

**Special issue: Human rights**

## The human rights context for ethical requirements for involving people with intellectual disability in medical research

T. Iacono<sup>1</sup> & R. Carling-Jenkins<sup>2</sup>

<sup>1</sup> La Trobe Rural Health School, La Trobe University, Bendigo, Victoria, Australia

<sup>2</sup> Department of Social Work and Social Policy, La Trobe University, Melbourne, Victoria, Australia

### Abstract

**Background** The history of ethical guidelines addresses protection of human rights in the face of violations. Examples of such violations in research involving people with intellectual disabilities (ID) abound. We explore this history in an effort to understand the apparently stringent criteria for the inclusion of people with ID in research, and differences between medical and other research within a single jurisdiction.

**Method** The history of the Helsinki Declaration and informed consent within medical research, and high-profile examples of ethical misconduct involving people with ID and other groups are reviewed. The UN Convention on the Rights of Persons with Disabilities is then examined for its research implications. This background is used to examine a current anomaly within an Australian context for the inclusion of people with ID without decisional capacity in medical versus other types of research.

**Results** Ethical guidelines have often failed to protect the human rights of people with ID and other vulnerable groups. Contrasting requirements

within an Australian jurisdiction for medical and other research would seem to have originated in early deference to medical authority for making decisions on behalf of patients.

**Conclusions** Stringent ethical requirements are likely to continue to challenge researchers in ID. A human rights perspective provides a framework for engaging both researchers and vulnerable participant groups.

**Keywords** ethics, human rights, informed consent, intellectual disability

### Introduction

Since the Declaration of Helsinki (World Medical Association 2004), the conduct of research involving humans has come under the scrutiny of research ethics committees. This Declaration has formed the basis for guidelines developed in individual countries with the aim of protecting people from exploitation in the name of research (Stanley 1987). Hence, modern research ethics guidelines have the protection of human rights, especially of vulnerable groups, as a core underlying principle (National Health and Medical Research Council 2007). Strict, but often varied, interpretation and application of

Correspondence: Prof. Teresa Iacono, La Trobe Rural Health School, La Trobe University, PO Box 199, Bendigo, Vic. 3552, Australia (e-mail: t.iacono@latrobe.edu.au).

these ethical guidelines (Lai *et al.* 2006) are often met with protests from researchers arguing that they can compromise the rigour, feasibility or creativity of proposals (Richardson & McMullan 2007; Boxall & Ralph 2009), and result in intellectual disability (ID) being understudied (Lai *et al.* 2006). Such concerns can be identified readily in the ID literature, as in other fields of research from which the ID field draws (e.g. Bonnie 1997; McDonald & Keys 2008).

The aim here is to explore the development of ethical guidelines through an historical account marked by human rights violations, in an effort to understand requirements that risk the feasibility of research with vulnerable groups in general and people with ID specifically. In particular, we sought to explain an apparent contemporary anomaly in requirements for the inclusion of people with ID in medical versus other research that exists in the state of Victoria, Australia, and which appears to have its basis in the development of informed consent in medical practice. Our key premise is that an understanding of the historical context may shed light on motivations for what appear to be increasingly stringent application of ethics guidelines and overly protectionist requirements that are applied in ID research. The international literature presented has been selected to shed light on reasons for these apparently stringent guidelines, and differences in how consent, in particular, has been addressed for the inclusion of people with ID without capacity to consent to participate in medical as opposed to non-medical research within an Australian context.

### **From Nazi Germany to Helsinki: a history of ethical guidelines**

Early guidelines for ethical conduct of research were encapsulated in Germany's *Rundschreiben: Regulations on New Therapy and Human Experimentation* issued by the Third Reich, which became law in 1931 and were in effect over the period of World War II (Sass 1983). These guidelines, and indeed previous government-issued regulations in 1900 (Vollman & Winau 1996) addressed the ethics of innovative therapies and human experimentation. They included stringent regulations placing responsibility for the care of participants with healing

professionals, stressed the need for voluntary informed consent of the participant and called for documented justification for the conduct of research, especially that involving vulnerable populations (Sass 1983; Vollman & Winau 1996).

In practice, however, *Rundschreiben* provided no human rights protection for people with ID who were particularly vulnerable in Nazi Germany where eugenic, as well as racial, purity were espoused (Evans 2004). Approximately 400 000 people with various types of disabilities were forcibly sterilised to prevent their procreation, using inhumane experimental procedures (Evans 2004). A euthanasia programme was established, directed initially at children with hereditary conditions, such as Down syndrome. This programme occurred in a context of human experimentation by medical practitioners with vulnerable groups that was rife during the period, and not restricted to Germany. According to Baader *et al.* (2005), research was conducted on vulnerable groups who provided convenient 'subjects' as a result of growing collaboration between the military and universities, in particular in Germany, but also Japan and the USA. Faden & Beauchamp (1986) state that, however, while not the first examples of ethical misconduct in research, experiments in Nazi Germany were considered to be the most extreme and callous; they were exposed at the Nuremberg Trials. Atrocities in other countries have since been discussed in the literature on human ethics and human rights violations (e.g. see Bassiouni *et al.* 1981; Baader *et al.* 2005).

The Nuremberg Trials of 1945–1946 resulted in the formulation of the Nuremberg Code in 1948 (Faden & Beauchamp 1986). In an attempt to avoid future violations, this Code enshrined human rights into 10 standards that formed the basis for the Helsinki Declaration, which underlies modern ethical guidelines. The Helsinki Declaration was first endorsed by the World Medical Organisation in 1964, with further modifications occurring periodically (the last being in Tokyo, 2004; World Medical Association 2004). As with its predecessor, the Nuremberg Code, it comprises obligations of researchers to participants. These guidelines specifically address clinical research, but by forming the basis of many ethical guidelines, they have had a significant influence on social research ethics as well.

According to Eckenwiler *et al.* (2008), the Declaration was heralded widely as a cornerstone of human research ethics. It encapsulated principles of protection and respect for human participants in terms of (a) considering the implications of the research on their health, dignity and integrity; (b) requiring the conformity of the research to scientific principles; (c) the provision of information about ethical considerations (e.g. conflicts of interest, and access to beneficial interventions); and (d) ensuring the autonomy of decision about participation, particularly in relation to unequal or dependent situations between researchers and participants (World Medical Association 2004). It has formed the basis for guidelines developed in individual countries with the aim of protecting people from exploitation in the name of research (Stanley 1987) and ensuring physician–researchers meet their obligations to research participants (Shuster 1997).

Central to the Helsinki Declaration is informed consent, although a waiver or consent by a proxy is allowed under certain conditions for research involving persons without decision-making capacity, such as people with certain psychiatric conditions, children and people with ID (see Iacono & Murray 2003 for a review). Of relevance to understanding divergences in the conditions in which consent can be waived is the history of the emergence of informed consent, a core human rights issue.

### The core issue of informed consent in medical research

Principles of informed consent, as enshrined in the Helsinki Declaration, include ensuring a person has sufficient information to make a choice, is capable of making a decision about participation and is in a situation in which that decision can be made autonomously and voluntarily (Iacono & Murray 2003). Consideration of a person's entitlement to make an informed decision and freely consent to participate in medical research has its basis in medical practice (Faden & Beauchamp 1986; Stanley 1987). According to Faden & Beauchamp (1986), guidelines for informed consent, at least in the USA, have been strongly influenced by notions of a medical practitioner's therapeutic privilege supported by beneficence-based premises, concepts that

pervade discussions of international practices in medical research (Bassiouni *et al.* 1981; Baader *et al.* 2005; Powell 2006). Faden & Beauchamp (1986) noted that, in the USA, prior to the 1960s, '... although routine consent to consequential interventions such as surgery existed, practices of benevolent deception and nondisclosure shaped the professional norm of standard practice, and benevolent deception in the obtaining of consent was not unusual' (p. 76). It seemed, then, that medical practitioners felt they knew best and judged how much the patient should or needed to know to make the *right* decision. Faden and Beauchamp noted that informed consent did not arrive in medical practice in the USA until the 1960s, and was driven by malpractice suits that fuelled debates about decisional capacity and the doctor–patient relationship.

Certainly, examples of medical authority overriding principles of informed consent abound in the medical research literature. Of relevance to ID is the well-known series of studies conducted by Krugman, Giles and their colleagues involving active and passive immunisation for the prevention of viral hepatitis (Beecher 1966). In these studies, children from Willowbrook, a state school for children with ID, were injected with the hepatitis virus in order to track its progression.

A series of letters to the editors of *The Lancet*, the prestigious medical journal, highlighted the moral debate arising from these studies. Concerns were raised that they were immoral and unjustifiable in that they continued after effective immunisation had been developed (Pappworth 1971). Krugman (1971), in his defence, argued that the children were under no additional risk given the inevitability that all would contract the disease. His beneficence-based argument for their participation was that, by purposeful injection, the children would contract the disease in a mild form under controlled conditions and receive good care. By calling on his previous successes through his measles immunisation research, Krugman appeared to appeal to practitioner privilege and moral authority. Finally, Krugman argued that the parents had given consent to their children's participation. His detractors, however, felt such consent had been obtained through coercion, since parents feared losing their children's placements in the school (Goldby 1971; Pappworth 1971). In this way, the principle of

voluntariness of consent had been violated. The influence of the Helsinki Declaration of 1964 would seem questionable given that the Willowbrook experiments ended long after it had been endorsed by the World Medical Association (Freedman 2001). Similar atrocities against people with ID, as well as other vulnerable groups, conducted in the name of population health that occurred after the development of the Nuremberg Code, and during the development of the Helsinki Declaration, abound. These include radiation experiments on children with ID in the 1940s through to 1961, and the Tuskegee syphilis study involving low-income African-American men from 1932 to 1972 (Freedman 2001). Many of these studies appear to have come to light following journalistic investigations that resulted in public outcry (West 1998).

### Apparent ineffectiveness of ethical guidelines

There is no shortage of evidence that ethical misconduct has been rife even in the context of the Helsinki Declaration (for numerous early examples, see Beecher 1966). Any hope that stringent ethics requirements might guard against ethical misconduct in current times would seem misplaced in light of recent revelations reported in medical journals (Dyer 2008) and the popular press (Wallis 2010) about research into the association between receiving the combined measles–mumps–rubella (MMR) vaccination and autism. Wakefield *et al.* (1998) reported on an apparent association between MMR vaccination and the onset of autism on the basis of data from 12 consecutive patients with autism or other pervasive developmental disorders referred to a UK paediatric gastroenterology unit. These children underwent a series of intrusive medical tests, some requiring sedation. Data were compared to those from a control group of children (although details of these children were not provided). The study has since been discredited, both in the professional (Godlee 2011) and public (Wallis 2010) media.

In 2004, *The Lancet*, which had published the original Wakefield *et al.* (1998) study, took the unusual step of retracting it (Wallis 2010) following the mounting scepticism about the veracity of the

results (Miller 2009). There was growing evidence of Wakefield's dishonest conduct and exploitation of his young son's friends to provide a control group (Dyer 2008). Wakefield *et al.* (1998) reported having obtained approval from the Royal Free Hospital NHS Trust, and to have received parental consent; but apparently not for the collection of blood samples from his son's friends, many of whom experienced adverse events, thereby indicating a failure to fully inform the consenting parents. Godlee (2011) provided evidence that research misconduct was not limited to Wakefield, but extended to his 12 co-authors in terms of misrepresentation of the children's characteristics and medical conditions. She also called into question the failure of their institution (University College London) to conduct an investigation. The consequences of the research misconduct included both a public health crisis related to dramatic drops in MMR immunisation rates (Sugarman 2007; Miller 2009) and damage to the public reputation of Britain's universities (Godlee 2011).

Ethical misconduct of relevance to ID has not been limited to medical research. Barnes & Mercer (2003), for example, described the outcomes of a study initiated by people with disabilities living in LeCourt Cheshire Home (a supported accommodation facility in the UK) who requested support to gain increased control over their lives. They described the way residents were alienated, ignored and betrayed by researchers with a self-serving agenda. This sense of betrayal led residents to denounce this and other similar research. Most notable was Hunt's (1981) famous accusation that academic researchers in the disability field acted like parasites.

In summary, of major concern is that the unethical conduct of researchers documented in the literature and popular media has occurred within the context of international debate about ethical practices, development of guidelines and the existence of stringent requirements by institutions. On the other hand, perhaps such stringency is a relatively recent phenomenon and a direct outcome of publicity about extreme misconduct, including that affecting or involving particularly vulnerable groups, such as children with autism (Dyer 2008). Such misconduct has pointed to continued abuses of human rights, and the ongoing need for their

protection, particularly in relation to vulnerable groups, including people with ID.

### **Relevance to research of the UN Convention on the Rights of Persons with Disabilities**

In addition to guidelines for the ethical conduct of research, protection against exploitation in research for people with disability should also be afforded through the Convention on the Rights of Persons with Disabilities (CRPD). The CRPD is an expression of the moral and political commitment of signatories who are urged to use it to guide enactment of legislation and/or to policy formulation (UN Enable 2010). It gives formal recognition to the vulnerability of people with disability throughout the world. The CRPD is the first human rights convention to specifically and deliberately protect people with disabilities (Harpur 2012) and is considered to be a significant landmark in the struggle to reframe the needs of all people with disabilities in terms of human rights (Kayess & French 2008). Researchers in countries that are signatories to the CRPD therefore have obligations in addition to local research ethics requirements to protect the human rights of people vulnerable as a result of disability to the potential for exploitation through participation in research. These obligations include informed consent as an underlying principle, but extend beyond it. Stevenson (2010), for example, argued that the CRPD invites researchers to include people with ID into all aspects of civil society – including into a research partnership that emphasises collaboration, participation and a genuine inclusion in research processes. The CRPD does not address research conduct specifically, but does have much to contribute to the direction that research with people with disability should take. Kayess & French (2008), for example, promoted the CRPD as containing ‘entirely new or amplified formulations of human rights, including a number of collective or social group rights, such as the right to research and development . . .’ (p. 32). This right to research and development that addresses issues faced by people with disability is contained within the General Obligations (Article 4). Specifically, research is called for in the areas of universal design of goods, services,

equipment and facilities (Article 4 (f)) and the availability and use of new technologies including information and communicative technologies (Article 4 (g)).

Within the Convention’s preamble, links can be made with three of the five key principles set out by the Helsinki Declaration: (a) supporting the protection and respect of people with disability, citing recognition of discrimination and diversity as ongoing concerns; (b) endorsing the autonomy of people with disability through freedom of choice, and active involvement in decision-making processes; and (c) a call to recognise the need to protect people ‘who require more intensive support’ (p. 2) to participate in decision making. Such recognition gives a sound foundation for inclusion of people with ID in research through the implementation of respectful, inclusive and supported processes for ensuring informed consent. It stands directly opposed to research characterised by non-disclosure, deception and exploitation, as described previously.

Principles of ethical research involving people with disability can be garnered from a number of CRPD articles. In brief, the CRPD calls for the promotion of equality and elimination of discrimination, stipulating the obligation of States Parties to provide ‘reasonable accommodation’ (Article 5), which can be interpreted to include accommodating people with disability within research. The CRPD also focus on awareness raising (Article 8), a desired outcome of research achieved through publication and other forms of dissemination. In addition, it promotes accessibility to information, assistance and support (Article 9), implying the need for research having a practical outcome for people with ID and to ensure research documents, such as explanatory statements, are accessible (e.g. using plain language). The CRPD also: (a) promotes freedom from undue influence or conflicts of interest (Article 12); (b) promotes freedom from exploitation, violence and abuse through the implementation of disability-sensitive supports (Article 16); (c) upholds physical and mental integrity (Article 17); (d) supports societal participation (Article 30); and (e) advocates for access to information through all forms of communication (Article 21). Furthermore, Article 22 (Respect for Privacy) promotes the right to privacy of personal, health and rehabilitation records,

therefore addressing a key principle of the Helsinki Declaration.

Informed consent is mentioned twice in the CRPD: in Article 25 in reference to providing health care and in Article 15 in relation to medical and scientific research. Article 15 (Freedom from torture or cruel, inhuman or degrading treatment or punishment) states 'No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation' (p. 15). This article no doubt echoes concerns about the prolific practice of human experimentation during war time (Baader *et al.* 2005). Unfortunately, the CRPD fails to define free consent, thereby, at first glance, contributing little to continuing debates regarding informed consent of people with ID without decisional capacity. The CRPD does, however, confirm the legal capacity of people with disability in Article 12 (Equal recognition before the law): point 3 states that: 'States Parties shall take appropriate measures to provide access by persons with disabilities to the *support* they may require in exercising their legal capacity' (authors' italics). This section of the CRPD confirms the legal capacity of all persons with disabilities and calls for measures to support rather than substitute decision making. This focus on the provision of support in making decisions seems to call into question of the demand of ethics committees for proof of independent capacity for consent. Rather, researchers abiding by this requirement must assume decision-making capacity – either independently or with support – prior to seeking alternative methods of consent (such as proxy consent) which are contrary to the nuance of Article 12.

### **Guarding the human rights of people with intellectual disabilities unable to provide consent**

Protecting the human rights of people with ID, particularly those unable to consent for themselves, presents a particular challenge for researchers wishing to include them in research. Contrasting arguments address their right to contribute to research versus their right to be protected from

exploitation (Lai *et al.* 2006). Boxall & Ralph (2009) argued that stringent ethical requirements in the UK for social research have resulted from the Department of Health's response to high-profile cases of inappropriate medical research practices in two children's hospitals. The outcome, they argued, has been the stifling of participatory research, particularly that seeking to use creative ways to include people with severe ID. Scott *et al.* (2009) also pointed to ethical requirements from multiple committees that have created a complex process for obtaining informed consent from parents of children with ID to participate in research. The result was a 2-year delay with their project and considerable time and financial resources. Finally, Lai *et al.* (2006) argued that lack of understanding of ID and the attitudes of members of ethics committees towards the inclusion of people with ID in research, as well as their variable knowledge about ethical guidelines, have created unnecessary complexity for researchers, particularly when approval is needed from multiple committees. Informed consent has posed the greatest challenge for the inclusion of people with ID in research. Iacono & Murray (2003) discussed the complexities of identifying potential participants who may lack capacity for consent. Their review of the literature indicated a lack of consensus about criteria an individual should demonstrate to provide assurance of his or her capacity for consent, but that minimally, a person needed to be able to indicate a preference between options and to be able to communicate these options. Strategies to address issues of being truly informed in the presence of severe ID have required creative solutions, such as providing picture supports, as well as highly persuasive arguments to obtain approval from an ethics committee (see Iacono & Murray 2003).

To add to the complexities, and sometimes controversy, surrounding informed consent for people with ID, strategies to include them vary across jurisdictions. The Mental Capacity Act (2005) guides the inclusion of people in England and Wales lacking capacity to participate in research (Department of Health 2005), while the Adults with Incapacity Act 2000 (The Scottish Government 2008) covers their inclusion in Scotland (Dye *et al.* 2007). In England and Wales, for example, a proxy cannot provide consent for the person's par-

ticipation in research other than clinical trials, which are governed by a particular set of regulations (Dobson 2008). In other types of research, the researcher must demonstrate to the ethics review committee that procedures are in place to consult others who are independent of the study but significant in the proposed participant's life (Department of Health 2008), thereby suggesting a process in line with Article 12 of the CRPD, as discussed above. Such consultees must consider the likely feelings, wishes and values of the person about the research had he or she had the capacity to make an autonomous decision about participation. In contrast to a supported decision-making process, for example, in Canada (Bach & Rock 1996), the final decision is not made by the research consultee, but by the researcher following a process of appraisal in which the consultee's advice is considered, taking into account the requirements of the Mental Capacity Act (Dobson 2008). Even so, should the consultee consider that the person's feelings or wishes may be such that he or she may be likely to decline to take part in a study, the researcher is obliged not to include the person.

Consideration of direct benefit to the research participant can be traced back to early distinctions between therapeutic and non-therapeutic research (World Medical Association 2004). According to the Helsinki Declaration, therapeutic research has potential diagnostic or therapeutic value for the research participant; all other types of research still must have some scientific value. This distinction, as well as an ongoing deference to medical practitioner therapeutic privilege, appears to have led to an apparent anomaly in legislation guiding the inclusion of people without capacity for consent in research within Victoria, Australia, which is not apparent in other legislative frameworks governing research (e.g. Department of Health 2005; Dobson 2008).

### The Victorian anomaly

Within Australia, the National Health and Medical Research Council (NHMRC) provides guidelines for the ethical conduct of research (National Health and Medical Research Council 2007). These guidelines, based on the Helsinki Declaration, are followed by all universities, hospitals and many

government and non-government bodies, with compliance determined by human research ethics committees (HREC) (Iacono 2006). The most recent NHMRC National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council 2007) acknowledges the rights of people with ID to consent to their own participation in research (s4.5.5), or, if incapable of providing consent, the obligation of the researcher to explain the research and what participation involves to that person as far as is possible (s4.5.8). The Australian National Statement has been applauded for being one of the few international examples of direct provision for the inclusion of people with ID (as well as those with 'mental impairment'), which places the onus on committees to weigh the benefits against risks (Lai *et al.* 2006). However, the focus is still on individual decisional capacity and there is a lack of clarity regarding the provision of approval for participation when a person is deemed to lack such capacity. In this situation, the National Statement also allows for consent to be provided on the person's behalf by that 'person's guardian or any person or organisation authorised by law' (S4.5.5; National Health and Medical Research Council 2007). In the state of Victoria, the process of identifying who can provide such consent on behalf of the individual is guided by the Guardianship and Administration Act (Victorian State Government 1986), under 42S within the context of Consent for Medical Research Procedures. Here, consent can be provided by 'the person responsible' for the person with disability, defined according to a hierarchy (Section 37). This hierarchy includes (among others) an individual appointed by a Victorian statutory body as a guardian, a spouse or domestic partner, a primary carer or a nearest relative.

A problem arises in situations in which there is no one who fits any of the categories of person responsible, or when such a person cannot be located or is non-responsive to attempts to contact. For medical research, including that considered high risk, procedural authorisation can be provided through a process whereby a medical practitioner involved in the research completes a form and lodges it with the Victorian Office of the Public Advocate. This is a process of notification rather than consent, and places decisional responsibility with the medical member of the research team.

For research that is not medical in nature (e.g. psychological or social), and, hence, does not involve medical procedures, there is no clear means of enabling participation of a person with ID unable to provide informed consent, and for whom there is no guardian or next-of-kin available. This includes both research that may be considered intrusive (e.g. accessing personal or health records, or direct observations with or without video recording) in other jurisdictions, such as under the Mental Capacity Act for England and Wales (Department of Health 2005), or low risk, such as under the National Health and Medical Research Council (2007) for Australia. For these individuals, the National Statement (National Health and Medical Research Council 2007) indicates consent can be provided by a person authorised by law: however, such authorisation for the purpose of participation in non-medical research does not occur in practice. A possible alternative is to allow paid support workers who are often responsible for day-to-day care to provide such consent or at least acknowledgement of participation, but they have been excluded by the Guardianship and Administration Act (Victorian State Government 1986), albeit in the context of medical research. The Act is silent on the issue of consent for non-medical research.

An option is for a HREC to allow the requirement of consent to be waived in the situation of there being no available person responsible. For low-risk research, particularly that requiring access to personal or health information that does not require direct involvement of the individual and is deemed to be in the public interest, such a waiver is allowable according to the National Statement (National Health and Medical Research Council 2007; S2.3.5) and Victorian privacy requirements in relation to health records (Office of the Health Services Commissioner (Victoria), 2002). However, waiving the need for consent in situations that require direct involvement of the individual (e.g. non-intrusive health checks, psychological testing, direct observation within the home) could be argued to violate the person's human rights according to Article 25 of the CRPD.

It is evident therefore that within Australia at least, ethics guidelines relating to medical research, including that considered high risk, provide a direct

process for the inclusion of people with ID who are unable to provide consent and have no next-of-kin. In doing so, deference is made to the judgement of a medical practitioner – researcher, arguably reflecting the history of informed consent in medical research (Faden & Beauchamp 1986). A parallel process is not evident in Australia for non-medical research (e.g. psychological and social), including that considered low risk, as is the case in England and Wales (Department of Health 2008). For such research, the onus is on the researchers to put their case to the HREC. It is our experience that HRECs are often unaware of their role afforded by the National Statement (National Health and Medical Research Council 2007) in making the decision as to whether a waiver of consent can be considered after weighing the risks against the benefits of the research. As a case in point, presentation of information regarding the anomaly that exists in Victoria, as presented here, resulted in two HRECs, one university-based and the other State government, reviewing their own role in allowing the inclusion of people unable to consent in research when there was no person who could provide consent according to existing legislation.

### Can researchers be trusted?

Many researchers have expressed despair at the apparent over-regulation by ethics committees of research involving people with ID (Masterton & Shah 2007; McDonald & Keys 2008; Boxall & Ralph 2009; Scott *et al.* 2009). In addition, Lai *et al.* (2006) argued that ethics committee members are often untrained, which Iacono (2006) suggested could be addressed only by researchers in ID providing an educative role when interacting with committees. The authors' recent experiences in supplying ethics committees with the results of their own detailed research into complex legislation and policy, as presented here, suggest a need for this role. Unfortunately, recent cases of serious research misconduct (e.g. Dyer 2008), with their adverse consequences for both participants and the larger community, only serve to heighten public distrust of researchers, and may increase the stringent application of ethical guidelines by review committees or encourage overly protectionist attitudes of



members (Lai *et al.* 2006). This stance is additionally regrettable as such breaches, while well publicised and thus in the forefront of public consciousness, represent only a small proportion of research conducted in the area of disability. Still, unethical practice could occur in more subtle forms.

### Advancing research in intellectual disabilities

The Australian National Statement (National Health and Medical Research Council 2007), in discussing the importance of informed consent, provided a reminder to researchers that adherence to ethical guidelines should be considered more than a formal requirement. It is suggested that, minimally, researchers engage in communication with participants to ensure mutual understanding of the research. Implicit in this suggestion is the need for researchers to develop an understanding of the intent of ethical guidelines to uphold the human rights of participants by respecting their autonomy (see also Dalton & McVilly 2004). The onus remains on the researcher to convince, not only ethics committees, but also the public, that research is a trustworthy endeavour conducted by researchers who understand and seek to address ethical issues in a way that honours the human rights of people with ID. Strategies that are likely to convince ethics committees and the public of their intent to respect the human rights of people with ID include engaging not only potential participants with ID, but also those who support them and to consider their roles in supporting their decision to participate or not. Established researchers may further advance research in ID by educating new researchers about the history of ethical guidelines and their intent to uphold the human rights of participants, as has been documented here, rather than simply ensuring they manage to navigate the ethics system (Masterton & Shah 2007).

### Concluding remarks

The history of ethical guidelines and ethical misconduct that has resulted in public reactions, with the potential negative influence on community attitudes towards research, may go some way to

explaining the stringent requirements placed on researchers in ID by ethics review committees. In addition, early debates about informed consent and resulting requirements were situated in both medical practice and medical research, thereby explaining contemporary requirements within one Australian jurisdiction. In light of this history, it would seem unlikely that ethical requirements will become less stringent. The additional challenge for researchers therefore is to continue to contribute to the knowledge base in the shadow of infamous studies that have exploited vulnerable groups, including, but not limited to, people with ID. Key strategies include ensuring an understanding and valuing of the intent of ethical guidelines to respect the human rights of all participants, with particular care needed for those vulnerable to exploitation. Further, there is a need for established researchers in ID to pass on this understanding and respect to new generations of researchers, as well as to work with and educate ethics committees. It is incumbent upon researchers to embrace these responsibilities as ethical practitioners in the field of ID, even though such a task appears daunting.

### Acknowledgement

This paper is based, in part, on an invited presentation at the Australasian Society for Intellectual Disability, Hobart (November, 2009).

### References

- Baader G., Lederer S., Low M., Schmaltz F. & Schwerin A. V. (2005) Pathways to human experimentation, 1933–1945. *Osiris* **20**, 205–31.
- Bach M. & Rock M. (1996) *Seeking Consent to Participate in Research from People Whose Ability to Make An Informed Decision Could Be Questioned: The Supported Decision-Making Model*. The Roeher Institute, Ontario.
- Barnes C. & Mercer G. (2003) *Disability*. Polity Press, Cambridge.
- Bassiouni M., Baffes T. & Evrard J. (1981) An appraisal of human experimentation in international law and practice: the need for international regulation of human experimentation. *The Journal of Criminal Law and Criminology* **72**, 1597–666.
- Beecher H. (1966) Ethics and clinical research. *New England Journal of Medicine* **274**, 1354–61.

- Bonnie R. (1997) Research with cognitively impaired subjects: unfinished business in the regulation of human research. *Archives of General Psychiatry* **54**, 105–11.
- Boxall C. & Ralph S. (2009) Research ethics and the use of visual images in research with people with intellectual disability. *Journal of Developmental and Intellectual Disability* **34**, 45–54.
- Dalton A. & McVilly K. (2004) Ethics guidelines for international, multicenter research involving people with intellectual disabilities. *Journal of Policy and Practice in Intellectual Disability* **1**, 57–70.
- Department of Health (2005) *Research Governance Framework for Health and Social Care*. Department of Health, London. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962) (retrieved 4 June 2012).
- Department of Health (2008) *Guidance on nominating a consultee for research involving adults who lack capacity to consent: issued by the Secretary of State and the Welsh Ministers in accordance with Section 32(3) of the Mental Capacity Act 2005*. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_083131](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131) (retrieved 30 May 2012).
- Dobson C. (2008) *Conducting Research with People not Having Capacity to Consent to Their Participation: A Practical Guide for Researchers* (ed. The British Psychological Association). The British Psychological Association, Leicester.
- Dye L., Hare D. & Hendy S. (2007) Capacity of people with intellectual disabilities to consent to take part in a research study. *Journal of Applied Research in Intellectual Disabilities* **20**, 168–74.
- Dyer O. (2008) Wakefield admits fabricating events at children's party. *British Medical Journal* **336**, 850.
- Eckenwiler L. A., Eells C., Feinholz D. & Schonfeld T. (2008) Hopes for Helsinki: reconsidering vulnerability. *Journal of Medical Ethics* **34**, 765–6.
- Evans S. E. (2004) *Forgotten Crimes: The Holocaust and People with Disabilities*. Ivan R. Dee, Chicago, IL.
- Faden R. & Beauchamp T. (1986) *A History and Theory of Informed Consent*. Oxford University Press, New York.
- Freedman R. I. (2001) Ethical challenges in the conduct of research involving persons with mental retardation. *Mental Retardation* **39**, 130–41.
- Godlee F. (2011) Institutional research misconduct. Failings over the MMR scare may need parliamentary inquiry [Editorial]. *British Medical Journal* **343**. Available at: <http://www.bmj.com/content/343/bmj.d7284> (retrieved 10 July 2009).
- Goldby S. (1971) Experiments at the Willowbrook state school [Letter to the Editor]. *The Lancet* **213**, 749.
- Harpur P. (2012) Embracing the new disability rights paradigm: the importance of the Convention on the Rights of Persons with Disabilities. *Disability and Society* **27**, 1–14.
- Hunt P. (1981) Settling accounts with the parasite people: a critique of 'A Life Apart' by E.J. Miller and G.V. Gwynne. *Disability Challenge* **1**, 37–50.
- Iacono T. (2006) Ethical challenges and complexities of including people with intellectual disability as participants in research. *Journal of Intellectual and Developmental Disability* **31**, 173–9.
- Iacono T. & Murray V. (2003) Issues of informed consent in conducting medical research involving people with intellectual disabilities. *Journal of Applied Research in Intellectual Disability* **15**, 41–52.
- Kayess R. & French P. (2008) Out of darkness into light? Introducing the Convention on the Rights of Persons with Disabilities. *Human Rights Law Review* **8**, 1–34.
- Krugman S. (1971) Experiments at the Willowbrook State School [Letter to the Editor]. *The Lancet* **213**, 966–7.
- Lai R., Elliott D. & Oullette-Kuntz H. (2006) Attitudes of research committees towards individuals with intellectual disabilities: the need for more research. *Journal of Policy and Practice in Intellectual Disabilities* **3**, 114–18.
- Masterton G. & Shah P. (2007) How to approach a research ethics committee. *Advances in Psychiatric Treatment* **12**, 220–7.
- McDonald K. & Keys C. (2008) How the powerful decide: access to research participation by those at the margins. *American Journal of Community Psychology* **42**, 79–93.
- Mental Capacity Act (2005) *Department for constitutional affairs*. Available at: <http://www.dca.gov.au> (retrieved 30 May 2011).
- Miller L. (2009) Autism and vaccination – the current evidence. *Journal for Specialists in Pediatric Nursing* **14**, 166–72.
- National Health and Medical Research Council (2007) *National Statement on Ethical Conduct in Human Research*. Australian Government, Canberra.
- Office of the Health Services Commissioner (Victoria) (2002) *Health Records Act 2001 (Vic.): statutory guidelines on research*. Available at: <http://www.health.vic.gov.au/hsc/downloads/guideres.pdf> (retrieved 10 July 2005).
- Pappworth M. (1971) The Willowbrook experiments [Letter to the Editor]. *The Lancet* **213**, 1181.
- Powell T. (2006) Cultural context in medical ethics: lessons from Japan. *Philosophy, Ethics, and Humanities in Medicine*. Volume 12006. Available at: <http://www.peh-med.com/content/1/1/4>. (retrieved 6 June 2012).
- Richardson S. & McMullan M. (2007) Research ethics in the UK: what can sociology learn from health? *Sociology* **41**, 1115–32.

- Sass H.-M. (1983) Reichrundschriften 1931: Pre-Nuremberg German regulations concerning new therapy and human experimentation. *Journal of Medicine and Philosophy* **8**, 99–112.
- Scott J., Wishart J. & Bower D. (2009) Do current consent and confidentiality requirements impede or enhance research with children with learning disabilities? *Disability and Society* **21**, 273–87.
- Shuster E. (1997) Fifty years later: the significance of the Nuremberg Code. *The New England Journal of Medicine* **337**, 1436–40.
- Stanley B. (1987) Informed consent in treatment and research. In: *Handbook of Forensic Psychology*, 1st edn (ed. I. Weiner & A. Hess), pp. 63–85. John Wiley & Sons, New York.
- Stevenson M. (2010) Flexible and responsive research: developing a rights-based emancipatory disability research methodology in collaboration with young adults with down syndrome. *Australian Social Work* **63**, 35–50.
- Sugarman S. (2007) Cases in vaccine court – legal battles over vaccines and autism. *New England Journal of Medicine* **357**, 1275–7.
- The Scottish Government (2008) *Adults with Incapacity (Scotland) Act 2000. Revised code of practice for persons authorised under intervention orders and guardians*. Available at: <http://www.scotland.gov.uk/Publications/2008/03/18094148/14> (retrieved 30 March 2012).
- UN Enable (2010) *Convention on the Rights of Persons with Disabilities*. UN Enable. Available at: <http://www.un.org/disabilities/default.asp?id=150> (retrieved 5 March 2009).
- Victorian State Government (1986) *Guardianship and Administration Act (Vol. 58/1986)*. Victorian State Government, Melbourne.
- Vollman J. & Winau R. (1996) The Prussian Regulation of 1900: early ethical standards for human experimentation in Germany. *IRB: Ethics and Human Research* **18**, 9–11.
- Wakefield A., Murch S., Anthony A., Linnell J., Casson D., Malik M. *et al.* (1998) Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *The Lancet* **351**, 637–41.
- Wallis C. (2010) Debunked. *Time* **175**, 18.
- West D. (1998) Radiation experiments on children at the Fernald and Wrentham schools: lessons for protocols on human subject research. *Accountability in Research* **6**, 103–25.
- World Medical Association (2004) *Declaration of Helsinki: ethical principles for medical research involving human subjects*. Available at: <http://ohsr.od.nih.gov/guidelines/helsinki.html> (retrieved 7 July 2009).

Accepted 6 August 2012

This document is a scanned copy of a printed document. No warranty is given about the accuracy of the copy. Users should refer to the original published version of the material.