Research Involving Participants with Limited Capacity to Give Informed Consent

(NZSRG Discussion, 10th September 2014)

No man is an island entire of itself; every man
is a piece of the continent, a part of the main;
if a clod be washed away by the sea, Europe
is the less, as well as if a promontory were, as
well as any manner of thy friends or of thine
own were; any man's death diminishes me,
because I am involved in mankind.
And therefore, never send to know for whom
the bell tolls; it tolls for thee.

John Donne

Summary

'Research Involving Participants with Limited Capacity to Give Informed Consent' is a much-discussed topic at present. Difficulties have arisen because principles are brought into juxtaposition, from a number of high level quasi-legal international documents, which are not entirely consistent with each other. The introduction outlines the founding principles of medical ethics - beneficence, non-malefience, justice and autonomy - and their historical development. A fifth principle – transparency – is added to the list. There follows a section on the principles in international documents, dealing with informed consent, disablity, vulnerability, reduced decision-making capacity and loss of legal competence, and how such principles influence considerations of informed consent, both for treatment and for participation in research, in those with reduced capacity to take decisions. The subsequent discussion has two parts. The focus of the first part is the essence of issues arising when legal sysems interact with individual persons, and covers topics such as autonomy, rationality, categorisation of persons according to their legal competence, decision-making capacity and vulnerability, some cultural comparisons, and ends with a neuroscientists' analysis of 'autonomy', 'rationality', and (most important) 'personhood'. The focus of the second part of the discussion is a number of issues which can be thought of in more generic, less personal terms. There follows a discussion of the rationale for having laws covering essential subtleties of human interactions. While the stark realities exposed at Nuremberg make it essential to have laws as a final safeguard, much of the detail of negotiating informed consent, especially with vulnerable persons, or those with limited decision making capacity, comes down to the subtleties of building trust between persons with very different life circumstances. As legalistic protocols are relaxed, the ethic of transparency becomes ever more important as a safeguard against malpractice. In present times, there are many factors which hinder development of truly trusting relationships between reserchers and their potential research participants. The final sections nevertheless offer suggestions on how to build such relationships, and the details which follow from this for the style of the actual consent process.

Contents

I. Introduction

'Research Involving Participants with Limited Capacity to Give Informed Consent' is a topic giving rise to much concern at present, and appears in a number of forums. The topic is similar in many ways to consent to *treatment*, but with some differences. Limited capacity arises in several circumstances: some mental disorders, intellectual disability as a developmental issue, and cognitive impairment in the elderly, due, for instance, to Alzheimer's disease, and acquired brain injury. Here the focus is on schizophrenia and related disorders, but we learn from other areas where it is relevant.

The initiative for this to be discussed in New Zealand Schizophtrenia Research Grup NZSRG) came from Wayne Miles, a member of the National Ethics Advisory Committee. The specific context in which the issur arose was the ambition of NZSRG to set up, nation-wide, a sstem for enlisting the partnership of volunters for research in its areas of concern (what is referred to as a Volunteer Research Register – VRR). The issue has probably become topical in ethics debates because of tension between high-level guidelines, hitherto developed independently, but now juxtaposed as new issues come to the fore. In addition, the issue becomes complicated in New Zealand in part because of our cultural diversity, and the need to assimilate very different world views in our systems. At the research meeting in Christchurch, on the afternoon of 10th Sepember, 2014, the topic was introduced by short talks from five invited speakers, with many themes in common, yet different emphases:

Helen Bichan, a semi-retired GP, with ethical issues amongst her interests, was concerned that persons with diminished capacity should not be excluded from research for their benefit; but also, for some groups, that reduced capacity is assumed too easily and wrongly. She asked: Who decides on capacity? By whose standards? What support is needed for participants? Who should provide it? What information should be provided to enable informed participation?

Sue Purdie, spoke from the perspective of a service user, and spokesperson on human rights. Her comments were mainly about consent to treatment, but her strongest points, which applied equally to research, were that more research should be driven by service users; and it is *always* possible to establish genuine communication, even for those who are very disturbed (a state which is usually temporary) or disabled. Her title - 'I could always be gotten through to' - quoted from another source, referred to the latter point.

Lynne Bowyer, from the Bioethics Centre at Otago University, dealt with fundamental philosophical questions, and their import in practice. She challenged hidden assumptions in which bioethical debate is usually framed, of autonomy, rationality, and implicitly, how human nature itself is conceived, and on which the debates rest.

Brigit Mifin-Veitch, is Director of the Donald Beasley Institute in Dunedin, a non-profit organization focusing on research and education about disability. She spoke in practical terms about what informed consent means, and how it can be obtained from persons for whom her institute is concerned.

Christine Neville is head of the School of Nursing and Midwifery, and Deputy Director of the Ipswich Clinical School, University of Queensland. To achieve true partnership, she emphasised the need to preserve people's rights and dignity, taking care how capacity is determined, and to match information shared to a person's capacity.

To analyse this complex issue, it is necessary to identify different strands contributing to the tension. These include the concept of Informed Consent itself, as it applies to any medical intervention, and to any research involving human participants; growing concern that people with disabilities (including cognitive disabilities) should be able to participate

to the fullest extent of their capacity in decision-making on both medical intervention or research participation; and the need for *their* issues to be matters for serious research, just as are concerns of other groups.

The four founding concepts for today's medical ethics are said to be *beneficence*, *non-maleficence*, *justice* and *respect for autonomy.* A fifth concept the *ethic of transparency,* is introduced towards the end of the discussion below. The first four are all controversial. Do the first two refer to a physician's *intentions*, or to *outcomes* of treatments? Do the first three refer to *individual benefits* (and therefore to personal healthcare, to research on this, and to *individuals* concerned), or to *social benefits* (and therefore mainly to public health measures, and to specified *groups*)?

The fourth concept – the principle of autonomy - refers almost entirely to *personal* autonomy – the right to personal self-determination. This principle, was fundamental to Immanuel Kant's moral philosophy, and is most relevant in this essay. The words used may differ: 'Respect for persons' is a related concept with a slightly different shade of meaning, as discussed below. Autonomy can also refer to a *collective* right, such as a right to self-governance of a group. This becomes relevant in ethics debates, when a group of persons with something in common, claim - or are given - rights, as a group.

II. Informed Consent: General Principles

The basic concept of informed consent is based both in the idea of personal autonomy, and the need for physicians to defend themselves against charges of malpractice, and was part of medical practice in classical times[1]. However, given that solid evidence for efficacy and safety of medical interventions was very limited in early days, physicians assumed a mantle of unassailable, quasi-religious authority (and legal immunity), which patients were not expected to challenge. So, for most of history, the benificence principle outweighed the autonomy principle by far, often as 'benevolent deception'. Introduction of the principle of autonomy gained ground from Enlightenment philosophers, especially Immanual Kant, and, in the USA, Bejamin Rush (1746-1813), a medical man, and one of the founding fathers. In 1847, the American Medical Association produced a document on medical ethics, including autonomy as well as beneficence as basic principles, no doubt influenced by U.S. legal traditions, as well as intentions of the founding fathers[2]. A legal statute embodying the principle of informed consent for medical interventions was enacted in France in 1910[3]. In New York in 1914, *Schloendorff v. Society of New York Hospital* was a case related to a surgeon who removed a tumour while examining a patient, against her expressed wish. This case established the principle that 'every human being of sound mind and adult years has a right to determine what shall be done with his own body'[4]. The modern concept of Informed Consent, as implemented in legal statutes

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[1] Dalla-Vorgia,P, Lascaratos, J, Skiadas,P, Garanis-Papadatos,T. (2001) Is consent in medicne a concept only of modern times? *Journal of Medical Ethics,* 27, 59-61; Mallardi, V (2005) The origin of informed consent. *Acta Otorhinolaryngolica Italica* 25, 312-327 [in Italian]).

[2] As far as I can discover, constitutional documents from the USA or its states refer to 'autonomy' as a feature of humans to be *protected from* intrusion by others (e.g. encroachment of government), rather than as an inalienable aspect of human beings *per se.*

[3] Moumjod,N, Callu, M-F. (2003) Commentary: Informed consent and risk communicatio in France. *BMJ,* 327, 734-735.

[4] Van Norman,G (2011) Informed consent: respecting patient autonomy. In*: Clinical Ethics in Anesthesiology: A Case-Based Textbook,* ed. Van Norman,G, Jackson,S, Rosenbaum,S, Palmer,S. Cambridge University Press. (http://www.csahq.org/pdf/bulletin/informed_consent_61_1.pdf)

(or more flexible guidelines) grew in the context of grossly unethical *research* rather than involuntary treatment, as exposed at the Nuremberg trials in December 1946.

Before the Nuremberg rulings, and for some time after, the need for informed consent in research was often avoided in clinical science, wth researchers often themselves being subjects for their own research. This was often by no means a trivial involvement, although I know of no serious misadventure resulting from this. The Nuremberg rulings were not the first to define 'informed consent' to research as statutes. The first effective statute was probably that enacted in Prussia in 1900, after a scandal related to research on sexually-transmitted disease in Breslau. The 'trial of doctors' at Nurenberg, where the judges were all American, came about through the initiative of John W Thompson, a Canadian physician[5]. During the war, he had been a psychiatrist and military scientific intelligence officer. Almost single-handedly he ensured that medical experimentation was included amongst crimes prosecuted at Nuremberg[6], and thus started modern concern over 'informed consent'.

Use of the actual term 'informed consent' goes back to 1952; serious discussion of what it might mean dates from the early 1970s[7]. Since then, debate has sharpened, not only on its philosophical bases, but also on procedures and documentation needed to ensure that informed consent is obtained in research studies. In most countries where research on humans is done, researchers are now obliged to obtain documented evidence of informed consent from participants, a practice which has spread to routine treatments in medicine and surgery, when there is significant risk. However, the need for informed consent in either research or treatment cannot be regarded as an inviolable set of principles. Ethical principles are 'guidelines' agreed collectively, no more. They can, and should be adjusted according to the urgency of the situation. In the extreme case of a rapidly-accelerating epidemic, with fatal consequences, such as Ebola, where any treatment is experimental, it would be absurd to insist on the full rigours of informed consent[8], as was the case in the early history of most medical specialties.

Procedures to ensure informed consent have similarities in research and medical intervention, but with a few differences: (i) For medical interventions, there may be significant risk if nothing is done; intervention, with attendant risks, aims to prevent or reduce such adverse outcomes. In research studies, by contrast, the primary objective is to obtain new knowledge, sometimes for its own sake, but often inseparable from this, to aid *future* progress in a relevant area of medicine. Seldom does research help individual participants. (ii) For medical interventions, a patient voluntarily seeks professional help, and then follows a physician's advice, seldom understanding it fully. This has been the norm for generations, but is often now questioned. In so far as it *is* still the norm, it implies that a patient vountarily relinquishes his or her autonomy to a degree. For a

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[5] Brody H, Leonard, SE, Nie,JB, Weindling,P. (2014) US responses to Japanese wartime inhuman exprimentation after World War II. *Cambridge Quarterly Healthcare Ethics,* 23 220-230.

[6] Weindling, PJ (2013) *John W Thompson: Psychiatrist in the Shadow of the Holocaust.* University of Rochester Press.

[7] Beauchamp,TL (2011). Informed consent: Its history, meaning, and present challenges. *Cambridge Quarterly of Healthcare Ethics*, 20, 515-523.

[8] Schattner,E. (2014) Ebola, experimental drugs and informed consent: Should those at risk simply take what the doctor orders? *Forbes* 31.8.2014.
http://www.forbes.com/sites/elaineschattner/2014/08/31/ebola-experimental-drugs-and-informed-consent-should-those-at-risk-simply-take-what-the-doctor-orders/

physician, then, beneficence often assumes greater importance than ensuring autonomy of patient choice. In research, the emphasis is different: Participants *may* suffer from a medical or psychiatric condition which is the object of study; but only occasionally can the research offer direct benefits. At other times, participants do not have the condition under study, and serve as comparison groups when there is a clinical trial, or to study related *normal* processes. Thus beneficence is a minor concern; non-malificence and autonomy remain important. Justice between groups, in terms of research priorities, may be relevant (see below).

In research studies, ethical injunctions have now spread beyond medical fields, for instance to relatively innocuous survey-type research. Some regard ethical procedures as excessive, an unnecessary hindrance to research, and that ethics committees may have too much power. On the other hand, in social and policy research, designs similar to those used in medical trials are sometimes adopted, with little concern over ethics, and ignoring the need for informed consent. Examples include studies to mitigate problems in children identified at school entry as having 'conduct disorder'. Large numbers of children may be involved, with randomisation between schools[9]. The fact that ethical scrutiny is lacking may be because this is research for social policy, rather than medical research. Tighter ethical scrutiny may be needed here. Another reason for tightening of ethical scrutiny is that, as higher education has expanded, and research is seen as part of career advancement for academic staff, far more human research is now done than ever before. The possibility of serious ethical lapses has thus increased. Conflicts of interest in this area are discused below.

The fact that the Nuremberg trial of doctors *did* take place, and then depended on insistence of a single physician, and that there was no such prosecution for similar atrocities by Japanese doctors (indeed, attempts to conceal what happened, in which occupying forces were complicit[10]) suggests that this origin of today's medical ethics was by no means inevitable. It also shows that another important principle for both medical ethics, and social policy research should be considered – *the ethic of transparency*. This does not mean that research activity or medical procedures should be widely broadcast, or that research laboratories and hospital wards are public places. Medical and research procedures, including goings-on in psychiatric wards, are disturbing to many people; and professionals directly involved, by virtue of their training, are to some extent able to distance themselves from their emotional instincts, while retaining ethical sensitivity. However, wards and laboratories where difficult treatment and research takes place are *not* places which should be hidden, or need hide from public scrutiny. There *should be* systems to ensure that assessment occurs, by those who are *knowledgeable, experienced, well-versed in ethical matters,* and *independent,* to check that nothing improper is going on. This may involve asking detailed questions on clinical practice and research, which lay people could not ask, with an expectation of receiving full answers.

Apart from such general principles, in New Zealand, an additional principle should be considered, related to the country's history, with impact on ways of obtaining consent for research. This is related to the need to incorporate the culture of Maori, the *tangata*

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[9] Miller,R. (2012). *B4 School Report: A Critique of a Child Health Screening and Intervention Programme*. www.robertmiller.octspan. org.nz

[10] Brody H, Leonard, SE, Nie,JB, Weindling,P. (2014) US responses to Japanese wartime inhuman exprimentation after World War II. *Cambridge Quarterly Healthcare Ethics,* 23 220-230.

whenua of Aotearoa at every level in state business. More broadly, in many countries, the issue is the impact of cultural diversity, especially if cultural traditions are old and strong. In principle, research which claiming to be in the natural science tradition, is supposed to be universal, and in some areas, probably is (albeit undoubtedly a product of Western culture). What then, one may ask, might be the impact when different cultures live side by side, as they do in New Zealand?

The Health and Disability Ethics Committees in New Zealand are Ministerial committees (established under the New Zealand Public Health and Disability Act, 2000), whose role is to check that 'health and disability research meets or exceeds established ethical standards'. 'Ethical standards' may be referred to as 'guidelines'[11], which has a different shade of meaning; and documents referred to are entitled 'Standard Operating procedures'[12]), which has another shade of meaning. The basis on which the standards, guidelines or operating procedures, *were* established, is not entirely clear.

Be this as it may, Standard Operating Procedures for ethics committees (August, 2014) state (clause 19), that 'Researchers are responsible for ensuring that Maori (and where relevant, other population groups) are consulted in the development and conduct of studies that are of relevance to them.' In the present context, 'other population groups', presumably implies that consultation should include users of mental health services. A principle, under the subheading *Justice* reads: 'There should be due recognition of Māori as the tāngata whenua and indigenous people of Aotearoa New Zealand.' An additional point under *Justice,* refers to the Treaty of Waitangi, requiring 'participation: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori'. The impact of such statements on the process of obtaining informed consent for research, especially from groups who are vulnerable or have limited capacity for decision-making, are complex, and may be seen as a mixture of good and bad. They appear to extend beyond the rights and status of the *tangata whenua,* and are included in the discussion below.

III. Disability.

Disability and vulnerability are related, but are not the same; neither is equivalent to a lack of capacity to consent (considered later), although they may related to that. The strongest statement about disability comes from the United Nations *Convention On The Rights Of Persons With Disabilities*[13]*,* now ratified by most countries[14]. It applies to any jurisdiction, and how its principles are implemented is up to each jurisdiction, as best suits its traditions, resources, and other priorities. Amongst many important clauses, some are *basic principles* for Research Involving Persons with Limited Capacity. Others, relevant to *implementing* its principles, are dealt with later.

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[11] HDEC (2012a) *Ethical Guidelines for Observational Studies. Revised edition; July 2012*. Ministry of Health. Wellington.
HDEC (2012b) *Ethical Guidelines for Intervention Studies: Revised edition, July 2012,* Ministry of Health. Wellington.

[12] HDEC (2014) *Standard Operating Procedures for Health and Disability Ethics Committees. August 2014;* Ministry of Health. Wellington.

[13] United Nations (2006) *Convention On The Rights Of Persons With Disabilitie*s.

[14] United Nations (2015) http://www.un.org/disabilities/countries.asp?navid=12&pid=166

In the Preamble to the Convention, it is clear that the United Nations' concern about disability starts from the orignal UN Charter of 1948[15], defining inalienable rights of all members of the human family, (whose Preamble beings: 'Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world'). According to Article 1: 'Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments, which, in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.' It thus includes disability related to mental disorders. The Preamble (item e) states that 'disability is an evolving concept and that disability results from the interaction between persons with impairments and attitudinal and environmental barriers that hinders their full and effective participation in society on an equal basis with others.' This implies that disability is not a set of scientific concepts independent of social context (as is the case for some 'disease' entities): The extent of disablement, and often a disability itself, depend on characteristics of each society.

In Article 3, under *General Principles*, the first mentioned is: 'Respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons'. This implies that autonomy is a defining characteristic of humans, an emphasis on '*freedom to*', different from documents which stress *'freedom from*' anything encroaching on or limiting autonomy. General Principle [c] refers to 'Full and effective participation and inclusion in society'. Article 30 (*Participation in cultural life, recreation, leisure and sport*) [2] requires that 'States Parties shall take appropriate measures to enable persons with disabilities to have the opportunity to develop and utilize their creative, artistic and intellectual potential, not only for their own benefit, but also for the enrichment of society.' The emphasis here is on what disabled people can contribute, including their own altruism and moral sense.

One might ask whether the Convention should focus on specific 'disabled' groups, or on humanity as a whole. In the Preamble [i] we read:- 'Recognizing further the diversity of persons with disabilities'; and in the Preamble [g]: 'Emphasizing the importance of mainstreaming disability issues as an integral part of relevant strategies of sustainable development'.This is expanded under *General Principles* [d], where we read of 'Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity'. Thus disability is inseparable from human diversity generally.

Item [h] of *General Principles* reads: 'Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities.' The term 'personal identity' does not appear elsewhere (except for 'linguistic identity' - a separate concept). However the notion of 'personal integrity' certainly does. Article 17 (*Protecting the integrity of the person*) reads: 'Every person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others.' Given 'a person' is both a physical and a metaphysical entity, extension to *mental* ingegrity is a sound move. Whether the term is 'mental integrity' or 'personal identity', it *does* refer to an important issue in the present context.

Finally, Article 9 (*Accessibility*), includes [2b]: 'Ensure that private entities that offer facilities and services which are open or provided to the public take into account all

[15] United Nations (1948) *Universal Declaration on Human Rights.*

aspects of accessibility for persons with disabilities'. That is, the convention applies primarily in the public domain, but also in the private domain if it offers a public service.

IV. Vulnerability

The concept of *vulnerability,* and its inclusion in discourse on medical ethics is relatively recent. The original version of the Declaration of Helsinki in 1964, set out ethical principles regarding human experimentation developed by the World Medical Association[16]. It made no mention of vulnerable groups, but did mention participants who are 'legally incompetent' (see below). In 1979, an influential document[17] from the US Department of Health and Human Services (the Belmont Report: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*) mentions special concern about vulnerable persons as research participants, and raises questions about whether such persons should be involved at all: 'When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits.' There is no detailed discussion of vulnerability, its definition, or special provisions needed for research with vulnerable persons. However, a chapter in an Appendix to the Belmont Report[18], specifies several classes of such persons: '. .society is obliged to guard against abuse of "informed consent" by experimenters of the rights and needs of those who are most vulnerable to unethical conduct by those doing research: the sick, the old, the retarded or mentally ill, children, prisoners, the impoverished, and those whom life has neglected or betrayed'. By 2000, a revision of the Helsinki Declaration included a paragraph on research with participants from vulnerable populations. By 2005, a document from UNESCO[19] (*Universal Declaration On Bioethics And Human Rights*) included (Article 8: *Respect for human vulnerability and personal integrity*) the statement: 'In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.'

Four points stand out about the UNESCO document: *First*, it is aspirational rather than judicial in intent, with no binding force. *Second*, vulnerability is defined both as individual rights, and as rights accruing from group membership. *Third*, in its Preamble we read 'a person's identity includes biological, psychological, social, cultural and spiritual dimensions'. *Fourth*, the phrase 'special vulnerability' is used once, without clarifying the meaning of the word 'special'. By 2013, after further debate by bioethics

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[16] World Medical Association (1964) *Declaration of Helsinki.*

[17] US Department of Health and Human Services (1979) *Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (Belmont Report) NIMH

[18] Natanson,M (1979) A Philosophical Perspective on the Assessment of Risk-Benefit Criteria in Connection with Research Involving human Subjects. US Department of Health and Human Services (1979) *Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (*Belmont Report), Appendix, Vol II, ch. 21*, pp.19-20.

[19] UNESCO (2005) *Universal Declaration On Bioethics And Human Rights.*

experts, a more discursive UNESCO document appeared[20] which defined 'special vulnerability', recognising that, since we are all, in one sense, vulnerable, the aim of the previous document was more specific than such universal vulnerability. Sections of the later document state:- 'Two fundamental categories are highlighted that are relevant to these special responsibilities and obligations: (a) special (temporary or permanent) disabilities, disease and limitations imposed by the stages of human life; (b) social, political and environmental determinants: for example culture, economy, relations of power, natural disasters.' The *first of these* have 'natural determinants': Children, elderly people, 'persons with disabilities need help to access and sustain the exercise of their self-determination', 'persons with mental disorders may not be able to defend themselves or claim their rights. The *second group* include natural disasters, but are defined in more complex ways: People become vulnerable due to situations created by other humans, and social structures they create: poverty, income inequality, hierarchical power relations, marginalization and exploitation, gender discrimination, prisoners, wars, climate change.

New Zealand has developed its own *Code of Health and Disability Services Consumers' Rights*[21], defining right for persons who use health or disability services, and persons entitled to give consent on behalf of such persons. Most of it is about delivery of those services, but includes several references to *research* on health and disability. 'Right 6 ('Right to be fully informed') includes '[1d]: Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval'; items [1f] and [1g] ('The results of tests', 'The results of procedures') is extended [3d] to include 'Results of research'. Right 7 (*Right to Make an Informed Choice and Give Informed Consent*) includes (item 6): 'Where informed consent to a health care procedure is required, it must be in writing if [a] The consumer is to participate in any research'; or [b] The procedure is experimental'. Right 9 states: 'Rights in Respect of Teaching or Research: The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.'

V. Informed consent to *Treatment* and Limited Capacity.

Several concepts in law need to be distinguished here. A *natural person*, is any individual from the moment of birth. The New Zealand Bill of Rights protects both 'natural persons' and 'legal persons' (such as corporations) from actions of the State. A 'natural person' may have conferred on him/her rights and responsibilities, and if so, may be held criminally liable. (Canadian law defines a natural person as 'a human being that has the capacity for rights and duties'.) *Mental capacity* in the law of US, UK, Canada, Australia and New Zealand, is recognized as a continuous variable, present 'to greater or lesser extent'. It is understood that capacity changes over time. Thus, medical procedures needing consent over lengthy periods may need repeat assessment of capacity. A decision that a person has 'reduced capacity' is not a legal one, and is usually made by mental health professionals. It has no direct legal consequence, but may lead a court to decide that a person is legally incompetent. In contrast to capacity, *legal competence* cannot be present 'to greater or lesser extent': It is a yes/no decision: If competence is at issue, a person is either entitled or not entitled, at law, to have their wishes respected regarding treatment. It is a legal decision, made only by a court. However, incompetence is not a

[20] UNESCO (2013) *The Principle Of Respect For Human Vulnerability And Personal Integrity.*
[21] Health and Disability Commission (1996). *Code of Health and Disability Services Consumers' Rights.*

comprehensive legal disability: In UK law, as in New Zealand, it is specific to the task in hand[22]: A person may be deemed competent to decide on healthcare matters, but not on financial ones; or about simple medical interventions, but not complex ones. (The distinction between competence and capacity is important; official documents often use the terms interchangeably.)

As far as consent to medical intervention goes, a critical issue is raised when a patient refuses treatment: The law in the UK, USA, and NZ requires that a patient's stated wishes be respected unless he or she is shown not to be legally competent. The Belmont Report states that 'individuals should be treated as autonomous agents', but 'persons with diminished autonomy and thus in need of protection are entitled to such protections'. Likewise, the 2006 UN Convention (Article 5) states: 'The autonomy of persons to make decisions . . .is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.' This is expanded in Article 7a: 'Authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent'. The Helsinki Declaration of 1964, produced by physicians more aware of clinical realities, recommended that if a person is found legally incompetent, yet medical intervention is thought necessary, consent may be transferred to another person (next of kin, or legal guardian). This is 'proxy' or 'surrogate' consent. Sometimes it is replaced by 'presumption of consent' (e.g. if a person is unconscious). The emphasis of the Helsinki Declaration is slightly different from that of the UN Convention, but the discrepancy is not serious, since beneficence tends to prevail over autonomy in many circumstances if medical intervention is the issue.

To show how surrogate decisions for treatment are authorised, a typical example, from the University of Washington[23], is as follows:-

Is it ever acceptable to not have a full informed consent?
Exceptions to full informed consent are:

- If the patient does not have decision-making capacity, such as a person with dementia, in which case a proxy, or surrogate decision-maker, must be found.
- A lack of decision-making capacity with inadequate time to find an appropriate proxy without harming the patient, such as a life-threatening emergency where the patient is not conscious
- When the patient has waived consent. When a competent patient designates a trusted loved-one to make treatment decisions for him or her. In some cultures, family members make treatment decisions on behalf of their loved-ones. Provided the patient consents to this arrangement and is assured that any questions about his/her medical care will be answered, the physician may seek consent from a family member in lieu of the patient[24].

[22] Department for Constitutional Affairs (2003) *Draft Mental Incapacity Bill, London, Stationery, Office*.
[23] De Bord,J. (2014) *On Informed consent for Medical Intervention.* University of Washington. https://depts.washington.edu/bioethx/topics/consent.html
[24] The last provision is now increasingly embodied in Advance Directives, but the legal status of such documents is at present in a state of flux, especially for persons whose mental disorder leads to continual fluctuation of their capacity.

The New Zealand 'Code of Health and Disability Services Consumers' Rights' (Right 7, item 2) states: 'Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.' Likewise, at the Christchurch meeting on 10.09.2014, Christine Neville, in a slide, stated that, by law, 'Every individual must be presumed to be able to make their own decisions, unless it is proven otherwise'[25] (IHC, 2008).

Criteria by which capacity and competence are judged can be arranged as a hierarchy, whose lower members are necessary but not sufficient to make a decision. According to Wong *et al*[26], the easiest criteria to meet are: [a] ability to communicate a choice, followed by [b] ability to retain information conveyed by a physician. A harder criterion [c] is to require a patient to appreciate the situation and its likely consequences. Yet more difficult to meet, and more problematic in principle is [d] the criterion of *understanding* information relevant to treatment. In someone who is actively psychotic, this may be compromised, but not necessarily so once their mental state has stabilised. [e] Legal competence also requires a patient to 'hold appropriate values and goals'[27], a statement amplified as 'sufficient internal consistency and stability over time in the values relative to a particular decision, are needed to yield a decision outcome'[28]. Thus, 'frequent reversals of choice because of psychiatric or neurologic conditions may indicate lack of capacity'[29]. [f] The most difficult, and most fundamental criterion is to meet standards of *rationality*. This is hard to define, as discussed below.

Speakers at Christchurch echoed such ideas. Christine Neville included two statements: 'Capacity to consent – ability to acquire the knowledge to select and express one's choices and to engage in a rational process of decision making'[30]; and 'A consenting individual – capacity to understand the protocol and decide whether or not to participate'[31].

VI. Informed Consent to Participation in *Research*

The focus here is on *any* research with *any* human participant. Of the four founding principles for bioethics, *justice* has been considered least so far. It *is* relevant to bio-medical research, not so much at an individual level, but when considering whether a group of participants is representative of a condition under study. For instance, university research on human psychology often uses psychology undergraduates, by no means a representative cross-section of any society. A sharper bias is clear in many studies of conditions affecting both men and women, but which yet exclude women of childbearing

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[25] IHC (2008) *Supporting Decision-making.*
*]*http://www.ihc.org.nz/wp-content/uploads/IHC-Supporting-Decision-Making

[26] Wong, JG, Clare, ICH, Gunn, MJ, Holland, AJ, (1999) Capacity to make health care decisions: its importance in clinical practice. *Psychological Medicine,* 29, 437-446.

[27] Buchanan, A. (2004) Mental capacity, legal compeence and consent to treatment. *Journal of the Royal Society of Medicine,* 97, 414-420.

[28] Buchanan,A, Brock, DW (1986) Deciding for others. *Milbank Quarterly*, 64, suppl 2, 2-79

[29] Appelbaum, PS (2007). Assessment of patinet;s competence to consent to treatment. *New England Journal of Medicine,* 357, 1834-1840.

[30] Turnbull, HR (1977) *Consent Handbook.* Washington DC, American Association on Mental Deficiency

[31] Black,B, Brandt,J, Rabins, PV, Samus, QM, Steele, CD, Lykestos, CG, Rosenblatt,A. (2008) Predictors of providing informed consent or assent for research participation in assisted living residents. *American Journal of Geriatric Psychiatry*, 16, 83-91.

age, although differences between men and women are to be expected in risk factors, how the condition manifests itself, complications of treatment, etc. (Helen referred to a comment she heard 30 years earlier on an ethics committee, that women of child-bearing age were excluded, although results of research on medication would be applied to them.) The issue of research priorities became more urgent a few years after the Belmont Report, as the nature of AIDS epidemic became clear[32]. Since then, pressure has grown from various interest groups to be included in research studies, for their own benefit.

Arguments based on justice also apply to research for vulnerable groups: Their problems deserve attention of researchers as much as those of more robust persons, possibly more so, since their condition may have been neglected, their problems often being compounded by lack of previous research. The UN *Convention On The Rights Of Persons With Disabilities* refers indirectly to this: Article 8 (Awareness-raising), includes: [1a]: 'To combat stereotypes, prejudices and harmful practices relating to persons with disabilities, including those based on sex and age, in all areas of life'. [1b] To promote awareness of the capabilities and contributions of persons with disabilities'. Article 29 (Participation in political and public life) reads: [b] 'Promote actively an environment in which persons with disabilities can effectively and fully participate in the conduct of public affairs, without discrimination and on an equal basis with others, and encourage their participation in public affairs. . .' Article 30 requires that: 'States Parties shall take appropriate measures to enable persons with disabilities to have the opportunity to develop and utilize their creative, artistic and intellectual potential, not only for their own benefit, but also for the enrichment of society.' In 2008, the revision of the Helsinki Declaration at Seoul[33] included (Item 5): 'Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.' These statements recognise: (i) neglect of interests of people with disabilities; (ii) their right to participate; (iii) the fact that such persons, like many others, *want* to contribute to society; (iv) implictly the basis of their commitment *is* to the society in which they live, including those with similar disabilities.

In the discussion at Christchurch, Helen Bichan asked 'Why should people with impairment be excluded from research which may have the potential to help them or others in their situation?' Logically, justice *requires* that persons whose condition limits their capacity to give informed consent are entitled to have their condition investigated by high quality research, as much as any other group, vulnerable or otherwise. However, while the driving motive is to fulfil justice in an abstract sense, implications for research ethics unfold at the individual level, in terms of all other ethical principles.

VII. Research Involving Persons Lacking Legal Competence.

As already mentioned the 1964 Helsinki Declaration, had little to say about research on vulnerable persons, but legal incompetence *was* mentioned. Item (I/11) reads: 'In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it

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[32] Levine, C (1996) Changing Views of Justice after Belmont: AIDS and the Inclusion of 'Vulnerable' Subjects. In Harold Y. Vanderpool, ed., *The Ethics of Research Involving Human Subjects: Facing the 21st Century* Frederick, MD: University Publishing Group, pp. 105–126.

[33] World Medical Association, 2008, *Declaration of Helsinki, Seoul revision.*

impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.' The Seoul revision of the Helsinki Declaration has more dedtailed statements. Articles 5 and 6 read: 'Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.' Article 9 reads: 'Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.' In Article 17 we read: 'Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research' (see also Bray[34]).

The UNESCO Universal Declaration on Bioethics and Human Rights (2005) has a different emphasis. Article 7b) states:-

'Persons without the capacity to consent: In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(b) Research should *only be carried out for his or her direct health benefit*, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.' [emphasis added]

Children are included amongst vulnerable groups. In law, they may be too young to give informed consent, yet old enough to understand a research proposal, attendant risks and possible benefits, and what might be expected if they agree to participate. In this case, informed consent in formal terms is signed off by a parent or other legal guardian, but affirmation by the child – referred to as 'assent', rather than 'consent' - is required. The age criterion varies between jurisdictions, but generally includes adolescents as well as children. Assent is to be an active process, and there may be stipulation that 'failure to object, should not, by itself, be construed as assent'. NIH has produced a document giving details of procedures they use for both consent and assent[35].

Clearly, the limits proposed by the UNESCO document on research for persons who are legally incompetent are stricter than those in the Helsinki Declaration, even in its 2008 revision. The Helsinki Declaration, prepared by medical professions, is acutely aware of realities of clinical research as well as those of practice; the UNESCO document

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[34] Bray,A (1998) *Research involving people with intellectual disabilities: Issues of Informed Consent and Participation.* Dunedin, Donald Beasley Institute, Hocken Lirary.

[35] Decker,J (2000) *Protomechanics – A Guide to Preparing and Conducting a Clinical Research Study (3rd Edition)*. The Clinic Centre.

is more legal in tone. The 2005 Declaration has no powers, and it is for each jurisdiction to devise methods of implementation. Nonetheless, the discrepancy between the Helsinki Declaration and the UN Convention is sharper than for consent to treatment, since the autonomy principle looms larger in research.

What is the legal situation with regard to 'surrogate' or 'proxy' content for research? Clearly the Helsinki Declaration accepted the principle. So does the NZ Code of Health and Disability Services Consumers' Rights, since the term 'Consumer' is defined as 'a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer'; and Right 7,4 c [ii] states: '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'. Saks et al[36] discuss this, and make many comparisons between surrogate consent for treatment and for research participation. In the USA, the latter topic is left to state rather than federal law; and across different states, the position is less clear than for proxy consent to treatment. Many states explicitly allow at least some types of proxy consent to research, and a few set specific limits. Many others are silent on the issue. In practice, in specific cases, it is often a court rather than a parent or legal guardian who gives consent. On surrogate consent for research participation, the University of California at Santa Cruz, includes the following in its documents[37]:

'IRB review of projects involving surrogate consent (as evidenced by a "legally authorized representative" signature line in the consent document) shall conform to the requirements of California law AB2328 that specifies the requirements for and procedures related to the surrogate consent process.' . . .'For research protocols involving subjects who have fluctuating or limited decision-making capacity, the IRB should ensure that investigators establish and maintain ongoing communication with involved caregivers. Periodic re-consent should be considered in some cases.'

VIII. Informed Consent to Research Participation and Limited Capacity.

The quotations from the Helsinki Declaration, and the 2005 UNESCO document dealt with research involving persons lacking legal competence. Different considerations apply to those whose capacity is *limited*, but are not incompetent in strict terms. In addition, in practice, the issue of consent is handled in different ways for transient periods of reduced capacity compared to permanent incapacity. In this case, in psychiatry, more incisive evidence may be obtained by waiting until incapacity has lessened, as recovery from an episode occurs. Then, a person who has good insight into a period of acute disturbance may give not only valuable descriptive information, but also a degree of analysis of what happened during that period.

Regardless of this issue, when necessary, capacity to give informed consent for research participation can be assessed, as it would be for consent to medical intervention,

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[36] Saks, ER, Dunn, LB, Wimer,J, Gonzales,M, Kim,S. (2008) Proxy consent to research: the legal landscape. *Yale Journal of Health Policy, Law and Ethics.* 8, 37-92.

[37] University of California at Santa Cruz (2014)
http://officeofresearch.ucsc.edu/orca/irb/irb-faqs/irb-vulnerable/surrogate-consent.html

but taking into account the fact that autonomy is more important[38]. Questions about surrogate decision-making, and a person's decision-making capacity are in any case more relevant when decisions about treatment are to made (and a patient refuses consent) than about participation in research. We can apply with little change criteria [a] (ability to communicate a choice), [b] (ability to retain information conveyed by a physician), and [c] (requiring a patient to appreciate the situation and likely consequences). In psychiatry this requires that a person recognises that he/she has a disorder. In research studies, other than clinical trials, this criterion may be less relevant. Criteria [e] (Consistency of values and goals) and [f] (Rationality) also apply much as in informed consent to medical interventions. However, criterion [d] (Understanding) may present greater difficulty for consent to research than for medical interventions, both in principle and in practice. In principle, an intrinsic part of many studies is that the design is not to be understood by participants, even if, as is usually the case, there is no intent to deceive. In practice, to understand what is involved in participating in research studies may be more demanding than for medical intervention.

IX. Discussion.

This discussion is divided into two sections. The *first*, and larger section addresses the most fundamental issues, where legal systems have to deal with persons in situations for which those systems may not have been designed. This leads inexorably to discussion of what may the core issue: Two very different concepts of human nature, one based on a very old philosophy from which Western legal traditions grew, the other possibly equally old, rooted in communal life in many traditional cultures, and which gains some support from recent neuroscience. The *second* part deals with legal/political issues which are more generic, less personal in their impact. At the end of this section, some hope of resolution seems possible; yet barriers obviously hinder this (discussed in a later section).

A: Issues at the Interface Between Persons and Legal/Social Systems.

(i) The Criterion of Autonomy

The Belmont Report was quoted above as saying that 'individuals should be treated as autonomous agents'. The words 'should be' imply this to be a moral injunction, perhaps a moral 'norm' for human nature, not a factual statement. Some philosophers assert that moral injunctions are logically independent of empirical facts. History's verdict suggests otherwise: Rationalist injunctions, found in some Christian traditions, that expressions of sexuality are less than the ideal for humanity, have come to grief in the face of facts of human behaviour; the same conflict plays out in our own time over acceptance of gay and lesbian sexuality. One therefore asks if the injunction in the Belmont report is plausible.

A background chapter to this Report by Engelhardt[39] reveals a determined rationalism in relation to the concept of autonomy. The author enunuciates the principle that 'One

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[38] National Bioethics Advisory Commission (1998) Informed Consent and Limitations on Decision making Capacity In: *Research Involving Persons with Mental Disorders that May Affect Decision-making Capacity*. Report and Recommendations of the National Bioethics Advisory Commission. Vol I, Chapter 2.

[39] Engelhardt,H.T. (1979) Basic Ethical Principles in the Conduct of Biomedical and Behavioral Research Involving Human Subjects, In: US Department of Health and Human Services (1979) *Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (*Belmont Report),* NIMH, Appendix, Vol I, chapter 8.

should respect human subjects as free agents out of a duty to such subjects to acknowledge their right to respect as free agents'. This is a curious circular statement; yet respect for persons 'as free agents' is clearly related to the principle of autonomy. The author insists that: 'Respect for persons is not a value among other values. It is rather the basis for our sense of moral responsibility', a view also found in writings of Immanuel Kant. In part, the statement seems to insist that autonomy is a defining feature for humanity, not just a moral imperative. His argument differentiates behaviour determined by *reasons,* from that determined by *causes:* 'Morality presupposes that individuals are worthy of blame or praise because they can freely choose between different lines of conduct. If that is not the case, then we are simply caused to engage in particular behavior and to call certain behavior moral or immoral, and there is no possibility to mean anything by 'right' or 'wrong' other than that one is caused to call some things right or wrong. In that case, any serious talk of ethical principles must cease.' Understandably, the author makes sharp distinctions between persons who *are* free, and are thus 'moral agents', and those who are not, whose behaviour is *caused* rather than based on reasoning (such as 'very young children, or many of the very senile, mentally ill, or mentally retarded'). Even if one accepts some of the argument, the sharpness of the distinction seems implausible, based perhaps on a dualist philosophy such as Plato, the Catholic philosophers, or Descartes might have advocated.

Engelhardt writes on core questions of moral philosophy – the possibility of existence of 'morally good or bad actions'. This possibility (for him, apparently, a *certainty*) seems to be the basis of his argument, a true *a priori* premise, impervious to external evidence (a definition strangely similar to one of the criteria by which a belief can be recognised as delusional); but there are alternative bases for morality. (i) Concepts of moral right or wrong need not be based on a person's moral rectitude as *publicly* perceived, and therefore on autonomy as an *objective fact:* It is possible for *me* to have my own sense of what *I* hold to be morally correct, rooted on *my* life experience, and sense of autonomy, yet I may scrupulously avoid suggesting that my standards apply to others, based on *their* sense of autonomy. In essence, this argument, on public concepts of right and wrong *vs.* individual conscience, was part of Martin Luther's opposition to the might of the Catholic church, in his well-known line '*Hier steh ich*, *ich kann nicht anders*' (Here I stand; I cannot do otherwise'). (ii) Article 3 of the 2006 UN Convention links respect for persons to the possibility of free choice by those involved (as in Engelhardt's chapter); but the emphasis has shifted. No longer is respect for persons justified in terms of their autonomy being necessary for them to have a sense of moral responsibility; rather it is the basis for choice more generally, even on issues which are not primarily moral. (iii) A sense of moral rectitude for human actions (or policies for action) *might* be grounded in their value to a social group (including mankind as a whole), rather than in *individual* autonomy. (iv) Ethics developed in ecology and environmental movements has a quite different basis. (v) One might also ask how the premise of autonomy fares in the face of views from neuroscience, or realities which neuro-psychiatrists meet every day in their patients, a matter explored later. (vi) Lastly, legal systems do not hold such a monolithic concept of autonomy: Different definitions of a person within one legal system confer different rights and responsibilities: A 'natural person' at law (see above) is not identical with a 'legally-competent person'. For instance, before the age at which they are legally competent, being a 'natural person' gives *anyone* the right to hold a nationality, with a lower degree of criminal liability (or none), compared with a legally-competent person.

At the Christchurch meeting, Lynne Bowyer put forward a contrasting view. 'Conceptions of autonomy, decision-making, consent . . are founded on a problematic reductive and essentialist theory of human beings. This theory has set people up as isolated individuals who are said to be autonomous when they are capable of making self-serving decisions by means of rational calculation. Such a theory overlooks our lived situation as finite, fallible creatures who are embedded in webs of relational significance that constitute and sustain us. Our autonomous actions arise within and connect us appropriately to meaningful, shared contexts of engagement with others.' Thus, complete autonomy (of *any* individual) is problematic. Because of the exigencies of their life, many persons, and not only those who are vulnerable or lack capacity, find the idea that they have any real choice to be foreign. Autonomous, supposedly rational decision-making makes little sense if a person has neither the education nor the knowledge-base to grasp all issues at stake. Many persons meeting research personnel will be aware immediately that the latter are of greater wealth, and higher social status than themselves, and may feel overwhelmed and confused if asked to decide about research participation, when their understanding can at best be partial. This is especially true for some immigrant groups, who have no idea of questioning authority of doctors or researchers, and for whom the idea that psychiatry is about *personal* healthcare is beyond their experience. Without considering defined disabilities, autonomy is thus easily conflated with education, socio-economic status, life experience, and culture. On the other hand, some participants, by virtue of their obliging personality, will be only too willing to cooperate, and are thus drawn into research which a more sceptical person would avoid. In terms of the letter of the law, their 'consent' would stand up in court; but one might question if it has been obtained in a fully ethical manner, taking ethics as an expression of morality, rather than of law. Pushed to the limit, 'autonomy' can be questioned *wherever* informed consent is sought: 'No man is an island', but always situated in his or her prevailing context.

(ii) The Criterion of Rationality

Is it correct to assign to 'rationality' the central role it has been given, in deciding whether or not a person has legal competence or capacity? (*Actual* criteria for making this decision are discussed later.) Our daily decisions are often – perhaps always – influenced by emotions as much as by reasoning. Reliance on emotions alone may have unfortunate consequences; but likewise, decisions based on 'pure reason' (whatever that is) are also risky, even dangerous: they lose touch with human values, and our understandable fears and hopes. Indeed a line of argument traces 'rationality', step-by-step from the eighteenth century 'Age of Reason', through rationalist social policies such as those which led in Britain to the workhouses, to eugenic notions, and then to the barbarity of Germany's Third Reich[40]. Ironically, these events eventually set in motion the Nuremberg trials, and modern medical ethics; so, if such a sketch is accepted, rationality as the *sole* basis for medical ethics should be questioned. The flaw is that, rational arguments – such as those which *migh*t be thought to underlie eugenic policies – stand or fall not only by the precision of reasoning, but by the original premises. In contentious areas of biomedicine, the most important of those premises are rooted in our emotional instincts. Often these are quite adequate for decision making:- 'We know more than we can say'; inability to *understand and articulate concepts in words* is not the whole deal. Emotional intelligence

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[40] Popper,K (1961) *The Poverty of Historicism*, Routledge and Kegan Paul, London; see also: Miller, R.(2010) A brief introduction to the anti-Darwinian heresy. (www.robertmiller-octspan,co.nz).

is also very important, and ID people (so-called) may be good at sizing people up in emotional terms. Nevertheless, by themselves, emotional instincts are uncertain guides, since our different instincts may be incompatible with each other. If we recognise this, and the tension in ourselves to which it leads, then, rational analysis is crucial in working out priorities. In the process, our own instinctive reactions may be modified, to match the rationality of our priorities; but by no means are emotional realities subjugated by rationality: *They* are the core of rational decision making.

(iii) On Separating Those Deemed Legally Incompetent, or 'Specially Vulnerable'.

An apparent 'default' assumption is that human beings are autonomous and rational; and any departure from this is abnormal, even pathological, the difference being a sharp, and categorical. For the exceptions, in a beneficent spirit, special provisions are said to be needed. Declarations and conventions discussed so far all seem to be based on this idea. Statements quoted above, from the 2006 UN Convention on Rights Of Persons With Disabilities, including Articles 3 [c] and 30 [2], are just a few which might be cited here. They assume that autonomy implied in giving consent is intrinsic to all covered by the convention, who are then characterised by intellect, creativity, self-interest and altruism; also that a similar assumption applies to persons identified as disabled or vulnerable.

These are laudable emphases; yet we cannot dodge the clash of principles, for research with persons who also have limited capacity to give consent. Indeed, in the Christchurch discussion we heard challenges to this view. From Lynne Bowyer we heard: 'We all require guidance and support in making, carrying through and modifying many of our decisions, sustaining one another's autonomy through empowering relations with one another. This richer understanding of our human condition has implications for many of our social practices, including the way in which we engage with people in research.' Essentially she pointed out the fallacy in separating those who are and are not fully 'autonomous': We all lie somewhere in between.

Helen Bichan said: 'In practice, informed consent may be seen as a simple matter of deciding whether a person has or has not the necessary capacity. Instead I propose recognition that the amount of information and the level of assistance required for informed consent will vary from person to person and may change over time. Many people live with some sort of impairment, and society is accustomed to supplying support/assistance with ADL/special equipment/etc to enable them to participate in society. What support might be appropriate in seeking informed consent to participate in research?' Her challenge was that concepts such as 'disability' or 'special vulnerability' might falsely be defined as categories, rather than as infinitely-fine gradations. She expanded on this as follows (slightly paraphrased):- 'In a variety of situations I suggest that there are far more people who experience diminished capacity than just those with obvious impairment – for example: ESL; deafness. The percentage of information taken in at an explanation, by an ordinary person is perhaps 20% . . . and if the news is complex or bad? In Porirua city we are very aware of the importance of culture as it affects personal interaction and capacity to understand and make decisions.'

Helen also spoke of schizophrenia: 'People with conditions such as schizophrenia, that affect mental functions, are sometimes assumed to have diminished capacity, when that is not the case.' For many such, a lack of capacity is not enduring or permanent. Education programs may raise someone who is legally incompetent towards the group who *are* competent, yet with reduced capacity. It is too easy to assume that, because a person does not interact in ways taken as 'normal', that he/she has disabilities far beyond what is the case, making a limited disability become a comprehensive one. One can ask: If you are

vulnerable once, are you vulnerable forever? For schizophrenia the question is asked with some feeling, since, permanent severe impairment was formerly held to be a defining feature, with no chance of recovery. According to HDEC guidelines on 'observational studies, 'more than "minimal risk" is *always* involved for vulnerable participants'. Does this *ipso facto* apply to persons with a diagnosis of schizophrenia? If so, should such a ruling be challenged? One might also ask 'When does vulnerability start and stop? In so far as children are vulnerable, when is a child not a child? Does competence differ, in age, from one child to another? The realistic answer is 'Yes'; the legal answer is 'No'.

In short, in any population, there is vast diversity of 'abilities' and 'disabilities', of perceptual, cognitive, emotional and social sensitivities. These have a huge impact on our success in education, employment, health-care (when it is least excusable), and in other settings, in short, on 'how we get on in life'. Education or employment opportunities which people can access seldom take account of their difficulties, or recognise the unique strengths inseparably linked to impairment in other areas. By making ability/disability an issue of 'problem categories', we ignore its universality, and dodge the need in education, employment and other arenas to match our interactions to a wider range of strengths and weaknesses. The UNESCO document refers to 'special vulnerabilities', but in truth it applies to some extent to all of us some of the time, and some of us all the time. As John Donne put it: 'Send not to know for whom the bell tolls; It tolls for thee'.

The two speakers mentioned apparently wanted to avoid defining consent in legalistic ways, favoring instead that it be realized as a relationship of developing trust between researcher (or a 'mediator') and participant. To define human interactions as written, signed documents appears to assume at the outset, that there is a potential conflict of interests between participants; but if defined as a *growing relationship* it assumes a need to build and sustain *trust.* Many situations (such as a marriage ceremony) mix the two; but one should not be led to accept false assumptions by the procedures adopted.

Apart from whether disability and vulnerability are sharply categorical or graded characteristics, there may also be concern (in Helen Bichan's words) that the concepts of disability and vulnerability are limited to too narrow a range of specific conditions, with little attempt to recognise special *strengths* and *abilities*. Here I list some characteristics which may seem like incapacity or vulnerability, but which, in reality, are not: Different people prefer different means of communication, both for taking in messages, and for expressing their ideas and wishes. The fact that someone does not use a medium preferred by the dominant group says nothing about their intelligence, determination or altruism. Some people have problems in holding attention, for instance to either the spoken or the written word. The spoken word requires focused attention which may be taxing if it is to be sustained without a break; so, there is an 'etiquette' of 'turn taking' in conversation (which is ignored by those who want to dominate); and some people are better at using the written rather than spoken word, when input is at a pace determined by the reader, rather than the speaker. The converse applies in other circumstances. Persons whose *conceptual* ability is limited are often *perceptually* better than normal (e.g. in recognising people by their face, or in their musical sensitivity). Some people excel in competitive situations, which disable others, who show their strength in other forums. Intelligence is not always shown by verbal or conceptual dexterity, but by shrewd decisions when it really counts, perhaps based on emotional intelligence. Persons classed as *intellectually* subnormal may have sensitive emotional 'antenae'. Researchers seeking authentic consent from participants might do better to focus on building rapport and trust, rather than on documenting consent or assent to a particular form of words.

Given that documents on informed consent and on protection of disabled or vulnerable persons developed independent of each other, it is hardly surprising that difficulties arise when the two meet. The most important clash is between the autonomy principle vs. the need to recognise and protect vulnerable persons if this limits their capacity for decision-making, or renders them legally incompetent. There is also a clash between autonomy and justice, such that research for marginalised or legally incompetent groups has been low priority. Clash between these different strands of ethical thinking is a recent trend, with, as yet, no agreed guidelines. However, since autonomy is built into volunteering for research more than for consent to treatment, when a clash occurs, it is sharper in a research context, than for medical intervention.

(iv) Criteria for Assessing Capacity to Give Informed Consent

The preceding section focused on intrinsic flaws in categorisation of groups, captured most strongly by the concept of legal incompetence. The present section focuses on the softer concept of 'incapacity', which has many grades. Some criteria discussed above ([a] the ability to communicate a choice; [b] ability to retain information conveyed by a physician) require little discussion; others do. Criterion [e] requires consistency of beliefs over time. Judged by this criterion, capacity may be compromised in someone who is actively psychotic, but once mental state has stabilised this may not be so. Other persons, stably-maintained patients, may have firm, fixed beliefs which are clearly delusional, by the way beliefs are held, and the manner of their formation, and impervious to influence by conflicting evidence; but if consistency of beliefs over time is a criterion for capacity, logic dictates that decisions about consent based on such beliefs should be taken as valid. Thus this criterion is problematic.

Criteria [c], [d] and [f] are discussed together. Criterion [c] requires that a patient appreciates the situation they are in and the likely consequences; criterion [d] requires understanding of research s/he might agree to participate in; and criterion [f] requires a standard of 'rationality'. This deserves detailed discussion, under three headings: 'ability to form concepts', 'understanding' and 'rationality'. They are also aspects of a larger concept - 'personhood' - discussed below.

[a] *Ability to form concepts*. Failure in this is held to be the reason why children, in legal terms, lack competence, a view that is definitely incomplete. My daughter at age six or seven, berated me when one of my jokes fell flat: 'That's not funny, Daddy; that's just silly' – a subtle conceptual distinction which was already clear in her mind! The point was made by Alfred North Whitehead[41] who writes as follows: 'It is not true that the easier subjects should precede the harder. On the contrary, some of the hardest must come first because nature so dictates, and because they are essential to life. The first intellectual task which confronts an infant is the accomplishment of spoken language. What an appalling task, the correlation of meaning and sounds! It requires an analysis of ideas and an analysis of sounds!' From this perspective, it seems that our ability to *develop* concepts is at its best when we are very young and declines thereafter, although flexible use of *pre-established* concepts may steadily increase.

[b] *Understanding.* Criteria [c], [d] and [e] all touch on understanding, but this can hardly be separated from formation and use of concepts. In psychiatry, to 'appreciate the situation' requires a person to grasp that he/she *has* a disorder which may be treatable. Understanding, in relation to consent to treatment, is then assessed by asking a person to paraphrase what a clinician has disclosed about a disorder, recommended treatment, and

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[41] Whitehead, A.N. (1929/1950). *Aims of education, and other essays. 2nd Edition,* New York, MacMillan.

its risks and benefits[42]. Failure here (that is in 'insight') is held to be a primary feature of many mental disorders, at least in their acute phases. Understanding *research* may be problematic because it is more complex than medical intervention, especially if complex designs are used. Explaining randomization in a clinical trial in any area of medicine may give rise to anxiety. Educational strategies have been used to enhance understanding, so that consent becomes valid[43]. Given this, and the principle that legal incompetence may apply to limited areas of decision-making, it is likely that such strategies may make consent to treatment valid for a person who is otherwise incompetent.

Our increasing fluency in using concepts as we grow older depends largely on the authority of others (e.g. parents, teachers). Children are easily coerced; but so too are adults, as our wily politicians know all too well, with their clever, over-concise slogans, familiar words and one-liners as political levers, while dodging debate needed to validate the concepts represented by their words. Many voters are easily coerced, submitting to covert authority, and avoiding the task of questioning authority. In referring to 'ability to understand concepts' do we mean '*willingness to accept somebody else's* concepts'? If so, should we be content to accept this? Protocols for assessing a patient's understanding can be seen in this light. All this begs the question: We may think we understand concepts; but how many of us can rigorously define and validate the concepts we habitually use? Few, I suggest.

In any case, in research, more perhaps than in clinical encounters, an assumption, not entirely hidden, is that a researcher has better access to 'truth' than human participants. There is 'asymmetry of information'; and if, as Francis Bacon asserted, 'Knowledge [or "information"] is power', such asymmetry implies an imbalance of power. In obtaining informed consent from participants, it is implied that the person *giving* information has accurate knowledge, as far as possible (which in turn is based on having valid concepts). Indeed, in written information for participants, it is likely that the protocol starts by naming a condition or disease to be studied; yet in psychiatry, it is an open secret that diagnostic concepts are by no means adequately validated scientifically, although those in use are not entirely useless. That a researcher has better knowledge is of course partly true, but not wholly: No-one can claim for themselves a privileged access to truth. Any such claim should be tested openly in the 'market place of ideas'.

Today, special issues arise in psychiatry, as a result of the higher level of education and greater knowledge of many service users, and growth of their collective awareness and capacity for action. Ideas now current amongst service user groups may lead a stabilised patient to argue that concepts such as schizophrenia lack scientific validity, and are poor guides to treatment; or, more broadly, that a medical concept of mental illness is based on a false analogy with general medicine. Spokespersons may prefer more holistic

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[42] Grisso,T, Appelbaum,PS Hill-Fotouhi,C. (1997) The MacCAT-T: a clinical tool to assess patient's capacities to make treatment decisions. *Psychiatric Services,* 48, 1415-1419.

[43] Carpenter et al (2000; Carpenter WT Jr, Gold JM, Lahti AC, Queern CA, Conley RR, Bartko JJ, Kovnick J, Appelbaum PS. Decisional capacity for informed consent in schizophrenia research. *Archives of General Psychiatry* 57:533-538

Dunn LB, Jeste DV (2001) Enhancing informed consent for research and treatment. *Neuropsychopharmacol*, 24, 595-607.

Dunn LB, Lindamer LA, Palmer BW, Schneiderman LJ, Jeste DV (2001) Enhancing comprehension of consent for research in older patients with psychosis: a randomized study of a novel consent procedure. *American Journal of Psychiatry,* 158, 1911-1913.

concepts of mental disorder, based on the universal quest for 'personal wholeness'. Sometimes the case advanced by spokespersons for service user groups is incoherent and exaggerated. In addition, pressure from service user groups may ask not so much for 'more research in my area' (related to the justice principle, discussed below [sect B (ii)], but to specify the *nature* of that research. Curious paradoxes then arise, for instance when mental health consumers want 'more psychosocial and less biological research', reflecting a supposed perception that psychology is closer to common sense and common understanding; while groups based around chronic fatigue syndrome, want exactly the opposite. This raises the fraught issue of 'understanding' by research participants.

The most thoughtful, articulate advocates have well-formulated views on what is a legitimate philosophy for research in mental health. Their case may be coherent, well argued, a challenge to orthodoxy, but starting from different assumptions. The present author has much sympathy for such views. Thus, when a patient refuses treatment such as prophylactic medicine, it is fair to ask if the patient *necessarily* lacks understanding. In a clinical situation of consent to *treatment* a good psychiatrist should be able to discuss this rationally, and reach a sensible agreement with his or her patient. The relationship is different in research: A researcher may have already presented a detailed design of his study to funding agencies, and ethics committees, and received their approval; and it is this which enables research to go ahead according to protocol. When informed consent is sought from a potential participant, it is not a suitable time to revisit this in detailed discussion, or to revise carefully-formulated plans. It might be the time for a potential participant to decide that he or she cannot take part. However a strategy to forestall this would be for the design to be discussed in advance in a group meeting with a number of potential participants, and/or their spokespersons, rather than individually with each participant. This is related to the legal concept of a 'class action', discussed later.

World-wide, there is growing awareness of the inadequacy of current concepts of mental disorder, spurred on by the fact that the new edition of the most prestigious diagnostic scheme in psychiatry, DSM 5, launched in May 2014, was rejected by NIMH, the world's largest funder of mental health research, for research it supports. Validity of diagnostic schemes is now debated at international congresses (for instance the Congress of European Psychiatric Association in Vienna in March 2015). Service user leaders are increasingly aware of this: their input is one force making professionals take notice of the issue. Such questioning is likely to become more common, making clinicians' task more difficult, if they cling to old styles. As for informed consent for mental health *research*, the conclusion of this intensifying debate may be that consent should not be tied to specific *diagnoses,* but should be specified in some other way. Perhaps it would be more straightforward to specify *symptoms* (or, avoiding medical terminology, *singular experiences*) for a researcher's study, not diagnoses.

[c] *Rationality:* Rationality is often taken as the central criterion for assessing a person's capacity to make decisions, such as giving informed consent. In practice, there are several ways in which the criterion is surreptitiously replaced by something else. In consent to *treatment*, it may be judged by an assessor who substitutes 'likely outcome of treatment, according to conventional medical wisdom', replacing any real criterion of rationality. Rationality may be transformed into 'long-held beliefs' (already discussed); but this is not 'rationality', and one has to ask 'for how long?' Rationality can also be confused with 'holding a system of belief, conforming to that of the prevailing society', or to 'beliefs of the clinician him/herself.' Decisions about health care, scientific research, and about research participation, are often based on a total world view, on which healthy

persons show great diversity; and undoubtedly, amongst those with mental disorders, as in other groups, strange world views may be held, as enduring beliefs. Such criteria for rationality are easily faulted for their lack of transparency or real engagement with service users, even of honesty; and in terms of the *justice* principle, excluding persons whose world view makes participation impossible, undoubtedly leads to biased sampling.

One might suggest that rationality should more properly be based on the nature of a person's thought processes; but then other problems arise. Grisso *et al*[44] describe an instrument (MacCAT-T) to assess a patient's competence to make treatment decisions (with schizophrenia in focus). Reasoning is assessed from a patient's explanations of his/her choices; what is envisaged to be the consequences of the choice; whether he or she compares their choices with alternatives; and whether the patient's choice follows logically from his or her explanations.

On processes of reasoning, especially after Immanuel Kant's *Critique of Pure Reason* in 1787, philosophers have endlessly debated the nature, the validity, even the possibility of sound reasoning, to resolve difficult issues. The greatest philosophers cannot agree what reasoning is. Kant's greatest insight might have been that any supposedly rational statement is based on a set of background assumptions, which need never be articulated. As a result, rational arguments starting from the same *overt* premises (but with different *unstated* contexts) can reach different conclusions. Moreover, precise reasoning depends on having precise concepts to work with; but who, in the flurry of debate, takes time to examine the logical foundations, and validity of concepts they use?

In more commonsense vein, clearly we often make instant decisions in a testing moment instinctively, without analysis, or putting into words how the decision is made; yet the decisions are fully valid. Rationality usually means 'verbally-expressed reasons' (as in the above protocol); yet, as in many situations 'we know more than we can say'. The validity of instantaneous decisions lies in the vast amount of prior life experience; crucial decisions made without a moments thought bring together a lifetime's experience – but by no means are they 'thoughtless'.

Against this history, Michael Foucault[45] described how the concept of 'mental illness' emerged in France during the Age of Reason prior to the Revolution of 1789. It was taken to be an 'illness' in so far as it departed from a supposed 'natural' human faculty for reasoning, which, implicitly was an absolute standard. The emphasis was strong a century later in a seminal text for psychiatry, Carl Wernicke's *Grundriss der Psychiatrie*. Today, rationality is taken as a criterion for legal competence. The psychiatric profession and its legal confréres seem ignorant of advances in philosophy, unfolding for over 200 years.

Another attack on the criterion of rationality to determine legal capacity comes from psychiatry itself: Many experts in psychopathology (including Carl Wernicke) have argued that delusional beliefs are formed in a quasi-rational way to interpret other experiences, which themselves are primary abnormalities; and, for some service users, beliefs about treatment, and how to do research, may be built into delusional systems in quasi-rational manner. If their belief system *is* taken as a form of rationality, does that mean that we should accept their decisions as authentic?

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[44] Grisso,T, Appelbaum,PS Hill-Fotouhi,C. (1997) The MacCAT-T: a clinical tool to assess patient's capacities to make treatment decisions. *Psychiatric Services,* 48, 1415-1419.

[45] Foucault M. (1961) Folie de déraison: Histoire de la folie à l'âge classique. Paris: Union Générale d'Éditions.

To give an example of how a 'rationality' criterion might play out in practice, consider the following quotation[46], referring to comments by Elyn R. Saks[47].

> 'Professor Saks identifies four categories: pure understanding, modified understanding, understanding and belief, and full reasoning. Under the "pure understanding" test, a patient must be able to assimilate the information that the caregiver provides. A "modified understanding" test, by contrast, requires that a patient not only comprehends the information, but also believes that the doctor believes it. With regard to the "understanding and belief" category, Saks also differentiates between what she refers to as a "naïve" test (a patient must comprehend the information and believe the information) and a "sophisticated" test (a patient must comprehend the information and form no 'patently false beliefs'). As Saks admits, a test based on sophisticated understanding and belief suffers from the need to establish what beliefs are "patently false." She attempts to define "patently false" as encompassing beliefs supported by no evidence. Saks defines "full reasoning" as requiring a greater capacity to assess evidence than the "understanding and belief" test, and focuses on the integrity of the "reasoning process." Integrity is not defined. Saks merely notes that "the full reasoning" view requires fairly intact reasoning ability. Although Saks' categorizations are closely linked to language found in cases and statutes, they do not adequately distinguish between different capacities. For example, her "sophisticated understanding and belief" test is a compound standard that encompasses various abilities, none of which is adequately identified. As a result, it is difficult to translate her legal competence requirements into cognitive abilities that health professionals can evaluate.'
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> 'The British Law Commission likewise only broadly defines different capacities. In a 1995 report it defined an incapacitated person as one who is :(1) unable by reason of a mental disability to make a decision on the matter in question or (2) unable to communicate a decision on that matter because he or she is unconscious or for any other reason. The British Law Commission (1995) defines the first requirement as encompassing both the ability to understand information relevant to the decision and the ability to use the information in making a decision. The latter concept - ability to use the information - seems to include the ability to process information logically, as well as to acknowledge its relevance to one's own circumstances. Further explanation of the understanding requirement shows that it, too, is intended to cover both factual understanding of information and the patient's appreciation of its relevance to one's own situation. Thus a number of different abilities are integrated into two articulated standards. The result is confusing: How does one evaluate an individual who understands all relevant information and is able to process it in a rational manner, but refuses treatment for schizophrenia because he does not believe he is mentally ill, and believes instead that "his brain has been blackened"? Clearly this person fails to appreciate the nature of his illness and the likely consequences of refusing treatment although he may factually understand the situation and employ logical reasoning to arrive at his decision.'[48]

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[46] extended footnote, no 17, in: Berg,J, Appelbaum,P, Grisso,T (1996) Constructing competence: formulating standards of legal competence to make medical decisions. *Rutgers Law Rev* 48, 345-396.
[47] Saks,ER (1991) Competency to Refuse Treatment. *North Carolina Law Review,* 69, 945-999.
[48] British Law Commission Report No. 231, *Mental Incapacity* 32-41 (1995)

[d] *Personal identity and integrity:* In the 2006 UN Convention, (Article 3, *General principles* [h]) we read: 'Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserving identity'; and Article 17 (*Protecting the integrity of the person*) states: 'Every person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others.' The Unesco document of 2013[49] is entitled 'UNESCO (2013) 'The Principle Of Respect For Human Vulnerability And *Personal Integrity'* (emphasis added). All of these refer to respect for an individual's sense of personal identiy - of 'personal wholeness'. Each of us builds this sense in different ways, by assimilating a number of diverse elements. These include awareness of our own bodily integrity (which changes slowly over the years), knowledge of the outside world, personal memories, including memories of our thought content and beliefs, and sometimes of our thought processes, and awareness of the emotional instincts which determine our personal values. These forms of awareness are usually based on association, less often on deduction. Integrating emotional awareness with rational thought is perhaps the most difficult task in building personal wholeness.

Some would claim that the concept of personal wholeness is closely linked to that of autonomy, freedom of choice, and with these, rationality. One criterion for rationality was consistency of beliefs over time, and another, the consistency of premises used to explain a decision with conclusions reached, and with inferential steps along the way[50]. A pioneer thinker in psychiatry, Carl Wernicke, also held in the 1890s that complete logical consistency of a person's thoughts was the hallmark of mental health; departures from this were signs of mental illness. Much as Wernicke is to be admired in other ways, this view is unrealistic. Our quest for 'personal wholeness', our sense of 'autonomy', and our 'rationality' can never be complete, and in any case is a subjective perspective, not an objective fact. We build our sense of identity in part, some would say *solely,* through social interactions[51]. Neither autonomy, nor personal identity is that of an independent being, even in the basic langauge we use. This can hardly be doubted (in so far as, usually, our parents are the biggest influence on our sense of identity). If identity is defined in a social context, so too must be autonomy.

Serious mental disorder can certainly undermine our sense of personal wholeness. Psychiatry is the branch of health care which, more than any other, deals with challenges to that sense, whether it is compromised due to factors intrinsic to an individual*,* or as a result of psychic trauma. At its best, this discipline should try in holistic fashion, to help people rebuild that sense. In terms of Article 17 of the 2006 UN Convention, one can argue that the 'mental integrity' to which it refers is often not met for persons with serious mental disorder. This can hardly mean that their issues should not be researched. Indeed serious issues for research include both clarifying profound scientific questions on how that sense is produced, and how it comes to be compromised; and, in more practical terms, to address complex matters on ways in which it can be restored, or how the effects of its being compromised can be mitigated. This might therefore mean that protocols to ensure ethical probity need to be radically revised to enable this type of research.

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[49] UNESCO (2013) *The Principle Of Respect For Human Vulnerability And Personal Integrity.*

[50] Grisso,T, Appelbaum,PS Hill-Fotouhi,C. (1997) The MacCAT-T: a clinical tool to assess patient's capacities to make treatment decisions. *Psychiatric Services,* 48, 1415-1419.

[51] Christman,J. (2015) Autonomy in moral and philosophy. *Stanford Encyclopedia of Philosophy*. *http://plato.stanford.edu/entries/autonomy-moral/*

The clause from Article 3 might be taken to imply that personal identity is fully established in childhood, and is static thereafter, with little more to be said. However, personal identity in ethics is much larger than this, relevant as much to adult as to child psychiatry. In the present context, if one follows the logic prevailing about 'informed consent', the authenticity of *any* decision is a reflection of that person's overall sense of wholeness. Rating scales do exist for assessing the solidity of a person's 'sense of self'. There appears to have been no attempt to follow through the logic, with such instruments, to assess a person's capacity for informed consent, in medical intervention, or in research. Conceptually and practically this may be something of a minefield; but, logically at least, this is a shortcoming in discussions about informed consent.

(v) Cultural Comparisons.

Whatever the merits of autonomy as a founding principle in bioethics, it certainly grows from western traditions, rooted in a particular view of human nature. Even across western societies the importance of the principle varies: It is strongest in the USA, while other western countries, with more social health-care systems, balance it to a greater or lesser extent with the other principles. In non-western societies, such as China or Pacific Island communities, including the New Zealand Maori, health-care decisions are taken more collectively, shared not just between doctor and patient, but between doctor, patient and his/her extended family (or other groups). How does this issue plays out in a very large society whose roots lie in collective traditions, namely the contemporary People's Republic of China? This is reviewed by Ng Wai I[52], for informed consent to treatment. It is relevant not only because of similarity to Polynesian ways of thinking, but also because of the large and growing number of East Asian immigrants now living in in Aotearoa.

In China, 'moral intuition as well as moral attitudes towards medical ethical issues and resolution of ethical dilemmas (at lay, professional and societal evels) are affected by the long-standing entrenched traditional values.' Traditionally, as in the West in former times, beneficence is a more important principle than autonomy. As with New Zealand Maori, personal identity is more collective and less individual (that is, it is based in the family, or wider social group). 'Informed consent' is thus a collective act. In principle 'the central theme of Confucius' ethics, "humaneness" (ren), which in Chinese character means "two persons", reflects the idea of relational personhood or interpersonal transactions in human society'. However the notion of 'informed consent' to treatment has growing currency, and the trend is likely to continue as private medicine, based on health insurance expands in China. However, because of old traditions of accepting authority, filial piety, and - for physicians – paternalism, "informed consent" in practice becomes a "formalised act", an act which weighs the consequences (consent) more than the process (informing). It is ultimately lacking a central idea of idividual understanding and autonomous choice.' Many of the ways in which the essentially relational principle becomes a fomalised act in practice, thereby losing touch with the basic principle, would be familiar in a western context. In so far as the principle of autonomy *is* recognised in East Asia, this is recent, and less well-formulated. As Chinese medicine becomes more westernised, it will be interesting to see if (and how) the autonomy principle so deeply embedded in western bioethics, can be integrated into collectivist approaches to ethics.

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[52] Ng Wai I (2005) Clinical practice of informed consent in the Chinese context: From retrospection to perspectives. *Macau Journal of Nursing*. 4 (1), 33-37.

This of course applies to the whole concept of 'rule of law' in China. It will also be interesting to see if (and how) informed consent comes to apply to research involving human participants, where autonomy is inevitably more important.

These transcultural insights should have their impact on the style of ensuring consent - or trust - in a research context. Indeed, it could be argued, that, if New Zealand is truly to embrace the spirit of the Treaty of Waitangi, a more holistic approach to legal procedure, such as already exists in some areas, might be explored in a more comprehensive way. This of course, is outside the agenda here, but is to some extent implicit in what follows.

(vi) General comments: Have our ethicists gone mad?

A few general comments are in order here. The complexity of the debate, and the fast footwork by legal minds, is, in the author's view, pervaded by a degree of absurdity, as if protagonists were debating 'how many angels could be put into the fine print of a legal footnote'. The distinctions made by Saks, in the passage quoted above are about fickle nuances of words to support *defensible* decisions, not about concepts that real scientist might struggle to validate. Obtaining informed consent seems beset by a façade of probity and rationality, making research *appear* ethically defensible, the underlying power imbalance, and all that follows, even in bland concepts such as 'beneficence', being little changed. The idea of getting a rigorous legal definition of competence in someone in developing stages of dementia is absurd, when the best that can be achieved is either in a highly relational way, in interaction with nearest and dearest, and with professionals who know a patient well, or in a paternalistic way by a supervising physician. Detailed protocols for assessing competence to consent to treatment are given in the MacCAT-T[53] by Grisso et al. The paper includes the authors' suggestion that it 'offers a flexible yet structured method with which caregivers can assess, rate, and report patients' abilities relevant for evaluating competence to consent to treatment'. Probably, 'caregiver' means 'concerned parents of offspring with disorders such as schizophrenia'.

At this point, I am moved to ask 'Have our ethicists gone mad?' In a different context, it has been suggested in the charged arena of today's gender politics, that signed consent should be obtained even before embarking on a sexual relationship (seriously!! see: Gaby Hinsliff, Guardian, 30.01.2015), yet the principle is the same: Legal nicety versus the reality of relationships. Get real! A detailed rationale for posing such questions has already been given, when it was hinted that Engelhard's concept of autonomy substituted genuine personal 'sense' of autonomy' as a subjective fact, for a supposed publicly-recognised autonomy principle, as an objective fact. To claim that an inner sense of reality is objective reality seems akin to a psychotic delusion. Other instances where this question is relevant soon follow.

As in many legal settings, the debate is over words (problematic ones here, such as 'autonomy', 'understanding', 'rationality'). The paper just cited about informed consent in China puts it well: '. . .a signature on a consent form in the clinical conext . .makes informed consent a word and paper game'. Individual words have no standard meanings accepted by everyone in the absense of a context, except when forced to do so by administrative or legal fiat ('force' being the operative principle). The process appears to be a 'pretend rationality'; but when close attention is paid to concepts for which such words are used, we find that they are not defined with sufficient precision to permit rational argument. The façade no doubt makes research consent defensible in the eyes of

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[53] Grisso,T, Appelbaum,PS Hill-Fotouhi,C. (1997) The MacCAT-T: a clinical tool to assess patient's capacities to make treatment decisions. *Psychiatric Services,* 48, 1415-1419.

legal experts; but there is scant grounding in empirical realities. The central realities to be considered *are* of personal interaction at the 'coal face', whose essence is about the subtelty of building and sustaining trust. Legal niceties are little help, and may be a hindrance. Not only are criteria legalistic, but emphases differ and are incommensurable between jurisdictions. Perhaps the *real* objective is to be 'legally sound' in a particular jurisdiction, to protect a treating physician or researcher against a lawsuit, rather than to ensure the best possible care for a patient, or that sustained trust is built to ensure that research goes ahead in the most fruitful manner.

The single concept which pervades most of the objections just raised is 'holism'. What does it mean? It applies at many levels, and in many scenarios: to *perception* (with the slogan of Gestalt psychology: 'the whole is greater than the sum of its parts'); to *meaning* (a Gestalt at a level higher than perception) including the *real* meaning of words, defined in part by their context; to *understanding*, which, like meaning is itself essentially holistic, and intrinsic to our shifting understandings of mental disorder, now gaining ground; to *rationality*, in so far as it depends on well-validated concepts, not just words; to *personal autonomy*; to *personal wholeness*, in so far as it brings together all our experience, and integrates all our faculties, especially reason and emotion. Last but not least, there is *social holism.* Donne's famous lines: 'No man is but an island'; and 'any man's death diminishes me, because I am involved in mankind' were echoed by Lynne Bowyer: 'We cannot exist in a human way in isolation'. These lines capture social aspects of holism, implying that each of us owes our being as persons to a network of social interactions. Nursing care, at its best is relational and holistic, not legalistic. A good physician who has 'seen it all' and wants to practice medicine rather than law, may, practice with an element of paternalism in the best sense of that word. Relational practice is indefinable and subjective; and such paternalism overrides autonomy. To practice in this way is a complex and subtle balancing act, like the best human relationships. It cannot and should not be subjugated by 'standard operating procedures'.

(vii) The Essence of the Debate: Rival Concepts of Human Nature

In the discussion at Christchurch, Lynne Bowyer commented that 'the ways in which we are involved in the world as human beings' . . is 'distorted by the current dominant way of thinking'. The entire western legal tradition assumes that rationality is not just an ideal, but the norm for human beings, a view which she clearly challenged. On hearing this, I responded: 'should we then be trying to redesign that whole legal tradition on a different basis?' I remember Lynne saying: 'You have to start somewhere.' This may be the core issue, spinning off from UN/UNESCO documents, part of an on-going international debate. This *could* force profound re-evaluation of western views of human nature, and legal systems derived from them, which often dominate debate over medical ethics. New Zealand may be the place where this could start, given the long experience here of trying to blend very different cultural traditions and world views.

This is not the place to expound rival views of human nature *in extenso.* Briefly, the western view has dominated legal systems since classical Rome, underpinned by matching theology. It is based on philosophical dualism, with roots going back as far as Pythagoras 2500 years ago, which split mind from body/brain, reason from emotion, and God from Nature. The added idea that mental disorders be defined as 'illnesses', because they are a breakdown of a supposed natural facility of rationality, grew later, prior to the French revolution, but its origins already existed in ancient themes of western culture.

Generally, this view of human nature has scarcely touched or been touched by the world view emerging after the scientific revolution of the seventeenth century, and which

has seldom been applied to the subtleties of mental processes and personal identity. When it *does* make contact, notably in our attitude to *abnormal* mental processes (a.k.a: 'mental illness'), the discrepancy is striking; and the harder we push together the two sides of the debate, the sharper becomes the conflict. The view that mental illness represents a failure of rationality fits nowhere into the advances achieved by the natural sciences, and *its* underlying world view. To some extent that world view has come to include the scientific basis of biology and medicine (but hardly its *ethical* basis, or views of personhood employed in psychiatry) The heart of the conflict lies in the fraught issue of determinism. The uncomfortable status of mental disorder then arises as a bi-product of the conjunction of two incompatible world views, and consequent incompatible models of human nature.

How can one define a 'responsible', 'rational' or 'autonomy' in a person? Can such concepts be squared with mechanistic accounts of personhood? Is such a mechanistic account a realistic view of human nature? A century after Isaac Newton's monumental *Principia*, Simon Pierre de Laplace, advocated in the anticlerical world prevailing after the French revolution, a perspective where every natural process was strictly determined by supposed causal laws, and for which he coined the word *determinisme*:

> 'We may regard the present state of the universe as the effect of its past and the cause of its future. An intellect which at a certain moment would know all forces that set nature in motion, and all positions of all items of which nature is composed, if this intellect were also vast enough to submit these data to analysis, it would embrace in a single formula the movements of the greatest bodies of the universe and those of the tiniest atom; for such an intellect nothing would be uncertain and the future just like the past would be present before its eyes.'

Today we cannot support Laplace's strident assertion: It is impossible in practice to ascertain all the data needed with the infinite precision needed; and there are fundamental flaws, arising from quantum physics, logical flaws arising with development of chaos theory, and the theorems of Kurt Gödel and Alan Turing. From the latter, it is now widely held that strict determinism (the 'billiard ball' analogy) cannot prevail: the calculus needed to determine the future from the past is insoluble even in principle: 'The future's not ours to see', a conclusion applying as much to mechanisms of our brain, to social interactions (including economic ones), as it does to other parts of the physical world.

The alternative? Certainly not that humans have 'metaphysical freedom' over their actions, as if a person's immaterial 'spirit' can override principles of physics built into our brains. Engelhardt, might try to argue that *most* humans adults *are* autonomous so long as they are rational, and those that are not rational have an entirely different nature, hostage to causal laws, as no doubt he would assume about our close primate relatives. But let us survey this from a perspective of neuroscience, focusing on outward behaviour rather than thought, since it is usually this, which, in the end, is evaluated in law.

(viii) Neuroscience basis of 'autonomy', 'rationality' and 'personhood'.

[a] *'Autonomy':* What could 'decision making', 'freedom of action' or 'autonomy' mean to a neuroscientist. Here we deal with the theory of the part of the brain called 'the basal ganglia'[54]. Brain biology sees a major mechanistic function of the brain being to sort out patterns of input to the brain (images, events, other experiences), and to allot to

[54] Miller,R. (2007) *A theory of the basal ganglia and their disorders*. Roca Baton, Fl, CRC Press.

each its 'motivational significance', as signposts to possible patterns of behaviour. Those patterns of behaviour are gradually learned, as fulfilling important goals; and when learned in relation to one goal, they can be used to fulfill others. 'Human freedom' then becomes the potential for *any* input pattern to trigger *any* output pattern of behaviour. The number of potential 'connections' is unthinkably large, but is not actually infinite - an impossible situation which might equate to the ideal of 'metaphysical freedom'. For any combination of input and output an active input could, in principle, either *trigger* corresponding output behaviour, or, alternatively could *inhibit* (or *'veto'*) it. Brain theory underlying this statement envisages that processes for triggering and vetoing behaviour are not just opposites, but are separate subsystems in the brain, under independent control. It is even possible for the two to be active at the same time, although this might be seen as a symptom of a neurological disorder. Which input/output connection is chosen, and whether it is to be triggered or vetoed, depends on past experiences, based on principles of psychological reinforcement, and on combinations which in the past actually had valuable or adverse outcomes. Just occasionally our choices are based deductively on predictions applied in advance to new situations.

According to this view, 'loss of autonomous action' means that the normal huge (but finite) range of strategies (both active ones, and those that 'veto' active strategies), becomes limited, or the relation between input and output becomes distorted. Behaviour cannot then be tuned to external circumstances as accurately as in normal mental states. Such a deficit is nothing to do with rationality, nor with the quasi-metaphysical notion of 'autonomy'. Sometimes people whose 'freedom of action' is so reduced speak with great insight about their problems, either in retrospect, or ocasionally in the midst of current problems. Rather, the deficit is in physical processes in their brain, which, to some extent, we can understand scientifically, but which are no different in principle from the limits on my freedom of action imposed by the law of gravity.

There are other brain processes to consider in this discussion. In addition to processes for decision-making, there are associative ones at various stages, by which we recognise patterns in information streaming into our brains. The human forebrain – notably the cerebral cortex, that most remarkable creation of evolution - is 'designed' to carry out many information processing tasks, some more easily than others if they match its instrinsic capability. The task that comes most easily to the cerebral cortex – built into its whole structure and function – is the process of association, that is detection and registering correlations – or, as a philospher would call it, inductive inference. This most natural faculty is shared with the cerebral cortex of all mammals. In contrast, deductive inference – 'reasoning', or 'rationality' to a legal mind – is *not* a natural means of information processing, as discussed below.

The associative processes for which our brains are designed are intrinsically error-prone: Any associative machine must rely on some 'critical point' or threshold, akin to the 'p-value' for significance in a statistical inference: If the significance or 'vividness' of a correlation exceeds threshold, a conclusion is accepted as valid and could determine action; if it is below threshold, it is rejected as no more than a 'chance effect'. Conditions in the brain may change, so that the threshold shifts. Shifts in one direction mean that fewer conclusions reach the level at which they become credible, but they will all be very secure. In other words we become 'sceptical'. Shifts in the other direction mean that far more conclusions are accepted as credible, a few perhaps correct, 'ahead of their time',

most others spurious, no better than chance: We become 'gullible'[55]. Then beliefs come to control behaviour, which are clearly false readings of the outside world. A simple example is that under normal circumstance a person may think 'My boss is a bastard'; but if the threshold is shifted, he may reach a less likely conclusion 'He is working for the CIA'. For present purposes, because of how the brain's associative processes operate (intrinsic to *any* associative machine), we are *all* prone to false readings of reality, some of us more so than others. The extent of our error-proneness may vary from time to time. Disciplined deductive checking can however help eliminate errors.

[b] *Rationality.* So, we come to ask: What, in terms of brain processes, *is* rationality? I referred above to Immanuel Kant's deep insight about reasoning, that any supposedly rational statement is based on a set of background assumptions, which need never be articulated. Kant's two statements are: 'A straight line between two points is the shortest', and '7+5=12'. Neither statement is valid without underlying assumptions (respectively, about concepts of Euclidian space, and number). We can call those unstated assumptions, the 'context' in which certain sorts of reasoning can occur. Kant regarded such assumptions as innate, *a priori* concepts from which one must start. However, a body of ideas suggests the opposite, that, even for basic notions such as 'space', we actively construct - or discover – concepts (or 'contexts') which work best. From this view, in 1991, I built a theory of interaction between a region of the brain called the hippocampus and the cerebral cortex to explain this principle in terms of brain science[56]. The cerebral cortex by itself, as an 'organ of association' is ambiguous in its operation. Activity spreads too freely. Briefly the theory is a way by which the two structures in interaction establish 'modes of operation', in which particular styles of information processing are made possible. This resolves the ambiguity inherent in the cortex which is otherwise inevitable (as, in principle, are *any* associative process). Those 'modes of operation' – 'context' is an alternative term - might be used for many purposes, and as much in other mammalian species as in humans – for instance in navigating through our environment (where the background assumptions are those which define 'space'). Even in humans, they are used mainly for purposes other than deductive reasoning. However, deductive inference in humans ('rationality' to a legal mind), becomes easier, once we have the facility for language, not shared with other mammals. Language itself is not used just to serve rationality: It has wider functions, and most people use language mainly for these other purposes. However, for present purposes, the points are these: Rationality (of which there are many types, according to the context for operations) is not a quasi-metaphysical faculty of heavenly orgin (as Pythagoras believed): It too is the product of our brain, but is *by no means* a natural or universal endowment for humans. For those whose minds *do* operate deductively, it is acquired by example from others, by direct tuition, and by practice; and to do it well, as a natural habit of thought, requires long experience.

[c] *Personhood.* Apart from rationality, a deeper concept which has already been mentioned underlies all debate on autonomy, rationality and informed consent (though not explicitly). This is the concept of *personhood*. Again we see a clash of notions inherited from the classical world, and ones which – though seldom well formulated – arise in the wake of the scientific revolution. The classical view is that each of us has an

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[55] I thank the late Samuel Fischer, for these two concise, evocative terms to capture the essence of my argument.

[56] Miller,R. (1991) *Cortico-hippocampal intrplay and the representation of Contexts in the Brain.* Studies in Brain Function series,. Heidelberg, Springer Verlag.

indivisible 'spirit', sometimes called our 'soul', when it may be held to be eternal. This is perhaps the most explicit impact of philosophical dualism, emerging in pre-Christian times, and pervading Christian traditions to this day. However, from many sources of evidence, we can easily conclude that none of us is, or can be, such wholly-integrated, atom-like unities, although for many of us, it is a life-long quest to approach this as closely as possible. There is abundant testimony to our incompleteness: We fail to notice things which are incompatible with the central core of our beliefs; we make far-fetched interpretations of experiences, to resolve such incompatibilities; we may catch ourselves carrying out behaviours in different contexts whose purposes flatly contradict each other; and we may have lapses of memory not due to forgetfulness, but because we habitually ignore what is incompatible with our central focus. These facts have been known to sages from time immemorial, and understood in psychiatry for more than a century.

What then could neuroscience say on human personhood? Few neurosicentists have ventured here: It is conceptually too difficult. One who did – now a figure in medical history – was Carl Wernicke (1848-1905). He was not only pioneer in neurology, but later in his career, in both the theory and practice of psychiatry. His writings on psychiatry[57] are based on understanding of fundamental issues in neuroscience, some of which were 50 years ahead of his time. His understanding of human personhood in a thorougly holistic sense, is, in my view, ahead of most neuroscientists and psychiatrists *today*. His views grew out of his understanding of memory as laid down by modification of connections between nerve cells (the physical basis of associative processes referred to above); and that any meaningful mental image we experience represents coordinated activity in many nerve cells, which have become connected in this way, and which are distributed across wide areas of the cerebral cortex ('organ of association', in Wernicke's terms). With this background, he sees the 'contents of consciousness' as having three main components, consciousness of our own bodies, consciousness of the ouside world, and consciousness or our own personal life story. By integrating these three, each of us in our own way constucts our concept of ourselves as a somewhat-integrated person. Here are some critical quotations:

About consciousness of our own bodies: 'A prerequisite for "consciousness of personhood", which we should now consider in detail, is the possibility of development of an "Ego". The main condition for this is the possible existence of an unchanging sense of corporeality, in contrast to the ever-changing environment.'

On consciousness of the outside world, he includes the ever-changing daily events, which also have intrinsic regularities; but sigificantly he writes: 'The first distinguishing hallmark of each human, is undoubtedly the social environment in which he grows up. Living examples have always been the most effective means of education, the more so when they combine with the obvious implicit authority of parents towards their child. Family life of parents is indubitably imprinted as the ultimate stamp on the child, his intellectual personality, and his future character. Consciousness of personhood thus includes all those properties arising as instinctive regularities in the social environment in which each individual grew up and lived.'

To these two is added the third component, consciousness of personal life story: 'To personalized consciousness belongs the sum of experiences peculiar to each individual. The individual we see before us always represents this sum total - be it knowledge, or

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[57] Wernicke,C. (1906/2015) *Grundriss der Psychiatrie in klinische Vorlesung* (Outline of Psychiatry in Clincial Lectures). Translated by KJDennison, edited by R Miller. Heidelberg, Springer Verlag

experiences - a sum having a definite value only at a specific point in time, but which undergoes new growth every hour and every day. The current state of the brain is always this final summation of all previous states.'

The defining faculty for human personhood is continuity of memory, that is, that a single psychological entity can access all memories, with no barrier to their being linked one with another across time. We acquire our sense of personhood at an early age, after which we start to have continuity of memory. However, our sense of personhood can be given deeper roots in brain mechanisms than Wernicke could have realised, which link back to previous paragraphs about 'contexts for mental operations'. Such contexts are used not only for spatial navigation, and in some humans, for rational thought, but, most fundamentally, to *retrieve memory*. Retrieval is easier - and sometimes is *impossible* without - the context of cerebral activity at the time of learning being reinstated when retrieval is needed. One might suggest that the most fundamental, and earliest-acquired context for cerebral operations, is that which permts continuity of memory. This context is equivalent to the otherwise problematic concept of personhood, which defines each of us thenceforth as 'somewhat-integrated' *persons*.

On this, Wernicke wrote in 1894s: 'A prerequisite for "consciousness of personhood" . . .is the possibility of development of an "Ego". . . As soon as a child begins to operate with the word "I", constraints are felt from these facts.' Wernicke then adds a key statement about mental illness: 'After a person has recovered from a mental illness, it is required that we ensure that he has achieved insight into the abnormality of the state he has experienced; for the sum must necessarily be inaccurate if it contains false elements.' This profoundly holistic maxim is presented within a thoroughly mechanistic (though not deterministic) view of a brain which embodies human personhood. Many of Wernicke's concepts of mental illness following in later lectures are then not categorical departures from normal – as though we have 'lost' our sense of personhood, or that there is a shortcoming in the normal complete integration of personhood or absolute rationality. Rather, his concept of mental illness is mainly a reduction in the ***always***-*incomplete* integration of our memories and faculties, to which we are all prey. Thus, there would be little place in his system for the strict concept of 'autonomy' of a human person. He included himself in his self-denying perpsective.

The most dramatic departure from the ideal of 'unified personhood' is what was called 'multiple personality' in Wernicke's day (or for him, the 'second state'; today renamed 'dissociative identity disorder'). These diagnoses have always been controversial, perhaps because they represent a philosophical challenge to western dualism, rather than for a scientific reason. Scientifically, there can be various factors, leading to such states of personhood: Some are intrinsic to an individual's make up, others arise as stark incompatibility in the social environment in which a child grows up (e.g. abuse at early age, by a primary caregiver). These might mean that brain process which normally build a somewhat-integrated sense of self, lead instead to construction of 'alternative senses of self', suitable for different scenarios. In this way, controversy is unnecessary.

In the context of debates on informed consent, one can then ask how one would obtain informed consent to research such disorders? This is not just an outlandish example in 'situation ethics' devised to provoke debate, however far such examples are from reality. Since the diagnoses in question *are* highly controversial, research on them *is* needed. Moreover, although strict criteria for Dissociative Identity Disorder are rarely met, in lesser degree, the phenomenon of dissociation is common, perhaps universal. It may occur as a result of altered states of consciousness due to alcohol or drugs, epilepsy, or

heightened levels of emotion (extremes of anger, sexual arousal); and, quite apart from such situations, any of us can recognise that, in lesser degree, we have many personas, many faces we present to the world, which may make it hard for us to retrieve memories acquired in one setting when we are negotiating a different one.

[d] *Universal Normal Delusions.* Subjectively, then, our sense of being autonomous, rational, and thoroughly unified psychic entities, are all *deceptions*, members of a class of 'normal delusions', around which we construct our self-image, no doubt to fulfill other important motives. In Western cultures, one motive, around which we build subsidiary beliefs, is to support the fiction that we are fundamentally rational; and, to follow the argument, a basic principle of western legal systems, its model of human nature, is part of the same socially-constructed delusional system. Perhaps the reader will now grasp why I asked in an earlier section if our ethicists had gone mad. (It is however necessary to point out, that Wernicke, while far ahead of his time, and of our own time, in understanding personhood, also held that rationality *was* the norm for mankind, a view inherited from physician-philosophers in France.[58] However, a little deeper introspection, and the examples given above, should remind us all that there are aspects of thought and behaviour of us all, over which we have little control: Our thoughts often appear to 'have a mind of their own', moving along lines quite unforeseen in advance if based on a model of ourselves as fundamentally 'rational'.

B. Generic Policy Issues

(i) Surrogate Decisions About Consent.

The Nuremberg rulings made no provision for consent to research on persons with limited capacity being given 'by proxy' of a legal guardian (so-called 'surrogate' decision), and probably did not foresee the issue. The Helsinki Declaration *did* make such a provision. The 2005 UNESCO declaration on bioethics had a different slant, that research involving such persons should be done only when it was for their direct benefit, a more restrictive ruling for researchers than if 'surrogate' or 'substitute' consent is adopted. These are alternatives ways to negotiate a tricky legal framework. Surrogate consent is widely accepted for treatment decisions, but, in the USA at least, the legal position on surrogate consent for research is less clear.

A recent dissertation from New Zealand (Ruth Jeffery, Bachelor of Law Otago dissertation, 2008) entitled: I*ncapacity and Consent to Medical treatment: Inconsistencies and Uncertainties in the Application of the Objectives of the Protection of Personal and Property Rights Act 1988*, discusses uncertainties and inconsistencies in the relevant Act, in relation to surrogate consent to treatment. Most are likely to apply to decisions on consent to research participation. The one most likely to apply to surrogate consent for research participation is about decision-making by a legal guardian: Should it be based on 'what a person would decide if not impaired', always a hypothetical judgment. Alternatively, the decision might consist of a guardian making up her/his own mind on perceived balance of the merits and dangers to the person whose interests they represent. Such a decision may easily incorporate motives beyond the interests of the person to be involved in research; and there is the obvious flaw that the patient has not actually participated in the decision. In addition, a quite holistic objective of the New Zealand Act is to enable and encourage a patient to exercise and develop such capacity as

[58] He died prematurely, his work incomplete; it is unsurprising that there are inconsistencies in his ideas.

they have, to the greatest extent possible. Although this is a side issue for the research itself, it is relevant for *consent* to research participation. A potential research participant may be hindered from exercising this capacity, for instance, if the decision of a partly-competent person is overridden by a legal guardian (as if capacity were all-or-none, as is legal competence). Moreover, Welfare Guardians can be appointed only when a person *wholly* lacks capacity to decide aspects of their personal care; but this is often taken as 'inability to make meaningful and important decisions', a lower level of incapacity. This might lead a legal guardian to exert too much influence. For fluctuating capacity, the Act has no way for a patient to give a valid decision until his or her full capacity is regained; and no-one can be given power of attorney to act at short notice according to the current mental state of the patient. Such inconsistencies and uncertainties derive from confusion of underlying concepts, especially autonomy, and the distinction between capacity and competence in law. Given this confusion, it is no surprise that implementation of related laws - what the law delivers in practice – is unpredictable; and this undermines one of the main reasons for having laws (see Sect X. below).

In this context, the quotation from University of California at Santa Cruz documents, already given, includes the following: 'For research protocols involving subjects who have fluctuating or limited decision-making capacity, the IRB should ensure that investigators establish and maintain ongoing communication with involved caregivers. Periodic re-consent should be considered in some cases.' This suggests that, whatever the letter of the law, it is unworkable in practice unless implemented flexibly in person-to-person encounters. In other words, in this situation, inevitably there is a move towards more holistic concepts.

(ii) Research Priorities, and Justice Between Groups

Justice between groups over research priorities has already been mentioned. At the discussion in Christchurch, we heard a number of comments related to this. One expressed frustration about being patronised 'You can phone hip replacement clients 5 years after an operation to invite them into a research study, using hospital records and patient details, but you can't with psychosis patients, because it is in breach of ethics committees rules. Researchers themselves cannot get this changed. But community groups respesenting service users might be able to achieve what the researchers cannot.' Sue Purdie (one of the invitees) noted that large populations of service users are often excluded from research; that the types of research - e.g. quantitative - may not reflect a service user's experience and their voice in sufficient detail; that research needs to be driven by service users; and that service users should participate in the research from its conceptual stage. (There followed a list of topics she recommended for research, all very practical ones for service users.)

Helen Bichan spoke strongly on this, based on her clinical experience: 'Many stages of life and a variety of conditions affect thinking, motivation, mood, accessibility and understanding, and so affect the degree to which a person needs assistance to participate in society. This may include the opportunity to take part in research. She asked: *'Why* should people with diminished capacity *be excluded* from research which may have the potential to help them or others in their situation? In my view, it is important to make it possible for such people to be included in relevant research.'

These comments emphasise the importance of taking note of research priorities, as seen by consumer groups. By so doing, one drawback of usual consent procedures may be mitigated: It gives a less biased, more representative group of all patients. This is one advantage of styles that engender trust. Admittedly those who don't want to be part of a

study probably have little contribution to make anyway, but this can be seen as failure to win the trust. If trust *has* been built, participants will be willing to cooperate fully, actively, and to give their feedback.

Other difficulties arise when views are developed collectively by persons identified by orthodox diagnoses, and who come together as social networks. Strong group identities - indeed group pride – can develop, which lead groups to set themelves apart from others. For instance, the term used by some groups with autism disorders refer to the rest of humanity – somewhat scornfully - as 'neuro-typicals'. Apart from the scorn, they have a point: Everybody grows accustomed to being who they are; they learn, and know better than anyone else, how to use their own strengths to cope with their shortcomings. Most psychiatric diagnoses are an inseparable mix of the two. Why then should psychiatric experts tell a person what should be right for them, especially if it involves a major shift of life-style, even of self-perceived identity, built over many years? It is not clear how the ethical principle of justice applies in such a minefield, except that such attitudes have grown from long experience of receiving adverse comments. One hopes such comments came not from professionals, but from less well-informed persons.

A further statement under *justice*[59] requires 'participation: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori'. This raises other important topics: Pragmatically, one asks: Is it possible? Is this an ethical or a scientific requirement? . . and which has priority? Specifically, is it required to meet this condition *before* or *after* funding decisions by state agencies are made? Since the statement appears in Standard Operating Procedures of Health and Disability *Ethics* Committees, one presumes it is the former; but in substance it appears to be the latter. One also asks: With whom should consultation over study design be conducted? This is problematic, since (as recognized in the document), design of research studies, especially ones involving intervention with control groups, random allocation and blinding as essential components, inevitably involve some concealment. In addition, if end-user groups are to be involved in 'analysis', do they have the expertise, or objectivity to do so? Might there not be some conflict of interest?

(iii) Individual or Class Protections in Law?

This discussion raises another issue, already touched on (Sects III and IV), that disability protections can be seen to apply not so much for individual rights, but as provisions for specially disabled *groups*. This is related to protection of disabled persons in sitations of informed consent. But who *are* the minorities, whose interests are protected by international convention? In 1992, the United Nations presented its *Declaration on the Rights of Persons Belonging to National or Ethnic, Religious and Linguistic Minorities*[60] Article 1 refers to minorities as based on national or ethnic, cultural, religious and linguistic identity. Two years later, the International Covenant on the Rights of Indigenous Nations[61] (1994), states **(Para 8)** 'The right of a person to belong to an Indigenous Nation or community is a matter of individual choice and the free right of an Indigenous Nation or community to define its membership, and no disadvantage of any

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[59] HDEC (2014) *Standard Operating Procedures for Health and Disability Ethics Committees. August 2014;* Ministry of Health. Wellington.

[60] United Nations (1992) *Declaration on the Rights of Persons Belonging to National or Ethnic, Religious and Linguistic Minorities*

[61] United Nations (1994) *International Covenant on the Rights of Indigenous Nations.*

kind may arise from the exercise of such a choice.' In addition **(Para 7)** 'Each Indigenous Nation has the inherent collective and individual right to maintain and develop its distinct characteristics and identities, including the right to identify or define itself'. In New Zealand this applies to rights of a culturally-diverse populace, particularly those of the *tangata whenua.* For research, it applies to the policy of 'research consultation' with the *tāngata whenua.* This can be justified on several grounds. At present at least, it can be claimed that Māori constitute a vulnerable group, as a result of past injustices by the Crown. Consultation at a collective level with *any* group who might participate in, and benefit from research, might in any case be a wholesome principle. Article 5 of the 2006 United Nations *Convention On The Rights Of Persons With Disabilities* reads: 'States Parties recognize that all persons are equal before and under the law and are entitled without any discrimination to the equal protection and equal benefit of the law'; but we read later 'Specific measures which are necessary to accelerate or achieve *de facto* equality of persons with disabilities shall not be considered discrimination under the terms of the present Convention.' This clause appears to validate policies of positive discrimination ('affirmative action') for *groups* whose interests have been ignored, but implicitly, *only as a short-term measure*. However, the 2006 UN Convention is fundamentally about *individual* rights, and freedoms from *individual* discrimination. Granted, Article 29 reads that 'States Parties shall guarantee to persons with disabilities political rights and the opportunity to enjoy them on an equal basis with others, and shall undertake to. . . form[ing] and join[ing] organizations of persons with disabilities to represent persons with disabilities at international, national, regional and local levels'. However, this Convention, unlike the 1992 Declaration, does *not* oblige signatory nations to recognise the *collective* identity of any disability group (although it comes close to it, referring to women and children specifically, and to access to buildings, and methods to enhance communication, for some disability groups).

The result is that, in Aotearoa New Zealand, I could self-identify as Māori, which would be quite *inappropriate*, and might thus be accorded some advantages; yet I cannot self-identify as a member of any disability group, which *would* be appropriate, and for which I would appreciate some policy adjustments. Another consequence of international covenants is that disadvantaged minority groups (as defined) who identify themselves, have certain rights protected, and in New Zealand, have historic injustices redressed. The far larger body of people around the world, whose communities were torn apart so severely in past times, that they had to completely reinvent any cohesive social structure for themselves *ab initio* have no such protection, nor any hope of historical redress. These include the millions forced off the land in England by the Enclosures Acts, to work in factories and coal mines of developing industrial cities, to say nothing of the vast movements of populations in continental Europe during world wars. In New Zealand, one might argue that the Treaty of Waitangi gave legal foundation for redress, which did not exist in the English case, or for the highland clearances (which were quite legal at the time); but the argument is contested, and Germany (collectively, although it was by then a quite different political entity) *did* make vast reparations for war crimes. There appears to be an unresolved legal issue here, about definition of group culpability and entitlement. In the US legal system this translates to debate on the reach of the principle of 'class

action'. This principle has been widely used in employment disputes, but has become weaker in recent years, and this has severely disadvantaged disability groups[62].

These comments do not seek to dismiss the crucial place of the *tangata whenua* within New Zealand (see below, where I seek support from Māori, for their philosophical style, and its advantages over the Pakeha/western style); but they point out clashes in principles embodied in various documents, produced at various levels, and applying in other settings. To be specific, the document from HDEC (Standard Operating Procedures) states a principle under subheading *Justice,* that *'there should be due recognition of Māori as the tāngata whenua and indigenous people of Aotearoa New Zealand'*. This seems to imply that the status of the *tangata whenua* be guaranteed in perpetuity, not just as affirmative action 'to accelerate or achieve *de facto* equality' (as the UN Declaration has it, in relation to disability groups). Is this a correct reading?

(iv) Stringency of the Consent Process in Different Situations. In the background papers to the Belmont Report, Jay Katz makes an important point[63]: 'Distinctions have traditionally been drawn between research conducted by investigators on "normal volunteers" in purely experimental settings, and by therapist investigators on "patients" in treatment settings. It has generally been assumed that more stringent controls should be placed on investigators whose actions are designed to gain knowledge, rather than to promote the subject's "best interests." Yet in most situations it is difficult to draw lines between "normal volunteers," "patient subjects," and "patients." Moreover, the therapeutic setting may be one which deserves the closer scrutiny. While a volunteering subject can be alert to protect his own self interest, a patient's need for treatment may cause him to overrate the benefits and underestimate the risks of a research technique.'

The 'general assumption' refers to a point already made, that consent to participate in pure research invokes the 'autonomy' principle more than when a person seeks treatment and then becomes involved in research on a therapeutic intervention. However, there is a strong counter-argument here, expressed best in the Christchurch discussion by Brigit Mirfin-Veitch: Amongst obstacles to genuine informed consent, there is a 'tendency to acquiesce' ('What do you want me to do, Doctor?): Participants with reduced capacity may be obliging, always willing to please, yet have less ability to protect their own self-interest. They may also 'believe that another person has to give consent on their behalf'; and may accept 'another person's belief that such a person has to consent on behalf of the person with a learning disability'. These comments emphasise the vulnerability of some potential participants, especially when they are referred to third parties for *their* research purposes. Brigit's comments highlight the tendentious nature of the autonomy concept; and as already mentioned such vulnerability goes well beyond the persons to whom *she* was referring. In the days of asylums, a feature of what was called 'institutionalisation', was exactly such lack of a sense of personal autonomy. Autonomy is not a natural default

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[62] Stein, MA, Waterstone, ME (2006) Disability, disparate impact, and class actions. *Duke Law Journal,* 56, 861-922.

[63] Natanson,M (1979) A Philosophical Perspective on the Assessment of Risk-Benefit Criteria in Connection with Research Involving human Subjects. US Department of Health and Human Services (1979) *Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (*Belmont Report), Appendix, Vol II, ch. 21*, note 5; Katz, J. (1972) ed., *Experimentation with Human Beings*. New York: Russell Sage Foundation, p. 727.

assumption, as many ethicists seem to think: It is encouraged or discouraged to different degrees, by the environment in which we live. Unresponsive research protocols procedures are amongst the factors which may diminish a person's sense of autonomy.

These considerations presumably underlie the recommendations of UNESCO (2005, Article 7), that for persons with reduced capacity, research should *only be carried out for his or her direct health benefit*, a ruling which places limits on research that can be done. Nonetheless, a conscientious researcher, aware of both dangers and benefits to come from his/her research may seek a more flexible ethical framework within which to work.

(v) Moral Absolutes and Legal Inflexibility.

The Nuremberg ruling – the maxim: 'to say "I was just obeying orders" is no defence' - was presented as a 'moral absolutes'. Today, many people in Germany take this with utmost commitment; and I have great respect for their sincerity. However, in normal times, and less extreme contexts, moral injunctions need not be so absolute. The stark facts revealed at Nuremberg led inevitably to strict legal codes; and I have no doubt that this is often still needed. Nonetheless, in a broader overview, they are best seen not as absolute prohibitions or fixed rules, but as 'guidelines' which, after due democratic discourse, can be modified. Let me give a few examples: In the USA, the Food and Drug Administration decides which medicines should be available for prescription; and it had strict principles governing the sort of evidence needed to authorise a new medicine. As the nature of the AIDS epidemic became clear, it was forced to change: In California it was known amongst communities at risk of AIDS that an existing medicine (or rather a special formulation of it) was effective in treating an opportunistic infections common in people with AIDS. As such, it was a life saver. However, it had not been tested with recommended protocols and was not approved by the FDA. At this point, AIDS activist groups set up their own trials, using a research design different from those recommended by the FDA. They sent their results to FDA, who eventually capitulated, and authorised that the medicine be made generally available. This campaign, led by a community activist, started a principle which has been extended to anti-cancer drugs. Very recently, a similar, more dramatic decision was taken at highest levels in relation to the Ebola epidemic in West Africa. As already mentioned, the Ebola epidemic was so urgent that concern over informed consent was a minor priority. More generally, in *every* specialty, early history involved styles of treatment which would never receive ethical approval today. The point is that ethical guidelines are not set in concrete as 'moral absolutes'; they are modified, and *should be* modifiable, according to the urgency of the situation.

(vi) Definition of 'Research'.

Of generic policy issues comsidered in this section, this may be the most problematic. It arises in psychiatry in relation to differentiating between research and routine practice. In the past, as every medical discipline emerged from deep ignorance, all practice was in a sense also research. Implicitly, the essential synergy of research and treatment was accepted in the Helsinki Declaration in 1964 (II/1): 'In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if, in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.'

Until recently there was little concern to separate research from routine practice: No-one considered the issue. However, the Belmont report *did* make it an issue, with sentences such as these: 'It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred . . because both often

occur together'. . . 'When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental", in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective.'

Chapters in the Appendix to the Belmont Report include several on the distinction between research and routine treament, including one (London and Klerman) on this distinction in the mental health field[64]. However, this was before psychiatry underwent its 'biological revolution', at a time when few thought of the need for informed consent for 'talking therapies'. Since then, administrative guidelines have insisted that research be separated from routine practice, a trend which has also taken place in New Zealand, the former being required to follow stricter guidelines than the latter. Despite this shift, the principle of an essential synergy between routine practice and research is still partly correct in every specialty, but especially so in mental health, for several reasons:

First, more than in any other specialty, the emphasis in psychiatry is on building relationships. Most applicants for research funds, or ethical clearance are asked for details of research protocols. For research on 'talking therapies' this is more difficult. In the USA, public funding of treatment has to define methods to be used, so that efficacy and safety can be assured. Strict definition of methods must also apply to research evaluating treatments, including psychotherapies, although this may defeat the objective of the treatment: Available evidence shows the effectiveness of talking therapies has little to do with the specific method used, because it is mainly a relational interchange, depending greatly on flexibility by the therapist[65]. Notions of documenting 'informed consent', based on understanding in advance, might then be confusing, frightening, or counterproductive, depending on the characteristics of each patient, the therapy and the therapist. On the other hand, some fringe variants of 'psychotherapy' use such extreme methods that there are real dangers. London and Klerman end their chapter by suggesting that 'despite the problems involved . . there cannot be any meaningful protection of research subjects in the field of mental health research unless there is regulation of innovative, experimental, research demanding mental health treatments.'

Second, one way or another, many psychotherapies assist clients by helping them to understand their own mental processes, or sometimes their own bodily reactions. Such growing self-knowledge is intrinsically highly individualised, not only in content, but in the level at which self-knowledge can be gained. Thus, in much psychotherapeutic practice, every case is its own research study. As already explained, the notion that mental disorders are to be defined as generic *illnesses*, is currently being challenged. Moreover, given the large variety of methods used, which merge into the grey area of 'fringe medicine', the distinction between research and rountine treatment becomes even more problematic. Even if such challenges are only partly correct, it implies that research based on groups with the same 'diagnosis', may completely miss the point: Advances in

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[64] London,P., Klerman,G. (1979) Boundaries between research and therapy especially in mental health. US Department of Health and Human Services (1979) *Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (*Belmont Report), Appendix, Vol II,* chapter 15

[65] Wampold,BE (2001) *The great psychotherapy debate.* Lawrence Erlbaum Associates.

treatment may occur not only in the macrocosm of large adequately-powered studies, but in the microcosm of numerous diverse one-to-one interactions between astute clinicians and individual patients, working together to resolve a patient's problem. The move to indivdualising treatment may be most needed in psychiatry, but is now promoted across the whole of medicine. Often this shift is advocated in relation to advances in molecular genetics, hoping that it will enable treatments to be more specific to individuals. Whether or not this is true, traditional approaches to diagnosis may be breaking down in areas far removed from psychiatry. The adminstrative approach which insists that diagnoses and methods to be used should be declared in advance, is bound to undermine the flexibility of therapy, by its being specified generically, rather than case-by-case. Overall, research into treatment may be undergoing a transformation. If so, ethical guidelines for research will also need to be updated, to avoid their becoming obsolete.

Third, the scientific basis even of 'main stream biological' psychiatry is less secure than elswhere in medicine, not just because of its essentially relational nature compared to other disciplines. This means that astute front-line clinicians, with no pretentions to research, may contribute key observations to research, by reporting unusual side effects of medications, new ways to describe or group symptoms which point to better treatment, or by making other distinctions seemingly important to practice. Take the instance of depressive illness: There are many effective means of treatment, some via 'talking therapy', some via pharmacotherapy; but any one is effective in only a fraction of patients said to be depressed. Part of the reason is that current diagnoses are inadequate to specify which treatment is best for each patient. So, a practitioner may try treatments empirically, to find one that works for each patient. In principle a frontline clinician might find a way to predict treatments which are best for a newly-defined class of patients. In one sense this is routine practice, in another, it is very important, innovative research, yet not quite a 'radical departure' from accepted practice. In such practice, it is hard to separate research from routine treatment. Should it be declared as research? . .or, should guidelines be revised, so that *either* innovative treatments are declared as research, *or*, in certain areas (which should be specified) the distinction between research and routine treatment should be softened, even abolished? These are not trivial issues, given that adverse side effects of even routine treatment are common, and that research ethics applications ask that foreseeable risks of intervention be explained to patients before asking for their consent.

Fourth, at times, even the founding concepts need revision – in the case of psychiatry, the diagnostic concepts. Then, the profession is 'back to square one': Research in this circumstance should *definitely not* be split from routine practice. Carl Wernicke in the 1890s worked at a time of such uncertainty. In his day, there were no barriers between research and routine practice. Today, with NIMH refusing to sponsor research based on DSM 5, we enter another such epoch, after a long period, arguably, of false certainty.

Thus, in this area, there is unresolved tension, surfacing periodically in practice; and it is evident in principle in the contrasting emphases of the Helsinki Declaration and the 2006 UN Convention. The tension is discussed further in the next section.

X. *Why have Laws on Medical Ethics?*

(i) Classes of Law.

The discussion so far may leave readers confused about the framework, legal or otherwise, in which debate over informed consent is best be framed. I have argued that usual jurisprudence concepts in which the debate is framed - autonomy, understanding, rationality, and underlying these, a certain view of personhood – are indefineable, untrue

to everyday experience, incoherent in themselves, or inconsistent with each other, or any of these in combination. So, one has to ask: Why have laws? A cynic might answer 'To show who is boss'. With complete lawlessness as the default, this answer is not stupid, one which many would accept. However, jurisprudence in today's world is seldom so stark, and seeks a more subtle response.

Many laws try to implement the widely-perceived concept of 'natural justice'. Sometimes, admittedly, legal rulings are needed when this abstraction is irrelevant (such as which side of the road we drive on). In such cases, laws, gain validity simply because everyone knows what they are, and that they apply to everyone; and in so far as everyone knows them, people can interact in predictable, and 'rational' ways, even when societies grow so large that interaction based on personally knowing ones fellows - and therefore on mutual trust - is no longer possible. For other human interactions, the concept of 'natural justice' cannot be avoided; laws then aim to bring a degree of natural justice into our interactions, notably when different interests are in conflict. This was surely a motive guiding the Helsinki Declaration, and later the 2006 UN Convention. Whether such laws are (or ever can be) implemented in a consistent manner, is an issue dealt with below.

For the class of law where the principle of natural justice *is* relevant, there is an important difference in their scope. Some – including those considered in Part A of the preceding Discussion section - are essentially about interactions between human players. They may involve abstract principles, but, perhaps more important, they are influenced by the endless variety of wisdom and foolishness, benevolence and malice, strength and vulnerability which individual humans exhibit. For this class of law, there are generic *flaws* in legal systems, arising from the problematic nature of concepts used ('autonomy', 'rationality', etc, as discussed), and often from legal procedures used to implement them. Admittedly, procedures may be implemented in a manner which is sufficiently flexible to cope with the vagaries of human interactions; but this is to the credit of individual legal practitioners who know how to 'game the system', not to the 'letter of the law'.

Other laws are *essentially* about abstract principles, with little need to adjust to cope with the subtlety of personal interactions. These were discussed in Part B of the previous section. They include the principle that decisions about consent be given 'by proxy'; 'justice' between groups in access to research; individual vs. group focus of protective measures; the strictness with which legal principles apply in different circumstances; the broader issue of when the law should define 'moral absolutes', and when a softer, more flexible approach should be adopted. The last, and for us the most interesting generic issue is the official distinction which has grown in recent years between 'research' and 'routine practice'. For such issues, careful wording of statutes seem appropriate and adequate, given that they include qualifiers of basic principles, to meet foreseeable variations; and, in common law traditions, statutes would be worked out as evolving precedents of case law. However, statutes seem inadequate for problems in differentiating research from routine practice, especially if research involves persons who are vulnerable or have reduced capacity to take decisions,

(ii) 'Guidelines' (Not 'Laws') When Human Relationships are at Issue.

For the first class of problem just described, a possible solution may be to adopt and extend the principle of guidelines suggested in the Hesinki Declaration, giving clinicians freedom to use whatever treatment they think best, even when new or experimental, and strictly to be classed as research. However, the dangers are obvious: Ambitious, over-zealous practitioners embark on radically-new, untried methods in pursuit of their own glory, regardless of patient well-being. Apart from the Nuremberg trials, the background

to modern concerns over ethics research has many such examples. Thus, if the recommendation of the Helsinki Declaraton is to be followed, it must be tied inseparably to another one: Practice which is novel or experimental, yet not fully-formulated as research, should be transparently declared as such, and open to independent scrutiny.

Two points are important here. First, a key distinction is made, already suggested in the previous section: Advances from 'research', especially in psychiatry, do not always come from large studies of people, with rigorous diagnoses, adequately powered, with all the methodology and statistial analyses which go along with this. In any case such studies often select unnaturally uniform cohorts of patients, or neglect differences within cohorts so defined. As already suggested, whether or not it is called 'a research study', important advances *do* occur in such innumerable, diverse, one-to-one interactions between astute clinicians and individual patients collaborating to resolve a patient's problem. This does occurs - and always did - and is hidden under the phrase 'clinical experience'. For the research enterprise as a whole, it would be an advantage if that experience were better documented, and made available to those doing more orthodox research.

Apart from this, *independent scrutiny* is an essential safeguard. Here we return to a principle mentioned early in this essay – the *ethic of transparency.* To reiterate: 'There definitely *should be* systems to ensure that assessment can take place, by those who are *knowledgeable, experienced, well-versed in ethical matters,* and *independent,* to check that nothing improper is going on; this may involve asking detailed questions on clinical practice and research processes, which lay people could not ask, and expecting to receive a full answer.' This recommendation has nothing to do with decision-making capacity of participants; it is about the conduct of the research itself. It is related to another principle, clinical independence and freedom for physicians. There is already reference to this in the 2006 UN Convention, whose Article 16 (Freedom from exploitation, violence and abuse; point [3]) reads: 'In order to prevent the occurrence of all forms of exploitation, violence and abuse, States Parties shall ensure that all facilities and programmes designed to serve persons with disabilities are effectively monitored by independent authorities.'

The principle of clinician independence is hallowed by time, but is increasingly now under administative constraint (partly because of real financial pressure). We should be clear that there is a good reason to uphold the principle: A clinician engaged in one-to-one encounters with patients needs the flexiblity to respond subtley to all personal aspects of the encounter, which are indefinable and hardly scientific, without being unduly bound by a web of legal constraints; yet, obviously such freedom has its dangers. The solution proposed avoids an over-legal approach, yet insists on transparency, at least an openness to scrutiny by knowledgable, experienced, independent observers, who check if practice meets accepted knowledge and standards. There are already many precedents for the ethic of transparency, especially when subtleties of developing or on-going relationships are involved. These are not strong rivals at present, but they could grow. Here are examples:

In British legal tradition since the civil war of the 17th century, a crucial guiding principle is that 'justice should be done, *and be seen to be done'*. This is an instance of transparent legal practice, although admittedly the brutality of some adversarial coutroom battles hardly deserve that term. Transparency is long-established in medical education: Anything a doctor does is seen by his students and their own activities is seen by him or her. In Britain, in response to long-standing controversy over animal experimentation, researchers must be licenced, and there is a government inspectorate: Inspectors have authority to call on any research facility day-or-night, to check what is going on, another example of transparency in action (although in my experience, it often amounted to

researchers being forewarned that 'the inspector is on the way', giving them a chance to stop doing anything that might be suspect.) With regard to research with human participants, the 2008 revision of the Helsinki Declaration (Item 15) states that: 'The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events.' However, the following line in the 2008 document seems to limit flexibility more than the 1964 version of the Helsinki declaration: 'No change to the protocol may be made without consideration and approval by the committee'.

For major innovations in medical practice (in effect, research), there is a long tradition of transparency: Transparent audit of health practice probably started with Theodor Bilroth, a gastro-intestinal surgeon in Vienna in the late nineteenth century. Despite his being at one point the target of public vilification when a patient died on the operating table during a pioneering operation, it was *he* who insisted on publishing all results, with the result that surgical safety and expertise steadily improved. Carl Wernicke was also not afraid to admit mistakes, at least to his class of very advanced trainee psychiatrists. Note that calls for transparency were not enforced by administrators, but came from practitioners, as the best way to safeguard their own practice. Recorded travesties of medical ethics have occurred in part because the tradition was not adhered to.

Implementation of principles of transparency in a New Zealand setting is interesting in itself, but also relevant in the present context. In criminal law, a holistic development is termed 'restorative justice', and there is also a wider concept of 'therapeutic/holistic jurisprudence'. In New Zealand, western legal systems were subject to challenge by more holistic views of the *tangata whenua*: Holistic law makes better sense in the Maori world view; and New Zealand is a country leading trials of restorative justice. Sometimes the reasons put forward for this are other than its intrinsic holism (for instance, that it gives justice to a victim of crime, rather than to the nation state). Evidence on its effectiveness is not yet conclusive, but it is safe to say that it has no worse outcomes than traditional western justice systems. In divorce law, some decades ago, New Zealand introduced 'no-fault divorce', a more holistic concept than the divisive and counter-productive legal battles over divorce in many other countries. This legislation is more realistic about relationship breakdowns, and the need to avoid inflaming tensions, and bring about a degree of 'healing'. It is a sharp contrast to legal scenarios, which (once more) seem to be based on flawed concepts of human nature ('autonomy', 'rationality', etc).

In policies for administering research in New Zealand, holistic concepts have already had an impact on how research is done. As a research proposal is developed, researchers who receive state funding must engage with local Maori groups ('Maori consultation'). The roots of this are related to redressing historic grievances, but can be justified on other grounds, as relationship-building across a cultural divide - in historic terms a form of social 'healing', and ensuring that research is embedded in the society in which it occurs; and that 'no researcher is an island'. In essence, the process is one of 'building trust'.

In mental health law in New Zealand, there is some suggestion of a holistic approach, though employed only in extreme cases: If there is a suggestion of serious flaws in a service, or in treatment an individual receives, the District Inspector in each region is charged with finding out what has been going on. In any case, the sort of scrutiny to which I refer - in animal experimentation, Maori consultation, or mental heath law - is a process needed in the difficult area of research involving participants said to have limited capacity to give authentic consent: It may be the way forward, but as yet is little explored. Such a development would be congruent with ideas mentioned in the NZSRG discussion

at Christchurch, of 'process consent', 'continual consent, or 'holistic decision making' mentioned by several speakers, with no dissenters.

What might the principal of transparency mean in the specific situation we consider here? Perhaps it means that there should be an inspectorate of people qualified in the area, who can call to meet - and talk with - persons who currently are, or recently have been, involved as participants in a researcher's project. This recommendation – combining respect for freedom and flexibility of physicians and researchers, with transparency, is another case of legal control being replaced by a more holistic style, to preserve and foster key relationships. This style may be the *only* way to negotiate the tricky area of research with participants with limited capacity to give informed consent, but has much to recommend it for research participation and informed consent in general.

Beyond this, practitioners and researchers may need to develop a personal style different from what is often the case today. It may require new training. However it is achieved, practitioners and researchers should have internalized the values underlying a more holistic style. Not only should discourse between researchers and participants in human research become more open, transparent and equal, but discourse amongst fellow researchers should also be more open, enabling better trust to be built amongst researchers. As a result, discussion of problems by a researcher with others they trust can take place, with honest sharing of views. This might become an aspect of transparency within which oversight by a professional inspectorate becomes an accepted routine.

XI. Pressures Which Make it Hard to Implement Ethical Guidelines.

Conclusions which flow from the preceding analysis are summarized later; but there are pressures preventing implementation of such a more holistic scheme:

(i) *Conflicts for Researchers in Environments not Bound by Medcal (or any) Ethics.* There are foreseeable conflicts of interest in environments where a researcher's career advancement (and 'fame and fortune') depend on his/her research productivity. This may lead a researcher to cut corners especially if ethical probity requires spending long hours gaining trust of each potential participant. Alternatively it may deter researchers from entering research areas where this is relevant. To illustrate the conflict, I give a couple of pertinent example from my own experience. A doctoral student of mine had great skill in interviewing people with diverse mental health issues, some of whom were severely impaired. To do the interviews well required her to be relaxed, and under no pressure; yet I felt that there *was* hidden pressure to complete the thesis quickly. I was not prepared to transfer the pressure I was under to her, to complete quickly; so, in the end, the thesis took a very long time to complete. Another story: A friend of mine, playing a key role in a quasi-autonomous NGO, produced a book, very attractive both visually and in content, describing life stories of twenty-one persons identified by their real names (two just as first names; no psuedonyms), some quite vulnerable, including their diverse journeys through mental health systems. When published, that book ('*A Gift of Stories*'[66]) went around the world, and was recognized as a pioneering work in previously uncharted territory. That was nearly fifteen years ago; but my friend, the editor stays in touch with all her contributors, follows their ups and downs, and in some cases, their deaths, despite

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[66] Leibrich, J. (ed.) (1999) *A Gift of Stories: Dicovering How to Deal with Mental Ilness.* University of Otago Press, in collaboration with the Mental Health Commission.

her own ups and downs. I am not sure that this qualifies as research for an administrator, but it was certainly a major advance, and has had a positive impact with regard to mental health. Whatever category it falls under, I hold it up as an example of true ethical probity in a project involving vulnerable people.

On reading this, some academic researchers might say: 'This is too hard!' Lo and behold! Research:– hard? Whoever would have thought it! Tell that to the administrators and policy makers. Make no mistake, in this area of research, a researcher *is* likely to be dealing with participants who are very vulnerable, some even at risk of suicide. To the faint-hearted who complain how hard it is, all I can say is: 'Stay of out of the kitchen!' It should be hard; or rather, it is only for those with the personal style and *mana* where it becomes possible, and then, as ever-vigilant exploration'

Similarly, administrators of health provider agencies may be instructed by political masters to cut costs, and they do so by implementing policies leading to breaches of ethical guidelines by frontline staff. This *does* happen, but mainly in routine practice; yet this administrative style impinges on research: Today, it is recommended that health specialists (especially medical consultants) build a research component into their practice. However, when high-level administrators exert pressure to cut costs, consultants either forget their role in research, or cut corners on ethics. The administrator, perhaps most aware of financial considerations, may not be aware of (or has had no training in) the clash with principles of medical ethics, which is the origin of the tension.

Perhaps the deepest tension is in models of funding. The dogma of market rigour, insists that funding be set up as a competition; it has to be contestable. In human services, where complementary services need to collaborate, they have instead to compete for funds. (I have seen this in its more absurd form in the government-sponsored program to reduce stigma and discrimination relation to mental disorder - called *Like Minds Like Mine*). The funding model also means that small agencies spend much energy chasing funds, supplied with no long-term guarantee, so that long-term planning is impossible. This is not irrelevant to research: The contestable nature of funding usually precludes long-term research studies, and collaboration between sectors.

The hardest task for any government is to reconcile ways of thinking of economic advisers with those needed in social policy. This plays out in innumerable ways, in this case in the clash between a model of funding and legitimate requirements for research and research ethics. To speak of different languages, the word *shibboleth* is appropriate. It originated in a Biblical account when pronunciation of this special dialect word was used to separate friend from foe. Economics sometimes claims to be 'rational science', although events of the last five years cast doubt on this. Perhaps, like other shibolleths analyzed here, it is 'pretend rationality', whose objective is exercise of unaccountable power; but because it claims to be something other than it is, using words in idiosyncratic ways, it is hard to challenge in an honest and democratic contest for power.

Administrators, policy makers, and those who assess researchers (and their research) by supposed quantitative measures, should take note. One may ask: What ethical guidelines do health administrators and policy makers follow? What are *their* conflicts of interest? Ethics committees are enmeshed in the conflicted motives within academia and health provider agencies. Protocols for ethical research *should* be strict; but, I ask, are ethics committees forced to connive at the dubious environments in which they are asked to operate? More generally, the environment in which researchers now have to work builds in serious conflicts of interest, which are nothing to do with the researchers' own probity. They can only be resolved by high-level policy change.

These questions take us well beyond the topic of this essay; but elsewhere I have given my views on how functions of academia and research have been subverted by political forces driven by a different and incompatible agenda[67]. A suitable quotation reads: 'A defining feature of universities - the synergy between research and teaching - should not be forgotten, although many factors conspire to break it down, reinforcing research at the expense of teaching. Several arguments suggest that too much research is done, much of it mediocre, or done for the wrong reasons.' This statement should not be misunderstood: I am decisively *not* against research; but the adminstrative framework for research unfolding since the early 1990s has subverted the research enterprise; few researchers now have freedom to do it in the spirit of the original research traditions.

How should an honest resercher behave in such an envirnment, to handle conflicts s/he feels between administrative and institutional demands, and personal values: These are not new isssues of course. (i) One way is to abide by the rules and guidelines, but 'game the system', or 'work round the rules' in creative ways. I remember at secondary school in Sheffield England, the best teacher I ever had in anyting (actually in music), who had a humanity notably lacking in other parts of the school, was not supposed to tell students what the actual marks were in the state-run exams. His approach was as follows: 'Well, Robert [and he was the only member of staff to use first names], you got somewhere between – er, let me see – 84 and 86%'! This approach is only a stop-gap measure, adopted by shrewd persons in situations where they have little power. A more effective way, is to find ways to challenge absurd rules, in open, vigorous, yet respectful debate.

(ii) *Tension Between the Defined Nature of Research Today, and the Relational Approach Sometimes Needed.*

In the recent past, especially for large clinical trials, funding depended on research done according to predetermined protocols. If, as suggested above, medical treatments, notably those in psychiatry are to become more personalized, there will need to be greater flexibility in research. This is likely to create two further tensions: *First*, by definition, research *is* a search, into unknown territory. It follows that, as far as possible, it should be open-ended, and able to take advantage of unexpected findings along the way. This is hindered if complex protocols have to be declared in advance. *Second*, with regard to informed consent, one asks, how full the consent should be? How completely should researchers declare their objectives, methods, and attendant risks? Is it possible to give full information without undermining aims of the research, and the flexibility needed as we move to more personalized health care? Different participants are likely to ask for information at very different levels. In principle it would be possible for a participant to ask a question which the researcher cannot honestly answer. What then? Rather than all the exact procedures to document informed consent, a flexible, holistic style, based on trust may be better, where participants can also become partners with researchers, in exploring hard question where neither has a sure footing.

(iii) *Differing Research Scenarios.*

After the Nuremberg trials, research ethics has been conceived mainly in a biomedical context, and norms were established, except in difficult areas. Apart from formalised ethical rules or guidelines, older medical traditions give medical professions some

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[67] Miller, R (2010) *Subversion of higher education: Origins, analysis, recommendations.* Lulu Enterprises, Morrinsville, NC.

grounding on ethical matters. It is appropriate for similar concepts to be applied to other areas of research with human participants, such as social or policy-development research, where ethical traditions and procedures are not well established, and sometimes given little attention at all. In some professional bodies, the ethos is distinctly at odds with that of medical professions. Such professions may hide prevailing racial prejudices; or there may be discriminatory attitudes to persons with mental disability in some professions, who also conduct their own research. The sharpest clash with the ethos of research in the biomedical area is in military research, or research related to miltary intelligence; and sadly as we have learned in recent months, flagrant and severe violations of human rights perpetrated on 'enemy combatants' (essentially prisoners of war, with no protection from the Geneva convention). These practices appear to have had a 'research' basis, long before they were deployed in theatres of war. Medical and psychological 'experts' were involved in the practices, and presumably in preceding research. Such likely involvement brings into sharp focus the topic of 'research involving persons with limited capacity to give informed consent', and prisoners *are* amongst the groups said to be vulnerable. In a similar sense, though not so starkly, it is true that, in New Zealand, persons in regular prisons, who have serious mental disorders, lose protection supposedly given by Human Rights legislation: The Mental Health Act, over-rides the Code of Health and Disability Services Consumers' Rights, which of course has to be compliant with Human Rights laws. One has to ask how the term 'human' can be defined, in so far 'human rights' refers to people who are in prison and are also mentally disordered, or in other quasi-judicial ways to those who have lost legal protections guaranteed to everyone else.

(iv) *Inculcating a Personalized Approach Amongst Researchers.*

If a more personalized approach is to come to the fore, with less emphasis on the letter of the law (which may have internal contradictions, or be hard to implement), a number of questions arise if the integrity of researchers working with human participants is to b e guaranteed. Given the pressures which may tend to undermine a personalized approach how *can* researchers be trained to internalize the morality and values which this entails? How, when getting involved in a more personal way with research participants, can they retain objectivity? Building trust and relationships is a two-way process, in which both may be changed; neither partner is an 'unmoved mover'. (In medical practice, I believe that many, practitioners learn how to do this; some clearly do not.) To relate well to a wide diversity of persons, with personal styles, life experiences, talents and disabilities which may be unusual and sometimes rare requires a researcher with skills in building such relationships; it requires someone who can cast aside immediate research objectives to concentrate on the other person; and this also takes long experience. How can a young researcher be expected gain such experience? It is not part of the training of non-medical research scientists. How can a young researcher, trying to learn from more experienced persons as guides, stand aside from inevitable peer pressure, and stand firm on principle, when asked to do something discordant with these principles. I have little experience here; but, in days before the Cartwright report, I was once involved in recruiting persons for research in a way which in retrospect was unsatisfactory, for reason given, including 'pressure from academic masters to "*do research*"'. The conclusion here must be that researchers who are to use human participants, need training in the necessary style, and perhaps need to be assessed in this as a core ability. This may be needed more when basic scientists get involved in human research than for those with medical training (which inevitably *does* include such training and assessment). It may also mean that ethics committees should include in their brief ways to ensure that researchers have sufficient

competence in a necessary style of interaction. For instance, Dalton and McVilly[68] include in their recommendations, in the context of multinational studies on persons with intellectual disability, item 13(c), 'that approval for an international, multicenter trial involving participants with intellectual disabilities should only be given, where the ethics committee is satisfied that those who are to conduct the research are competent to do so and/or will be supervised by appropriate specialists.' If that slows down the research process, and 'productivity' (as measured) so be it.

XII. Styles and Processes of Interaction.

(i) *Introduction*

This section attempts to define what a more personal, relational, and transparent style might mean, focussing on informed consent for research participation, but with examples of consent to medical intervention, when relevant. Replacing a legalistic style by a relational one makes sense for several reasons. Before legal systems were developed, and today in societies where they are weak or poorly implementated, the natural 'currency' for social interactions are bonds of mutual trust. Trust can likewise be built as valid currency, even if one or other participant does not understand the rigours of the law. However, by analogy with monetary 'currency', another principle follows: Just as it is reprehensible to debase a monetary currency, anything which undermines a bond of trust, and the currency so established should by all means be avoided. An implication follows, that personnel who develop such relationships of trust should not be subject to frequent change – continuity, even permanency, in the currency of trust is needed.

In the next subsections, general topics come before specifics. Building trust is the larger task, within which obtaining consent should be a natural, easy component. Overall, style is more important than specific content, although less easily defined. Much of the next section comes direct from the discussion in Christchurch, sometimes referring to the intention of NZSRG to develop a Volunteer Research Register.

(ii) *Ways to Foster a Flexible Relational Approach.*

[a] *Communication:*- Sue Purdie spoke strongly on this: Informed consent for those with diminished capacity is every bit as important for persons with limited capacity as for those who can give their valid consent more easily. The same process needs to be followed, whether or not a person is under the Mental Health Act, or whether they have (or have not) given signs of diminished capacity in some areas. If limits arise because of communication difficulties, that for a researcher to resolve, if possible. Sue referred us to Right 5, in Code of Health and Disability Services Consumer's Rights (1996):

> Right 5: Right to Effective Communication
> (1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.
> (2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

[68] Dalton,AJ and McVilly, KR. (2004) Ethics Guidelines for International, Multicenter Research Involving People with Intellectual Disabilities. *Journal of Policy and Practice in Intellectual Disabilities,* 1, (2) 57-70.

She illustrated her point with a vivid quotation from another source:

> 'John . . . was admitted to an inpatient setting with psychosis. John notes that all he could hear were the voices in his head. A nurse sat down with John and spent a long time talking to him. Eventually the nurse's voice penetrated the other voices and he could focus on what the nurse was saying. I think John made the most powerful statement I have ever come across: "I could always be gotten through to…". This is a statement about being informed despite what would be called "limited capacity"; this is about professional nursing wherein a nurse shows empathy, caring and a belief that they will get through to John; a nurse who persisted despite time constraints that may have existed; a nurse who believed in John's Human Rights; a nurse he could trust. All depicted in one phrase.'

[b] *Encouraging True Partnership.* A significant part of gaining trust is to ask stakeholders – potential research particpants, especially ones who identify as having the condition under study - for their views on the type of research they want done. Researchers should listen carefully, and respond positively if they can, and not just with words. If suggestions for research suggested by participants seem to be valuable, and have not previously been explored, and the researcher him/herself cannot undertake the suggested research, an alternative response is for the researcher to refer the topic to a wider research community, in the hope that others, with different skills and opportunities can take up the issue. It does not mean that a reserchers' own ideas have to be shelved, nor that the balance shifts overwhelmingly to topics with possible immediate pay-off, neglecting long-term goals. It may however lead to the overall portfolio of research being a better balance between the two, and sometimes that something arises different from what a researcher initially wanted to do. Beyond this, if trust could be won with persons whose concerns do not fit the mould within which a researcher initially cast his research, such that they agree to participate, it would reduce sampling bias, and consequent skewing of results. Further ways to encourage group involvement are discussed below under *Enduring Commitment to Sustain Trust.*

[c] *Researchers engaging with Potential Participants as a Group.*

At various point in this essay, the necessity for researchers to discuss their proposals with groups rather than individuals, and to gain trust of a group, has been mentioned. This might mean arranging sessions at which one or two researchers meet a gathering of potential participants, on *their own turf* (when collectively *they* are in a stronger position). This situation allows people who may be diffident or disabled, intellectually or in other ways, to gauge a researcher's trustworthiness, using their emotional intelligence ('Is this a person I can trust?). Consent based on such meetings, combined with individual meetings, would have authenticity regardless of documented evidence, which would in any case be easier to obtain once trust had been built.

[d] *Support, Assistance, Mediators, and Proxies in Decision-Making.* A researcher negotiating informed consent with individual persons has an obvious conflict of interest, especially if he or she is under pressure to improve their research performance, to ensure continued finicial support of research and career advancement. In any case assumptions about autonomy and rationality, if ever applicable, are less so if participants' capacity is

reduced; and thus more creative, and time consuming approaches are needed to gain trust and genuinely informed consent, for both medical interventions and research[69]. This has ben discussed by Chris Taua, present at the Christchurch meting. If ethics committees do not now grasp this, they should be encouraged to re-examine the issue.

When negotiating consent, especially for participants with reduced capacity, it may be necessary to arrange for assistance by a support person or experienced mediator, independent of the research program. *In the specific context of setting up a Volunteer Research Register for schizophreniua and related disorders, a professional mediator may be needed*, *for forseeable situations of a potential participant requiring it.* In developing the VRR, its organization should be largely separate from NZSRG, for several reasons. One of these is to give a degree of indpendence to the VRR and any mediators they might provide. For such a person to have a permanent position, as the direct interface between participants and researchers would give permanency to a key point where trust is to be established, and through which research engagement becomes possible. There would then be less danger of the 'currency of trust' being debased. The amount of information provided, and the level and type of support required by such 'go-betweens' will vary from person to person, and may change over time and in different circumstances. In any case, involvement of a mediator to negotiate consent should not absolve the researcher of the need to provide information for, and answer questions from participants.

Who could, or should provide that support, or mediating role? . .and how it should be provided? These are tricky issues. Misjudgements are easily made in either direction. In the case of medical iterventions, one speaker at Christchurch raised the possibility that some people fail to gain access to appropriate treatment at a time when their ability to consent is seriously impaired. The stark slogan here is that people can 'die with their rights on'. Helen Bichan recalled a 'woman with advanced bowel cancer.

> A surgeon wanted me to overrule her objection to treatment, but I found she was able to understand and was clear about her refusal to have palliative surgery which might have prolonged her life, but would have left her with a colostomy. We agreed on good terminal care in the ward among the people who knew and cared about her.

More recently a speaker had heard the claim that an advisor 'saved' someone from a particular treatment – it seemed because the adviser was opposed to its use. We canot judge the rights and wrongs of the case here; but we can ask what is actually meant by 'supporter' or 'mediator'? All such difficulties also apply to decisions about research participation: In the paper by Taua *et al,* incidents are described of potential participants who disagred with a decision by a surrogate, who in one case favoured participation, and in another favoured non-participation. Such stories alert readers to hard-to-control dangers of covert or (more likely) unconscious coercion to participate, or to refuse participation. Taua *et al* also suggest that gatekeepers or proxy decision-makers may be overprotective, and discourage participation on grounds other than their stated ones, of

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[69] Taua,C, Neville,C, Hepworth,J. (2014) Research participation by people with intellectual disability and mental health issues: An examination of the processes of consent. *International Journal of Mental Health Nursing*, 23, 513-524.

'protection'. One covert motive is a fear that the service in which a participant is receiving care might be evaluated in a negative light – a defensive tactic which reinforces the argument made above for *transparency* as the best protection, and best indicator that a service has nothing to hide. Under ideal circmstances, gatekeepers themelves can be effective in facilitating and safeguarding research. All-in-all, mediators are required to have remarkable personal attributes. The topic is developed further below.

[e] *Style of Interaction.* In presenting information the importance of a relational approach, and the likelihood of impairment in taking in or conveying information should be borne in mind. The approach needs to be flexible, without forgetting or hiding the real objective of the interaction. It depends on several features: In asking for consent to participate in research, how informed is a patient already? This affects what information s/he might require, in order to give consent. It also depends on differences in personality of potential participants: Are they intrinsic gamblers, or are they naturally pessimistic or altruistic? The attitude, demeanour, and personality of a clinician, researcher, or mediator, and the way questions are asked and information conveyed make considerable difference to the outcome of negotiation. The role of such advocates in research involving people with dual disability (ID and mental health issues) is described by Taua *et al* along with a list of guidelines on the style of communication, and ways it is reflected by the participant (to check that understanding has been truly obtained).

Consent of someone diagnosed with schizophrenia may be hard to get because of ideas of persecution, which are by no means confined to this disorder; and validity of consent may be hard to verify as truly 'informed'. For people with schizophrenia beset by such ideas, there may be an issue of actually having to *sign* a consent form, especially after having already negotiated verbal consent. This is part of a wider problem: Immigrants from countries with no tradition of mental health care as personal medicine may hold similar suspicions. Taua *et al* write vividly of the special fears of people with intellectual disabilities, who are unable to understand the full context of a research study, and the import of the consent procedure.

(ii) *Style of Consent Process Itself*

[a] In formal terms the basic protocol for volunteering is likely to go through several levels, or degrees of consent.

- For a system such as that conceived by NZSRG, a Volunteer Research Register which may make possible a wide variety of projects in a defined research area, the first stage is no more than an 'expression of interest', and wish to be informed of up-coming projects.
- Then, after meeting with personnel running the VRR, with a chance for discussion and responding to general questions about participation, there could be an agreement 'in principle' for a person to be approached in relation to forthcoming projects. Volunteers at this stage could be called 'prospective research participants'.
- Later, when projects have been proposed by researchers, funding and ethics issues cleared, and VRR has itself approved the project, such volunteers could be approached by about the project. If the person is still interested, he or she would then be put in touch with the researcher(s).
- When researcher(s) and participants first meet, it would be the time for detailed discussion of the particular project, with documents to be signed, by participant, researcher, and personnel from the VRR who had negotiated the arrangement.
- In addition, any signed document giving consent should include an 'escape clause', such that a participant could withdraw consent at any time. The signature might then

indicate that the participant 'signs and understands' rather than 'signs and agrees to participate'. Th form of words needs to be resolved

- Later still, after a participant had made his/her contribution, volunteers should be ewncouraged to give feedback on their experience and to receive feedback on progress or results of the research.

These would be the basic steps in participation. However, given that some participants would have greater impairment and vulnerability, additional stages may be needed. An immediate issue is whether impairment is permanent or temporary. This has implications for ways to seek consent, as it has for research design. For people who are acutely unwell, but likely to recover, there is much to be said for waiting until the person is in a better state to give consent, before attempting to involve them in research (see below). For those who have reduced capacity as an enduring feature, but who may yet want to participate, the initial approaches (first three bullet points, above) might best conducted through a support person, such as a relative, and any discussion at the second stage, should include such a person as well as the participant themself. Communication and discussion should be alert to personal differences in preferred style of comunication. Since attention span may be short for unfamiliar information, an explanation may need to be revisited several times, with gradually increasing comprehension. In any case, language should be simple and direct, especially for participants who might be intellectually disabled. Complex issues can often be dealt with when they arise in discussion.

[b] *How is Informed Consent to be Achieved?* In the discussion at Christchurch, Brigit Mirfin-Veitch and Christine Neville provided most detail. There was little emphasis on quasi-legal documentation, and little or no reference to formal asessment of capacity to consent, such as discussed in an earlier section. Rather the emphasis was on defining and formalizing the process of building trust in the most flexible manner, the underlying aim being to seek consent which was genuinely informed and truly voluntary. Nevertheless in Christine Nevilles slides (referring to Dougall and Fiske[70]), guidelines are given, for occasions when there appears to be impairment of or disturbance in a persons's mental functioning (specifically that related to neurological or autistic disorders). If so, criteria to be used before deciding that a person cannot give genuinely informed consent are incapacity to understand relevant information, to retain the information presented, to use it and weigh it up, and to communicate their decision. As aids to understanding, Brigit's slides included: 'Provide study information in accessible formats'. Christine's talk included the maxim that 'information and documents [should be] provided at an appropriate level for understanding'. Both statements imply a process more flexible than a routine protocol or 'standard operating procedures'.

Since the degree of impairment and reduction of capacity may vary greatly, Brigit Mirfin-Veitch recommended that discourse should start 'from the position that people with learning disability *do* have the capacity to provide informed consent'. Her guidelines stressed slowing down the tempo of dialogue. 'Take time to talk and listen'; then 'Step back'; 'Incorporate several opportunities to learn about a study and opt in'; 'Revisit and revise research processes'; 'Remind people they can opt out'. The idea that the researcher might revise the research processes in the light of experiences in obtaining consent presents *does* some challenges to the way research studies are developed at present.

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[70] *Dougall* A, *Fiske,* J (2008) Access to special care dentistry, Part 2. Communication. *British Dental Journal*, 205, 11-21.

[c] *What Information Should be Provided for Informed Consent to Participate in Research?* In a strict sense, a large body of information could be relevant, which a purist might insist should be made available in written form[71]. However, in the context of the discussion at Christchurch, Helen Bichan spoke as follows: 'Being "informed" matters, but there are levels of understanding that different people need. As a young doctor, having read the literature on hospice care, I was concerned to give a terminally-ill patient full information about his condition. Then the chaplain gently reminded me that he did not have to have his condition spelled out in painful detail; he just needed to have his questions answered. Later, as a patient, I learned that there are times when trust in those providing treatment matters far more than being informed or consulted!' The principle highlighted by this anecdote applies to consent for research, especially when one hears (as we did at Christchurch) of 'an information sheet provided as a 23 page booklet'. Thus, information provided should not be too much, enough to indicate to potential volunteers essential points about the nature of the project, and what is implied by volunteering and giving consent. Further detail can be given in response to follow-up questions.

Amongst topics best left to such follow-up are:

- *The concept of research itself.* For persons with intellectual disability, it may be necessary to clarify that research is for future, and for persons at some future time, probably not for themselves at the present time.
- *Voluntariness.* The idea that their involvement is entirely voluntary; and that if, at any time during their involvement, they want to end their participation, there will be no adverse consequences for them; and that this right is protected in law.
- *The tempo of research.* Funding of research today *may* be tied to benefit for a currently-present situation, not a distant hypothetical one. However, benefits research may not be immediate. Outcome from research may be beneficial or not, and this is not known until the research is complete. Sometimes, the potential of results may not be known until much later. Psychiatric drug development may take 15 years.
- *What do I stand to gain?* Potential participants need to know who might benefit from the research, and how? Research can be done for many reasons but it is important for participants to know what the end result might be, whether this be to healthcare generally, or of personal value to participants. This needs to be considered at the earliest stage of research design. As Taua *et al* state, in the context of research with

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[71] For instance, the University of South California, includes the following in its 'Informed Consent in Human Subjects' Booklet:- Purpose of the research; Procedures involved in the research; Alternatives to participation; All foreseeable risks and discomforts to the subject (not only physical injury but also possible psychological, social, or economic harm); discomfort, or inconvenience; benefits of the research to society and possibly to the individual human subject; length of time the subject is expected to participate; Person to contact for answers to questions or in the event of a research-related injury or emergency; Statement indicating that participation is voluntary and that refusal to participate will not result in any consequences or any loss of benefits that the subject is otherwise entitled to receive; Statement regarding the subjects' right to confidentiality and right to withdraw from the study at any time without any consequences; Waiver of one or more elements of informed consent may be obtained from the IRB for some research projects that could not practically be done without an alteration to the required elements or for studies where required elements are not applicable (University of Southern California (2013) *Informed Consent in Human Subjects.* http://oprs.usc.edu/files/2013/04/Informed-Consent-Booklet-4.4.13.pdf)

people of reduced capacity: 'Research design must be rigorous, relevant, and of significance to the participants'.

- *How would their contribution be shared*. It is important to emphasise that anything which identified them as a person is irrelevant to research reports, and would in no way be discernible in such reports.

[d] *What Information, and what Understandings Should be Obtained by a Researcher in discussions about consent*? During the dialogue a researcher needs to obtain understanding from potential participants on several points, before an agreement about consent is finalised.

- *What do participants expect from the research?* It is important to clarify what participants understand about a project they are to be part of, what are its objectives, and what benefits short- and long-term might come from it. Misunderstandings on such matters may lead participants to feel disappointed, even exploited.
- *Voluntariness.* It is likewise important for a researcher to be sure that consent has been truly voluntary, and that q participant has felt under no pressure to comply. This is specially important for persons with intellectual disability. In this case non-verbal signs of enthusiasm or non-engagement may be as important as, or more important than verbal ones.
- *When informed consent is truly given,* it can be ascertained in several ways: Participants will understand what they are agreeing to; have freely chosen to become involved; understand what the research can and cannot achieve; know they can withdraw from the study at any time; where relevant, know they can decide not to respond to certain questions; know that processes and procedures can be altered by a researcher to meet their needs; is aware how research information will be used; and, where relevant, has the support of their legally mandated welfare guardian.

[e] *Koha/Incentives*. In the USA, monetary payment for participation in research is common, but this practise is somewhat problematic. Such incentives may encourage participation by those who do not genuinely fit inclusion criteria for a study, which could bias results. In countries where this tradition has grown, some people 'make a career' out of it. This may be bad for their health, as well as for research. As with the tradition of not giving tips at restaurants in New Zealand, it is worthwhile to resist introduction of this tradition. A Koha does not have to be monetary, although costs incurred by a participant (for instance, travel costs to get to and from the centre where the research is carried out) should be reimbursed. If research involves persons who may be genuinely struggling financially, an exception can be made, in the form of small payment for participation, and costs of this should be built into research grants. For mental health research, being valued, having personal stories heard and understood (perhaps for the first time) may be more important, as may be gaining better understanding of one's own condition. Gaining a sense of contributing to a larger goal to help future generations may be enough incentive to encourage volunteers to participate. A specific point needs to be added: At suitable times, cups of tea/coffee, or some chocolate, or biscuits is likely to be much appreciated. Early morning starts, or the stress of participating, which may be significant for both biological and questionnaire-type research, can lower blood sugar. Researchers should be alert to signs of this (as they would be at centres for blood donation). Such matters are best seen as natural courtesies, rather than incentives or rewards.

[f] *Enduring commitment to sustain trust.* If trust is a currency, it should be durable. What does this mean? In research where participants interact personally with researchers, a bond of trust may be established. This would not apply at an individual

level for anonymous questionnare completion, but could apply at a group level. Trust established between researcher and participants, whether at individual or group level, should represent, in some sense, an enduring commitment. Undoubtedly the import of this point will be greater, the more time and stress a project has involved for each participant, and the more impaired participants were. In most generic terms, it should mean that there be feedback to participants about results of the project in which they have been involved. For longer-term studies, or for a single project which is part of a larger program of linked studies, it may mean a need for periodic updates on the progress of the research. The most serious commitment of which I am aware has already been referred to (Julie Leibrich's '*A gift of stories'*). The resulting book, giving vivid insights into the life and difficult journeys of each of the persons portrayed therein, meant that the editor developed a close bond with all those people, a bond which will undoubdtedly be lifelong. Enduring comitment may be at a community level, or, for Maori, to the iwi or other group who collectively took part in a project. The extent of commitment needs to be worked out, according to the degree of involvement, and how close was the rapport developed during the project. In any case, research conclusions should not be considered as intellectually property 'owned' by the researcher or the funding body, but should be shared collectively with participants, probably in advance of publication.

[g] *Forensic situation/compulsory treatment situation*:- Persons who are involuntary patients in a psychitric facility under mental health law, are specially vulnerable. In New Zealand, the relevant legislation is the Compulsory Asssessment and Treatment Act (1992), an Act which overrides the Code of Health and Disability Services Consumers' Rights (derived from the Bill of Rights). A recent United Nations report[72] makes it clear that this act is implemented in New Zealand in a very draconian manner compared to its equivalent in many other countries, with excessive use and misuse of seclusion. Another special group, the substantial fraction of the prison population with serious mental health problems, are even more vulnerable. Such persons have lost fundmental rights of citizens, including, since 2010, the right to vote. In addition, I am told by a knowledgeable expert, that they have lost the right to compulsory treatment, a curious phrase, but actually a very serious issue. Reference to prisons in the Compulsory Asssessment and Treatment Act (1992), makes provision for *assessment* of prisoners, with no mention of compulsory treatment. Such administrative practices appear to be in breach of Article 12 of the 2006 UN Convention (Equal recognition before the law), which read [Point 2] that: 'States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.'

Any moves to rectify these shortcomings are in the political rather than the research realm. However, the history of medical ethics makes it clear that such vulnerable groups have been used for highly unethical research. Any suggestion that such persons now become participants in research without full ethical safeguards has to be strongly resisted. There is little documentation of issues arising for research consent in such populations. One study finds little difference in the willingness of psychiatric in-patients to give consent between involuntary patients and those with voluntary status[73]. Another study, of

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[72] United Nations (2014) *Convention on the Rights of Persons with Disabilities: Concluding Observations on the Initial Report of New Zealand.* 3rd October, 2014.

[73] van der Veer, NL, Drachman, D, Ahad, S, Silvers, G, Ramos, G. (2011) Voluntariness to consent to research in voluntary and involuntary hopsitlised psychiatric population. *Journal of Empirical Research on Human Research Ethics.* 6, 55-62.

30 mentally ill prisoners[74] found that almost all prisoners were able to make the decision, although, their capacity was reduced compared to a control group. However, for the prison group, the main reasons for willingness to participate was to relieve boredom, to meet someone new, a chance to help society and to show cooperativeness.

[h] *Research approaches which should* ***not*** *be attempted.* From all the above discussion, we are left with areas where research should not be attempted, nor consent sought. When a patient is acutely disturbed, it is not the time for systematic research study, although documentation of the events in such situations can of course be parts of clinical reports, as incidental aspects of interaction with mental health staff involved in treatment. I can speak in personal terms of such a situation, when, as a recently-admitted in-patient, I was approached about a research study, and refused point blank. The reason was that my capacity to fix my attention on *anything* was at the time so limited that, any demands of a research study would be too much. The situation becomes quite different if and when the same person has recovered, and can then give insightful reflection on the time when they were seriously disturbed. Experience has shown that a variety of do's and don't's apply to the consent process. An important 'don't's' is that consent obtained at one time, should not be subsequently backdated.

Research done equally well with people having full capacity, for instance fundamental research on biological mechanisms should not be undertaken on people with limited capacity. Under no circumstance should vulnerable groups be used by researchers for questionable research (envisaging that 'they will never complain'). Researchers might be surprised (and should be warned) how, in the fullness of time, just how forceful such once-silent persons can become, in their criticism of what they had been subjected to!

[i] *Independent ethics adjudicator.*

There are two possible roles to be defined here. One, mainly related to medical interventions, is the need for an independent, respected overseer in controversial situations (such as an emergency ethical decision). At a Bioethics conference in January 2014, one speaker at the Christchurch meeting had addressed issues around treatment of children with serious and/or life threatening conditions. She recognised the role of parents to seek the best interests of their child, and the potential for their personal views to act against this, for instance when Jehovah's Witnesses, refuse blood transfusion. 'That's a simple one – in a life-threatening situation a court can quickly decide on the best interests of the child. It's less straightforward when professionals and parents disagree on choice of treatment and/or the child is old enough to have his/her own views considered in decision making. It is even more complex when research is unlikely to benefit a particular child but may have the potential to benefit others, perhaps its own sibling(s). In a large teaching hospital where the speaker had worked, difficult situations could be referred to an independent ethics committee at short notice. That is not so easy in smaller places like most centres in Aotearoa New Zealand.

The second situation, applying more specifically to research has already been mentioned, the need for an inspector, or an inspectorate body, to ensure the probity of research using human participants.

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[74] Moser, DJ, Arndt,S, Kanz, JE, Benjamin,ML, Bayless, JD, Reese, RL, Paulsen, JS, Flaum,MA (2004) Coercion and informed consent in research involving prisoners. *Comprehensive Psychiatry*, 45,1-9.

XIII. Conclusions and Final Remarks

Let us sum up this long argument:-

When a difficult problem arises and protagonists seem to be doing a lot of 'fast footwork' to resolve discrepancies and inconsistencies in a conventional framework, perhaps we should all 'back off', look around, and seek a more detached view of the problem; in particular we should shift our attention from answers, to a dispassionate look at the question: Are there assumptions, perhaps hidden deep in the question itself, leading inevitably to insoluble conflicts, revealed only when we get close to implementation of its principles. For research involving particpants with limited capacity, several conflicts in underlying assumptions have been identified here:

- Autonomy *vs* beneficence;
- The demand for autonomy of participants *and* justice for all in access to research;
- Respect for individual autonomy *and* recognition that we are located in complex social networks;
- Disability/Vulnerability/Incapacity defined categorically, *vs* these seen as essential aspects of our collective shared humanity;
- Legal precision *vs* requirement for flexibility of human relationships;
- Legal protection at individual *vs* group levels;
- Administrator's power[75] *vs* ethical and moral probity;
- Human nature defined in relation on western concepts of rationalism *vs* that evolving in communal life in many traditional societies (which latter is arguably more compatible with neuroscience emerging after birth of the natural science tradition).

After discussing these conflicting principles we are led to more practical conclusions:-

(i) The four founding principles on which modern medical ethics is based are beneficence, non-malefience, justice and autonomy. The last of these is closely linked to the notion that a defining characteristic of human beings is rationality. The model of human nature so defined is rooted in ancient philosophy, and is unrealistic. A more plausible, more holistic model might be constructed today; and there are forerunners of this in scientific and psychiatric literature. Implications of adopting such a model would be profound, especially for jurisprudence and some aspects of economic theory.

(ii) Procedures for obtaining informed consent based on principles of autonomy and rationality which are problematic even in the best circumstances, become frankly impossible for persons whose capacity for decision making is impaired (a constraint, which strictly applies to us all at some times).

(iii) The modern history of bioethics related to research started from rulings at Nuremberg, and bioethics necessarily became legalistic, based on ancient traditions of western legal philosophy. Legal formalities and judicial sanctions *are* necessary to prevent extreme abuses, as exposed at Nuremberg, and some formalization of consent processes *is* needed in most routine research endeavours. Nonetheless, this needs to be

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[75] This essay may seem to be endlessly critical of administrators – but undoubtedly, we all need good adminstrators of health and social services, as well as good clinical and other front-line staff. My criticism is probably mainly against administrators who use their position to filfill agendas that are not a true part of the mission of those health and social services, such as an economic/financial philosophy, or, the mantra of 'effiiciency' without answering the question'to what end?'

combined with a more holistic, relational approach in many situations, especially for persons who are vulnerable, disabled, or have reduced capacity. This leads to several further implications:-

(iv) A distinction for legal statements may be needed between laws which are mainly impersonal, and those where all the subtleties of relational interaction between persons come into play. For the former, the rigour and exactness of legal style is needed; for the latter, a more flexible conceptualisation is better. This applies specifically to ethical principles for research on persons with limited capacity to give informed consent.

(v) 'Ethical codes' are different from legal statutes: They should be seen as guidelines, to be interpreted in contextualised manner, rather than as enforceable rules or laws. Researchers using human subjects, notably those without clinical training, need to internalise the morality underlying a relational approach to recruiting participants in human research. This may have an impact on how researchers are trained, and may require ethics committees to have ways to ensure that researchers have suitable attitudes and personal style for research with human particpants.

(vi) 'Consent', or whatever concept it is replaced by, should not be a one-off tick-box exercise: A continuing *process* of consent is needed, to build and sustain trust, and this should continue while ever a volunteer is engaged in a research project, and sometimes long after that, so that the currency of trust is not debased.

(vii) There is an inevitable power imbalance between researcher and volunteer, especially if the latter is reduced in his/her capacity. This may make it hard to build a relationship built on trust. That may in turn mean that a researcher should sometimes negotiate consent collectively with a *group* who are likely to participate in and benefit from the research (when the power imbalance is shifted), as well as individually.

(viii) There are obvious dangers as well as opportunities in fostering a relational approach to reseach participation and the consent process. The best safeguard against the danger is to add to the four principles on which bioethics is founded a fifth one: the ethic of transparency. For participants whose decision-making capacity is limited, this fifth principle assumes greater importance, as the autonomy pinciple loses its relevance.

(ix) What should be strongly resisted is single persons - researchers, clinical leaders, or ethicists - dictating the way rules are to be implemented, without scrutiny. Likewise the idea that bioethics is no more than 'following a code', should be resisted.

This esssay started from what seemed to be a difficult, yet confined and specialised topic; yet we have been drawn into fundamental questions of the concepts of human nature, of law, and of political and economic systems. I had a similar experience in another recent essay[76]; and again in trying to understand what has gone wrong with our systems for higher education (as I dug deeper into the subject), I had the same experience[77]. At our Christchurch discussion, Lynne Bowyer was also drawn to consider these larger over-riding issues of our times. In one of her Power Point slides, she referred to the 'Dominant Approach to Knowledge [which] separated, isolated and categorises, in order to code and order the world in a particular way, [the] system of ideas [which] underpins neo-liberal political and economic theory.' Wherever one starts, so it seems,

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[76] Miller,R. (2012). *B4 School Report: A Critique of a Child Health Screening and Intervention Programme*. www.robertmiller.octspan. org.nz

[77] Miller R. (2010) *The subversion of higher education: Origins, analysis, recommendations.* Lulu Enterprises, Morrinsville, NC

one is led towards the same flaws, the same paradoxes in guiding principles on which our societies are constructed today; and one begins to grasp the meaning of the phrase: 'All roads lead to Rome.' In analysis of philosophical and theological origins to the natural sciences, a similar line of reasoning was developed by the late Harold Turner (date) in his *Roots of Science*[78].

The specific case about informed consent comsidered here is but one example of larger tensions in human services between administrators or policitians and front-line workers. So often, we see tension between necessarily categorical thinking of the former which tends to minimize human diversity, and the flexible relational approach of those at the front line (in this case a researcher, or someone in role of mediator), accepting and even celebrating diversity. Ideally, when the latter encounter people who are alienated from society, the response should be: 'Welcome, we want to know you. There things we can learn from you.'

The tensions discussed here may seem novel, but when reduced to their most generic form, are very old. Tension between legalistic and holistic, relational interactions became inevitable once humans started to live in complex societies requiring legal codes. Lynne Bowyer captured the tension inherent in the very word *consent.* As a legal term, for her it 'is the mechanisms to regulate this sphere of interaction'; but she reminded us that its etymological origin is different, intrinscally relational: 'consent' (*con* – together; *sentire* – to feel); to 'feel together'.

The tension is defined in some of the best-known myths and phrases in the English language. The Biblical story from which we get the phrase 'the wisdom of Solomon' was a case of disputed custody of an infant, possibly our earliest example of a decision which could never be codified as statute law, but, in context, was a wise solution to a problem otherwise intractable according to the letter of the law. Another Biblical line, attributed to Jesus Christ, conveys the same message: *'The Sabbath was made for man, not man for the Sabbath'*[79]; or, from Friederich Nietzsche we have '*The most fundamental form of human stupidity is forgetting what we were trying to do in the first place'*[80]*;* or, from Aldous Huxley: *'Men are forever creating organizations for their own convenience and forever finding themselves victims of their home-made monsters'*[81].

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[78] Harold Turner (2009) *Roots of science.* Deepsight Trust.
[79] Mark 2:27
[80] Well-known quotation, Origin uncertain.
[81] Huxley, Aldous (1950) (Well-known quotation: exact reference not traced).