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*Celia B. Fisher**

INTRODUCTION

The orientation of legal advocates and social policy makers regarding the rights of the mentally infirm has shifted considerably over the years. Historically, adults with known mental disorders were presumed incompetent and restricted from opportunities to make decisions for themselves.[1] Disregard for the rights of institutionalized and impaired persons resulted in abuses, such as the infamous case at the Willowbrook State School, where biomedical researchers infected children identified as "mentally defective" with viral hepatitis without their knowledge, and with the questionable voluntary consent of their parents.[2]

In the wake of Willowbrook, advocates for people with mental retardation have made significant legal gains for individuals with decisional impairments. This movement led to including policies requiring the deinstitutionalization of individuals whose futures had largely been relegated to severely restricted institutional living, regulations for intermediate care facilities, court decisions guaranteeing the right of persons with mental retardation to make their own decisions, and ultimately, recognition by the courts that a diagnosis of a mental disorder is not a presumption that the individual is incompetent to make decisions.[3]

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1. *See* RUTH R. FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT 290 (1986); ARNOLD J. ROSOFF, INFORMED CONSENT: A GUIDE FOR HEALTH CARE PROVIDERS 234 (1981).

2. T.D. v. N.Y. State Office of Mental Health, 626 N.Y.S.2d 1015, 1022 (Sup. Ct. 1995); *see also* JAY KATZ, EXPERIMENTATION WITH HUMAN BEINGS 1007 (1972).

3. *See* Rogers v. Okin, 478 F. Supp. 1342, 1359 (D. Mass. 1979), *aff'd in part, rev'd in part*, 634 F. 2d 650 (1st Cir. 1980), *vacated sub nom.* Mills v. Rogers, 457 U.S. 291 (1982); *certified questions answered sub nom.* T.D. v. N. Y. State Office of Mental Health, 650 N.Y.S.2d 173 (App. Div. 1996); Rennie v. Klein, 462 F. Supp. 1131, 1147 (D.N.J. 1978), *modified and remanded*, 653 F.2d 836 (3d Cir. 1981); *vacated and remanded*, 458 U.S. 1119 (1982), *on remand* 720 F. 2d 266 (3d Cir. 1983); *Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded*, 53 Fed. Reg. 20,448, 20,505 (June 3, 1998) (codified at 42 C.F.R. pt. 483); AM. ASS'N ON MENTAL RETARDATION, A GUIDE TO CONSENT 95-125 (Robert D. Dinerstein et al. eds., 1999); PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. &

Despite these gains, balancing the obligation to respect the rights of those with mental impairments to be treated as autonomous members of the moral community with the need to ensure that ill-informed or incompetent decisions will not jeopardize their welfare remains an ongoing ethical challenge for legal advocates, practitioners, and family members.[4] This Essay argues that informed consent policies for adults with mental disorders need to reflect a relational approach that re-conceptualizes consent vulnerability in terms of a "goodness-of-fit" between patient characteristics and the consent context.

I. CONSENT VULNERABILITY AS A RELATIONAL CONSTRUCT

Adults with mental disorders, like all people, are linked to others in relationships of reciprocity and dependency.[5] Conceptualizing consent impairments as a product of the relationship between the person and the consent context shifts ethical inquiry away from an exclusive focus on the patient's or research participant's mental infirmities. Instead, it focuses on those aspects of the consent setting that are creating or exacerbating consent vulnerability, and considers how the setting can be modified to produce a consent process that best reflects and protects the patient's/participant's hopes, values, concerns, and welfare.[6] From a relational perspective, morally responsible informed consent practices require more than simply evaluating whether a patient/participant understands the nature, risks, and benefits of procedures for which consent is sought, toward a reconfiguration of the consent context itself. Such reconfigurations involve remedial efforts to enhance consent comprehension coupled with efforts to attain mutual understandings among consent stakeholders regarding their values and concerns.[7]

BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 169-88 (1982); WOLF WOLFENSBERGER, THE PRINCIPLE OF NORMALIZATION IN HUMAN SERVICES 208-36 (1972).

4. *See* Donald N. Bersoff et al., *Legal Issues in the Assessment and Treatment of Individuals with Dual Diagnoses*, 62 J. CONSULTING & CLINICAL PSYCHOL. 55, 55-62 (1994); J. W. Ellis, *Decisions by and for People with Mental Retardation: Balancing Considerations of Autonomy and Protection*, 37 VILL. L. REV. 1779, 1804-09 (1992); Celia B. Fisher, *Relational Ethics and Research with Vulnerable Populations*, *in* 2 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING PERSONS WITH MENTAL DISORDERS THAT MAY AFFECT DECISIONMAKING CAPACITY 29-51 (1999);.

5. Margaret Urban Walker, *Autonomy, Beneficence, and Justice in the Wider Context*, 12 ETHICS & BEHAV. 291, 292 (2002).

6. *See infra* notes 43-45 and accompanying text.

7. *See infra* notes 43-45 and accompanying text.

Embedded in law and professional standards, the modern doctrine of informed consent is too often grounded in a limited definition of autonomy that is restricted to respect for an individual's right to self-governance and privacy.[8] However, as Professor James Childress has pointed out, the ideal of autonomy must be distinguished from the conditions for autonomous choice.[9] Within this framework autonomy need not be conceptualized as isolated or isolating,[10] but as an expression of connectedness to others. From this relational perspective, respect for autonomy requires that practitioners and investigators make every attempt to create a goodness-of-fit between the person and the consent context that maximizes opportunities for the individual to provide informed, rational, and voluntary decisions. When such efforts are insufficient to insure adequate consent, individuals should be encouraged to either select a consent partner, or to yield decision-making to a consent surrogate who can help arrive at a decision that best reflects the patient's wishes and concerns.

From a relational perspective, autonomy involves not only an obligation to self, but also to others.[11] Thus, when individuals with impaired decisional capacity choose to use a consent partner or surrogate, the patient and the partner/surrogate are obligated to understand and respect each other's concerns and values. Thus, a goodness-of-fit ethic encourages an exchange of views between persons with mental disorders and their formal or informal consent partners that illuminates, rather than eliminates, the moral positions of each. This exchange of views in turn leads to a consent decision that accommodates, rather than subjugates, these values.[12]

II. INFORMED, RATIONAL, AND VOLUNTARY PERSON-CONTEXT CONSENT

Informed consent to medical treatment and research represents a mutual agreement between a practitioner and patient, the validity of which requires that the consent be informed, rational, voluntary, and competent.[13] The informed aspect of consent requires

8. FADEN ET AL., *supra* note 1, at 7-9.

9. James F. Childress, *The Place of Autonomy in Bioethics*, HASTINGS CENTER REP., Jan.-Feb. 1990, at 12-13.

10. *See* Walker, *supra* note 5, at 293.

11. Donna M. McKenzie, *What Theological Understandings Contribute to Protecting Mentally Impaired Persons in Medical Treatment and Research*, 12 ETHICS & BEHAV. 287, 288 (2002).

12. *See* Fisher, *supra* note 4, at 30-31.

13. *See generally* FADEN ET AL., *supra* note 1, at 3.

that practitioners provide information about the purpose, procedures, potential risks and benefits, and alternative options of treatment or research sufficient for an individual to make a reasoned decision. Such information, however, may not be sufficient for individuals with mental disorders who either lack general knowledge about health care treatments and patient rights, or who have not had the opportunity to make autonomous decisions. In these situations, a goodness-of-fit between the person and consent context might require modifying consent procedures to include "reasonable disclosure" of practical information about those general aspects of health care, or research essential for a knowledgeable decision to be made.[14]

To meet the rational requirement of informed consent, an individual needs to be able to understand the information presented and appreciate the consequences to oneself of agreeing or declining treatment or research participation.[15] Although impairments in abstract reasoning can limit this ability, matching the language level of consent information to that of a patient/participant with a mental disorder, and modifying those aspects of the consent setting that may be stress provoking for that particular individual, can reduce person-context consent vulnerability.

The voluntary requirement of consent is meant to insure that individuals are not coerced into participation, and are free to withdraw from treatment or biomedical research at any time.[16] In some contexts people with mental disorders may be particularly vulnerable to coercion and exploitation.[17] For example, they may fear disapproval from family caretakers or may feel that they must be compliant in deference to the authority of the requesting practitioner. Some may have had little experience in exercising their rights, or may fear the discontinuation of other services if they are living in a treatment residence. Modifying the consent setting to reduce the perception of power inequities, to provide opportunities to practice decision-making, and to construct concrete ways of demonstrating that other services will not be compromised, can strengthen the goodness-of-fit between person and consent setting.

14. *See* Allan M. Tepper & Amiram Elwork, *Competence to Consent to Treatment as a Psycholegal Construct*, 8 LAW & HUM. BEHAV. 205, 213 (1984).

15. *See* FADEN ET AL., *supra* note 1, at 250.

16. *Id.* at 8.

17. *See id.* at 288-92.

III. DEFINING CONSENT COMPETENCE

How to judge whether an individual is competent to consent continues to be debated in ethical and legal arenas.[18] Appelbaum and his colleagues have developed the most influential taxonomy for evaluating capacity to consent based on a consideration of the practical context in which clinical and legal decisions are made.[19] According to this taxonomy, consent competence can be evaluated in terms of four psycho-legal standards.[20]

The first, and least stringent of the four standards, is *communicating a choice*.[21] In obtaining consent to treatment from persons with mental impairments, failure to object has commonly been construed as an expression of voluntary agreement.[22] Thus, a minimum psycho-legal standard requiring documentation that the patient or research participant has communicated a choice orally or in writing will protect the individual against excessive paternalism.

The second psycho-legal standard, *factual understanding*, pertains to comprehension of information about the nature, timing, and potential risks and benefits of treatment.[23] As mentioned previously, factual understanding is not simply dependent upon intellectual capacity, but is linked to the degree to which an individual has had previous experience with the treatment in question, and the extent to which the practitioner or legal advocate educates the individual regarding treatment options.[24]

The third psycho-legal standard, *appreciation of the situation,* requires that the individual understand not only the procedures, risks, and benefits of the research, but also the medical and personal implications for her own circumstances.[25] In some instances this may be difficult for adults with mental disorders. For example, lack of insight into the presence of the illness is common in schizophrenia and some other psychiatric disorders, making it difficult

18. *See* PAUL S. APPELBAUM ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 83-90 (1987); Barry Rosenfeld, *Competence to Consent to Research: Where Psychology, Ethics and the Law Intersect*, 12 ETHICS & BEHAV. 284, 284-87 (2002).

19. *See* THOMAS GRISSO & PAUL S. APPELBAUM, ASSESSING COMPETENCE TO CONSENT TO TREATMENT 127-48 (1998); Paul S. Appelbaum & Loren H. Roth, *Competency to Consent to Research: A Psychiatric Overview*, 39 ARCHIVES GEN. PSYCHIATRY 951, 952-56 (1982).

20. Applebaum & Roth, *supra* note 19, at 952-53.

21. *Id.*

22. *See* Ellis, *supra* note 4, at 1808.

23. Appelbaum & Roth, *supra* note 19, at 953-54.

24. *See supra* note 14 and accompanying text.

25. Appelbaum & Roth, *supra* note 19, at 954.

for some people in the acute stages of these illnesses to evaluate the risks and benefits of treatment.[26] Some studies, however, have questioned whether denial of mental illness is sufficient justification for a finding of incompetence.[27]

The fourth psycho-legal standard, *rational manipulation of information*, is the most stringent, requiring the ability to weigh risks and benefits in order to arrive at a "reasonable" outcome of choice.[28] Roth, Meisels, and Lidz warn that holding patients to a standard that requires the calculation of risks and benefits poses legal and ethical problems because it is difficult to demonstrate that any person's preference directly relates to the rationale she may offer, and rejection of an individual's rationale can potentially be used to justify widespread substitute decision-making for those with cognitive impairments.[29] Moreover, for adults with mental disorders who may not make decisions based upon rational calculations, applying a risk-benefit analysis as the primary standard of moral agency can deny them freedom of action based upon more concrete or emotional factors that are equally legitimate expressions of the rights of personhood.[30] Holding persons to this last standard of cognitive competence has often justified widespread substitute decision-making for those with mental impairments, especially when the disabled person disagrees with the risk-benefit assessment of her physician or family members.[31] Furthermore, since the decision-making styles of those assumed to have no mental disorder are rarely evaluated, some researchers have warned that adults with mental illnesses may be unfairly held to a

26. Paul S. Appelbaum, *Decisionally Impaired Research Subjects,* (Commissioned Paper), *in* 2 NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 4, at 1-4.

27. *See* Trudi Kirk & Donald N. Bersoff, *How Many Procedural Safeguards Does It Take to Get a Psychiatrist to Leave the Lightbulb Unchanged? A Due Process Analysis of the MacArthur Treatment Competence Study*, 2 PSYCHOL. PUB. POL'Y & L. 45, 64 (1996); Elyn R. Saks, *Competency to Decide on Treatment and Research: The MacArthur Capacity Instruments* (Commissioned Paper), *in* 2 NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 4, at 59-78.

28. Appelbaum & Roth, *supra* note 19, at 954.

29. L. H. Roth et al., *Tests of Competency to Consent to Treatment*, 134 AM. J. PSYCHIATRY 279, 282-83 (1977).

30. *See* M. MERLEAU-PONTY, PHENOMENOLOGY OF PERCEPTION xviii (1945); Fisher, *supra* note 4, at 41; McKenzie, *supra* note 11, at 289; Guy A.M. Widdershoven & M. Smits, *Ethics & Narratives*, *in* ETHICS AND PROCESS IN THE NARRATIVE STUDY OF LIVES 275, 280 (Ruthellen Josselson ed., 1996).

31. *See* Fisher, *supra* note 4, at 41.

higher standard of competency than commonly applied to the general population.[32]

While state laws provide standards and procedures for appointing guardians to individuals declared legally incompetent, these judicial proceedings are generally not required for treatment or research consent decisions for individuals who, although not declared legally incompetent, have diagnosed mental disorders that may impair their decision-making in particular contexts.[33] From a relational perspective, appointment of a consent surrogate in these gray legal areas is only ethically justified if: (1) the person has agreed that proxy oversight or assistance is a desirable means of protecting her interests; (2) her assent to participate is sought in addition to the surrogate's consent; and (3) her dissent over-rides the proxy opinion.[34]

IV. ASSESSING AND ENHANCING INFORMED CONSENT COMPETENCE

To date there is no widespread consensus on how consent capacity should be measured.[35] Despite the lack of valid assessment techniques, individuals with and without mental impairments, often assume that irrespective of a person's legal status or actual decision-making capacity, permission of a surrogate is required when consent is sought from a patient with an identified mental disorder.[36]

Paul Appelbaum and Thomas Grisso have constructed a popular series of instruments known as the "MacArthur scales" to measure the four psycho-legal standards of consent.[37] Using these scales,

32. C. LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY 17 (1984); *see* Appelbaum & Roth, *supra* note 19, at 952; J. F. Drane, *The Many Faces of Competence*, HASTINGS CENTER REP., Apr. 1985, at 17-21; Fisher, *supra* note 4, at 41; C. Donald Morris et al., *Determining the Capability of Individuals with Mental Retardation to Give Informed Consent*, 98 AM. J. MENTAL RETARDATION 263, 263-72 (1993).

33. Elizabeth Cooper, Panel Remarks on Legal and Psychological Foundations of Informed Consent, at Conference at the Fordham University School of Law entitled *Religious Values and Legal Dilemmas in Bioethics* 358-66 (Jan. 29, 2002) (transcript on file with the *Fordham Urban Law Journal*).

34. *See* Fisher, *supra* note 4, at 42; Celia B. Fisher, *Respecting and Protecting Mentally Impaired Persons in Medical Research*, 12 ETHICS & BEHAV. 280, 282 (2002).

35. *See generally* Saks, *supra* note 27, at 59.

36. *See* C. Ficker-Terrill & L. Rowitz, *Choices*, 29 MENTAL RETARDATION 63, 63 (1991); Ellis, *supra* note 4, at 1779-1809; Fisher, *supra* note 4, at 31.

37. Paul S. Appelbaum & Thomas Grisso, *The MacArthur Treatment Competence Study I: Mental Illness and Competence to Consent to Treatment*, 19 J.L. & HUM. BEHAV. 105, 105-26 (1995); *see* GRISSO & APPELBAUM, *supra* note 19, at 101-26;

researchers have found that hospitalized patients with schizophrenia, Alzheimer's disease, and depression have a poorer understanding of consent information than individuals with physical illnesses.[38] Others have found that intellectual classifications of adults with mental retardation are predictive of global indices of consent capacity.[39] However, few studies tell us about the particular aspects of consent that may be easy or difficult for individuals with mental impairments to understand.[40]

The National Bioethics Advisory Commission has stated that it is "inappropriate to suppose that those who exhibit some decision making deficit cannot be helped to attain a level of functioning that would enable them to be part of a valid consent process."[41] Yet, techniques that could improve consent competence have rarely been examined. Nonetheless, preliminary findings on the efficacy of brief written or video presentations on improving prospective patients' understanding of rights in treatment and research have been encouraging.[42]

The Roeher Institute proposed a supported decision-making model as a means of helping adults with questionable consent competence to exercise self-determination and in recognition that all adults draw upon the advice and support of others in making important decisions.[43] Adults with decisional impairments are asked to select a family member, friend, or other trusted person to be present during an informed consent discussion. The individual and her support person review information and decide together whether or not the individual will consent to participation. Sup-

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Thomas Grisso et al., *The MacArthur Treatment Competence Study II: Measures of Ability Related to Competence to Consent Treatment*, 19 J.L. & HUM. BEHAV. 127, 127-48 (1995).

38. Scott Y. H. Kim et al., *Assessing the Competence of Persons with Alzheimer's Disease in Providing Informed Consent for Participation in Research*, 158 AM. J. PSYCHIATRY 712, 712-17 (2001).

39. P. Lindsay & R. Luckasson, *Consent Screening Interview for Community Residential Placement: Report on the Initial Pilot Study Data*, 29 MENTAL RETARDATION 119, 119-24 (1991); *see* Morris et al., *supra* note 32, at 270; R. D. Tustin & M. J. Bond, *Assessing the Ability to Give Informed Consent to Medical and Dental Procedures*, 17 AUSTL. & N.Z. J. DEVELOPMENTAL DISABILITIES 35, 35-47 (1991).

40. Katy Arscott et al., *Consent to Psychological Research by People with an Intellectual Disability*, 11 J. APPLIED RES. INTELL. DISABILITIES 77, 77-83 (1998).

41. 1 NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 4, at 20.

42. *See* A. Tymchuck, *Assent Process*, *in* SOCIAL RESEARCH ON CHILDREN AND ADOLESCENTS: ETHICAL ISSUES 128, 135-36 (B. Stanley & J. E. Sieber eds., 1992).

43. ROEHER INST., SEEKING CONSENT TO PARTICIPATE IN RESEARCH FROM PEOPLE WHOSE ABILITY TO MAKE AN INFORMED DECISION COULD BE QUESTIONED: THE SUPPORTED DECISION-MAKING MODEL 5 (1996).

ported decision-making can safeguard against the potential for triggering of a legal competency review for adults with disabilities who do not have legal guardianship. In such cases, being deemed incompetent solely for the purposes of a single treatment decision has the potential to jeopardize their autonomy rights in other contexts.

As new techniques for assessing and enhancing consent capacity evolve, they must not ignore the importance of individual variations in the strengths and vulnerabilities that each person brings to the consent context, and the importance of engaging persons with intellectual infirmities as partners in the decision-making process.

V. APPLYING RELATIONAL ETHICS—THREE CASES[44]

A. Case One—The Right of Adults with Mental Retardation to Reject Psychopharmacological Treatment

John is a forty year old man with mental retardation who has lived in a community residence for the past twenty years. His legal competency has never been challenged and he does not have a legal guardian. For the past ten years he has sustained a job at a sheltered workshop, and with assistance from the community residence staff, he is able to manage his small income. Over the past twelve months, he has been involved in physical fights with other consumers at his residence. Standard behavioral and psychopharmacological treatments for aggressive disorders have not helped John, and his aggressive behavior is increasingly perceived as dangerous to the staff and other residents. If he cannot control his behavior he may have to be moved to a more restrictive institution. John is eligible for treatment at a nearby hospital testing a new drug for aggressive disorders, but he refuses to participate because he distrusts the new doctors and is concerned that the side effects of the medication will prevent him from going to work. The supervisor of John's residence wishes to overrule John's judgment and enroll him in the study, because the supervisor believes it may be John's only chance to keep his job and stay in the residence where he feels happy and safe.

Does the supervisor have the right to override John's rejection of treatment? Does he have the obligation to do so? Would the decision be different if John did not have mental retardation? What

44. *The Forum*, 12 ETHICS & BEHAV. 279, 279 (Celia B. Fisher ed., 2002) (detailing the cases that have been adapted here).

steps might the supervisor take to achieve the best goodness-of-fit between John's abilities and the consent context?

First, the supervisor needs to engage in dialogue with John to understand the reasons for John's refusal of treatment and to share his own concerns about possible future consequences. The supervisor could take steps to alleviate those concerns, perhaps by having John visit the hospital, meet the doctors, or discuss how to minimize the treatment's side effects. The supervisor must also consider that his own hopes for John may be clouding his judgment regarding the probability that the new treatment will work. After exploring all these avenues, the supervisor could help John consider the pros and cons of his decision, including John's obligation to himself, and to others in the residence.

Respecting a person's autonomy means respecting, and sometimes protecting, not just their abilities to make choices at particular moments in time, but their abilities and prospects to live autonomous lives over the longer term.[45] The supervisor must carefully consider whether overriding John's decision-making authority could have harmful practical consequences. For example, petitioning the court to appoint a guardian or turning to one of John's family members to provide surrogate consent (a common, but legally questionable practice in many community residences serving adults with mental retardation) could inadvertently initiate an investigation into John's legal competency to make decisions in other situations, diminish John's hard won confidence in his decision-making abilities, and hamper his freedom to make autonomous decisions in the future. Such consequences might be just as hazardous to John's welfare as the possibility of leaving the residence.

In some instances, when a person's decision-making ability is limited, it is ethically justifiable to make a substitute decision that will protect her from harm. However, in this case there is no evidence that John's decision-making is any different from the range of responses that a person without mental retardation might make in this situation. There is no guarantee that the new treatment will work, and no one can say with certainty that moving to a more restrictive setting will be harmful to John, especially given the fact that he is having such difficulties in his current residence. Thus, in this situation, having achieved the best possible goodness-of-fit be-

45. *See* Walker, *supra* note 5, at 291.

tween John's abilities and the consent context, the supervisor should respect John's right to dissent to the treatment.

B. Case Two—Advanced Directives by an Individual with Alzheimer's Disease

Nina, a seventy-six year old woman in the beginning stages of Alzheimer's disease wants to sign an advanced directive consenting to participate in an experimental treatment study that will not begin until she has reached the advanced stages of Alzheimer's. Her adult children are afraid the treatment may quicken their mother's mental decline, and question Nina's authority to provide consent for a time in the future when her decision-making capacity will be deficient.

Nina's case illustrates a problem inherent in issuing and following advance directives: neither Nina nor her children can know with certainty how she will think and feel in a diminished state. In the face of such uncertainty, the protectionist stance taken by Nina's children does not satisfactorily resolve this issue. Despite limitations in predicting future reactions, Nina in her present mental condition, is the most expert in envisioning how she will respond in an eventual state of cognitive impairment. To respect Nina's right to self-determination and to insure that her future welfare is protected, a goodness-of-fit process of obtaining ethically acceptable advanced directives should include a series of information sharing sessions among Nina, her children, and the medical scientists during which: (a) the physicians provide Nina and her family with information about the anticipated course, nature of, and potential risks and benefits of the experimental treatment; (b) Nina provides the practitioners and her children with information to help them understand her value system, the way she evaluates physical or emotional pain, her views on the altruistic value of research participation, and other personal perspectives that would allow her children to make future decisions from her perspective; and (c) Nina's children share their moral philosophies on consent-relevant dimensions so that Nina and they can decide whether or not the advance directives can be carried out in a manner that honors everyone's value orientations.[46] This last step recognizes that Nina is also obligated to respect the values and welfare of her children.

46. *See* Fisher, *supra* note 4, at 43; Fisher, *supra* note 34, at 282-83.

C. Case Three—Withdrawing a Schizophrenic Patient from Medication-Free Research

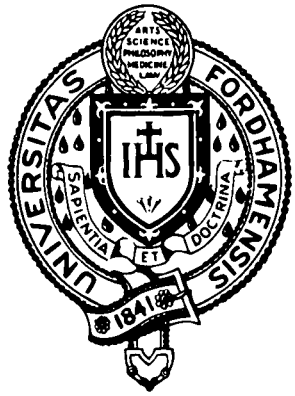
Alice, a twenty-five year old woman with schizophrenia, hates the disabling physical side effects of the psychoactive medication she is taking, even though it is successfully controlling her thought disorder. She consented to be in a medical study designed to test how long persons with schizophrenia can remain free of psychiatric problems after stopping medication. Two weeks into the study, her parents began to worry that some of Alice's "bizarre" behavior was returning since she stopped the medication. When they asked Alice to withdraw from the study, she refused. Her parents approached the hospital conducting the study and challenged the legitimacy of Alice's consent to remain in a study that places her mental health, and perhaps her life, at risk. The hospital refused to release her from the study, citing their consent agreement with Alice.

What went wrong with this consent process? The possibility of fluctuating consent capacity was easily predicted by the clinical investigators, since the purpose of the research was to determine how long individuals with schizophrenia would remain in remission after the medication was withdrawn. From a goodness-of-fit ethic, it was incumbent upon the investigators to develop a consent process that included Alice, the scientists, and either Alice's parents, another adult of her choosing, or a participant advocate who would be available to make research withdrawal decisions in the event that Alice's psychotic symptoms returned. During the pre-consent discussion, investigators should have provided information regarding: (a) anticipated fluctuations in Alice's decision-making capacities; (b) the safety and monitoring procedures that would be employed by the research team to protect her welfare; and (c) the specific criteria for determining that Alice was no longer competent to make decisions regarding her continued involvement or withdrawal from the study. In addition, during the pre-consent meeting, Alice and her decision-making partner should have been given the opportunity to discuss their views regarding the point at which decline in Alice's mental health would justify withdrawal from the study. The goal of the discussion would have been to arrive at a shared understanding of the conditions under which the judgment of Alice's consent partner(s) would ethically override her desire to remain in the study.[47]

47. *See* Fisher, *supra* note 34, at 283.

CONCLUSION

In summary, these three cases illustrate the importance of seeking a goodness-of-fit between a person's decisional capacities and the consent context. To do so involves engaging adults with mental disorders as partners in creating respectful and compassionate consent procedures. All people are unique individuals. Thus, consent procedures should be based upon an understanding of each prospective patient or participant's special characteristics, her consent strengths and weaknesses, life experiences, and practical concerns. Such an understanding can be achieved through ongoing dialogue among patients, their family members, legal advocates, and practitioners to insure that consent procedures reflect an ethic of mutual obligation, respect, and care.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