ss 58 and 59 of the Act to: "accept such treatment for mental disorder as the responsible clinician shall direct" during the assessment procedure and for the first month of the currency of a compulsory treatment order. At the end of one month, such a patient is only required to accept such treatment if he or she has consented in writing to the treatment, or the treatment is considered to be in the interests of the patient by a psychiatrist.

If "treatment" is capable of including an experimental treatment, then these provisions might permit therapeutic experiments on persons unable to consent.

E Applying Sections 4, 5 and 6 of NZBORA

1 *The Health Code*

Right 7 of the Health Code allows a doctor to treat someone without capacity where it is in the patient's best interests. This would include participation in an experiment in the event that such was truly in the patient's best interests. The Health Code is part of a regulation enacted under statute and clearly passes the "prescribed by law" test. Such a limit on the the right of person without capacity is surely justified in such circumstances: the objective is sufficiently significant to warrant overriding the right and the means chosen are both reasonable and proportional. It follows that the limit is demonstrably justifed in a free and democratic society. Since the limitation is reasonable, there is no need take the analysis further.[195]

A question arises as to implications of reg 5 of the Health Code Regulations. The right not to be experimented against creates a corresponding obligation not to perform such experiments. It could be argued, therefore, that reg 5 is subject to s 10 of NZBORA and, therefore, does not apply to experiments. However, taking the approach that the Health Code is subject to s 10 as abridged by any reasonable limitations enables the provisions to be reconciled.[196]

2 *The Guardianship Act and the CYP Act*

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195 Adopting the analysis of Cooke P in *Noort* (above n 83) could produce a different result. An interpretation consistent with NZBORA could be that "treatment" excludes experiments so that the provision is not inconsistent with, and therefore, overrides NZBORA.

196 Consistent with the approach of Richardson and Hardie Boys J in *Noort* above n 83.

For the reasons set out above, neither of these acts authorises proxy consent to any kind of medical treatment except by the court. As a result, there is no need to apply the analysis to them.

Where the court is appointed guardian it is obliged to act in the best interests of its ward and could, therefore, only authorise participation in an experiment on this basis. For the reasons set out in the discussion of the Health Code this is a reasonable limitation prescribed by law.

3 *The PPPR Act*

A welfare guardian can only consent to a medical experiment on behalf of a person without capacity where its purpose is to save that person's life or prevent serious damage to that person's health. This probably articulates those circumstance when an participation in an experiment can be said to be in a person's best interests. For the reasons set out above in relation to the Health Code, this is a reasonable limitation prescribed by law and there is, therefore, no need to take the analysis any further.

4 *Other legislation*

I have discussed above legislation which permits compulsory treatment, particularly the Mental Health Act. The first point to note is that the Mental Health Act only compels the subject to accept treatment *for mental disorder*. In my view, and for reasons expressed earlier, this provision is a reasonable limit on the right not to be experimented upon to the extent only that the patient could be compelled to participate in an experiment which is in his or her best interests. The same result is achieved if the analysis is taken a step further: treatment can be construed in a way which is consistent with s 10 as abridged; that is, as treatment which is in the best interests of the patient.

Similar reasoning can no doubt be employed in relation to other legislation which requires compulsory treatment.

IX THE COMMON LAW

A Introduction

The common law allows proxy consent to medical treatment and medical treatment without consent in limited circumstances. It is beyond the scope of this paper to discuss the case law in this area in detail. However, below I set out the general principles in this area and discuss when these principles could result in a person without capacity participating in an experiment. I then go on to consider whether these principles are reasonable limitations under s 5 of NZBORA.

B Proxy Consent

1 *Children*

We have seen that the Guardianship Act describes who may consent as proxies but does not authorise proxy consent; and that the PPPR Act allows proxy consent to participation in a medical experiment in relation to people who have been married, people over 20 years and to others only where there is no available guardian.

In relation to children, the common law recognises that parents do have rights over them which extend to consenting to medical treatment on their behalf where they are not competent to do so themselves. The position is clearly stated by Lord Scarman in *Gillick.*[197]

> Parental rights clearly do exist, and they do not wholly disappear until the age of majority. But the common law has never treated such rights as sovereign or beyond review and control. Nor has our law ever treated the child as other than a person with capacities and rights recognised by law. The principle of the law ... is that parental rights are derived from parental duty and exist only so long as they are needed for the protection of the person and property of child. ...
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> ... when a court has before it a question of the care a upbringing of a child it must treat the welfare of the child as the paramount consideration in determining the the order to be made. There is here a principle which limits and governs the exercise of parental rights of custody, care and control. It is a principle perfectly consistent with the law's recognition of the parent as the natural guardian of the child; but it is also a warning that parental right must be exercised in accordance with the welfare principle and can be challenged, even overridden, if it be not. ...
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> It is abundantly plain that the law recognises that there is a right and a duty of parents to determine whether or not to seek medical advice in respect of their child, and, having received advice, to give or withhold consent to medical treatment.

Thus a parent consenting to the participation of child without capacity in a medical experiment can only do so if it is in the child's best interests. However, it appears that parents may have some leeway in determining what the best interests of the child are. For example, where there are a range of therapies available, parents may choose one perhaps not recommended by the doctors concerned as long as their choice is within reasonable bounds.[198] It may be that on this basis parents could choose that their child participate in an experiment in order to take advantage of a newly developed therapy. However, for their decision to be reasonable, the risks involved would, in my view, have to be minimal.

2 *Parens patriae*

The High Court of New Zealand has *parens patriae* jurisdiction in relation to young and old alike. It enables the court, inter alia, to to authorise the performance of medical procedures on behalf of someone who does not have the capacity to consent.[199] The purpose of the jurisdiction is to protect the interests of those unable to look after themselves. It is clear, therefore, that

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197 *Gillick v West Norfolk and Wisbech AHA* [1985] 3 All ER 402 (HL).

198 See Kennedy and Grubb above n 2, 272.

199 See Collins above n 2 ,104.

before the court could authorise participation in an experiment it would have to be satisfied that it was in the best interests of the person concerned.

C Necessity

It will frequently arise that persons without capacity to consent require emergency or essential medical treatment. Examples are an unconscious accident victim requiring urgent treatment to save his or her life; or an elderly person suffering from Alzheimers' disease who has toothache.

The courts have developed the common law doctrine of necessity to protect doctors from liability in such circumstances.[200] The rationale behind the doctrine is the preservation of life or health The exact scope of the doctrine is unclear. To the extent that it extends beyond emergency situations it is clear that a minimum requirement is that the intervention is in the interests of the patient's health.

D Reasonable Limits

We have seen that common law principles may be "prescribed by law" for the puposes of s 5 of NZBORA. The issue is, therefore, whether they prescribe reasonable limits on the right of a person without capacity not to be experimented upon which can be justified in a free and democratic society.

To the extent that the best interests of the subject are the criteria, the limits are reasonable for the reasons set out in the earlier discussion of the Health Code. In the case of parents it seems that if they reasonably form the view that participation in an experiment is in the child's best interests, their decision will not be interfered with. This is really to say that the court will not substitute for the parents' reasonably formed view its or the medical profession's view of what are a child's best interests. This approach appears to be one which can be justified in a free and democratic society.

X CONCLUSIONS

Medical experimentation on human subjects remains an important human rights' issue. The existing system of regulation of medical research in New Zealand stresses the need for informed consent where the subjects have capacity and it, therefore, seems unlikely that non-consensual experimentation is being performed on such subjects within the scope of this regulation. It should be borne in mind, however, that experiments may be conducted which are not caught by the regulation described in part VII of this paper in which case there is no requirement of independent ethical review and compliance with the National Standard.

Medical experimentation on subjects without capacity is, however, very much a live issue. It is clear that such experiments are continuing in New Zealand and

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200 See Collins above n 2, 69.

it is important that the rights of this particularly vulnerable group are safe-guarded. It should be lawful for persons without capacity to participate in experiments where it is in the best interests of that person to do so; for example, where there is no alternative therapy available and participation offers a prospect of saving life or preventing serious damage to health. However, to prohibit totally all other experiments on this group would be to prevent future members of the group from enjoying the benefits of medical advances. In my view such experiments should be permitted where the risks to the subject are minimal.

On its face, s 10 of NZBORA precludes all experiments on those without capacity to consent. Section 10 is derived from the second part of article 7 of ICCPR which is a non-derogable right. However, the two provisions are not analogous: article 7 relates to experiments which constitute cruel, inhuman or degrading treatment, whereas s 10 applies to all experiments. It follows that the New Zealand courts should treat s 10 as prohibiting absolutely all cruel, inhuman or degrading experiments; but prohibiting other experiments subject to such reasonable limitations prescribed by law as are demonstrably justified in a free and democratic society, and to any enactments which are inconsistent with the right as limited.

The rights of people without capacity not to be experimented upon are limited in New Zealand by requirements that medical experiments be approved by and independent ethics committee and by the professional ethical code of doctors. However, this system is not prescribed by law and is not, therefore, effective to limit s 10. The limits set out in the Health Code, the PPPR Act and s 9 of the Guardianship Act are reasonable limits as is legislation which provides for compulsory medical treatment provided that it is interpreted in accordance with s 10 as abridged by its reasonable limitations. The Common Law also sets out reasonable limitations which relate to the rights of proxies to consent and the protection from liabilty of persons who act under necessity. This is because, broadly speaking, under all these provisions non-consensual experiments are permitted only where it is in the best interests of the subject.

It follows that all experiments being performed in New Zealand on persons without capacity which are *not* in the subjects' best interests are now illegal. This is likely to comprise the bulk of such experiments since most of the subjects of experiments are likely to be participating in clinical trials which test new treatments or procedures. It will generally be difficult to establish that these trials are in the best interests of the subjects since the whole purpose of the trial is to see just how safe and how effective the new treatment is and there is, therefore, a greater risk of harm than would be the case if the person was treated using, say, an already tested treatment.

For the reasons already expressed, this is not a good state of affairs: there are powerful arguments for allowing experiments on persons without capacity where the risks involved are small. Given that only limits prescribed by law are acceptable, it is essential that legislation is enacted to permit the appropriate degree of such experimentation. Before any enactment is drafted the importance of allowing such experiments should be carefully investigated, and

it must be ensured that the proposed legislative restriction on the right impairs it to the minimum extent necessary to achieve the objective.[201]

In the meantime, there is the prospect of legal proceedings being brought in respect of the public bodies involved in experiments which are not in the best interests of the subjects. Proceedings for an injunction or declaration could be brought seeking an order that all non-complying experiments cease. Furthermore, it is possible that in a suitable case, an action could be brought seeking public law damages.[202]

Finally, s 10 of NZBORA must make it more likely that a doctor could be successfully prosecuted for assault in relation to an experiment performed on a person who has not consented due to lack of capacity;[203] or that a successful civil action could be brought by or on behalf of such a person seeking damages for the tort of battery.[204]

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201 That is, the restriction will have to be demonstrably justified etc. See discussion in text at n x above. This will be necessary for the purposes of s 9 of NZBORA.

202 *Baigent's Case* above n 84.

203 Sections 2 and 9 of the Summary Offences Act 1981; ss 2 and 196 of the Crimes Act 1961. Unless the experiment is a surgical operation performed for the benefit of the patient and was reasonable having regard to the patient's state at that time and to all the circumstances of the case or can be justified on the basis of the common law defence of necessity.

204 The scope for this type of claim is limited by ss 8 and 14 of the Accident Rehabilitation and Compensation Act 1992 the combined effect of which is that civil proceedings for damages arising out of medical misadventure as defined in the Act cannot be brought. Thus, if the experiment constituting the battery is medical misadventure (defined as personal injury resulting from medical error or medical mishap - ARCI Act, s 5) proceedings for damages for battery may not be availableSince there will only be a battery if the person has not consented s 5(8) will not operate to expand the scope of potential civil liability for battery.

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