The developmentally disabled constitute a vulnerable population in the context of nontherapeutic experimentation. Their vulnerability is characterized by diminished decision-making capacity and by susceptibility to coercive situations that may bring voluntariness into question. The international consensus is that research involving this population should be permitted, but only if the consent of a legal guardian is obtained and appropriate safeguards are introduced. Therefore, legislation regulating the ethical conduct of research should be enacted, including provision for substituted consent in the research context. Although researchers seeking the participation of a developmentally disabled individual in a protocol must presume the person to be capable of participating in the decision, they must conduct competency assessments if the person’s ability to make such a decision is in doubt. Information must be presented in such a way as to maximize the individual’s contribution, and capacity must be reevaluated on an ongoing basis. In addition, research on the developmentally disabled presents specific challenges to establish competency, the selection of subjects, the characteristics of the decision maker, and the model to be used in making substituted decisions.

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Special Characteristics of the Developmentally Disordered

The developmentally disabled are distinguishable from other vulnerable populations on the basis of their never having possessed and their being likely incapable of ever possessing sufficient competence to make all decisions affecting their welfare. Although developmental disabilities have often been included in broad definitions of “mental disorder” based on the shared feature of cognitive impairment (1,2), a general classification neglects 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 disabled 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 varying extent (3).

Developmental disabilities include a broad range of conditions such as mental retardation, pervasive developmental disorders, learning disorders, motor skills disorders, and communication disorders, each requiring the researcher to adjust the approach taken to assess the person’s decision-making ability. Mental retardation, for example, covers a wide spectrum of disabilities with varying degrees of severity that reflect different levels of intellectual impairment (1). According to a widely accepted definition, mental retardation manifests before age 18 and is characterized by “significantly sub-average intellectual functioning, existing concurrently with related limitations in two or more of the following applicable skill areas: communication, self care, home living, social skills, community use, self-direction, health and safety, functional academics, leisure, and work” (4). This functional definition focuses on a notion of intellectual impairment that is accompanied by related limitations in particular skill areas (3).

Although there is considerable variation in levels of intellectual impairment, developmentally disabled persons share certain characteristics: 1) a deficit in basic knowledge relevant to making decisions; 2) significant impairment of communication skills; 3) a mask of competence, preventing the person from seeking help in making decisions when such help may be badly needed; 4) a reduced ability to make
decisions that, for example, may lead the individual to impulsively seize onto the first solution that comes to mind, regardless of consequences, when faced with decisions requiring a greater degree of assertiveness or in which options for action are not clear; 5) exposure to potentially coercive settings that may call into question the legal adequacies of the decision the individual is asked to make; and 6) permanence of disability 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 life span of the person, and his or her ability to make choices may be affected by successful special education programs or environmental changes (3,5). As a result, researchers have increased responsibility at the information stage of the consent process; they cannot assume silence to be either a lack of comprehension or an assent.

There is also a significant likelihood that individuals with mental retardation will be affected by some other form of mental disorder. 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” (1, p 42). For example, poor communication skills may render it impossible for the patient to provide the personal history adequate for an accurate diagnosis to be made. Any assessment of an individual’s capacity to participate in biomedical experimentation, therefore, must be sensitive to the possibility that the individual may belong to more than one vulnerable population. In such cases, the individual is entitled to the protections applicable to all of the groups to which he or she belongs (6).

**Institutionalization and the Effect of Deinstitutionalization**

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 research but whether such persons were suitable subjects for experimentation (7). 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 (8). Institutionalization made such individuals particularly convenient subjects for a broad range of protocols unrelated to their particular disabilities (9–12).

The trend toward 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 shift 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. Most importantly, deinstitutionalization has helped to create a group of competent lay persons who possess a unique insight into the health care needs of this special population and who have a particular interest in influencing future research in the direction of habilitation within a developmental model that stresses learning life skills.

Ironically, however, deinstitutionalization and enhanced requirements for consent have made recruiting research subjects a much more onerous task and, in some cases, have actually cast doubt on the perceived cost-efficiency of conducting any research whatsoever into the specific needs of the developmentally disabled. While it may be satisfying 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. The developmentally disabled have the right to the best methods of care, treatment, education, and habilitation that we have the power to give them—the right not to participate in research, however, may come into direct conflict with the impetus to achieve concrete improvements in these areas (13). The potential of enhanced procedural safeguards for recruiting subjects to reduce the pace at which medical advances are accomplished should inspire 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.

**Safeguards for Research on the Developmentally Disabled: Problems and Solutions**

The need for the protection of vulnerable populations from exploitation in the context of nontherapeutic biomedical experimentation has been addressed primarily by international and domestic ethical codes. Most of these guidelines refer broadly to subjects possessing mental or behavioural disorders (14). In a nutshell, the international position on nontherapeutic research involving cognitively impaired subjects, including the developmentally disabled, has fluctuated from the outright prohibition stipulated in the Nuremberg Code (15) and the *International Covenant on Civil and Political Rights* (16) to the current, more balanced position, which condones research of this nature as long as there are appropriate safeguards in place for the protection of subjects (17). The consensus is also that these safeguards should be prescribed by legislation (18), which should include various general requirements (19), but which must also take into account the special characteristics of this population.

Members of vulnerable populations should be enrolled in nontherapeutic experiments only when there is no alternative pool of subjects. Furthermore, prospective subjects should be chosen in a hierarchical fashion, with those considered least capable of ever giving informed consent being considered. 

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last. It should be required that a research protocol explicitly indicate how this assessment is made and how it will be applied in recruiting subjects. Finally, developmentally disabled persons should not be submitted to experiments involving more than a minimal risk.

Additional safeguards designed to protect and assist the developmentally disabled must confront 2 basic questions: 1) Can the person give a valid consent to participate in the proposed experiment? 2) If not, can consent be obtained from a substitute decision maker (SDM)? Although these procedures will increase the responsibility of researchers who are already constrained by subject recruitment policies and procedures, delays caused by consent procedures, and fears of litigation (20), it should be acknowledged that researchers themselves receive benefits. Often, participation in such projects enhances career prospects or provides the researchers with that very sense of well-being and altruism that, in promoting a substitute decision, they would attribute to the incompetent person. It is therefore reasonable to ask researchers to assume responsibility to ensure that the research stays within the proposed protocol, that capacity assessments are made appropriately, and that the participation of the developmentally disabled person in decision making is maximized (21,22).

The Assessment and Presumption of Competency

For the developmentally disabled, reduced cognitive capacity calls into question the ability to make an informed and voluntary choice to become a research subject. Effective consent requires the ability to understand the nature of the various research procedures concerned, to appreciate the consequences of a decision to participate in research, and to communicate the nature of such a decision. The existence of these abilities cannot be presumed in the case of those with developmental disabilities (3). Furthermore, as with the mentally disordered, individuals may claim to understand when objectively they do not. Competence must not be confused with alleged comprehension (23).

Although in common law mental competency is presumed, its assessment requires special considerations, which imply the avoidance of certain assumptions, including: 1) an understanding of standard explanations of ordinary procedures; 2) acquiescence merely because of the failure to voice an objection; 3) incompetence as an automatic consequence of a developmental disability; 4) the automatic presence of a legally authorized SDM; or 5) an eventual increase in capacity, as with children, which can allow certain decisions to be postponed (3).

Neither legal nor functional competence is a general concept, and each should be evaluated in relation to specific decisions. A person may be able to function competently in a specific environment but be unable to consent to an experiment or even to a particular research protocol (3). Also, decision-making capacity will vary among the developmentally disabled. Persons with only a mild degree of mental retardation may be capable of making decisions on their own, particularly if they receive help and support. Those with severe or profound levels of mental retardation will require the help of a third party to give consent. Factors to consider in assessing whether an individual will be able to consent to participate in an experiment include the abilities of the person, the nature of the decision to be made, and its likely consequences (5). The more invasive or risky the procedure, the higher is the degree of competency required. As the project progresses, the level of risk may decrease, lowering the threshold for legal competency. Finally, an individual’s capacity should be reassessed whenever a reasonable doubt is raised as to the existence of (or change in) decision-making 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.

It is also important not to ignore the potential for abuse that can result from presuming competence in an individual who may be 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. 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 (24,25).

Maximizing the Capacity to Provide Consent

Researchers should recognize their ethical responsibility to foster functional competence where possible because of its significance in habilitation. A more positive environment is created when researchers seeking to enroll a developmentally disabled person in a research protocol devise methods of presenting information to maximize the contribution of the individual and reconsider the capacity of the individual on an ongoing basis. Participation in the decision-making process may improve skills so that competency may increase as the individual’s knowledge of the research project and comfort level with any changes in the environment caused by the project increase (5).

Voluntariness

Problems discerning capacity are exacerbated by the fact that the developmentally disabled generally live in a coercive environment created by 1) the power of a legal guardian, or the authority of institutional staff and 2) 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” (3 p 1802).

For these reasons, voluntariness can be compromised. Individuals might assent to participation in an experiment because they feel they are expected to by others. A person may not have capacity to give a valid consent, but may assent to the procedure by not objecting. In a coercive atmosphere, this assent (which is really a lack of objection) may not be truly voluntary. Nevertheless, 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 (19).

Substitute Consent

The legal limits on the authority of SDMs remain unclear. Indeed, the legality of a substituted decision consenting to participation in nontherapeutic research, which provides no direct benefit to the subject, is questionable in the common law provinces (17,19,26,27). 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 (28), and is therefore a legal fiction. Harmon concludes that the substituted judgment test permits the invasion of the bodily integrity of an incompetent person without justification (29). 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. SDMs lack the opportunity to take into account a developing, diminishing, or previous capacity for independent decision-making. Naturally, the applicability of this observation will be determined by the nature and extent of the cognitive disability.

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 love and care for that person, and the concerns of the greater community (30). Caregivers have a particular responsibility to encourage control by the developmentally disabled over values, decisions, and choices. This also means, however, that 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 (5).

Selection of a Decision Maker

Legislation should recognize the unique qualities required by SDMs of developmentally disabled persons in the context of consent to research. First, the person’s willingness to serve as a SDM should be expressed, and his or her reasons for doing so must be established (31). Second, the SDM must be competent to make the decision to consent to research. The SDM must be capable of assessing possible risks and be aware of any specific personal characteristics that would put the developmentally disabled 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 assessment of risks and benefits be made. Moreover, the SDM must be able to ascertain the wishes or feelings of the developmentally disabled person. Third, the SDM should disclose his or her 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 also that the decision maker feels pressured to appear cooperative with the staff in order to assure good treatment for the developmentally disabled person. Fourth, 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. Such a situation 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. Finally, 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, a person who is able to meet the criteria should be named. 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, which must be honoured by the SDM. Finally, whenever conditions permit, the opinion and approval of the developmentally disabled person should be obtained in the selection of the SDM.

Conclusion

Owing to the unique factors that affect the capacity of developmentally disabled persons to provide consent, it should be recognized that there is a substantial difference between this population and other vulnerable groups. There are 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 (3). 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 disabled persons in the deci-
sion-making process, taking into consideration the variance in levels of capacity that exists in this population. Competency assessments should be reevaluated during the course of an experiment, if required, because of the likelihood that increased familiarity with and understanding of the nature and consequences of participation will improve the subject’s competence. In the event of a declaration of incompetence, research should be conducted only with the consent of a legally appointed SDM authorized to make decisions with respect to research.

**Clinical Implications**

- As a vulnerable research population, mentally disabled patients require higher protections under the law.
- Cognitive deficits and incapacities impose higher standards on researchers when assessing patients’ competency to participate in research.
- Clinicians, as primary providers of care, should not engage their own patients as subjects of research.

**Limitations**

- More duties are placed on clinicians who engage their mentally disabled patients in research activities.
- More controls will increase the costs of conducting research with this population.
- External regulations may be seen as interference with clinical decisions.

**References**

24. See, for example, the current regulations in Ontario: O Reg 19/95.

**Résumé**

Les personnes ayant un handicap développement constituent une population vulnérable dans le contexte de l’expérimentation non thérapeutique. Leur vulnérabilité est caractérisée par une capacité réduite de prendre des décisions et par une sensibilité aux situations coercitives pouvant faire planer un doute sur la nature volontaire de leurs actes. Les experts internationaux conviennent qu’il faut permettre la recherche portant sur cette population, mais seulement après avoir obtenu le consentement du tuteur légal et avoir pris des mesures de protection appropriées. Par conséquent, on devrait adopter des lois régissant la conduite éthique en matière de recherche, notamment une dispositions visant le consentement de substitution dans le contexte de la recherche. Bien que les chercheurs voulant obtenir la participation d’une personne ayant un handicap de développement à un protocole doivent prouver qu’elle est en mesure de participer à la décision, ils doivent évaluer sa capacité s’il doutent qu’elle soit capable de prendre une telle décision. L’information doit être présentée de façon à maximiser la contribution de la personne, et il faut continuellement réévaluer sa capacité. En outre, la recherche chez les personnes ayant un handicap de développement présente des difficultés particulières quant à l’établissement de la capacité, la sélection des sujets, les caractéristiques du décideur et le modèle servant à prendre des décisions par voie de substitution.