Ethical Research with Vulnerable Populations: The Developmentally Disabled

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A. Introduction

Although developmental disorders have often been included in a broad notion of “mental disorder” based on cognitive impairment, general definitions of developmental disability neglect important and unique characteristics of this population that affect both their capacity to make autonomous choices and the ability of others to help them improve their lives. Whereas all mentally retarded individuals have a level of intellectual functioning that places them in the lowest 2.5% of the population, developmental disabilities impair intellectual activity to a much more varying extent. This fact distinguishes the developmentally disabled from the other vulnerable populations. Children show an increasing capacity to make decisions. The elderly, while presumably fully competent for most of their lives, may potentially exhibit the opposite

1 See, for example, the definition for mental disorder in DSM IV. See American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 4th ed. (Washington, D.C.: A.P.A., 1994) [hereinafter DSM IV] at xxi-xxii. The Office for Protection from Research Risks defines the “cognitively impaired” as those persons:

[h]aving either a psychiatric disorder (e.g. psychosis, neurosis, personality or behaviour disorders), an organic impairment (e.g. dementia), or a developmental disorder (e.g. mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.


tendency of decreasing decision-making capacity. The mentally disordered have been characterized as having fluctuating periods of lucidity, and may have been mentally competent at some point in their lives. The developmentally disabled, however, have never possessed and are never likely to possess sufficient competence to make all decisions regarding their own welfare. And in cases where such persons are institutionalized, the voluntariness of their decisions to participate in an experiment may be cast into doubt.

Any discussion with regard to the participation of developmentally disabled persons in non-therapeutic biomedical research must therefore, address issues of competence and voluntariness. A policy governing experimentation on this population must also aspire to maximize and assist the decision-making capacity of such individuals. But before addressing these issues, it is important to define this population in light of its special characteristics.

B. Definitions

Members of special populations are not all equally vulnerable. This is no less true of the developmentally disabled where disorders include a broad range of conditions such as Mental Retardation, “Pervasive Developmental Disorders” (e.g. Autistic Disorder), 3 Learning Disorders, Motor Skills Disorders, and Communication Disorders. 4 Each disability has characteristics that will require the researcher to adjust the approach taken to assess the person’s ability to make decisions. For the purposes of this discussion, the category of Mental Retardation is the one which is most likely to generate concerns about the capability of a potential subject to give a valid consent to participation in biomedical research. According to the DSM IV, the criteria for this condition are the following:

… significantly subaverage general intellectual functioning (Criterion A) that is accompanied by significant limitations in adaptive functioning in at least two of the following skill areas: communication, self-care, home living, social/interpersonal skills, use of community resources, self-direction, functional academic skills, work, leisure, health and safety (Criterion B). The onset must occur before age 18 years (Criterion C). 5

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3 Pervasive Developmental Disorders are characterized by “severe deficits and pervasive impairments in multiple areas of development. These include impairment in reciprocal social interaction, impairment in communication skills, and the presence of stereotyped behaviour, interests, and activities.” See DSM IV, supra note 1 at 38.
4 Ibid. at 37-39.
5 Ibid. at 39.
This category covers a broad range of disabilities which, according to the *DSM IV*, can exist in four degrees of severity, reflecting the level of intellectual impairment:

- **Mild Mental Retardation**, which reflects an IQ level from 50-55 to approximately 70; approximately 85% of all those persons with Mental Retardation fall within this particular group;

- **Moderate Mental Retardation**, which reflects an IQ level from 35-40 to 50-55; individuals in this group constitute about 10% of all those affected by Mental Retardation;

- **Severe Mental Retardation**, which refers to those individuals with an IQ level from 20-25 to 35-40: this group constitutes some 3% to 4% of all individuals with Mental Retardation; and

- **Profound Mental Retardation**, which reflects an IQ level that is below 20 or 25; this group comprises only 1% to 2% of people with Mental Retardation.\(^6\)

Another widely accepted definition of mental retardation is that of the American Association on Mental Retardation (“AAMR”):

Mental retardation refers to substantial limitations in present functioning. It is characterized by significantly sub-average intellectual functioning, existing concurrently with related limitations in two or more of the following applicable adaptive skill areas: communication, self care, home living, social skills, community use, self-direction, health and safety, functional academics, leisure, and work. Mental retardation manifests before age 18.\(^7\)

This definition focuses on a functional construct requiring that the intellectual impairment be accompanied by related limitations in particular skill areas.\(^8\) This requires researchers to consider the individual in the context of a specific experiment.

Although there is considerable variation in their levels of intellectual impairment, developmentally disabled persons share certain characteristics:\(^9\)

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\(^6\) *Ibid.* at 40-42.

\(^7\) This is a recent revision of the AAMR’s definition of mental retardation. Mental retardation previously referred to a “significant sub-average general intellectual functioning existing concurrently with deficit inadaptive behaviour and manifested during the developmental period.” See American Association on Mental Retardation, *Mental Retardation: Definition, Classification and Systems of Supports*, 9th ed. (Washington, D.C.: American Association on Mental Retardation, 1992).

\(^8\) See Ellis, *supra* note 2 at 1782.

(i) There is a deficit in basic knowledge; they often lack basic information that is relevant to making a decision. This means enhanced duties at the information stage of the consent process.

(ii) Communication skills are greatly impaired. Researchers cannot assume silence is either a lack of comprehension or an assent.

(iii) The individual often denies the disability preventing him or her from seeking help in making a decision when such help may be badly needed.

(iv) There is a reduced ability to make decisions. For example, the individual may impulsively seize on the first solution regardless of consequences when faced with decisions which require a greater degree of assertiveness, or which could have major consequences, or in which options for action are not clear. ¹⁰

(v) The settings in which the individual is asked to make a decision may be so coercive as to call into the question the legal adequacies of the decision the individual is asked to make.

(vi) The disability is permanent in the sense that the intellectual impairment is not “curable” or “changeable” in the ordinary sense of those terms, although significant changes may occur over the lifespan of the person and the ability to make choices may be affected by successful special education programs or environmental changes. ¹¹

There is a significant likelihood that individuals with Mental Retardation will also be affected by some other form of mental disorder. According to DSM IV,

Individuals with Mental Retardation have a prevalence of comorbid mental disorders that is estimated to be three to four times greater than in the general population. In some cases, this may result from a shared etiology that is common to Mental Retardation and the associated mental disorder (e.g., head trauma may result in Mental Retardation and in Personality Change Due to Head Trauma). All types of mental disorder may be seen and there is no evidence that the nature


¹¹ See Ellis, supra note 2 at 1784-6
of a given mental disorder is different in individuals who have Mental Retardation.12

The DSM IV also points out that diagnosing comorbid mental disorders may be complicated by “the fact that the clinical presentation may be modified by the severity of the Mental Retardation and associated handicaps.”13 For example, poor communication skills manifested by a person with Mental Retardation may render it impossible to acquire the personal history adequate for an accurate diagnosis. Indubitably, it is vital that any assessment of an individual’s capacity to participate in biomedical experimentation should be extremely sensitive to the possibility that the individual may belong to more than one special population. In such cases, the individual is entitled to the protections applicable to all of the groups to which he or she belongs.

C. Issues For The Developmentally Disabled

C. 1. Historical Influences

It is not necessary to reach far back into history to encounter a period during which the central question raised by biomedical research was not whether it was appropriate for the developmentally disabled to participate in such research but whether such persons were suitable subjects for experimentation.14 Unfortunately, this suitability was greatly enhanced by the widespread practice of institutionalization, which itself was a product of common prejudices supported by crude scientific theories.

C. 1. (a) The Effect of Institutionalization

In a “vignette” of the work of the Vineland Training School,15 Crissey discussed the utilization of the family-history chart developed at

12 See DSM-IV, supra note 1 at 42.
13 Ibid. at 42-43.
14 On the question of the suitability of the institutionalized disabled for research, it is apparent from a summary of conference proceedings of the National Association for Retarded Children that, as recently as 1964, there was a consensus that the challenge in this area, especially in the case of isolated rural institutions not directly affiliated with a major university or general hospital, was to attract researchers and the financial assistance provided by research grants. It was further agreed that this could be done by encouraging the research community to regard such a facility as a “ready-made laboratory” in which environmental controls and the establishment of control groups was more easily accomplished than in other settings. See E. Hart, The Role of The Residential Institution in Mental Retardation Research (Report of the Conference Sponsored by The National Association for Retarded Children, 23-25 May 1964) at 8-11.
the Eugenics Record Office of the Cold Spring Harbor Laboratory and the scale of mental levels brought from Paris by the School’s director, Goddard. This scale enabled the School’s staff to “confirm” through “scientific means” the commonly-held belief that developmental disability was principally of hereditary origin. This dogma fueled the notion that the risk of being affected by such a disability could be safely ruled out for the great majority of the population; as a consequence, the problems and concerns of the developmentally disabled were marginalized. Society as a whole sanctioned the physical segregation of the developmentally disabled from others, as well as widespread programs for sterilization and other “treatments” that health care professionals would certainly not have regarded as being suitable either for themselves or for their families.

Physical segregation and the gathering of the developmentally disabled in institutions made them particularly convenient subjects for a broad range of protocols unrelated to their particular disabilities. There are several notorious examples of abusive research that was undertaken with the developmentally disabled, including the Fernald School radiation experiments.\textsuperscript{16} Institutionalization was considered to be such a significant factor in the creation of conditions permitting abuse that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research identified it as a necessary condition for inclusion of potential subjects in the special populations that were being reviewed. Yet, the Commission did not investigate the particular needs and vulnerabilities of either the developmentally disabled or psychiatric patients except to the extent that they were “Institutionalized as Mentally Infirm.”\textsuperscript{17}

The developmentally disabled represent a vulnerable population whose interests and needs cannot be assimilated to those of the majority at some point in their lives. Decisions about their involvement in research must therefore be based on something other than a pragmatic or consequentialist rationale. Unlike “normal” children, the developmentally disabled will not become the providers for today’s adult generation in their old age and, unlike the elderly, they at present do not motivate the majority to develop techniques and patterns of care from which ultimately they themselves hope to benefit. Indeed, it is a sad comment that, in the


past, this lack of a pragmatic or consequentialist interest in the needs of the developmentally disabled has often removed them from human reference points and reduced the evaluation of research into their health needs to a mere cost-benefit analysis.

Those who set the objectives and standards for research involving the developmentally disabled have done so, historically, on the basis of limited personal experience with their particular fears, aspirations, dislikes, and desires. As their perceived differences from the majority of the population once justified institutionalizing the developmentally disabled in remote rural facilities, it was rare for those who had not themselves experienced a form of developmental disability to have encountered a disabled individual in “normal” social interactions and to have acquired insight into their special interests and needs.

C. 1. (b) The Impact of Deinstitutionalization

Much has changed over the past few decades. The trend towards deinstitutionalization and integration within the community has meant that developmentally disabled persons are much more likely to be known and understood as individual members of families in private households, or as residents of group homes, than as inmates of distant institutions. This has greatly increased the hope that the interests of this special population will be addressed not only in terms of their need for protection as research subjects, but also in terms of the value and quality of the research conducted, as well as the global allocation of research resources.

If we are incensed by inmates’ being subjected at institutions like Willowbrook to non-consensual participation in biomedical research, then we should be similarly troubled by the research design and the use subsequently made of studies conducted in institutions such as the Vineland Training School. These studies were motivated by the ill-treatment of those deemed “retarded,” and in turn were actually used to

18 During the conference of the National Association for Retarded Children referred to supra, “the question was raised whether it is appropriate to establish an animal laboratory within an institution [for disabled children]. On the positive side, it was pointed out that ideas gained from the behaviour of children may be explored and studied in animals and that juxtaposition has heuristic virtues.” See Hart, supra note 14 at 11.

19 Conference participants recognized that continued delay in developing the full potential for collaborative research activities within institutions means that many individuals are bearing the impact of retardation, and society is bearing the cost of services for such individuals, unnecessarily. Ibid.

20 The trend towards deinstitutionalization is observed in the United Kingdom as well as in Canada. See The Law Commission, Mentally Incapacitated Adults and Decision-Making: A New Jurisdiction (Consultation Paper No. 128) (London: HMSO, 1992). at para. 2.2.
justify that treatment. The developmentally disabled were abused not only as a consequence of their involuntary exposure to an unacceptable degree of risk in the research of this era, but also by virtue of the nature of the treatment that was “indicated” by the results of these studies.

In marked contrast, during more recent times, the reintegration of the developmentally disabled into the community has helped to create a group of competent lay persons who possess a special insight into the health care needs of this special population and who have a particular interest in influencing the direction of future research. They can point out the political short-sightedness that neglects public health concepts of prevention and early intervention in favour of crisis management. Most importantly, they advocate habilitation within a developmental model that stresses learning life skills, but much remains to be learned about how this can be effected. When members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research visited the Eunice Kennedy Shriver Mental Retardation Research Centre, they were particularly impressed by three facts:

1. There was a large number of individuals with retardation over age 21 who were in a consent limbo: they were clearly incompetent to make decisions, but no guardian had been appointed for them by a court and often there was not an involved parent;

2. There was a lack of a clear transitional line from innovative research or training to standard practice; and

3. The patients they saw made them question whether it was ethical not to conduct research when there is a clear need to improve the care and training of persons with retardation, not only to prevent mental retardation but to avoid placement in an institutional setting.22

Ironically, the global improvement in the lot of this special population has transformed a concern for the financial burden they placed on society for their care into a complaint about the increased cost of undertaking research. It was once asserted that medical research should be considered economically prudent insofar as it reduced the need to


maintain the developmentally disabled in rural institutions. Today, the complaint is increasingly being expressed that deinstitutionalization and enhanced requirements for consent has made recruiting research subjects a much more onerous task and, in some cases, has actually cast doubt on the perceived cost-efficiency of conducting any research whatsoever into the specific needs of the developmentally disabled.

While it may provide satisfaction to those concerned with preventing abuse to discover that both the challenge to find willing subjects and the enhanced procedural protections now entrenched in enrolling them may deter abuse, it is nevertheless sobering to bear in mind the other, perhaps more subtle and damaging, form of abuse found in the neglect of, and indifference to, the particular needs of this population.23 A quarter of a century ago, Haywood spoke of “the right of mentally retarded persons, as well as of other persons, to the best methods of care, treatment, education, and habilitation that we have the power to give them,” adding that the right not to participate in research may come into direct conflict with the impetus to achieve concrete improvements in these areas.24 It may seem axiomatic, in light of current ethical principles, that members of a special population should enjoy the benefits of high standards of care regardless of their participation in research. Nevertheless, the potential of enhanced procedural safeguards in recruiting subjects to restrain the pace at which medical advances are accomplished should spur those concerned with the welfare of the developmentally disabled to ensure that these safeguards are limited to those measures truly necessary to preserve the safety and dignity of the individuals involved.

The inherent magnitude of this dilemma is reflected in the fact that it was one of the underlying reasons for the failure of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to have its Recommendations for those Institutionalized as Mentally Infirm be implemented as concrete regulations. The Commission’s proposed regulations, influenced by its concern that too little research was being undertaken into the needs of the developmentally disabled, were subsequently rendered far more stringent by the Department of Health, Education & Welfare (DHEW) and, in turn,

23 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was given the mandate to examine a variety of populations that were potentially in need of regulatory protection against abuse in research. However, it was impressed in its consideration of mentally retarded persons by the ignorance relating to the care and treatment of these persons and it was anxious to make recommendations that did not unnecessarily impede the research it believed critical to improved diagnosis and treatment of mental disabilities. Ibid. at 48-50.

the resulting popular protest on the part of researchers and advocacy
groups effectively prevented regulation in this area.\textsuperscript{25} A general
requirement that Institutional Review Boards (IRBs) should ensure that
“appropriate additional safeguards have been included in the research
protocol in order to “protect the rights and welfare” of research subjects\textsuperscript{26}
has encouraged these IRBs to consider both the National Commission’s
original Proposal and the DHEW’s rejected regulations; however, that this
issue is unresolved serves as a powerful reminder of how profound is the
controversy involved.

\textbf{C. 2. Specific Concerns}

Today, researchers who wish to conduct non-therapeutic
experiments involving the developmentally disabled confront two main
questions:

1) Can a person from this population give a valid
consent to the proposed experiment?

2) If not, can a substitute decision-maker (SDM)
ever consent to non-therapeutic
experimentation?

\textbf{C. 2. (a) Validity of Consent}

The very expansive range of disabilities that may be present
among those with differing levels of Mental Retardation requires a close
examination of the extent to which a potential subject is capable of
making an independent decision whether to participate in biomedical
experimentation. This question can be satisfied by utilizing a mental
competency assessment.\textsuperscript{27} For example, it may well be the case that many
of those individuals with only a mild degree of Mental Retardation may be
capable of making such a decision on their own, particularly if they
receive help and support from relatives. On the other hand, those with
severe or profound levels of Mental Retardation will clearly not be able to
engage in such decision-making and, if they are to participate at all, then
consent must first be given by a third party.\textsuperscript{28}

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\textsuperscript{25} See Alexander, \textit{supra} note 23 at 51.
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\textsuperscript{26} 45 C.F.R. 46 (1991) \$ 46.111 (7)(b)
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\textsuperscript{27} See D.N. Weisstub (Chair), \textit{Enquiry on Mental Competency: Final Report}
(Toronto: Queen’s Printer, 1990) for a detailed discussion of competency
assessments.
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\textsuperscript{28} Also, the “markedly abnormal or impaired development in social interaction and
communication,” that is characteristic of Autistic Disorder clearly implies that
individuals with this disorder would almost always be considered incapable of
consenting to participation in research. For discussion of Autistic Disorder, see
\textit{DSM IV}, \textit{supra} note 1 at 66-71.
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Consequently, the focus of inquiry in respect of this population will be on competence and voluntariness of consent, and recommendations will emphasize the need to assess and maximize the decision-making capacity of the developmentally disabled, as well as the ambit and influence of SDMs.

C. 2. (a) (i) Competency Assessments

For the developmentally disabled, reduced cognitive capacity places into question their ability to make, or effectively communicate, independently an informed and voluntary choice to become involved in biomedical research. Effective consent requires the ability to understand the nature of the various research procedures concerned, appreciate the consequences of a decision to participate in research, and communicate the nature of such a decision.

Although at common law mental competency is presumed, assessing the competency of a mentally disordered person requires special consideration:

The nature of Mental Retardation is a disability and the status of adults with Mental Retardation in society combine to shape consent issues in a unique way. Unlike mentally typical adults, it cannot be assumed that mentally retarded adults understand the standard explanation of ordinary procedures, nor can it be assumed that they have chosen to acquiesce in a proposal merely because they do not voice an objection. Unlike minors, adults with Mental Retardation cannot be assumed, because of their status, automatically to be incompetent (or competent) to make their own decisions. If there is doubt about particular individuals’ capacity to consent, they cannot be presumed to have a legally authorized surrogate decision maker in place. Nor can it be assumed that adults with Mental Retardation will eventually become competent through the passage of time, thus allowing postponement of some decisions for the duration of their incompetence.

There are also relevant differences between mental illness and mental retardation. Unlike adults with mental illness, any possible legal impairment of decision-making capacity in individuals with Mental Retardation is likely to result from failure to comprehend what is proposed or an inability to communicate a choice, rather than society’s concern that their disability might lead them to irrational choices.

The potential incompetence of particular individuals with Mental Retardation to make decisions is also more likely to be disguised than in cases of mental illness. Individuals who have mental retardation often attempt to mask their disability and “pass” as “mentally typical.”

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29 See Ellis, supra note 2 at 1791-1792 [Footnotes omitted].
Neither legal nor functional competence is a general concept, but should be evaluated in relation to required specific decisions. Whether an individual will be able to consent to participate in an experiment depends on the abilities of the person, the nature of the decision to be made, and the likely consequences of the decision for the person.\textsuperscript{30} The same person may be able to function competently in a specific environment, but be unable to consent to an experiment. Conversely, he or she may need a great deal of assistance physically, but be competent to consent to a specific procedure. Although not expressly developed, this philosophy was evident in \textit{Clark v. Clark}.\textsuperscript{31} The court recognized that the need for assistance in some areas of life did not determine overall capacity. This concept is also enshrined in the present Ontario legislation.\textsuperscript{32}

It is important to realize that competency can vary among the developmentally disabled. A particular individual may have capacity to consent to some proposed experiments, but not to others, and often, it is not clear whether that individual is capable of making a particular decision.\textsuperscript{33}

\textbf{C. 2. (a) (ii) Voluntariness}

Problems discerning capacity are exacerbated by the fact that the developmentally disabled generally live in a coercive environment created by:

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\item the power of a legal guardian, or the authority of institutional staff; and
\item the belief (usually valid) that: “as a practical matter, they must obtain ‘permission’ from non-disabled individuals to do things that no other adults in society must obtain permission to do. Both people with Mental Retardation and non-disabled individuals who deal with them on a regular basis assume that such authority is natural, necessary and appropriate.”\textsuperscript{34}
\end{enumerate}

Thus, voluntariness is severely compromised. Individuals will assent to participation in an experiment because they feel they are expected to by others. This will not be a valid consent in the technical meaning of the term. A person may not have capacity to give a valid consent, but may assent to the procedure by not objecting. In a coercive

\textsuperscript{30} See Jenkinson, \textit{supra} note 10 at 372.
\textsuperscript{31} (1982), 40 O.R. (2nd) 383 (Co.Ct.).
\textsuperscript{33} See Ellis, \textit{supra} note 2 at 1802.
\textsuperscript{34} \textit{Ibid.} at 1802.
atmosphere, even this assent (which is really a lack of objection) may not be truly voluntary. It is for this very reason that, wherever possible, the subject’s assent, to the extent of the subject’s capabilities, must be sought. Failure to provide assent or mere cooperation should not be treated as assent, and continued assent should be monitored throughout an experiment.\textsuperscript{35}

\textit{C. 2. (a) (iii) Substitute Decision Making}

Where decisions are being made about the participation of children, the elderly, or the mentally disordered, it is usually feasible to create an external reference point based on the anticipated or remembered personality of the specific individual concerned. In the case of the developmentally disabled, however, it is manifestly impossible to establish such a standard. For this special population, there is no opportunity for SDMs to take into account a developing, diminishing, or previous capacity for independent decision-making.

Indeed, it seems to be doubtful that it would be \textit{he} who was normal, since everything about him that has been asserted to be relevant to personal identity - personality, character traits, and even, possibly his brain - would have to be different for him to be intellectually normal.\textsuperscript{36}

Therefore, the focus of inquiry for developmentally disabled persons will often not be on the adequacy of consent, but on what areas of protection are needed and when. A person who is severely retarded may have no preference, or may not be committed to preferences or values or to anything that would determine what the person’s preference would be if not disabled.

At common law, a SDM is restricted in his authority. The decision of the Supreme Court of Canada \textit{Re Eve}\textsuperscript{37} indicates that the Crown, not the family, has the power to make decisions for persons found to be incompetent. This \textit{parens patriae} jurisdiction does not permit either the court or its delegates to consent to non-therapeutic procedures. \textit{Re Eve} has limited application to research projects because of the extremely intrusive nature of the proposed intervention in that case (most research projects would not involve a high risk or be extremely intrusive; the technique in \textit{Re Eve}, sterilization, was both) and the fact that the intervention was

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\item[35] D.N. Weisstub, J. Arboleda-Florez & G.F. Tomossy, “Establishing the Boundaries of Ethically Permissible Research with Special Populations” (1996) [In this Volume].
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medical as opposed to behavioural or environmental. In any event, it is open to the Legislature to address concerns in this context.

Treatment decisions for incompetent persons are now made under the Consent to Treatment Act, 1992, but those powers may only be exercised if the individual is found incompetent.\(^{38}\) The Substitute Decision Act, 1992, gives the legally appointed decision-maker the duty to ascertain current wishes and to encourage the participation of the individual in the decision.\(^ {39}\) It is recommended that similar principles apply to decisions made on behalf of participants in non-therapeutic research, because there can be a therapeutic benefit conferred by the opportunity to participate in choice. All caregivers have a particular responsibility to encourage control by the developmentally disabled over values, decisions and choices. This means SDMs should ensure that their own values and preferences do not have undue influence on the choices and options provided to the developmentally disabled person.\(^ {40}\) This process should not be confused with obtaining informed consent in the legal sense from the individual:

Individual[s] with Mental Retardation need to be protected from deprivation of liberty accomplished under the ruse of consent, when knowing voluntary consent was not truly given, and often was not even sought. True autonomy is not promoted by pretending that an individual is competent to make choices that he or she cannot in fact understand.\(^ {41}\)

SDMs who have received their authority through legislation or other government delegation will have their powers subject to the Charter of Rights and Freedoms, particularly sections 7, 12 and 15. Limitations on the powers of parental guardians were recently explored in B(R). v. Children's Aid Society of Metropolitan Toronto.\(^ {42}\) In that case, although the Jehovah Witness parents of B, a premature baby, objected to diagnostic and medical treatment for religious reasons, procedures were ordered under the Ontario Child and Family Services Act.\(^ {43}\) Among other issues, the parents argued that the denial of the right to choose medical treatment for their child infringed their Charter s. 7 liberties. The Justices varied in their reasons, but sent a clear message that the state can properly intervene when parental conduct falls below the socially acceptable threshold, and, according to Iacobucci and Major JJ., it will be protecting the child’s Charter s. 7 rights when so doing. These same principles may be extended to the developmentally disabled.

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\(^{38}\) Consent to Treatment Act, 1992, supra note 32, s.17. See also Substitute Decision Act, 1992, supra note 32, s. 58.

\(^{39}\) Substitute Decision Act, ibid., ss. 66(4) & (5).

\(^{40}\) See Jenkinson, supra note 10 at 370.

\(^{41}\) See Ellis, supra note 2 at 1809.


C. 2. (a) (iv) Nature of Research on the Developmentally Disabled

Current theories of competency to consent connect the ability of an individual to consent to the nature of the experiment. The more invasive or risky the procedure, the higher is the degree of competency required. It is, therefore, essential to understand the nature of non-therapeutic research on the developmentally disabled. The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in the United States found that:

[N]on-therapeutic research involved evaluation of alternatives to institutionalization such as outpatient care, community care, and other community support programs. Variations in within-institution care may also be studied, such as effects of differences in resident/staff ratios and staff-patient interaction. Such studies may or may not provide direct benefit by demonstrating the harmful effects of institutionalization and encouraging improvements and alternatives.\(^{44}\)

D. Ethical And Legal Principles

The developmentally disabled are vulnerable to exploitation in non-therapeutic biomedical experimentation. The need for a system of protection has primarily been addressed by international and domestic ethical codes. Most of these guidelines do not refer specifically to the developmentally disabled, but include this population in their recommendations concerning experimentation with the mentally disordered.\(^{45}\) Although most of the recommendations made in respect of experimentation with mentally disordered persons are equally applicable to the developmentally disabled, given that the members of both populations possess varying degrees of cognitive impairment, the unique situation of the developmentally disabled requires that application of these principles take into consideration the special characteristics of this population.

In sum, international sentiment on non-therapeutic research involving the developmentally disabled has fluctuated from the outright refusal stipulated in the Nuremberg Code\(^ {46}\) and the International

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\(^{44}\) See Alexander, \textit{supra} note 23 at 44.
\(^{45}\) See J. Arboleda-Florez & D.N. Weisstub, “Ethical Research with Vulnerable Populations” (1996) [In this Volume]
\(^{46}\) The \textit{Nuremberg Code} constituted part of the judgement resulting from \textit{U.S. v. Karl Brandt et al., Trials of War Criminals Before the Nuremberg Military Tribunal Under Control Council Law No. 10.} (October 1946-April 1949).
Covenant of Civil and Political Rights\textsuperscript{47} to a more balanced position, where research of this nature is allowed for as long as there are appropriate safeguards for the protection of the subject.

E. Safeguards For Research On The Developmentally Disabled: Problems & Solutions

Non-therapeutic research involving developmentally disabled persons is justifiable when conducted within constructs of ethical permissibility. Because it is unlikely that a SDM can make a truly substituted decision and because an individual’s best interests are not always the paramount consideration, special safeguards must be put in place. There is the lingering controversy over the appropriate degree of protection that should be applied in relation to research involving the developmentally disabled, but as Baudouin noted: “… what appears of utmost importance is then clearly to establish the parameters of the legitimacy and legality of experimentation … [and that such restrictions] should be very clearly spelled out in the legislation and not merely left to ethical rules.”\textsuperscript{48} Some form of enforcement should also be included.

It is important to re-emphasize that the developmentally disabled should not be presumed to be incapable or entirely incompetent; therefore not all members of the population may require stringent limitations. However, as a matter of social policy, owing to the vulnerable nature of the population as a group and the extraordinary impact that changes in environment can have, general restrictions governing their participation in biomedical experimentation are justifiable.

It is recognized that these procedures will increase the responsibility of researchers who are already limited by subject recruitment policies and procedures, delays caused by consent procedures, and fears of litigation.\textsuperscript{49} However, it should be acknowledged that researchers themselves benefit from the project. Often participation in such projects enhances career prospects or provides the researchers with that very sense of well being and altruism that those who promote a substitute decision attribute to the incompetent person. Therefore, it is reasonable to ask researchers to assume responsibility to ensure that (i) the research stays within the proposed protocol; (ii) appropriate assessments of capacities are made of the developmentally disabled person and the

\textsuperscript{49} See P.S. Siegel & N.R. Ellis, “Note on the Recruitment of Subjects for Mental Retardation Research” (1985) 89 American Journal of Mental Deficiencies 431 at 432.
SDM; and (iii) consent capacities are maximized. It has been said that a patient’s greatest safeguard is a responsible compassionate physician. The same might be said of the researcher’s relationship with the developmentally disabled subject.  

**E. 1. Special Considerations of the Population**

Researchers seeking the participation of a developmentally disabled individual in a protocol must presume the individual to be capable of participating in the decision; they must devise methods of presenting the information to maximize the individual’s contribution, and they must be prepared to reconsider capacity on an ongoing basis.  

In addition, research on the developmentally disabled presents specific challenges to establish competency, the selection of subjects, the needs to reassess and maximize capacity, the model to be used to substitute consent, and the characteristics of the decision-maker.

**E. 1. (a) Presumption of Competency**

The presumption of competency is based in the principle of respect for persons, and has as its correlate the requirement that incompetency not be presumed without substantiating evidence. This includes recognition of the fact that incompetence in one area of decision-making does not imply the inability to make decisions in other aspects. However, these concepts must be considered in conjunction with the potential for abuse made possible by presuming competence in one who is incapable of understanding and does not actively object to the performance of a procedure for research. Although people with developmental disabilities have every right to take risks and accept both benefits and burdens as they choose, this right should be exercised only in accordance with a requisite level of competence.

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51. The following guidelines are provided by the Medical Research Council of Canada: Mentally handicapped individuals cannot be presumed to be incompetent to comprehend information and exercise choice. The issues must be determined on the facts of each case. Where intellectually-impaired adults are assessed to establish their mental capacity, the principles outlined above regarding children and adolescents may be applicable in principle….The ability of all incompetent potential subjects to exercise choice must be maximized, and their dignity must not be compromised by exposing them to procedures which demean them or exacerbate their dependency.

It is also recognized that, notwithstanding the shared diagnosis of developmental disability, individuals within this special population span the entire spectrum from those capable of making independent decisions through those who are capable of making such decisions with assistance to those incapable of involvement in any decision-making of this sort. The common law presumption of competency should be respected, but the rights of the developmentally disabled person must be protected by a competency assessment whenever there is a reasonable doubt as to the individual’s capability to make a specific decision.  

E. 1. (b) Methods of Assessing Competency

Having considered some of the implications of the existence of a broad range of capacities among the developmentally disabled, one obvious challenge presented by this range is that of finding an accurate method to assessing competence so that individual procedural safeguards may be fashioned. Furthermore, the method of assessment ultimately employed must be directed toward identifying the specific ability of the individual to make decisions concerning participation in the research process. With the elderly, the principal uncertainty with regard to their ability to understand basic issues is not likely to relate to the nature of the procedure as much as to its purpose (i.e. whether it can be considered as therapy or research). However, in the case of a developmentally disabled person, the capacity to make any medical decisions whether in relation to research or treatment may be ambiguous at best. Also, as with the mentally disordered, individuals may claim to understand when objectively they do not. Therefore, competence must not be confused with alleged comprehension.

The considerable literature on methods of assessing competency has been the subject of The Enquiry on Mental Competency. As well, advances have been made in the accuracy of methods of assessing consent. For many developmentally disabled individuals, the reduction of the competency threshold to a level commensurate with the risk presented by the research project will mean these persons will have capacity to make this decision. Where the research is not invasive and

52 The current Ontario Regulations enforce the presumption of competency, and provide a list of the reasons upon which a practitioner may base a belief that a person may be incapable to consent to a proposed treatment. See O. Reg. 19/95. These reasons should also be made applicable to decisions made in respect of consent to research.


54 See Weisstub (1990), supra note 27.

involves low risk, individuals who normally would be unable to make medical or therapeutically beneficial decisions may have capacity to participate in a project.

**E. 1. (c) Subject Selection According to Capacity**

Among the many requirements for ethically permissible research is the critical stipulation that the involvement of incapable persons be considered only in relation to research that cannot be conducted with persons capable of giving informed consent. It is recommended that this requirement be vigorously sustained within this population as well. To be more specific, not only can research with incapable persons be considered only when that research is not possible with capable persons, but subjects must also be selected in a hierarchical fashion, with those considered least capable of ever giving consent being selected last for the study. In this respect, it should be required that a research protocol explicitly indicate how this assessment is made and how it will be observed in recruiting developmentally disabled subjects.

**E. 1. (d) Reassessment of Capacity**

From the perspective of the busy researcher, once a developmentally disabled individual has been determined incapable of providing independent consent and the caregiver has expressed willingness to support participation in research presenting only a minimal degree of risk, it may seem expedient to deal on other occasions in the future with the caregiver alone. An individual’s capacity to make decisions should be reassessed whenever a reasonable doubt is raised as to the existence of this capacity, whether because of the passage of time, variations in the protocol, or other significant changes in circumstances. In all cases, the researcher should proceed on the basis of the most recent appraisal of capacity.

**E. 1. (e) Maximizing the Capacity to Provide Consent**

Researchers also have an obligation to their developmentally disabled subjects to maximize capacity itself. Although legal competence may be absent, researchers should recognize an ethical responsibility to foster functional competence where possible, because of its significance in habilitation. The developmentally disabled individual may lack the legal ability to provide a valid consent to participate in research, but retain functional capacity to make certain decisions. As Jenkinson noted:

Decision-making by people with an intellectual disability is not only in accord with principles of human dignity and autonomy, but also conveys benefits such as increased motivation and improved task performance. Despite this, and despite an awareness by service
providers and care-givers of the need to encourage and create opportunities for decision-making, there is still considerable evidence that even in many routine activities of daily life opportunities for self-determination are not occurring to the same extent as for others in the community. Environments should be structured to allow the individual maximum control over options, to ensure that options are clear, and to help the decision-maker become aware of his or her preferences without feeling under pressure or influenced.56

A more positive environment is created when researchers seeking the participation of a developmentally disabled individual in a protocol presume the individual to be capable of participating in the decision, devise methods of presenting the information to maximize the contribution of the individual, and reconsider the capacity of the individual on an ongoing basis.57 Participation in the decision-making process may improve the skills of the individual so that competency may increase as the individual’s knowledge of the research project increases and as his or her comfort level with any changes in the environment caused by the project increases. As well, as the project progresses, the level of risk may decrease, lowering the threshold for legal competency.

E. 1. (f) Limits on Ability to Consent

The desire to grant individuals with the ability to make independent decisions that affect their personal welfare respects a fundamental aspect of their right to self-determination. Together with other special populations, however, it is necessary to indicate that research on the developmentally disabled should be routinely subjected to a number of significant restrictions, the foremost of which would be to prevent an individual from being submitted to experimentation involving more than a minimal risk.58

E. 1. (g) Substitute Consent

The legal limits on the scope of substitute consent for persons who, even with the support of others, are incapable of making the decision

56 See Jenkinson, supra note 10 at 372.
57 The following guidelines are provided by the Medical Research Council of Canada:
Mentally handicapped individuals cannot be presumed to be incompetent to comprehend information and exercise choice. The issues must be determined on the facts of each case. Where intellectually-impaired adults are assessed to establish their mental capacity, the principles outlined above regarding children and adolescents may be applicable in principle. … The ability of all incompetent potential subjects to exercise choice must be maximized, and their dignity must not be compromised by exposing them to procedures which demean them or exacerbate their dependency.
See Medical Research Council of Canada, supra note 51.
58 Only with the exceptional approval of a judicial or quasi-judicial authority should this level of risk be exceeded.
whether or not to participate in research are still unclear. The substitute decision model is one solution proposed to enable incompetent developmentally disabled persons to be incorporated in biomedical experimentation. However, the legality of a substitute decision consenting to non-therapeutic experimentation, a procedure which provides no benefit to the subject, is questionable. After Re Eve, there is some doubt in the common law provinces as to the validity of third-party consent for a developmentally disabled person to participate in non-therapeutic research. As well, the substitute decision model raises many moral concerns.

It can be argued that the term “substitute consent” is a misnomer when applied to the condition of a person who has never possessed the capacity to express a value, belief or desire. In these circumstances, substitute consent has been described as a legal fiction. In the context of treatment decisions, Dresser has pointed out:

the effort to force these patients into the model of ourselves as autonomous decision-makers (seeking desperately to avoid their dire situations) distracts us from the real people before us. In consequence, we miss seeing who they are. It is all too true that these patients are difficult to find. Many cannot speak with us; those who can tend to speak in tongues that seem impossible to decipher. If we want to know them, to understand the value life has for them, we must depart from the customary, comfortable methods we have for exploring the subjective world of another human being. We must undertake a different approach, since these patients typically cannot talk with us about “what it is like” to be in their situation. Yet, the existing legal doctrine barely recognizes this need and consequently creates little incentive for decision-makers to do so.

Harmon concludes that the substituted judgment test allows the state to invade the bodily integrity of the incompetent person without having to justify the invasion. As an alternative, Dresser suggests that it is preferable to drop, or at a minimum, seriously reroute the effort to identify the individual’s hypothetical choice. Instead, decision-makers should focus on the person’s current conditions, the concerns of those who

59 See Re Eve, supra note 37
60 See R.M. Veatch, “Persons with Severe Mental Retardation and the Limits of Guardian Decision Making” in P.R. Dodecki & R.M. Zaner, eds. Ethics of Dealing with Persons with Severe Handicaps (Baltimore: Paul H. Brooks, 1986) 239 at 244 in which it is said that for all patients who have never been competent, the moral mandate is to promote the patient’s best interest.
63 See Harmon, supra note 61
love and care for that person, and the concerns of the larger community to which she belongs.\textsuperscript{64}

English and Canadian courts have differed in their approaches to substitute decision making. Some of the above considerations, along with the intrusive nature of the proposed procedure, influenced the decision in \textit{Re Eve} that only therapeutic measures based on a determination of the incompetent person’s best interests were acceptable. However, a substitute judgment test was applied by the English Court of Appeal in \textit{Re J}.\textsuperscript{65} In deciding whether or not to continue treatment of a severely handicapped child, the court said a balancing exercise must be performed to decide what was in the best interests of the child. Balanced against the strong, but not irrefutable, presumption in favour of prolonging life was the pain and suffering a child would experience if life were prolonged. But, Lord Donaldson said, the quality of life must be looked at from the assumed point of view of the patient, not the decider, to give effect “to the fact that even very severely handicapped people may find a quality of life rewarding which to the unhandicapped may seem manifestly intolerable.”\textsuperscript{66} In \textit{Frenchay Health Care NHS Trust v. S.},\textsuperscript{67} the Court of Appeal reaffirmed that it can not be assumed that the individual’s best interest is in what the doctor says (although courts are reluctant to go against professional opinions), thus implying more subjective factors can be considered.

Finally, reform in England has also endorsed a form of substitute decision making. The Law Commission has proposed the following: \textit{We recommend} that in deciding what is in a person’s best interests regard should be had to:

(1) the ascertainable past and present wishes and feelings of the person concerned, and the factors that person would consider if able to do so;

(2) the need to permit and encourage the person to participate, or to improve his or her ability to participate, as fully as possible in anything done for and any decision affecting him or her;

(3) the views of other people whom it is appropriate and practicable to consult about the person’s wishes and feelings and what would be in his or her best interests;

(4) whether the purpose for which any action or decision is required can be as effectively achieved in a manner less restrictive of the person’s freedom of action.\textsuperscript{68}

\textsuperscript{64} See Dressser, supra note 62 at 612.
\textsuperscript{65} [1990] 3 All E.R.930.
\textsuperscript{66} \textit{Ibid.} at 938.
\textsuperscript{67} [1994] 2 All E.R. 403
\textsuperscript{68} The Law Commission, \textit{Mental Incapacity} (London: HMSO, 1995) at 44-45.
These guidelines are helpful. For non-therapeutic research, the third guideline should be adapted to weigh the risk to the individual against the likely benefits of the research to other persons with that disability.

E. 1. (h) Selection of a decision-maker

Legislation should recognize the unique qualities required by a SDM of a developmentally disabled person, particularly in the context of consent to research. As such, the following would apply:

1. The SDM’s willingness and reasons for serving as SDM must be established.69

2. The SDM must be competent to make the decision to consent to research. The SDM must be capable of assessing possible risk to a particular individual and be aware of any specific personal characteristics that would put the person at increased risk. The decision-maker should be sensitive to various types of harms (social or moral, not only medical) to which this particular person is vulnerable. Only then can a proper balance of risks and benefits be made.

3. The SDM should disclose reasons for the decision. This should indicate that the decision-maker recognizes the complexities of making these decisions for another person, and, in particular, understands the standards to be applied. Any connections between the researcher and the SDM should be revealed. It may be the case, for example, that pressures be exerted on the decision-maker to appear cooperative with the staff in order to assure good treatment for the developmentally disabled person.

4. Conflicts of interest must be revealed. For example, if a proposed project would relieve the decision-maker of some of his or her caregiving responsibilities, and thus confer a benefit, this should be revealed. This would not necessarily constitute a ground for refusing to give the SDM powers, but the information should be revealed. If the conflict of interest is serious, another decision-maker should be sought.

5. The SDM should be able to describe steps taken to engage the participation of the developmentally disabled individual in the ongoing consent process.

If the SDM first named fails to meet these guidelines, the person next listed in the Substitute Decision Act who is able to meet the following criteria should be named. In this regard, such a person must have:

1. competency to make decisions;
2. willingness;
3. no serious conflict of interest;
4. the ability to ascertain the wishes or feelings of the developmentally disabled person; and
5. the ability to engage the developmentally disabled person in the decision-making process.

Whenever the condition of the developmentally disabled person permits, the opinion and approval of that person should be obtained in the selection of a SDM.

E. 2. General Safeguards

In addition to the specific recommendations stated above, general safeguards should be adopted. These include: the requirement of the scientific validity and importance of an experiment; the requirement on the part of all participants in the research process to minimize risks and to balance possible risks with potential benefits; a general limitation of the level of risk to which a vulnerable person may be exposed; the requirement of assent; and the importance of respecting an individual’s right to object to and withdraw from (or be withdrawn from) an experiment. It was also stated that an individual should have the right to object, regardless of the person’s mental competence at the time. However, in certain situations a person’s objection might not be genuine, in which case an appeal should be made to a judicial or quasi-judicial authority, which could then over-rule an objection in exceptional circumstances, and must provide a written decision to that effect.

Any objection by the subject, even if he or she is legally incompetent, should be respected and should supersede the decision of a SDM.70 The UK Law Commission Paper #128 stated that it is not reasonable for a researcher to force an incapacitated person to act in accordance with a decision to which the incapacitated person objects, unless such action is essential to prevent an immediate risk of serious harm to that person or others. These principles should be applied when considering whether to overrule the objection of a subject.

70 See Weisstub, Arboleda-Florez & Tomossy, supra note 35.
When developmentally disabled persons are research subjects, it is recommended that:

1. the assessment of competency includes the assessment of the ability of the developmentally disabled person to express his refusal. Severely and profoundly retarded persons may have difficulty communicating their refusal. If this is the case, a record should be made to alert researchers and SDMs that extra care should be taken in monitoring the experiment.

2. If a SDM has been appointed for the person, the SDM should monitor the progress of the experiment and be sensitive to expressions of disapproval by the person. A researcher may not know the individual well enough to recognize signs of objection. The SDM must recognize that in addition to providing consent of behalf of the individual he or she must also honour an objection on behalf of the developmentally disabled person.

F. Conclusion

Owing to the unique factors that affect the capacity to provide consent in developmentally disabled persons, it should be recognized that there is a substantial difference between this population and other vulnerable groups. There are substantial mental and communication disabilities that may not be apparent to outsiders, the individuals may live in a uniquely coercive environment, and many of the decisions involve possible deprivation of fundamental rights. In this regard, the issues involved depend on the incapacity of the developmentally disordered person to give an informed consent, and on the potential involuntariness brought about by either institutionalization or complete dependence on SDMs. Every attempt should be made to maximize and facilitate the participation of developmentally disordered persons in the decision-making process, taking into consideration the variance in levels of capacity that exists in this population. Competency assessments should therefore be reevaluated during the course of an experiment if required, owing to the likelihood of increased familiarity and understanding of the nature and consequences of participation by the part of the subject. Finally, the point is often made that to establish the parameters, and the internal structure for the process of obtaining a valid consent to participate in non-therapeutic experimentation, “diagnoses are not always accurate and the levels of mental acuity may vary considerably within the category

71 See Ellis, supra note 2 at 1804.
and over time.”72 Rather, assessments for competency should be made on
the issue of competence independent from the issue of diagnosis or the
level of intellectual capacity.

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