Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity

VOLUME II

COMMISSIONED PAPERS BY THE

NATIONAL BIOETHICS ADVISORY COMMISSION

MARCH 1999

National Bioethics Advisory Commission, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892-7508
Telephone: 301-402-4242 Facsimile: 301-480-6900 Website: *www.bioethics.gov*

NATIONAL BIOETHICS ADVISORY
COMMISSION

Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity

Commissioned Papers

March 1999

Table of Contents

PAPER ONE

DECISIONALLY IMPAIRED RESEARCH SUBJECTS

Disorders and Research Promises

Paul S. Appelbaum, M.D.
A.F. Zelesnik Professor and Chairman
Department of Psychiatry
University of Massachusetts Medical Center
55 Lake Avenue North
Worcester, Massachusetts 01655

The Nature of Disorders that Affect Decisionmaking Ability

Any disorder that alters mentation may adversely affect decisionmaking ability. When such a disorder is present in an early or mild phase, the resulting impairment may not rise to the level at which a potential research subject would be considered unable to consent to research participation, although extra care in the informed consent process may be required. More advanced or severe forms of disorder, however, may render the subject incapable of independent choice. Thus, identification of a potential subject as suffering from a disorder that may impair mentation does not obviate the need for an individualized assessment of the person's decisionmaking abilities.

A relatively small body of research has documented the effects of various disorders on decisionmaking capacity per se, but this is supplemented in many cases by data on cognitive functioning in general and by a good deal of clinical experience with these populations.

Dementia

Dementias are characterized by multiple cognitive deficits, most prominently impairment of memory. The best known of these conditions is dementia of the Alzheimer's type, a progressive disorder whose cause is presently unknown, the incidence of which increases with age, from 2 to 4 percent in the population over 65 years old to 20 percent or more in persons over 85 years old.[1] Dementias may also be caused by vascular infarcts of the brain, head trauma, HIV infection, and other neurological conditions, such as Parkinson's disease and Huntington's disease.

Study of decisionmaking impairment in persons with dementia has focused on Alzheimer's disease. Even patients with mild Alzheimer's dementia may evidence deficits in understanding relevant information and reasoning sufficient to call their capacities into question, although the choices they make about treatment and research may not differ at this point from non-impaired populations. As dementia progresses to the moderate stage, however, the range and magnitude of deficits

1 American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, 4th ed. (DSM-IV)*. Washington, DC: APA, 1994.

expands, and many more persons fail even the simplest tests of decisionmaking capacity.[2] The co-occurrence of other disorders, such as delirium or depression, may exacerbate the impact of dementia on the ability to make decisions.

Delirium

Like dementia, delirium involves alterations in cognition, but usually evolves over hours to days. Disturbances of consciousness and attention are prominent. Delirium is most often caused by systemic medical conditions, side effects of medications, intoxication with or withdrawal from psychoactive agents, or toxins.[3] Studies demonstrating high rates of decisional impairment in severely ill, hospitalized patients are probably detecting the effects of delirium secondary to the underlying conditions and, in some cases, the treatments being administered.[4] In contrast, other work suggests that serious medical illness that does not directly impair brain function, even when it results in hospitalization, is not likely, by itself, to result in limitations on decisionmaking abilities.[5]

Schizophrenia

Schizophrenia is a severe psychiatric disorder marked by delusions, hallucinations, disorganized speech or behavior, and diminished affect and initiative. A variety of cognitive dysfunctions, including several related to processing information, have been associated with the disorder. Its onset typically occurs in early adulthood and, although its course is variable, symptoms often wax and wane, with the result that functional impairment fluctuates over time.[6] Many of its manifestations can be reduced with antipsychotic medication, but residual symptoms are frequent and relapse is not uncommon.

As many as one-half of acutely hospitalized patients with schizophrenia may have substantially impaired decisionmaking abilities, including understanding, appreciation, and reasoning.[7] Since many of these impairments appear to be related to active symptoms, the prevalence of reduced capacity is likely to be lower among outpatient groups.[8] Lack of insight into the presence of illness and need for treatment is common among persons with schizophrenia;[9] this may make it especially difficult for them to anticipate consequences of their decisions related to the risk of future relapse.

Depression

Symptoms of major depression include: depressed mood; feelings of worthlessness; diminished interest and pleasure in most activities; changes in appetite, sleep patterns, and energy levels; and difficulties in concentration.[10] Cognitive impairments may exist in information processing[11] and reasoning,[12] among other functions. It has also been suggested that decreased motivation to protect their interests may reduce depressed patients' abilities to make decisions,[13] and alter the nature of those decisions.[14] Less clear is the extent to which these consequences of depression impede decision making. One study suggested that hospitalized depressed patients may manifest problems roughly half as often as patients with schizophrenia, that is, in about one-quarter of cases.[15] But it is likely that the degree of impairment relates to the intensity of depressive symptoms, and thus will vary across populations.

Other Disorders

Although less subject to formal study in the context of consent to treatment or research, there is good reason to believe that other conditions may also predispose to impaired decisional functions. Mental retardation, affecting as it does a range of cognitive abilities, is more likely to impair capacities as severity increases. Bipolar disorder results in alternating states of depression and mania, the latter comprising elevated mood, increased impulsivity, and reduced attention, among other features; manic patients are notorious for making poor decisions about money and personal affairs, and it is probable that this deficit extends into research decision making for some subset of this group. Other psychotic disorders involve some of the symptoms seen in schizophrenia, including delusions and hallucinations, and probably have some of the same consequences

2 Marson, Ingram, Cody, and Harrell. "Assessing the competency of patients with Alzheimer's disease under different legal standards," *Archives of Neurology* 52 (1995): 949–54; Stanley B, Guido J, Stanley M, and Shortell D. "The elderly patient and informed consent." *Journal of the American Medical Association* 252 (1984): 1302–1306.

3 American Psychiatric Association, *DSM-IV*, op. cit.

4 Cohen, McCue, and Green. "Do clinical and formal assessment of the capacity of patients in the intensive care unit to make decisions agree?" *Archives of Internal Medicine* 153 (1993): 2481–85.

5 Appelbaum and Grisso. "Capacities of hospitalized, medically ill patients to consent to treatment," *Psychosomatics* 38 (1997): 119–25.

6 American Psychiatric Association, *DSM-IV*, op. cit.

7 Grisso and Appelbaum. "The MacArthur Treatment Competence Study, III: Abilities of patients to consent to psychiatric and medical treatment," *Law and Human Behavior* 19 (1995): 149–74.

8 Rosenfeld, Turkheimer, and Gardner. "Decision making in a schizophrenic population," *Law and Human Behavior* 16 (1992): 651–62.

9 Amador, Strauss, Yale, and Gorman. "Awareness of illness in schizophrenia," *Schizophrenia Bulletin* 17 (1991): 113–32.

10 American Psychiatric Association, *DSM-IV*, op. cit.

11 Hartlarge, Alloy, Vazquez, and Dykman. "Automatic and effortful processing in depression," *Psychological Bulletin* 113 (1993): 247–78.

12 Baker and Channon. "Reasoning in depression: impairment on a concept discrimination learning task," *Cognition and Emotion* 9 (1995): 579–97.

13 Elliott. "Caring about risks: are severely depressed patients competent to consent to research?" *Archives of General Psychiatry* 54 (1997): 113–16.

14 Lee and Ganzini. "Depression in the elderly: Effect on patient attitudes toward life-sustaining therapy," *Journal of the American Geriatrics Society* 40 (1992): 983–88.

15 Grisso and Appelbaum, op. cit.

for decision making. Substance use disorders, including use of alcohol and illegal drugs, result in states of intoxication and withdrawal that resemble delirium in their effects on attention, cognition, and other mental functions.

This list, while highlighting the major conditions that impact decisionmaking ability, is by no means exhaustive.

The Promise of Research with Disorders that Cause Decisional Impairments

Psychiatric, neurological, and other disorders that may render persons decisionally impaired account for enormous morbidity, with associated human and economic costs. Of the ten leading causes of disability in the world, according to a recent World Health Organization report, five were psychiatric conditions: unipolar depression, alcohol use, bipolar affective disorder, schizophrenia, and obsessive-compulsive disorder.[16] It has been estimated that direct and indirect costs of mental illness and substance abuse in the United States totaled more than $313 billion in 1990.[17] Alzheimer's disease now afflicts approximately 4 million people in this country and, with the number of persons over 65 years of age expected to double by the year 2030, the resulting morbidity will grow proportionately.

Given the scope of these disorders, when treatments can be identified that mitigate their impact, the benefits are substantial. Since 1970, the cumulative savings to the U.S. economy from the introduction of lithium as a treatment for bipolar disorder is estimated at $145 billion. No dollar figure can be put on the benefits to patients and families spared the anguish of manic and depressive episodes, which often tear apart the fabric of family life and social relationships. Similarly, the introduction of clozapine for treatment of schizophrenia has been estimated to have yielded savings of $1.4 billion per year since 1990.[18] Thus, every incentive exists to improve our understanding of disorders affecting brain function and to develop more effective treatments for them.

Research on these conditions falls into two broad categories: studies aimed at elucidating the underlying pathophysiologic bases of the disorders; and studies intended to develop or test new treatments for them. Among the most powerful approaches to examining basic aspects of brain function and dysfunction are new techniques that allow imaging of the working brain. Positron emission tomography (PET), fast magnetic resonance imaging (fMRI), single photon emission computer tomography (SPECT), and related devices facilitate identification of the anatomic location of brain areas involved in cognitive and affective functions.[19] Comparisons of normal and afflicted populations permit localization of regions affected by the disease process. These techniques also allow monitoring of the effects of treatment regimens at the level of the brain.[20]

Medications are the mainstay of treatment for severe psychiatric and neurologic disorders—although behavioral interventions can be useful adjuncts—and thus are the primary focus of treatment-oriented research. Development of new medications is being facilitated by studies of brain neurotransmitter receptors, which allow new molecules to be created that have the desired therapeutic effects with minimal side effects. More innovative approaches still on the drawing boards include insertion of new genes to correct identified defects underlying brain disorders ("gene therapy"), and use of immunologic therapies, like the recent successful inoculation of rats against the psychostimulant effects of cocaine.[21]

Some basic research (e.g., on brain receptor mechanisms) can be performed with animal subjects rather than with humans. But when disease processes themselves are under study, the absence of animal models for most psychiatric and neurologic syndromes means that research on both underlying mechanisms of disease and on promising treatments must involve human subjects. Moreover, unless research is to be limited to the mildest forms of the disorders—which may differ substantively from more chronic or severe forms—persons whose decisionmaking capacities may be impaired are likely to be involved. From this reality flows the central dilemma of designing appropriate protections in research on decisionally impaired populations: protection of subjects from harm must be balanced against the potential for benefit to subjects themselves, and to other persons with their disorders, that may arise from research participation.

16 World Health Organization. *The Global Burden of Disease*. Cambridge, MA: Harvard University Press, 1997.

17 American Psychiatric Association. *Opening Windows into the Future: Psychiatric Research in the 21st Century*. Washington, DC: APA, 1997.

18 Testimony of Steven Hyman, Director, National Institute of Mental Health, U.S. Senate Appropriations Subcommittee Hearings, 1997; Meltzer, Cola, Way, Thompson, Bastani, Davies, and Snitz. "Cost effectiveness of clozapine in neuroleptic-resistant schizophrenia," *American Journal of Psychiatry* 150 (1993): 1630–38.

19 Andreasen, O'Leary, and Arndt. "Neuroimaging and clinical neuroscience: basic issues and principles," in Oldham, Riba, and Tasman (eds.), *American Psychiatric Press Review of Psychiatry*, Vol. 12. Washington, DC: American Psychiatric Press, 1993.

20 Baxter, Schwartz, Bergman, Szuba, Guze, Mazziotta, Alazraki, Selin, Ferng, Munford, and Phelps. "Caudate glucose metabolic rate changes with both drug and behavior therapy for obsessive-compulsive disorder," *Archives of General Psychiatry* 49 (1992): 681–89.

21 American Psychiatric Association, *Opening Windows*, op.cit.

PAPER TWO

RESEARCH INVOLVING PERSONS WITH MENTAL DISABILITIES

A Review of Policy Issues and Proposals

Rebecca Dresser, J.D.
John Deaver Drinko-Baker & Hostetler Professor
Case Western Reserve University
School of Law
Professor, Center for Biomedical Ethics
School of Medicine

Mailing Address:
Case Western Reserve University
School of Law
11075 East Boulevard
Cleveland, Ohio 44106
Telephone: (216) 368-6071
E-mail: rsd2@po.cwru.edu

Introduction

Developing a federal policy to govern research involving adults with cognitive impairment poses numerous challenges. Some challenges are related to the diverse abilities and situations of individuals in this population. Due to this diversity, relatively detailed standards and procedures are required to discern which persons are capable of independent decisions to enter and remain in a study, and which need the assistance of another to act as research decision maker. Challenges also arise from the effort to show respect for the varied present and former preferences of decisionally incapable persons. Additional challenges are posed by the lack of clear consensus concerning the acceptable balance of risk and expected benefit in studies involving incapable subjects.

Practical challenges face those creating federal policy on research involving adults with mental disabilities as well. Some proposals in the literature may be too complex for real-world application. Federal policy must be reasonably attainable by, and conveyed in language comprehensible to, Institutional Review Board members, researchers, clinicians, and lay persons.

I begin by describing the historical context of the current debate over research involving adults with mental disabilities. Then, with the goal of delineating the choices before you, I discuss six basic concepts relevant to potential policy. Though the concepts merit separate analysis, they often are combined in various policy proposals. For example, some proposals favor a higher standard for capacity to enter a research study when the risks of participation are significant; other suggest that higher-risk studies for incapable subjects should be permitted only as long as the subject affirmatively assents or previously consented while competent to participate.

The following is a list of basic questions to be addressed in the deliberations on appropriate federal policy for research involving adults with mental disabilities:

- What capacity standard(s) should apply to persons deciding about research participation? (Should a lower standard be applied to persons designating a research proxy decision maker?)
- What procedures, if any, should be required to ensure that an individual's decision to enter (and remain in) research is capable, informed, and voluntary? Should special procedures be

required only in certain cases, such as research presenting no prospect of direct benefit? When, if ever, should an independent monitor be involved in such evaluations?

- Should federal policy encourage or require specific qualifications for persons making research decisions for incapable individuals (e.g., legal guardianship, prior designation as research or health care proxy, legislative authorization to make health care decisions)?
- Should substantive standards be adopted for decisions by subject representatives (e.g., choose according to subject's prior express wishes or general values and preferences, or subject's best interests)?
- Should requirements be adopted for education and screening of subject representatives? (If so, who should perform these tasks?)
- Should affirmative subject assent (always/sometimes/never) be required? Should research ever be permitted when subjects appear partially or completely incapable of assent? If so, when? What constitutes an objection sufficient to block continued participation? When, if ever, may research proceed despite an incapable subject's objection?
- What procedures should be applied to monitor an incapable subject's continued willingness to participate in research? When, if ever, should an independent monitor be required?
- Should research advance directives be encouraged or required? If so, what constitutes informed advance consent to research participation? How should the subject's right to withdraw be respected in this situation? When, if ever, should a research directive be a permissible basis for conducting research presenting greater risk to an incapable subject than is ordinarily permitted?
- Should policy specify the appropriate direct benefits, indirect benefits, and risks to be weighed in evaluating studies involving incapable subjects?
- Should policy incorporate the concepts of "minimal risk" and "a minor increase over minimal risk"? If so, should the concepts be defined with greater precision than in current federal policy?
- Should limits be placed on the degree of risk permissibly presented in research involving incapable subjects? What prospect of direct benefit to subjects or benefit to society is sufficient to justify various degrees of research risks? Should a national review process be adopted to consider the justification for certain categories of research with risk-expected benefit ratios unfavorable to incapable or questionably capable subjects?
- Should monitoring procedures be required to ensure that acceptable risk-expected benefit standards are observed in ongoing research?
- Should IRBs be required to include representatives of relevant subject groups when reviewing studies involving mentally disabled persons? Should policy direct IRBs or investigators to arrange for notice to, and consultation with, representatives of affected communities regarding proposed, ongoing, and completed research?

Historical Context

International Developments

The subject's informed and voluntary consent is the strongest basis for enrollment in a research study. Certain persons diagnosed with psychiatric disorders, developmental disabilities, dementia, and other conditions associated with mental disability possess the necessary cognitive abilities and are sufficiently independent of others to provide informed and voluntary consent. Many others, however, are not. A basic moral and policy question is whether these individuals should ever be involved in research.

The Nuremberg Code, the first international document on human subjects research, appears to forbid such research. According to the Code, "[t]he voluntary consent of the human subject is absolutely essential." Adequate consent requires the subject's: (1) "legal capacity to consent"; (2) ability "to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, or over-reaching, or other ulterior form of constraint or coercion"; and (3) "sufficient knowledge and comprehension of the elements of the subject matter involved," including "the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment."[1] Absent from the Code is any provision authorizing surrogate consent to research on behalf of subjects incapable of producing a decision that meets these criteria.

Later research codes and policies have rejected the Nuremberg Code's apparent position that informed and voluntary

1 United States v. Karl Brandt, reprinted in Katz, *Experimentation with Human Beings* (1972): 292, 305.

consent is an absolute prerequisite to a human subject's research participation. Two justifications are offered for this rejection. One rests on an interpretation of the Code in light of its historical origins. The Code was formulated in response to the Nazi experiments conducted on competent subjects without their consent. The judges issuing the Code may not have intended to take a specific position on research involving incapable subjects.[2] The second justification for rejecting a ban on research involving incapable subjects is based on moral considerations. Because new treatments must eventually be tested in persons suffering from the relevant condition, a policy totally excluding incapable subjects from research would preclude the development of improved treatment for persons with serious psychiatric disorders, dementia, and other mentally debilitating conditions.

The next major international research code reflects these views. The World Medical Association's Declaration of Helsinki, first issued in 1964, provides for limited research involvement of incapable human subjects. The most recent version of the Declaration states, "[i]n the case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation."[3] The Declaration divides research into two categories: "therapeutic" and "non-therapeutic." The Declaration appears to rule out the participation of incapable subjects in research that fails to offer them the possibility of direct benefit. When research has the advancement of knowledge for the benefit of others as its sole objective, the Declaration states, "[t]he subjects should be volunteers ...."

Two other recent documents address research involving incapable human subjects. The International Ethical Guidelines for Biomedical Research, issued in 1993 by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO), allow an incapable individual's research participation to be authorized by a "legal guardian or other duly authorized person." The guidelines permit research involving incapable subjects only if "the degree of risk attached to interventions that are not intended to benefit the individual subject is low" and "interventions ... intended to provide therapeutic benefit are likely to be at least as advantageous to the individual as any alternative." Incapable subjects' objections to participation must be respected; the sole exception would be the rare case in which "an investigational intervention is intended to be of therapeutic benefit to a subject, ... there is no reasonable medical alternative, and local law permits overriding the objection."[4]

Last November, the Council of Europe's Committee of Ministers adopted the Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine. This document allows persons without the capacity to consent to be involved in research if all the following conditions are met: (1) "the results of the research have the potential to produce real and direct benefit to his or her health"; (2) "research of comparable effectiveness cannot be carried out on individuals capable of giving consent"; (3) participation is authorized by the incapable person's "representative or an authority or a person or body provided by law"; and (4) the incapable person does not object to participation.

The document also permits research that fails to offer subjects potential direct health benefit if the study meets conditions two through four, above, and: (1) is designed to produce knowledge for the benefit of persons with the same condition; and (2) "entails only minimal risk and minimal burden for the individual concerned."[5]

U.S. Policy Development

In the aftermath of Tuskegee and other disturbing studies by U.S. researchers, Congress enacted legislation establishing the National Commission for the Protection of Human Subjects in 1974. Besides its work addressing the ethics of human subjects research in general, the commission produced analyses of the ethical and legal issues raised by the involvement of certain groups deemed especially vulnerable to inappropriate research practices. These groups included children, who are legally incompetent to make independent decisions, and persons institutionalized as mentally infirm, whose mental impairment and institutionalized status can prevent them from making informed and voluntary decisions to participate in research.[6]

In its 1977 Report and Recommendations on Research Involving Children,[7] and its 1978 Report and Recommendations on Research Involving Those Institutionalized as Mentally Infirm,[8] the commission rejected both the Nuremberg Code's complete ban and the Helsinki Declaration's limitation on the involvement of incapable subjects. The commissioners believed a less restrictive approach was justified to avoid harm to incapable persons as a group:

2 McCormick, Proxy Consent in the Experimentation Situation, *Perspectives in Biology and Medicine* 18 (Autumn, 1974): 2.

3 World Medical Association, Declaration of Helsinki, *Journal of the American Medical Association* 277 (1997): 927.

4 CIOMS/WHO, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* 22 (1993).

5 Council of Europe, Convention on Human Rights and Medicine (Nov. 1996). Member states will be invited to ratify or otherwise respond to this document.

6 Some infamous incidents of human subjects use in the U.S. involved children with developmental disabilities (the Willowbrook State School hepatitis study and the radiation study at Fernald State School) and debilitated elderly adults (the cancer study at the Jewish Chronic Disease Hospital). See *Advisory Committee on Human Radiation Experiments, Final Report* (1995): 342-46; Bein, "Surrogate Consent and the Incompetent Human Subject," *Food Drug Cosmetic Law Journal* 46 (1991); 739, 756–57.

7 National Commission, *Report and Recommendations, Research Involving Children* (1977) [hereinafter *Report on Children*].

8 National Commission, *Report and Recommendations, Research Involving Those Institutionalized as Mentally Infirm* (1978) [hereinafter *Report on Institutionalized Persons*].

> since some research involving the mentally infirm cannot be undertaken with any other group, and since this research may yield significant knowledge about the causes and treatment of mental disabilities, it is necessary to consider the consequences of prohibiting such research. Some argue that prohibiting such research might harm the class of mentally infirm persons as a whole by depriving them of benefits they could have received if the research had proceeded.[9]

The commissioners concluded that the dual goals of benefiting the class of mentally infirm persons and protecting individual subjects from undue harm could be met by a third approach: incapable subjects could be involved in studies offering them potential direct benefit, as well as studies failing to offer potential direct benefit, as long as the burdens and risks of research participation did not exceed a certain level.

Based on this general approach, the commission created a framework for evaluating research involving incapable subjects. The commissioners' proposals regarding children and institutionalized persons with mental impairments were similar, though with some variation. The proposals had in common the following: (1) a requirement to justify the involvement of these subject groups rather than alternative, less vulnerable subject populations; (2) a hierarchy of research categories establishing more rigorous substantive and procedural standards for proposals presenting more than minimal risk to incapable subjects; and (3) a mechanism for incapable subjects to provide input in the form of "assent" or objection to study participation.

Differences in the recommendations on children and institutionalized persons were based on the commissioners' recognition that some adults institutionalized as mentally infirm retain the ability to issue an informed and voluntary decision. Because of concerns about the vulnerability of institutionalized persons, however, the commission recommended that IRBs be given discretion to appoint "an auditor to observe and assure the adequacy of the consent process for research" presenting greater than minimal risk. Moreover, the commissioners believed such auditors should be required in projects presenting no prospect of direct benefit and more than minimal risk to subjects. The commission's proposals also gave incapable adults more authority than children to block study participation.[10] Finally, because incapable adults lack the clear legal guardian that most children have, the commission noted that in some cases a court-appointed guardian would be required to provide adequate authority for research participation.

In response to the commission's work, the Department of Health, Education and Welfare (DHEW) proposed regulations to govern research on the two populations. The regulations on research involving children were adopted by the Department of Health and Human Services (DHHS) in June, 1983.[11] Proposed regulations on persons institutionalized as mentally disabled were never adopted, however.[12]

The Secretary of DHHS attributed the government's failure to issue final regulations on research involving institutionalized persons to "a lack of consensus" on the proposed regulatory provisions and to a judgment that the general regulations governing human subjects participation sufficiently incorporated the commission's recommendations.[13] Robert Levine blames the reported lack of consensus on DHEW's earlier failure to adhere to the commission's recommendations. The agency's proposed regulations indicated that consent auditors might be mandatory for all research involving institutionalized, mentally disabled persons. Moreover, they suggested that the authorization of an additional person, assigned the role of independent advocate, might be necessary before an incapable person could become a research subject. During the public comment period, many responded negatively to these additional procedural requirements, presumably on the belief that they were unnecessary and overly burdensome to research.[14]

Current U.S. Regulations

At this time, no special regulations govern research involving adults diagnosed with a condition characterized by mental impairment. Such research is governed by the "Common Rule,"[15] the general federal provisions governing human subjects research. A few Common Rule provisions address research involving persons with mental disabilities. The rule identifies "mentally disabled persons" as a vulnerable population. Institutional review boards are directed to include "additional

9 Id., 58.

10 The commission required explicit court authorization to involve an objecting institutionalized person in research. In contrast, the group recommended that parents be permitted to authorize research over a child's objection if the study presents a prospect of direct benefit to subject not available outside the research context.

11 Protection of Human Subjects, *Additional DHHS Protections for Children Involved as Subjects in Research*, 48 Fed. Reg. 9818 (Mar. 8, 1983).

12 Protection of Human Subjects, *Proposed Regulations on Research Involving Those Institutionalized as Mentally Disabled*, 43 Fed. Reg. 53950 (Nov. 17, 1978).

13 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Implementing Human Research Regulations* (1983): 23–29.

14 Levine, "Proposed Regulations for Research Involving Those Institutionalized as Mentally Infirm: A Consideration of Their Relevance in 1996," *IRB* (Sept.-Oct. 1996): 1. See also Bonnie, "Research With Cognitively Impaired Subjects," *Archives of General Psychiatry* 54 (1997): 105, 107 (debate over proposed regulations provoked division between scientists concerned that safeguards, especially consent auditors and subject advocates, would significantly hinder research and advocates for mentally disabled persons, concerned about subjects' vulnerability). Bonnie also refers to opposition to special regulations for persons with mental illness on grounds that such an approach would foster negative stereotypes about such individuals.

15 Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28012 (1991).

[unspecified] safeguards ... to protect the rights and welfare" of mentally disabled research subjects; IRBs are also advised to ensure that "subject selection is equitable," and that mentally disabled persons are not involved in research that could be conducted on a less vulnerable group.[16] Finally, "[i]f an IRB regularly reviews research that involves a vulnerable category of subjects, such as ... mentally disabled persons, consideration should be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects."[17] The rule allows an incapable individual's "legally authorized representative" to give valid consent to the individual's research participation,[18] but provides no definition of incapacity, no guidance on the identity or qualifications of a subject representative, and no statement on acceptable risk-expected benefit ratios for research involving decisionally incapable subjects.

In the 1980s and 1990s, numerous groups and individuals expressed dissatisfaction with gaps in the existing regulations. These included the Advisory Committee on Human Radiation Experiments, which reviewed eight studies conducted in the early 1990s involving adult subjects with questionable decision-making capacity. Four of these studies required that subjects undergo diagnostic imaging that offered them no prospect of direct benefit, and two appeared to present greater than minimal risk. Yet, as the Committee noted, "there was no discussion in the documents or consent form of the implications for the subjects of these potentially anxiety-provoking conditions. Nor was there discussion of the subjects' capacity to consent or evidence that appropriate surrogate decision makers had given permission for their participation."[19] Inquiries into studies involving medication withdrawal from persons diagnosed with schizophrenia also have raised questions about the adequacy of existing federal policy.[20]

Dissatisfaction with the current regulatory system also has driven many organizations and individuals to offer proposals for additional provisions to govern research on mentally disabled persons in general, as well as on particular subgroups, such as persons with dementia and persons diagnosed with psychiatric disorders. These proposals, and their underlying positions on the major ethical issues, are discussed in the remainder of this paper.

Capacity Assessment

Determining the proper standards and procedures to govern capacity assessment poses a major challenge in formulating policy on research involving subjects with mental disabilities. Persons with mental disabilities vary widely in their ability to engage in independent decision making. Persons with psychiatric disorders may retain such capacity, possess it intermittently, or be permanently unable to make decisions for themselves. Individuals with dementia frequently retain decisionmaking capacity early in the course of the illness, but with time they become intermittently, and then permanently, unable to make their own decisions. Some individuals with developmental disabilities are capable of making many choices for themselves; others completely lack such capacity.[21]

Incorrect capacity determinations are problematic because of their moral consequences. A judgment that a capable person is incapable of exercising autonomy is disrespectful, demeaning, and stigmatizing to that individual. Conversely, a judgment that an incapable person is capable leaves that individual unprotected and vulnerable to exploitation by others.[22] The presence of many "borderline" cases among members of the relevant populations triggers concern about the adequacy of subject capacity assessments. Although it is important to accord due respect to mentally disabled persons capable of autonomous choice, it is also important to recognize that investigators seeking to enroll subjects may be too willing to label prospective subjects capable when this will advance their research objectives.[23]

Existing federal policy fails to provide guidance to investigators and IRBs on the appropriate substantive and procedural standards applicable to capacity determinations in research involving mentally disabled subjects. In the current situation, individual IRBs determine how investigators are to address

16 Sec. ___.111 (a)(3) and (b).

17 Sec. ___.107(a).

18 Sec. ___.116

19 *Final Report*, supra, 706–07.

20 Office for Protection from Research Risks, *Evaluation of Human Subject Protections in Schizophrenia Research Conducted by the University of California, Los Angeles* (1994). See also Shamoo and Keay, "Ethical Concerns About Relapse Studies," *Cambridge Quarterly of Healthcare Ethics* 5 (1996): 373 (in review of 41 U.S. studies involving relapse published between 1966 and 1993, authors found frequent lack of attention to capacity assessment, subject or proxy consent, risk reduction and justification, and monitoring to avoid harm to subjects after studies were initiated).

21 See generally Thomasma, "A Communal Model for Presumed Consent for Research on the Neurologically Vulnerable," *Accountability in Research* 4 (1996): 227; Sachs, et al., "Ethical Aspects of Dementia Research: Informed Consent and Proxy Consent," *Clinical Research* 42 (1994): 403.

22 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979) [hereinafter Belmont Report].

23 See, e.g., Marson, et al., *Journal of the American Geriatrics Society* 45 (1997): 453, 455 ("researchers increasingly desire and encourage" patients with Alzheimer's disease (AD) to participate in research, but at the same time, "the progressive cognitive impairment characteristic of the disease relentlessly erodes decision-making capacity and makes AD patients vulnerable to coercion and exploitation"); Shamoo and Keay, supra, (1996) 373 (expressing concern about researchers' assumptions of subject capacity, for example, in one study authors asserted that all 28 acutely psychotic subjects with schizophrenia "were capable of informed consent and entered voluntarily").

these matters. The likely result is substantial variation in the criteria and safeguards applied to this form of research.[24] Most of the commentary supports more systematic and specific federal direction on capacity assessment.[25] Greater guidance is needed on defining decisional capacity in the research context, and procedures for assessing such capacity.

Substantive Requirements for Research Decision Making

An autonomous choice to enter a research study is both informed and voluntary. To be capable of informed choice, it is generally agreed that a prospective subject should demonstrate the ability "to understand the nature of the research participation; appreciate the consequences of such participation; exhibit ability to deliberate on alternatives, including the alternative not to participate in the research; and evidence ability to make a reasoned choice."[26] Subjects also should "comprehend the fact that the suggested intervention is in fact research (and is not intended to provide therapeutic benefit when that is the case)," and that they may decide against participation "without jeopardizing the care and concern of health care providers."[27]

There is consensus that decisional capacity requires a certain level of cognitive ability. Less agreement exists on whether subjects should be judged incapable if they lack affective appreciation of the choice before them. In a recent article, Carl Elliott argues that some depressed persons "might realize that a protocol involves risks, but simply not care about the risks," or "as a result of their depression, may even want to take risks."[28] Elliott believes that judgments on a person's capacity to consent to research should take into account such emotional attitudes. He also proposes that subjects failing to exhibit a "minimal degree of concern for [their] welfare" should be deemed incapable of independent decision making. Others oppose this position, contending that such an approach could yield excessive paternalism toward persons diagnosed with mental disorders, insufficient data exist on the extent of incapacitating emotional impairment among depressed persons, affective impairment is difficult to assess, and normative consensus is lacking on "how much impairment we as a society are willing to tolerate before we consider someone incompetent."[29]

It is generally agreed that a prospective subject's capacity to decide whether to participate in a particular research project cannot be determined through a general mental status assessment.[30] Instead, investigators must present the specific material relevant to that project and evaluate the prospective subject's ability to understand and appreciate that information.[31]

Some commentators endorse a "sliding-scale" approach to decisional capacity in the research setting. This approach demands an increasing level of understanding and appreciation as study risks increase and potential benefits to subjects decrease.[32] Similarly, some suggest that many prospective subjects incapable of independent research decision making remain capable of selecting a research proxy, since "the decision-making capacity that is required to designate a proxy is far less than the capacity required to understand a detailed protocol."[33]

Besides being informed, a decision to enter research should be voluntary. The Nuremberg Code provides descriptive characteristics of a voluntary decision.[34] The National Commission's Belmont Report characterizes a voluntary decision as "free of coercion and undue influence." According to the report, "[c]oercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence ... occurs through an offer of an excessive, unwarranted, inappropriate or improper

24 Bonnie, supra, 109.

25 E.g., id.

26 High, et al., "Guidelines for Addressing Ethical and Legal Issues in Alzheimer Disease Research: A Position Paper," *Alzheimer Disease and Associated Disorders* 8 (Supp. 4, 1994); 66, 69. In discussing decisional capacity in the research context, many writers also cite the President's Commission's requirements for treatment decisionmaking capacity: (1) possession of a set of values and goals; (2) ability to communicate and comprehend information; and (3) ability to reason and deliberate about the choice at hand. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* (1982): 60.

27 Melnick, et al., "Clinical Research in Senile Dementia of the Alzheimer Type," *Journal of the American Geriatrics Society* 32 (1984): 531, 533.

28 Elliot, "Caring About Risks," *Archives of General Psychiatry* 54 (1997): 113.

29 Appelbaum, "Rethinking the Conduct of Psychiatric Research, "*Archives of General Psychiatry* 54 (1997): 117, 119. See also Hirschfeld, et al., "Protecting Subjects and Fostering Research," *Archives of General Psychiatry* 54 (1997): 121.

30 High, et al., supra; Marson, "Determining the Competency of Alzheimer Patients to Consent to Treatment and Research," *Alzheimer Disease and Associated Disorders* 8 (Supp. 4, 1994): 5.

31 According to the Common Rule, prospective subjects should understand: (1) that the study involves research; (2) the purposes of the research; (3) the expected length of time of research participation; (4) the procedures to be performed and which, if any, are experimental; (5) reasonably foreseeable risks and discomforts; (6) reasonably expected benefits to subjects or others; (7) alternatives, including treatment, that could benefit the individual more than research participation; (8) the level of confidentiality protecting any identifiable information recorded on the subject; (9) whether compensation and medical treatment will be available for injuries resulting from research; (10) the identity of the person(s) to notify if the subject has questions or suspects research-related injury; and (11) that participation is voluntary, refusal will not be penalized, and participation may cease at any time without penalty. 56 Fed. Reg. sec. ___.116(a). Additional information must be disclosed and understood when relevant to a particular study, such as any additional costs subjects may incur as a result of study participation. Id., sec. ___.116(b).

32 Elliott, "Mentally Disabled and Mentally Ill Persons: Research Issues," in *Encyclopedia of Bioethics*, rev. ed., W.T. Reich (ed.) (1995): 1760; Appelbaum, "Drug-Free Research in Schizophrenia: An Overview of the Controversy," *IRB* (Jan.-Feb. 1996): 1; Annas and Glantz, "Rules for Research in Nursing Homes," *New England Journal of Medicine* 315 (1986): 1157.

33 Sachs, et al., supra, 410.

34 See p. 5, above.

reward or other overture in order to obtain compliance." In addition, the report notes, an inducement that is not overly persuasive to most adults could unduly influence the judgment of vulnerable subjects. The commissioners acknowledged that unjustifiable external influence cannot always be precisely defined, but that "undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would be otherwise entitled."[35]

Due to its limited congressional mandate, the National Commission considered only the potential pressures on institutionalized persons to enroll in research. Recent commentary favors expanding this concern, on grounds that persons with mental disabilities are especially vulnerable to such pressures no matter where they reside.[36] Prospective subjects living in the community frequently rely heavily on the assistance of professionals and family members and may perceive research participation as essential to maintaining the approval of their caregivers.[37] Some support also remains for providing special protections to persons in residential facilities, due to their near-complete dependence on the goodwill of the staff.[38]

A final element of decisional capacity, implicit in the above discussion, is the subject's ongoing ability to make a voluntary and informed choice to participate. Some persons with psychiatric disorders and dementia can issue an adequately informed and voluntary consent to participate in a study, but subsequently lose their capacity for independent choice. As a result, they become unable to exercise their right to withdraw from a study. Studies involving subjects with fluctuating or declining decisional capacity must include mechanisms to ascertain and address this possibility, including provision for appointment of a representative for subjects who become incapable.[39]

Procedures for Capacity Assessment and Information Disclosure

Existing federal regulations acknowledge that mentally disabled persons may be vulnerable to undue influence or coercion, but leave the adoption of special safeguards up to individual IRBs. The regulations also fail to provide guidance on the process that should govern capacity assessments and information disclosure.

Shortcomings in the process of capacity assessment were cited in a recent New York appellate court decision invalidating state regulations governing nonfederally funded research involving incapable adult residents of facilities operated and licensed by the New York State Office of Mental Health. Plaintiffs in the case were involuntarily hospitalized individuals deemed incapable of making treatment decisions who feared they would also be labeled incapable of research decision making and then "forced" to participate in greater than minimal risk studies.

The New York regulations gave the IRB "complete discretion in designating the individual or individuals who will make the assessment [of subject] capacity and who will thereafter review the researcher's initial assessment." This flexibility, together with the absence of "appropriate and specific provisions for notice to the potential subject that his or her capacity is being evaluated and for appropriate administrative and judicial review of a determination of capacity" contributed to the court's conclusion that the regulations violated the due process requirements of the New York State Constitution and the Fourteenth Amendment to the U.S. Constitution.[40] This decision raises questions about the constitutional status of the existing federal regulations as well, since they closely resemble the invalidated New York regulations.[41]

A variety of approaches to capacity assessment are endorsed in the literature on research involving adults with cognitive impairment. Most commentators believe that IRBs should at minimum require investigators to specify the method by which prospective subjects' decisional capacity will be evaluated and the criteria for identifying incapable subjects.[42] A major point of contention, however, is whether capacity assessment and information disclosure should be conducted by an individual not otherwise connected with the research project.

The National Commission recommended that IRBs have discretion to require an independent "consent auditor" for projects presenting greater than minimal risk to persons institutionalized as mentally infirm. The auditor would observe

35 *Belmont Report*, supra, 6.

36 Bonnie, supra; Levine, Proposed Regulations, supra.

37 Relatives may view research participation as improving their own chances for avoiding conditions that appear genetically linked or as a means to reduce their caregiving burdens. Keyserlingk, et al., "Proposed Guidelines for the Participation of Persons With Dementia as Research Subjects," *Perspectives in Biological Medicine* 38 (1995): 319.

38 Elliott, supra; High and Doole, "Ethical and Legal Issues in Conducting Research Involving Elderly Subjects," *Behavioral Sciences and the Law* 13 (1995): 319. See also American College of Physicians, "Cognitively Impaired Subjects," *Annals of Internal Medicine* 111 (1989): 843 (recommending that IRB "consider asking a committee composed mostly of representative residents of, for example, a nursing home, to review proposed research projects to be conducted at the facility).

39 Appelbaum, *Drug-Free Research*, supra.

40 *T.D. v. N.Y. State Office of Mental Health*, 650 N.Y.S. 2d 173 (App. Div. 1996).

41 See Capron, "Incapacitated Research," *Hastings Center Report* (Mar.-Apr. 1997): 25.
New York's highest court has agreed to hear plaintiff's appeal of T.D. Plaintiffs argue that the intermediate appellate court's decision should apply to all research involving greater than minimal risk (including studies presenting a prospect of direct benefit) and to federally funded research. The appeal will involve the court in a direct evaluation of the existing federal policy.

42 E.g., Bonnie, supra; Melnick, et al., supra.

and verify the adequacy of the consent and assent process, and in appropriate cases observe the conduct of the study to ensure the subject's continued willingness to participate.[43] The commission recommended that such auditors be required for projects presenting greater than minimal risk and no prospect of direct benefit to subjects. The DHEW regulations contemplated mandating auditors for all projects involving this subject population, but opposition to this proposal reportedly was one reason the regulations never became final.

More recent commentary includes a spectrum of views on the need for an independent consent auditor. Some echo the National Commission's view that a requirement for an independent evaluator becomes increasingly justified as net research risks to subjects increase. A Canadian group took this position in its recent recommendations on dementia research.[44] According to this group, the role of consent assessor/monitor ordinarily can be filled by a researcher or consultant "familiar with dementias and qualified to assess and monitor competence and consent in such subjects on an ongoing basis." This individual should be knowledgeable about the project and its risks and potential benefits. On the other hand, if the research team lacks a person with these qualifications, if there is "a real danger of conflict of interest" for team members who might evaluate and monitor capacity, or if the project involves greater than minimal risk and no prospect of direct benefit to subjects, an independent assessor/monitor should be appointed.[45]

Others appear open to general use of outside observers and examiners. Recent guidelines adopted by the Loma Linda University IRB state, "[c]onsent observers who are independent of the investigator and of the institution will be required by the IRB in those conditions where the potential subject's decision-making capacity is suspect."[46] In testimony before the National Bioethics Advisory Commission, representatives of Citizens for Responsible Care in Psychiatry and Research recommended that "[a]n independent psychiatrist ... determine the capacity of [the] potential participant to comprehend the risks and benefits of enrolling in the proposed research study."[47] Recent articles also endorse the participation of a "special research educator" in the disclosure and decision process, particularly to ensure that prospective subjects understand that advancement of general knowledge is the primary goal of the project at hand.[48]

A 1991 article makes a strong case for an independent, federally employed patient-advocate's involvement in capacity determinations, as well as in assisting and monitoring decision making by family surrogates for incapable persons. Philip Bein notes that courts have demanded relatively strict procedural safeguards in the context of imposed psychiatric treatment and sterilization for persons with mental disabilities. He makes the following argument for a similar approach in the research context:

> As with psychotropic medication and sterilization, several distinct features of experimentation suggest the need for special protections. First, the history of medical experimentation has been characterized by significant incidents of abuse, particularly where members of vulnerable populations have been enlisted as subjects. Second, the interests of medical researchers in securing participation in the experiment often conflicts with their duties as treating physicians to inform, advise, and act in the best interests of their patients. Third, experimentation is inherently highly intrusive and dangerous, as the nature and magnitude of risks involved are largely unknown and unknowable.[49]

In contrast, Bein suggests that courts have not demanded such safeguards for decisions on life-sustaining treatment, based on an absence of the above features in the treatment setting. He also argues that an IRB-administered system of patient-advocates would provide inadequate oversight because such a system would be too responsive to institutional interests.[50]

Other recent commentary proposes more diverse methods for ensuring against inappropriate capacity determinations. Bonnie opposes a federal requirement for any specific procedure, rather "the regulations should provide a menu of safeguards" from which IRBs could choose, including "specially tailored follow-up questions to assess subject understanding, videotaping or audiotaping of consent interviews, second opinions, use of consent specialists, or concurrent consent by a family member."[51]

Many groups advise the involvement of a trusted family member or friend in the disclosure and decisionmaking

43 The commission discussed the auditor's observation of ongoing research as a means to ensure continued assent, but the mechanism could also be adopted to monitor a capable subject's continued consent, especially if a decline in capacity is possible.

44 Keyserlingk, et al., supra.

45 Id., 343–44. See also Melnick, et al., supra.

46 Orr, "Guidelines for the Use of Placebo Controls in Clinical Trials of Psychopharmacologic Agents," *Psychiatric Services* 47 (1996): 1262.

47 Shamoo and Sharev, "Unethical Use of Persons With Mental Illness in High Risk Research Experiments," *BioLaw* 2 (1997): S:23.

48 DeRenzo, "The Ethics of Involving Psychiatrically Impaired Persons in Research," *IRB* (Nov.-Dec. 1994). In a study of this approach, researchers found that the participation of a trained educator increased the comprehension of psychiatric patients asked to enroll in research. Appelbaum, et al., "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception," *Hastings Center Report* (April 1987): 20.

49 Bein, supra, 748–49.

50 Id., 762.

51 Bonnie, supra, 110.

process. Capable subjects reportedly are often willing to permit such involvement. Dementia researchers frequently adopt a mechanism called "double" or "dual" informed consent when the capacities of prospective subjects are uncertain or fluctuating.[52] This approach has the virtue of providing a concerned back-up listener and questioner who "may help the cognitively impaired individual understand the research and exercise a meaningful informed consent."[53] On the other hand, the presence of a caregiving relative could, in some cases, put pressure on subjects to enter a research study.[54]

Another suggestion is to require the use of a two-part consent process. In this process, information about a study is presented to a prospective subject and a questionnaire administered to determine the individual's comprehension. The subject is then provided with a copy of the questionnaire to refer to as needed. If the individual initially fails to demonstrate an adequate understanding of the material, written or oral information is presented again, and the subject retested. This process is likely to yield more accurate judgments of subject capacity than a less systematic and rigorous inquiry.[55]

Finally, numerous ideas have been offered to make information more accessible to subjects capable of exercising independent choice. Simple perceptual aids, such as increasing the type size of printed material, may enhance the ability of elderly subjects to comprehend the necessary information. Information can be delivered through videotape, slides, or pictorial presentations. A creative suggestion is for investigators to ask representatives of the affected population to critique drafts of information materials prior to their actual research use.[56]

The literature offers fewer suggestions for ensuring adequate voluntariness. The Helsinki Declaration includes a provision advising "the physician obtaining informed consent for the research project [to] be particularly cautious if the subject is in a dependent relationship or him or her may consent under duress." In these circumstances, "informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship."[57] To guard against pressure from family or other caregivers, someone should talk separately with consenting subjects on their reasons for participating. Again, the issue is whether a research team member, independent evaluator, or IRB representative should be given this responsibility.

Research Decisions for Persons Incapable of Independent Choice

Many persons diagnosed with mentally disabling conditions are unable to make their own decisions on research participation. Others may become incapable while they are participating in a study. In these circumstances, persons other than the incapable individual must make the choice for or against that individual's research involvement. Decisions on the permissible conditions for enrolling and retaining incapable subjects must be made at the policy level, as well as by IRBs and the subject's personal representative.

Existing federal policy is largely silent on these matters. According to the Common Rule, the risks presented by any proposal to involve human subjects must be reduced to the minimum necessary to obtain the desired data, and must be "reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."[58] No additional limits or criteria for evaluating permissible risk in research involving incapable subjects are included in the rule. Special DHHS regulations establish such conditions for research involving children, but research involving incapable adults is governed solely by the Common Rule's general provisions.

Existing federal policy also gives little direction on who should act as the incapable subject's personal representative in making decisions on research participation. The Common Rule simply provides that "[i]nformed consent will be sought from each prospective subject or the subject's legally authorized representative."[59] The rule fails to address the desirable qualifications of a representative or the substantive criteria that should guide that person's choices. The Belmont Report simply states that third-party decision makers "should be those who are most likely to understand the incompetent subject's situation and act in that person's best interest."[60]

Improvements in current policy will require attention to five areas: (1) selection of an incapable subject's representative; (2) substantive criteria governing the subject representative's decision making; (3) the incapable subject's assent or objection to research participation; (4) the incapable subject's preferences while capable; and (5) permissible levels of risk in research involving incapable subjects. Although these areas are discussed

52 High, et al., supra. See also Bonnie, supra, 110 ("participation of surrogate decisionmakers can be a useful safeguard even if the subject has the requisite capacity to provide legally valid consent").

53 Karlawish and Sachs, "Research on the Cognitively Impaired: Lessons and Warnings from the Emergency Research Debate," *Journal of the American Geriatrics Society* 45 (1997): 474, 477.

54 Id.

55 Ratzan, "Technical Aspects of Obtaining Informed Consent from Persons with Senile Dementia of the Alzheimer's Type," in *Alzheimer's Dementia: Dilemmas in Clinical Research* 123 (Melnick and Dubler, eds., 1985) (citing Miller and Willner, "The Two-Part Consent Form," *New England Journal of Medicine* 290 (1974): 964.

56 Melnick, et al., supra.

57 World Medical Association, supra.

58 Sec. ___.111(a).

59 Sec. ___.111(4).

60 *Belmont Report*, supra, 6.

in separate sections, they are significantly related, and are likely to be combined in any policy revision.

The Incapable Subject's Representative

The Common Rule's use of the phrase "legally authorized representative" leaves many unanswered questions. State laws contain general provisions on the standards and procedures governing appointment of guardians for persons declared legally incompetent. Guardianship requires a judicial proceeding and ordinarily authorizes someone to make financial decisions, personal decisions, or both types of decisions for the incompetent person. Limited guardianships covering a narrower area of decisionmaking responsibility are also possible.

Relatively few states have laws specifically addressing the area of research decision making by legal guardians. Existing state legislation limits the involvement of incapable subjects in research in various ways; a number of laws require guardians to obtain specific court authorization to make decisions on a ward's research participation.[61]

Federal research policy is not intended to preempt or otherwise affect state or local laws applying to research, including those conferring additional protection on subjects.[62] Thus, investigators and IRBs in jurisdictions with specific law governing the identity and authority of research decision makers for incapable subjects must comply with that law. Yet in the many states without clear law, it will be left to federal policy, investigators, and IRBs to determine who may act as an incapable subject's surrogate decision maker in research.

The literature indicates that at present legal guardianship is rarely, if ever, mandated in the research setting. Instead, close family members, who may or may not have formal guardianship status, are the customary decision makers when the research participation of incapable adults is sought.

Should federal policy require formal legal guardianship? The underlying question is whether such a requirement is necessary or sufficient to provide adequate protection against inappropriate research use of a vulnerable population to advance the interests of others. The National Commission recommended that the permission of either a legal guardian or a judge be required to authorize the research participation of subjects institutionalized as mentally infirm in the following situations: (1) the incapable subject objects to participation; or (2) the subject is incapable of assent (see below) and the research presents more than minimal risk to subjects.[63]

Later commentary questions whether formal legal proceedings are necessary to provide adequate protection for incapable subjects, particularly those not residing in an institutional setting. As one writer notes, IRBs requiring legal guardianship "to be on the safe side" could end up contributing to a deprivation of general decisionmaking rights of subjects.[64] Moreover, the guardian appointment process ordinarily will not address research participation issues in any explicit way. In most cases, a judicial decision to confer guardianship status on a particular person is made without consideration of that person's suitability as a research decision maker.

Dissatisfaction with a requirement for legal guardianship has led to proposals of alternative mechanisms for granting authority to act as an incapable person's representative in research decision making. One option is to allow decisionally capable persons to authorize in advance a specific individual to make decisions on research participation during a future period of incapacity. This device, which is modeled on the durable power of attorney (DPA) for health care, has the virtue of promoting the capable individual's autonomous views on who is best suited to act on his or her behalf in the research context.

The primary advantage of the research DPA is the explicit authority granted by the subject, who presumably will choose someone likely to express her values and protect her welfare. Intramural research at the National Institutes of Health (NIH) Clinical Center is governed by a policy that encourages this approach.[65] The American College of Physicians and numerous others express support for use of these devices.[66] As a practical matter, however, it is unclear whether many individuals will be interested in or willing to complete such a document.[67] Moreover, the device cannot be applied to the population of persons with mental disability who are currently incapable and not expected to recover capacity.[68]

---

61 See Appendix for brief descriptions of existing state legislation.

62 Common Rule, Sec. ___.101(f).

63 National Commission, *Report on Institutionalized Persons*, supra, 11–20. At least one commentator supports a requirement for explicit judicial authorization prior to an incapable subject's enrollment in research if relatives are unwilling to act as subject representatives or if a subject-advocate questions a family surrogate's good faith or decisionmaking capacity. Bein, supra. Others have criticized this view as intrusive, unnecessarily adversarial, and too great an impediment to research. Berg, "Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines," *Journal of Legal and Medical Ethics* 24 (1996): 18; Kapp, "Proxy Decision Making in Alzheimer Disease Research: Durable Powers of Attorney, Guardianship, and Other Alternatives," *Alzheimer Disease and Related Disorders* 8 (Supp. 4, 1994): 28.

64 Office for Protection from Research Risks, *Protecting Human Research Subjects: Institutional Review Board Guidebook* (1993): 6–30. See also High and Doole, supra, 328 (guardianship process may produce rights deprivation and "is often intrusive, humiliating, expensive, and time-consuming").

65 Fletcher and Wichman, "A New Consent Policy for Research With Impaired Human Subjects," *Psychopharmaceutical Bulletin* 23 (1987): 382; NIH Clinical Center, *Consent Process in Research Involving Impaired Human Subjects* (Mar. 30, 1987). If no relative or friend is available, prospective subjects may designate the Center's patient representative or a chaplain or social worker not assigned to the research unit.

66 American College of Physicians, supra. See also Kapp, supra; Melnick, et al., supra.

67 See High and Doole, supra.

68 See pp. 40–51, below for further discussion of the research DPA.

A second potential source of authority is an existing health care power of attorney. In this situation, the now-incapable subject previously exercised an autonomous choice to delegate medical decision making to a particular person. The question is whether an individual's choice of a friend or relative to make treatment decisions in the event of incapacity is defensibly interpreted as an authorization for research decision making as well. The NIH Clinical Center policy allows previously chosen health care proxies to make research decisions for subjects.[69]

A third alternative is to regard state legislation authorizing family members to make certain treatment decisions on behalf of relatives as conferring authority for research decisions as well. It might be argued that such legislation embodies a recognition that important health-related decisions for decisionally incapacitated persons are properly assigned to relatives. Most reasonable would be to extend the laws' application to a close relative's decision regarding research offering potential health benefit to an incapable subject.[70] Others believe that these laws should not be interpreted so expansively and that amendments or new legislation would be required to provide explicit statutory authority for delegation of research decision making to relatives.[71]

The final possible option is to assign research decisionmaking authority based on the simple status of being a close relative. Support for this alternative comes from the long-held tradition in health care of relying on families to make decisions for incapable persons, as well as from the belief that relatives are most likely to make decisions in accord with the incapable person's values, preferences, and interests.[72] This approach also is easy to administer; moreover, it apparently has been, and continues to be, a common practice in the actual research setting.[73]

Each of the above options presents advantages and drawbacks. Requiring judicial involvement raises the costs of research and does not necessarily advance respect for, and protection of, incapable persons. Requiring explicit DPAs for research poses practical difficulties, since relatively few persons have, or can be expected to complete, these documents. Another question is whether the power of DPAs to accept research risks to an incapable individual should be equal to the power of competent adult subjects to consent to such risks for themselves (see below). New legislation authorizing relatives to make research decisions for incapable persons would require action by the states; such legislation would emerge slowly and in some states, not at all.

All of these alternatives also raise questions about the accuracy with which incapable subjects' values and preferences as competent persons will be expressed by formal or informal representatives.[74] The problem of potential conflicts of interest between subjects' interests and those of their representatives exist as well. Those most likely to act as representatives are family members, who may see the subject's research participation as an avenue "that may lighten the burden of caregiving or lead to treatment from which the family member may benefit."[75] Two empirical studies found some family members willing to allow an incapable relative to be entered in a research study even though they thought the relative would refuse if competent. Some family members also stated they would allow an incapable relative to become a subject even though they would refuse to enroll in such a study themselves.[76]

One response to the above concerns is to conduct screening and education of subject representatives, with the goal of ascertaining inappropriate decision makers and enhancing the likelihood that representatives will make choices that adequately respect the subject's competent preferences and current interests.[77] Adopting a requirement for screening and training would raise the further question of whether this procedure should be conducted by a member of the research team, the IRB, or someone otherwise independent of the project.[78]

---

69 NIH Clinical Center, supra.

70 Bonnie, supra, 110.

71 Kapp, supra.

72 This position is endorsed in policy guidelines adopted by Alzheimer Disease Centers in the U.S. See High, et al., ("[u]nless there is statutory or case law to the contrary, family members should be recognized as having surrogate authority without prerequisite appointment as guardians or proxies through the use of instruments such as durable powers of attorney").

73 Kapp, supra; High and Doole, supra.

74 See Sachs, "Advance Consent for Dementia Research," *Alzheimer Disease and Related Disorders* 8 (Supp. 4 1994): 19 ("I think it is fair to assume that most proxies [in the current consent process] know very little about their demented relative's preferences regarding research participation").

75 Keyserlingk, et al., supra, 346.

76 Sachs, et al., supra; Warren, et al., "Informed Consent by Proxy," *New England Journal of Medicine* 315 (1986): 1124. There were also cases in which family members would not allow an incapable subject's participation even though they thought the subject would consent if competent or the family members would enter such a study themselves.

77 See, e.g., High and Doole, supra 328 ("family members may be disqualified to serve as surrogates for a variety of reasons, including lack of capacity, inattention to the subject's well-being, self-interested motives, or unavailability"); American College of Physicians, supra, 844 ("researchers must inform [proxies and surrogates] of the standards for decisionmaking").

Some concerns about the quality of third-party decisions are raised by empirical studies of parents consenting to their children's' research participation. For example, a recent study of 64 parents whose children had participated in a clinical trial found that only a small number recognized that drug trials are designed to test safety as well as efficacy, while the majority believed such trials posed either no risk or low risk. Fewer than half realized that they had the right to withdraw their children from the trial at any time. Harth and Thong, "Parental Perceptions and Attitudes About Informed Consent in Clinical Research Involving Children," *Social Science and Medicine* 41 (1995): 1647.

78 For contrasting views on this point, see Berg, supra, 26 (investigator or IRB could prepare document for subject representatives on substantive standards for decision making, and giving examples of how to apply them; in complex protocols, neutral educator could be assigned to explain relevant information) and Bein, supra, 761 (independent, government-employed patient-advocate could present information to and advise family-surrogates on research decisions for incapable relatives; advocate questioning surrogate's "good faith or ability to make a proper decision" could initiate court proceedings to resolve whether incapable person should participate in study).

An alternative or additional approach is to limit the authority of any third party to consent to research participation by an incapable subject. Three forms of substantive limitations are commonly endorsed. One is to allow guardians, proxies, and informal surrogates to give valid consent to studies if the incapable subject assents or fails to object to initial or ongoing research participation. The second is to require that third parties make research decisions consistent with the incapable subject's prior instructions issued while competent. The third is to permit subject representatives to authorize the involvement of incapable subjects only in studies that meet certain risk-potential benefit standards. Many of the recommendations on research involving persons with mental disabilities apply each of these limits, but combine them in a variety of ways.

The Incapable Subject's Research Preferences

According to the Belmont Report, respect for persons incapable of fully autonomous choice "requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research."[79] Consistent with this view, the National Commission recommended that under specified conditions, researchers should obtain assent to research participation from subjects incapable of independent decision making. According to the commissioners, persons are capable of assent if they "know what procedures will be performed in the research, choose freely to undergo these procedures, communicate this choice unambiguously, and [know] that they may withdraw from participation."[80]

The commission recommended that an incapable subject's overt objection to initial or ongoing participation should rule out research involvement unless the study offers the subject a prospect of direct benefit and a court specifically authorizes the subject's participation. The commissioners also stated that an objecting incapable subject should be involved in research presenting a prospect of direct benefit and more than minimal risk only when the benefit is available solely in the research context.

The commissioners recommended procedural mechanisms to ensure application of these substantive provisions. They stated that IRBs should have discretion to appoint an independent auditor to verify the subject's assent or lack of objection. They also recommended that independent auditors be required to monitor the incapable subject's initial and ongoing assent in research presenting more than minimal risk and no prospect of direct benefit to subjects; if subjects object at any time to this category of research, they should be removed from the study.

Not all incapable individuals can provide assent as defined by the National Commission. Some persons may satisfy certain elements of the standard, but not all of them.[81] Should the physical or verbal indications of persons incapable of assent be considered in research decision making? A related question is "whether the failure to actively object to participation in a protocol is enough to be interpreted as a tacit or implied form of assent or whether some more affirmative agreement is necessary."[82] According to the National Commission, "mere absence of objection" ought not be interpreted as assent.[83] The commission recommended requiring the consent of a subject's legal guardian to authorize more than minimal risk research involving nonobjecting subjects incapable of assent. Whether this situation might be adequately addressed through less formal procedural safeguards, or by imposing special limits on research risks, remains unsettled in the existing literature.

There is general agreement that the sole potential justification for imposing research interventions on actively resisting subjects would be to advance the goal of protection; that is, to provide a potential material health benefit unavailable outside the study. Recent commentary generally supports a requirement for subject assent, or at minimum, lack of objection, except in the unusual case when research participation offers the subject direct benefits not otherwise obtainable in the clinical setting.[84] Yet not all commentators agree that potential direct benefit should be sufficient to override the incapable subject's behavioral resistance to research participation.

A Canadian group considering research involving persons with dementia recently noted:

> Faced with an objection by a patient of impaired capacity, the justification advanced for nevertheless imposing the investigational intervention is that it holds out the prospect of direct (therapeutic) benefit. However, it is normally not legitimate to impose even established therapy on a patient refusing it. The case for proceeding may be stronger regarding the incom-

79 *Belmont Report*, supra, 6.

80 *Report on Institutionalized Persons*, supra, 9.

81 An empirical study found that many dementia patients incapable of independent decision making were nevertheless "able to provide useful information on their values and preferences that was pertinent to making research enrollment decisions." Sachs, et al., supra, 410.

82 Kapp, supra, 34.

83 *Report on Mentally Disabled Persons*, supra, 14.
What constitutes a recognizable objection is another question. Subjects might exhibit a transient unwillingness to participate, due to temporary fatigue or distraction. Should any sign of unwillingness suffice as grounds to remove the subject from research, or may the investigators be given another opportunity to seek the subject's cooperation? See Keyserlingk, supra, 341 (should not assume that "transient lack of cooperation always signifies an objection"; instead, "[d]ecisions as to whether a patient is clearly or probably objecting will obviously be a matter of judgment"). A related issue is whether such judgments should be made by an investigator, independent evaluator, the subject's representative, or an IRB representative.

84 E.g., Berg, supra; High and Doole, supra; High, et al., supra; Melnick, et al., supra.

> petent ... patient who objects, but it is difficult to equate an intervention which is investigational in nature—whatever its potential for direct (therapeutic) benefit—with an intervention "which would be ordered in a purely therapeutic context."[85]

This group was "not fully persuaded" that potential therapeutic benefit provides ethical justification for compelling an objecting subject's research participation. In their view, this "is at best a position in need of further debate."[86]

Draft legislation under consideration in Maryland completely bars investigators from conducting research involving a decisionally incapable individual "who refuses to perform an action related to the research."[87] The T.D. case labeled constitutionally deficient New York's provision allowing the involvement of an objecting incapable subject in potentially therapeutic research because the state regulations failed to provide patients or their representatives notice and an opportunity to challenge this involvement.[88]

The Incapable Subject's Preferences While Competent

Various groups and individual commentators have explored the relevance of advance decision making in the research context. Two types of research advance directives are discussed. Through an instruction directive, a competent person may consent to or refuse future research involvement during a period of temporary or permanent incapacity. Through a proxy directive (also known as a research DPA), a competent individual may choose someone else as her research decision maker if she subsequently loses decisional capacity.

As in the treatment area, advance research decision making is supported as a means of extending respect to the autonomous choices of capable individuals. Advance decision making is also seen as protective in that it can prevent a surrogate from authorizing an incapable subject's involvement in research the subject previously deemed unacceptable. The primary issues raised by research advance directives are: (1) whether advance decisions can be adequately informed; (2) how to safeguard the subject's right to withdraw from research; and (3) whether advance choice is a morally defensible basis for permitting otherwise prohibited levels of risks and burdens in research involving incapable subjects.

The concept of advance research decision making was initially discussed in the 1980s. In his volume on clinical research, Robert Levine discussed the "research living will" as an avenue for competent persons to authorize future research involvement while incompetent.[89] In 1987, the NIH Clinical Center adopted a policy in which persons "who are or will become cognitively impaired" are asked to complete a durable power of attorney (DPA) document appointing a proxy research decision maker.[90] Such proxies may authorize an incapable subject's participation in research presenting greater than minimal risk to subjects. In such cases, an ethics consultation is conducted to verify the proxy's capacity to understand information relevant to the research decision. If no DPA exists, the consent of a court-appointed family guardian is required. The Clinical Center policy deems a subject's prior exercise of choice an acceptable basis for permitting higher risk research than is otherwise permitted for subjects lacking court-appointed family guardians.[91]

In 1989, the American College of Physicians (ACP) gave qualified endorsement to instruction and proxy mechanisms permitting competent persons to register advance consent to research. According to the ACP, investigators seeking advance consent would be required to disclose to the competent person the usual information on a study's purpose, methods, risks, and potential benefits. Moreover, the ACP recognized a need for more caution regarding advance research decisions than advance treatment decisions:

> In nonexperimental care, advance directives are generally used by patients to indicate their intent to refuse procedures ... which they believe will be contrary to their interests. Respect for autonomy creates a strong presumption for adherence to instructions for nonintervention. In contrast, advance directives for research purposes would authorize interventions that do not benefit the subject in the case of nontherapeutic research, or that may not benefit the subject in the case of therapeutic research.[92]

Accordingly, this group took the position that research advance directives "may be abrogated if it is later determined that the proposed research would unduly threaten the subject's welfare."[93]

---

85 Keyserlingk, et al., supra, 342, quoting Melnick, et al., supra.

86 Id., 342.

87 Office of the Maryland Attorney General, Second Report of the Attorney General's Research Working Group (May, 1997).

88 *T.D.*, 650 N.Y.S. 2d, 193.

89 R. Levine, *Ethics and Regulation of Clinical Research* 270–74 (rev. ed. 1986).

90 Subjects "not seriously impaired" are viewed as capable of completing a research DPA. If a prospective subject is "so seriously impaired as to be incapable of understanding the intent or meaning of the DPA process, a next of kin surrogate may be chosen by the physician." In addition, if a prospective subject has a previously completed health care DPA or a court-appointed guardian, no research DPA is sought. NIH Clinical Center, supra.

91 Research presenting greater than minimal risk is not permitted for subjects lacking a DPA or court-appointed family guardian.

92 American College of Physicians, supra, 844.

93 For example, the proxy decision maker should withdraw an incapable subject from a study if risks or burdens increase due to changes in research methods, changes in the subject's physical condition, or the incapable subject's lack of cooperation with study procedures. Id., 844.

Despite these cautions and restrictions, the ACP deemed an incapable subject's prior consent an acceptable basis for allowing that subject's involvement in higher risk research than is permitted for other incapable subjects. The position paper states that incapable subjects with informal proxies should not be involved in greater than minimal risk research offering no prospect of direct benefit. In contrast, subjects with advance directives may be involved in such studies, as long as the above limitations are observed.

Other groups and commentators have expressed general support for advance research decision making without addressing the concept in detail.94 Four articles published between 1994 and 1996 present more lengthy analyses of advance research directives and are discussed below.

In reviewing the advance directive's potential application to dementia research, Greg Sachs suggests it is unlikely that many individuals will prepare research directives. He notes that relatively few person make treatment directives, even though many fear overtreatment at the end of life. Even fewer will make research directives, he predicts, because "the fear of missing out on being a subject in a promising dementia study, or of being inappropriately volunteered by one's relatives, is simply not a prevalent or powerful concern."[95]

Federal policy establishes stringent disclosure requirements for investigators recruiting competent persons for research. An individual considering whether to authorize future research participation ought to be informed about a prospective study as well. But problems in information delivery are posed by the time lapse between a capable individual's decision to enter a future study and the onset of actual participation. As a Canadian group points out, "[t]he research intervention, process, or technology may have evolved; the risk of harm may have increased beyond what was originally predicted; the patient's medical conditions, relationships, level of family support, and daily routine may have changed and deteriorated."[96]

In light of these possibilities, commentators agree that a third-party decision maker should be appointed to withdraw the subject from a study if previously unrecognized risks and burdens become apparent.[97] They differ, however, on the standard third parties should apply when exercising the subject's right to withdraw from research the subject previously authorized.

Some writers favor withdrawal only when the factual circumstances become materially different from what the individual agreed to in a directive.[98] Others contend that withdrawal should also occur if it becomes apparent to others that research participation threatens the incapable subject's welfare. According to this position, a research proxy's or surrogate's obligation to respect the person's prior wishes is limited by the obligation to protect the person. The function of the [third-party decision maker] is to promote what subjects think are their best interests, which necessarily excludes consenting to being intentionally harmed or to being unreasonably exposed to the risk of harm.[99]

This dispute is related to disagreement on the appropriate scope of a competent person's advance consent to research. Commentators are divided on whether policy should permit an incapable subject to be exposed to otherwise impermissible levels of research risks and burdens based on the subject's prior instructions. Moorhouse and Weisstub contend that directives should be restricted to authorizing research "with a negligible or less than substantial risk."[100] Their position is based on the belief that capable individuals cannot predict with complete accuracy how they will experience research as incapable subjects. These authors also argue that the competent individual's freedom to volunteer for research to advance the interests of others is qualified by society's responsibility to protect vulnerable individuals from material harm.

A Canadian group addressing dementia research proposes that research directives should apply to studies offering no

94 E.g., Melnick, et al., supra (endorsing research directives and implying that such documents could authorize otherwise questionable research presenting more than minimal risk and no prospect of direct therapeutic benefit to subjects); Annas and Glantz (competent person diagnosed with disorder expected to produce incapacity could designate proxy decision maker; such document could authorize participation in otherwise prohibited nontherapeutic studies posing "any risk of harm," but should be used only if instructions are specific and address "reasonably well defined" research, and subject retains right to withdraw even after he or she becomes incapable).

95 Sachs, "Advance Consent," supra. Sachs refers to unpublished survey data finding that while 16 of 21 ethicists expressed enthusiasm for advance research directives, only eight out of 74 investigators agreed that directives would be a workable approach. In a different survey of healthy elderly persons, many respondents indicated they would be unwilling to complete "blank checks" authorizing participation in a wide range of future studies. Respondents were more positive about advance directives authorizing research offering a reasonable prospect of direct benefit, but only if interventions were restricted to the specific procedures, pain, and discomfort set forth in the document. Keyserlingk, et al., supra, 347.

96 Keyserlingk, et al., supra 347.

97 See, e.g., Moorhouse and Weisstub, "Advance Directives for Research: Ethical Problems and Responses," *International Journal of Law and Psychiatry* 19 (107): 135 ("in the event of the development of unforeseen risks, a change in the subject's condition, or an objection expressed by the incapable subject or a concerned third party," subject's surrogate decision maker must have power to remove subject from study).

98 Berg, supra, 22 (surrogate has responsibility to withdraw subject only if research or risk-benefit ratio changes substantially from what subject consented to).

99 Moorhouse and Weisstub, 135. See also Shamoo and Sharev, supra, S:29 (advance directives should not bind a subject to research participation).
An intermediate position is presented in Keyserlingk, et al., supra, 352 (advance directive should be overridden if "no direct benefit is anticipated for the subject and it becomes apparent that enrollment or continued participation would seriously endanger that subject's welfare to an extent not foreseen by the subject, or even if foreseen, to an extent judged by the substitute [decisionmaker] to be socially or morally unacceptable").

100 Moorhouse and Weisstub, supra, 134.

direct benefit to subjects only if the risk is minimal or a minor increase over minimal.[101] They suggest one exception to this limit, however: "[i]f a subject who provides a directive specifying a willingness to undergo a higher risk level also provides evidence of having already experienced a similar level of physical or psychological pain or discomfort in another research setting, then the cap of allowable risk for that subject could be raised accordingly."[102]

Berg supports full implementation of advance research instructions without regard to the risk level. She argues, "[b]ecause competent subjects do not have limits placed on the types of research in which they can participate while they remain competent (as long as the protocol is approved by an appropriate review board), they should not have limits placed on the types of research in which they can consent, in advance, to participate should they become incompetent."[103] Conversely, when an advance directive refuses research participation, Berg suggests that the subject's refusal could be overridden if a study offers possible direct benefit unavailable in the clinical setting. She fails to explain why concern for the incapable subject's best interests justifies disregarding a directive in one situation and not the other.

A few public policy developments are relevant to this topic as well. In 1996, the Food and Drug Administration and NIH adopted new regulations governing research involving incapable subjects in the emergency setting.[104] The new regulations allow research to proceed in the absence of consent by a subject or subject representative if a number of conditions are met. One such condition is that investigators cannot reasonably obtain prospective consent from competent individuals likely to be candidates for later study enrollment.[105]

The regulations and agency comments do not address the rationale for, or implementation issues raised by, prospec tive consent. The commentary implies that the ordinary disclosure requirements for informed consent govern advance research decision making.[106] According to agency officials, when IRBs determine that investigators can reasonably identify and seek prospective consent from persons likely to become eligible for a study, "[t]hose individuals who either did not make a decision or who refused would be excluded from participation in the investigation."[107] In response to a public comment describing "the difficult task for potential subjects to imagine the kind of research they would want should they suffer a catastrophic illness," officials acknowledged possible difficulties in implementing the prospective decisionmaking process, but suggested that IRBs could adequately address these matters.[108] The New York court decision invalidating regulations governing research at the state's mental health facilities also expressed support for prospective decision making on research participation. In T.D., the appellate court took the position that without an incapable subject's previous consent or the consent of someone the subject specifically chose as her research decision maker, "[i]t may very well be that ... there is at present no constitutionally acceptable protocol for obtaining the participation of incapable individuals" in studies posing greater than minimal risk and no prospect of therapeutic benefit.[109] By implication, then, the court deemed advance consent or the consent of a specifically authorized research proxy a constitutionally adequate basis for an incapable subject's participation in research posing more than minimal risk and no prospect of direct benefit to subjects.

The court's position was based on earlier New York decisions addressing surrogate decision making on life-sustaining treatment for incapable patients. These decisions established a rule that "in the absence of specific legislation, and where there is no evidence of personal intent, a surrogate has no recognized right to decide ... that treatment should be withheld...."[110] Because "participation in studies involving greater than minimal risk exposes the subjects to possible harmful, and even fatal, side effects," the court determined that explicit legislation or the subject's prior expression of intent should be required in the research context as well.[111]

The state of Maryland has initiated a third policy effort relevant to advance research decision making. Draft legislation includes a framework for third-party decisions on research for decisionally incapacitated persons. Research is permitted with consent of an incapable subject's "legally authorized representative." Unlike current federal policy, this proposal specifies who may fill this role. Subject representatives may be, in the follow-

101 Keyserlingk, et al., supra, 351.

102 Id.

103 Berg, supra, 22.

104 Department of Health and Human Services, Food and Drug Administration, Protection of Human Subjects; Informed Consent, 61 Fed. Reg. 51498 (Oct. 2, 1996).

105 21 CFR 50.24 (a)(2)(iii).

106 The FDA's comments on the regulations include as examples of when "prior informed consent" could be used, "use of a surgical procedure with a known severe consequence; administration of a drug product with a known serious adverse reaction; identification of a population with a particular disease or condition who are at an extremely high risk for a serious event." 61 Fed. Reg. 51511.

107 Id.

108 Id.

109 *T.D.*, 650 N.Y.S. 2d, 177.

110 Id., 190.

111 Id., 191. This support for advance decision making also reflects the judges' apparent view that requiring a prior choice shows respect for the competent person's right of self-determination and provides better protection of incapable subjects than the state's invalidated provisions on surrogate decision making. The opinion fails to discuss how to ensure that advance decisions on research are adequately informed or how to implement the subject's right to withdraw from a study.

ing priority order, (1) a research agent designated in an advance directive for research; (2) a health care agent designated in an advance directive for treatment; (3) a surrogate authorized by statute to make health care decisions for an incapable person; or (4) a monitor designated by the IRB to act as a research decision maker for an incapable person.[112]

The draft gives greater decisionmaking authority to third parties expressly chosen by an incapable individual. In the absence of an instruction directive, only research agents and health care agents are authorized to consent to an incapable subject's involvement in research presenting a minor increase over minimal risk and no expected direct benefit. Only a research agent may authorize an individual's involvement in research presenting more than a minor increase over minimal risk and no direct benefit.

The legislation also recognizes a limited role for instruction directives. A monitor may consent to an incapable individual's participation in research presenting minimal risk and no direct benefit if the individual's advance directive explicitly authorizes such participation. A research agent may permit an incapable subject to be involved in research presenting more than a minor increase over minimal risk only if "the research is unambiguously included in the individual's advance directive authorizing research participation."[113] Thus, otherwise prohibited research risk is permitted based on the prior competent choice of a now incapable subject.

The draft does not discuss the study information that must be disclosed to a capable person making an advance research directive. Withdrawal from research is addressed, however. Any third party consenting to an incapable subject's participation must (1) take reasonable steps to learn whether the experience of the individual in the research is consistent with the expectations of the legally authorized representative at the time that consent was granted; and (2) withdraw consent if continued participation would, considering all relevant circumstances be detrimental to the well-being of the individual.[114]

In sum, advance research decision making has been widely discussed in the literature and included in some recent policy initiatives. Numerous conceptual and practical questions remain unresolved, however. The number of persons willing to prepare research directives may be small, especially if rigorous standards for information disclosure are observed. Investigators and IRBs face challenges in providing competent individuals with up-to-date information on a future study. Finally, the literature reveals disagreement on the significance policy should assign to the competent individual's preferences about future research participation posing more than minimal risk to incapable subjects.

Should federal policy regard the incapable subject's past competent instructions as an acceptable basis for initial or ongoing participation in studies that otherwise would be prohibited? To answer this question, policy makers must first decide whether certain types of studies are too risky or burdensome to conduct on incapable subjects who have not prepared advance research directives. This issue is discussed in the next section.

Balancing Risks and Expected Benefits in Research Involving Incapable Subjects

A generally accepted principle is that research risks to human subjects must be justified by expected benefits to subjects, to others, or to both. The Common Rule directs IRBs to ensure that research risks are minimized and are "reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."[115] These provisions govern all research involving human subjects. Many commentators and organizations, as well as the international documents described above, favor placing additional constraints on acceptable risks in research involving decisionally incapable subjects.

As was noted earlier, the National Commission proposed a research review framework in which greater substantive and procedural demands would be applied to research presenting relatively high risks to children and incapable individuals institutionalized as mentally infirm. The current DHHS regulations governing research involving children incorporate such a framework.[116] The regulations classify research using the somewhat controversial concept of "minimal risk." According to the Common Rule, a study presents minimal risk if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[117]

The DHHS regulations on research involving children permit IRBs to approve research presenting no more than minimal risk as long as requirements for parental permission and child assent are satisfied. Studies presenting greater than minimal risk must meet additional requirements. If a study in this category also offers a prospect of direct benefit to subjects, criteria for IRB approval include: (1) a finding that the risk is justified by the prospective direct benefit; and (2) a finding that the research presents at least as favorable a risk-expected benefit

112 Office of the Maryland Attorney General, supra.
113 Id., 15.
114 Id., 16.
115 Sec. ___.111(a).
116 45 CFR 46 (1991). See appendix for a copy of the regulations.
117 Sec. ___.102(i).

ratio for subjects as that presented by available alternatives in the clinical setting.

If a study presenting more than minimal risk offers no prospect of direct benefit to child subjects, criteria for IRB approval include: (1) a finding that the research presents a minor increase over minimal risk; (2) a finding that "the intervention or procedure presents experiences that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;" and (3) a finding that the study is likely to produce generalizable and vitally important information on the subjects' condition.

The regulations also provide for a special review process to address an otherwise unapprovable study determined by an IRB to offer "a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children." The Secretary of DHHS may approve such a study if, after consultation with experts in relevant fields and the opportunity for public review and comment, he or she concurs with the IRB's finding on research significance and determines that "the research will be conducted in accordance with sound ethical principles."[118]

These regulations, the National Commission's recommendations on research involving children and institutionalized persons, and the literature on research involving incapable adults present the following policy matters for consideration: (1) the appropriate definitions of risk and benefit to be adopted in policy on research involving incapable adult subjects; (2) the appropriate limitations on risk for research involving this population; and (3) the appropriate procedures for ensuring that the chosen substantive standards are observed during the research process.

Defining Risks and Benefits in Research Involving Incapable Subjects

Risks

Incapable subjects are vulnerable to a variety of possible harms when they participate in research. Risks to incapable subjects "range from physical injury and pain at one extreme, to discomfort and inconvenience at the other, including at various points along the continuum such effects as frustration, dislocation, confusion, and shame."[119] The Common Rule's definition of minimal risk refers to "harm or discomfort," which seems clearly to include experiential burdens as well as health risks.

The most thorough published analysis on risks and potential benefits in research involving incapable adults suggests that review committees should consider "physical, social, psychological, and economic," risks, including "foregone benefits, ... violations of privacy, ... effects upon the subject's relationship with family members, [and] the new anxiety associated with being invited to participate in ... research before having come to terms with one's affliction."[120] Risk assessment also involves probability judgments: "[t]he quantification of risk involves an examination of both the degree or magnitude of harm that could occur and the possibility that such harm will occur."[121]

Evaluating risks to incapable subjects requires familiarity with how subjects in the relevant population may respond, both generally and as individuals, to proposed research interventions and procedures. What may be a small inconvenience to ordinary persons may be highly disturbing to some incapable subjects. Thus, for example, a diversion in routine can for some dementia patients, "constitute real threats to needed order and stability, contribute to already high levels of frustration and confusion, or result in a variety of health complications."[122] Similarly, as the National Commission observed, some subjects institutionalized as mentally infirm may "react more severely than normal persons" to routine medical or psychological examinations.[123]

Because of this special vulnerability to harm and discomfort, risk evaluation should incorporate reliable knowledge on the range of anticipated reactions subjects may have to study procedures. Though conceding that precise risk and benefit assessments rarely are attainable, the Belmont Report states, "the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated as far as possible."[124] The National Commission's Report on Research Involving Children advised IRBs to assess risks from the following points of view: "a common-sense estimation of the risk; an estimation based upon investigators' experience with similar interventions or procedures; any statistical information that is available regarding such interventions or procedures; and the situation of the proposed subjects."[125]

Like the current DHHS regulations on research involving children, many proposals on research involving incapable adults employ the concepts of minimal risk and minor increase

118 Apparently, to date, no study has been approved under these provisions.
119 Keyserlingk, et al., supra, 326.
120 Id., 326–27.
121 Berg, supra, 24.
122 Keyserlingk, et al., supra, 324.
123 *Report on Institutionalized Persons,* supra, 8–9.
124 *Belmont Report*, supra, 7.
125 *Report on Children*, supra, 8–9.

over minimal risk. Giving substance to these concepts poses difficulties, however.

The Common Rule's minimal risk definition is tied to the risks of ordinary life and medical care. The minimal risk concept is praised for its flexibility: "[i]t is inescapable and even desirable that determinations of risk level (and its acceptability when balanced with benefit consideration) are matters of judgment rather than detailed definition, judgments which are patient-specific, context-specific, and confirmed after consideration and debate from many points of view."[126] In addition, the concept's reference to "risks of everyday life" is supported as conveying a defensible normative judgment that the sorts of risks society deems acceptable in other contexts may be acceptable in research as well.[127]

In contrast to the minimal risk concept's reference to the life and medical experiences of ordinary persons, the DHHS regulations' concept of minor increase over minimal risk is tied to the prospective subject's individual situation. Because persons with psychiatric and other disorders undergo treatment and tests involving some discomfort and risk, a study presenting similar procedures and potential for harm may qualify as presenting a minor increase over minimal risk to them.[128] For subjects not accustomed to or in need of such medical interventions, however, the same study would present a higher level of risk.

In its Report on Research Involving Children, the majority of National Commission members defended this approach on grounds that it permitted no child to be exposed to a significant threat of harm. Further, they noted that the approach simply permits children with health conditions to be exposed in research to experiences that for them are normal due to the medical and other procedures necessary to address their health problems. One member was highly critical of this approach, however, contending that it was wrong to take a more permissive approach to research risk in children with health problems than in other children. He argued that the only morally defensible differential treatment of sick and healthy children would be one that was more permissive about research risks to healthy children than to children already burdened by their health problems.[129]

Commentators have criticized both the Common Rule's "minimal risk" definition, and the DHHS regulations' term "minor increase over minimal risk." Loretta Kopelman provides the most detailed critique. First, she finds the risks of ordinary life too vague a notion to provide a meaningful comparison point for research risks. Ordinary life is filled with a variety of dangers, she notes, but "[d]o we know the nature, probability, and magnitude of these 'everyday' hazards well enough to serve as a baseline to estimate research risk?" Second, though the comparison to routine medical care furnishes helpful guidance regarding minimal risk, it fails to clarify whether procedures such as "X rays, bronchoscopy, spinal taps, or cardiac puncture," which clearly are not part of routine medical care, could qualify as presenting a minor increase over minimal risk for children with health problems who must undergo these risky and burdensome procedures in the clinical setting. Kopelman argues that the phrase minor increase over minimal risk should be replaced or supplemented by a clearly defined upper limit on the risk IRBs may approve for any child subject.[130]

A few empirical studies indicate that there is a real possibility of variation in how IRBs and investigators classify protocols using the current federal risk categories. For example, a 1981 survey found differences in how pediatric researchers and department chairs applied the federal classifications to a variety of procedures commonly used in research.[131] Similarly, there was substantial disparity in how the nine members of a special NIH review panel applied the federal classifications to a trial of human growth hormone in which healthy short children were subjects.[132] A survey asking research review committee members and chairs in Canada to classify four different dementia studies "confirmed that there is considerable disagreement and uncertainty about what risks and benefits mean and about what is to be considered allowable risk."[133]

126 Keyserlingk, et al., supra, 329.

127 Freedman, Fuks, and Weijer, in "Loco Parentis: Minimal Risk as an Ethical Threshold for Research Upon Children," *Hastings Center Report* (Mar.-Apr. 1993): 13, 17–18. According to the National Commission, "where no risk at all or no risk that departs from the risk normal to childhood (which the Commission calls 'minimal risk') is evidenced, the research can ethically be offered and can ethically be accepted by parents and, at the appropriate age, by the children themselves." *Report on Children*, supra, 137.

128 The DHHS regulations on children in research provide that studies may be approved as presenting a minor increase over minimal risk as long as the risks and experiences "are reasonably commensurate with those inherent" in the child subjects' actual or anticipated medical or other situations.

129 *Report on Children*, supra, 146 (dissenting statement of Commissioner Turtle).

130 Kopelman, "Research Policy: Risk and Vulnerable Groups," in *Encyclopedia of Bioethics* (W. Reich (ed.), rev. ed. 1995): 2291, 2294–95; Kopelman, "When Is the Risk Minimal Enough for Children to Be Research Subjects?" in *Children and Health Care: Moral and Social Issues* (Kopelman and Moskop (eds.), 1989): 89–99. See also Berg, supra, 24 (noting possible interpretations of minimal risk and concluding that "[i]t clearly does not mean only insignificant risk, but its exact scope is unclear").

The Maryland draft legislation adopts a definition of minimal risk similar to that in the Common Rule. It also refers to minor increase over minimal risk, which is defined as "the probability and magnitude of harm or discomfort anticipated in the research, including psychological harm and loss of dignity, are only slightly greater in and of themselves than those ordinarily encountered in the daily life of the potential research subjects or during the performance of routine physical or psychological examinations or tests." Office of the Maryland Attorney General, supra, 4.

131 Janofsky and Starfield, "Assessment of Risk in Research on Children," *Journal of Pediatrics* 98 (1981): 842.

132 See Tauer, "The NIH Trials of Growth Hormone for Short Stature," *IRB* (May-June 1994): 1.

133 Keyserlingk, et al., supra, 326.

In sum, if policy on research involving incapable adults incorporates the concepts of minimal risk and minor increase over minimal risk without providing further guidance to investigators and IRBs, the concepts may be interpreted in materially different ways. A study classified as minimal risk at one institution could be classified as higher risk at another. Also needed is more discussion and clarification of acceptable risk in research involving incapable adults whose health problems expose them to risks in the clinical setting. Incapable persons accustomed to certain procedures may experience fewer burdens when undergoing them for research purposes. Thus, it is defensible to classify the risks to them as lower than they would be for someone unfamiliar with the procedures. On the other hand, some procedures entail material burdens each time they are administered. Procedures of this sort ought not be classified as lower risk for subjects who have had the misfortune of enduring them in the treatment setting.[134]

One way to reduce variance in risk classification would be to provide examples of studies that ordinarily would be expected to present a certain level of risk to members of a certain research population. The discussion could also include general considerations relevant to risk classification. For example, one author proposes that lumbar punctures and positron emission tomography "can be reasonably viewed as having greater than minimal risk for persons with dementia because 1) both procedures are invasive, 2) both carry the risk of pain and discomfort during and after, and 3) complications from either procedure can require surgery to correct."[135] The Maryland draft legislation states that an IRB may not classify a study as presenting minimal risk if the study would expose incapable subjects to "a loss of dignity greater than that ordinarily experienced by individuals who are not decisionally incapacitated during the performance of routine physical or psychological examinations or tests."[136] The draft legislation also prohibits IRBs from applying the minimal risk or minor increase over minimal risk categories to studies exposing incapable subjects to possible "severe or prolonged pain or discomfort" or "deterioration in a medical condition."[137]

Another document lists as minimal risk for dementia patients "routine observation, data collection, answering a questionnaire, epidemiological surveys, venipuncture, and blood sampling," as well as neuropsychological testing.[138] Though some reportedly classify lumbar punctures and bone marrow biopsies as presenting a minor increase over minimal risk, this document suggests that such procedures may present "greater risks for some patients with dementia who are unable to understand or tolerate the pain or discomfort" accompanying the interventions.[139] Finally, the document notes that repeated performance of procedures ordinarily qualifying as minimal risk could at some point create sufficient burdens to subjects to merit a higher risk classification.

Benefits

Research involving incapable adults may yield three types of benefit: direct benefit to subjects, indirect benefit to subjects, and benefit to others. Direct benefit to subjects includes health improvements which may or may not be related to the disorder responsible for the subject's incapacity.[140] The National Commission stated that research offering potential benefits to persons institutionalized as mentally infirm includes studies to improve existing methods of biomedical or behavioral therapy, or to develop new educational or training methods. The studies may evaluate somatic or behavioral therapies, such as research designed to determine differential responsiveness to a particular drug therapy, or to match particular clients with the most effective treatment. Studies may also assess the efficacy of techniques for remedial education, job training, elimination of self-destructive and endangering behaviors, and teaching of personal hygiene and social skills.[141]

According to the commission, "[t]o be considered 'direct,' the possibility of benefit to the subject must be fairly immediate [and t]he expectation of success should be well-founded scientifically."[142] A more recent statement on dementia research limits direct benefit to:

> a short- or long-range improvement, or a slowing of a degenerative process, in the specific medical condition of the relevant subject, whether in the patient's condition of dementia, a medical symptom associated with dementia, or another physical or mental condition unrelated to dementia. Such direct benefits

134 Prior exposure to procedures could actually increase the fear and anxiety for some incapable subjects. Incapable adults with memory impairment may not recall undergoing procedures; for them, each procedure will be experienced as a new one.

135 DeRenzo, supra, 540.

136 Office of Maryland Attorney General, supra, 7.

137 Id.

138 Keyserlingk, et al., supra, 330.

139 Id., 330.

140 Keyserlingk, et al., supra, 327.

141 *Report on Institutionalized Persons*, supra, 31.

142 Id., 13.

Berg also emphasizes the need to weigh the likelihood of direct benefit to subjects. In clinical trials, for example, "the benefit calculation must take into account how probable it is that a particular subject will get the experimental medium as well as the probability that, once received, the intervention will help." Berg, supra, 25.

include those resulting from diagnostic and preventative measures.[143]

Subjects may obtain other forms of benefit from research participation. As the National Commission noted, "[e]ven in research not involving procedures designed to provide direct benefit to the health or well-being of the research subjects, ... there may be incidental or indirect benefits."[144] Examples of indirect benefits are, "diversion from routine, the opportunity to meet with other people and to feel useful and helpful, or ... greater access provided to professional care and support."[145] According to one group, indirect benefit may be acknowledged, but should not be assigned the same weight as direct benefit in research review and discussions with prospective subjects and their representatives.[146]

The T.D. decision criticized New York's failure to include a more precise definition of direct subject benefit in the regulations the court invalidated. The regulations referred to "direct benefit that is important to the general health or well being of the subject and is available only in the context of the research." Because otherwise applicable limitations and safeguards could be waived if a study offered potential direct benefit to subjects,[147] the court seemed to favor a narrow definition encompassing only expected benefits produced by the research procedure, related to the incapable subject's psychiatric condition, and reasonably equivalent to those provided by currently available treatments.[148]

The court's response supports, at minimum, a need to scrutinize investigators' characterizations of research offering potential direct benefit to subjects.[149] Such claims require careful scrutiny by IRBs and other reviewers. Specific definitions of direct and indirect benefit, and a statement on the relative significance of the two, could assist investigators and reviewers in evaluations of the benefits anticipated from particular studies. The decision also questions the justification for a policy adopting less rigorous limits and safeguards for studies offering prospective direct benefit to subjects, if direct benefit is defined as broadly as it was in the New York regulations.

Research benefit to others encompasses benefit to a subject's family or other caregivers, to persons with the same disorder as subjects, and to persons diagnosed with the disorder in the future. This category of research presents the greatest challenge for those seeking the appropriate balance between subject protection and the welfare of others. As one group noted, when such research is invasive and presents no realistic possibility of direct health benefit, it "poses in the most dramatic form the conflict between the societal interest in the conduct of important and promising research and the interests of the potential subject."[150]

Acceptable Risk-anticipated Benefit Ratios in Research Involving Incapable Subjects

Proposed policies on research involving incapable adults generally engage in a balancing of risks and potential benefits to determine when such research is acceptable. Most proposals take the position that incapable adults may be involved in studies presenting little or no risk to them, as long as requirements for third party consent are met and the research offers a reasonable prospect of advancing knowledge or benefiting the subject, or both. There is substantial support, however, for adopting additional restrictions and review requirements for studies presenting higher risk, particularly for higher risk studies failing to offer subjects a reasonable prospect of direct benefit.

Research presenting more than low risk to subjects is generally classified into one of two categories. The first category is research offering subjects a reasonable prospect of direct benefit. Though the moral justification for such research is enhanced by the potential for improving subjects' health or welfare, most proposals incorporate the view that limits on risk are still needed to provide adequate protection to incapable individuals.

Greater than Minimal Risk Research Offering Direct Subject Benefit

The general view is that it is permissible to include incapable subjects in potentially beneficial research projects as long as the research presents a balance of risks and expected direct benefits similar to that available in the clinical setting.[151] This

143 Keyserlingk, et al., supra, 327. This group notes that currently direct benefits to subjects in dementia research are limited to symptom control. There may be disagreement on whether research with the potential to extend life for someone in the later stages of a progressive dementia ought to be seen as offering the prospect of direct benefit to subjects.

144 *Report on Institutionalized Persons*, supra, 31.

145 Keyserlingk, et al., supra, 327.

146 Thus, indirect benefit ought not be deemed sufficient to enter an incapable subject in studies presenting more than a "minor increment over minimal risk." Id., 333–34. The group characterized indirect benefits as "by nature difficult to predict with any accuracy and ... often very person-specific." Id., 327.

147 The regulations permitted the involvement of incapable subjects in greater than minimal risk research with the prospect of direct benefit without otherwise applicable requirements for an absence of subject objection and a finding that the study could not be conducted without the participation of incapable subjects. *T.D.*, 650 N.Y.S. 2d, 187–88, 193.

148 Id.

149 Capron, supra.

150 Melnick, et al., supra, 535.

151 The standard is similar to the general demand for clinical equipoise when human subjects participate in clinical trials. Freedman, "Equipoise and the Ethics of Clinical Research," *New England Journal of Medicine* 317 (1987): 141.

position is adopted in current DHHS regulations on research involving children.[152] It is also endorsed in most of the proposals on incapable adults.

The American College of Physicians' document allows surrogates to consent to research involving incapable subjects only "if the net additional risks of participation (including the risk of foregoing standard treatment, if any exists) are not substantially greater than the risks of standard treatment (or of no treatment, if none exists)." In addition, there should be "scientific evidence to indicate that the proposed treatment is reasonably likely to provide substantially greater benefit than standard treatment (or no treatment, if none exists)."[153]

The Maryland draft legislation deems "expected medical benefit" research permissible if an agent or surrogate, "after taking into account treatment alternatives outside of the research, ... concludes that participation is in the individual's medical best interest."[154] The NIH Clinical Center permits greater than minimal risk research offering a prospect of direct subject benefit with the consent of a DPA or court-appointed family guardian, following an ethics consultation to ensure that the third-party decision maker understands the relevant information. For subjects without a DPA or court-appointed guardian, this form of research is permitted, "if the situation is a medical emergency, when a physician may give therapy, including experimental therapy, if in the physician's judgment it is necessary to protect the life or health of the patient."[155]

Greater than Minimal Risk Research Offering No Reasonable Prospect of Direct Subject Benefit

The American College of Physicians and other groups take the position that greater than minimal risk research offering subjects no reasonable prospect of direct benefit should be permitted only when authorized by a research advance directive[156] or after review and approval at the national level, through a process resembling that set forth in the current regulations governing research involving children.[157] The National Commission also recommended a national review process for studies that could not be approved under its other recommendations on research involving persons institutionalized as mentally infirm. However, others see this position as either too liberal or too restrictive.

On one hand, some favor an absolute prohibition on moderate or high-risk research offering no benefit to subjects but great promise of benefit to others, based on the Nuremberg Code's and Helsinki Declaration's "conviction that vulnerable and unconsenting individuals should not be put at undue risk for the sake of patient groups or society."[158] Supporters of this position contend that when these documents were created, "it was presumably well understood that a price of that prohibition would be that some important research could not proceed, some research answers would be delayed, and some promising therapies and preventive measures would for the time being remain untested and unavailable."[159] Some writers explicitly label this stance the most ethically defensible position.[160]

A position paper representing federally funded Alzheimer Disease Centers adopts a somewhat different view: "[r]esearch that involves potential risks and no direct benefit to subjects may be justified if the anticipated knowledge is vital and the research protocol is likely to generate such knowledge."[161] This group also believes that a national review process is not necessarily the best way to decide whether to permit research presenting no potential direct benefit and more than minimal risk

152 See pp. 52–54, above.

153 American College of Physicians, supra, 845. A limited exception is permitted for incapable individuals who consented to higher risk through an advance directive.

154 Office of Maryland Attorney General, supra, 11.

Commentators take a similar position. See, e.g., Berg, supra, 25 (approving this category of research if "no alternative treatment is available of at least equal value, and the experimental treatment is not available through any other source").

Much of the recent controversy over trials involving medication withdrawal for persons with serious psychiatric disorders concerns whether sufficient potential direct benefit exists to justify allowing subjects of questionable capacity to enter or remain in such trials. See Appelbaum, supra; Gilbert, et al., "Neuroleptic Withdrawal in Schizophrenic Patients," *Archives of General Psychiatry* 52 (1995): 173. The Loma Linda IRB Guidelines for use of placebos in studies involving persons with psychiatric illness present specific exclusion and inclusion criteria for such studies. Enrollment is limited to persons whose use of standard treatment has produced responses or side effects deemed unacceptable by the patient or an independent psychiatrist. Orr, supra, 1263. Similarly, Appelbaum endorses a requirement for an independent clinician to screen prospective subjects with the goal of excluding those facing a high risk of harm from psychotic deterioration. Appelbaum, supra, 4.

155 NIH Clinical Center, supra.

156 Even in this case, the ACP would rule out research that "would unduly threaten the subject's welfare." See pp. 41–42, above.

The Maryland draft legislation would permit research presenting more than a minor increase over minimal risk and no reasonable prospect of direct benefit only when subjects appointed a research agent and "the research is unambiguously included in the [incapacitated] individual's advance directive authorizing research participation." Office of Maryland Attorney General, supra, 15. Berg proposes that high-risk research offering little or no prospect of direct subject benefit should be prohibited unless there is clear evidence that a subject's competent preferences would support participation. Berg, supra, 28.

157 American College of Physicians, supra, 846. See also Melnick, et al., supra, 535 (advising national ethics review prior to any decision to permit studies in this category).

158 Keyserlingk, et al., supra, 334.

159 Id.

160 Id., 334. The group would accept this form of research for a small group of incapable subjects who previously consented to it in an advance directive, however. See pp. 45–46, above. Annas and Glantz also contend that without previous competent and specific consent, incapable nursing home residents should not be enrolled in "nontherapeutic experimentation that carries any risk of harm with it." Annas and Glantz, supra, 1157. See also Shamoo and Sharev, supra (calling for "moratorium on all nontherapeutic, high risk experimentation with mentally disabled persons which is likely to cause a relapse); Thomasma, supra, 228 (incapable persons should not be involved in research failing to offer direct benefit if study presents more than "very mild risk").

161 The group does not explicitly address whether limits on risk should be applied to this form of research. High, et al., supra, 72–73.

to incapable subjects. They acknowledge that "there may be some advantages" to national review, but contend that "immediate and direct monitoring of such research and on-site assurance of its humane ethical conduct are at least as important as the process of evaluation and approval of any proposed research."[162]

In sum, there is a range of opinion on how federal policy should address risks to incapable subjects in studies conducted solely for the benefit of others. The literature presents at least three options: (1) adopt an absolute risk limit, such as minimal risk or minor increase over minimal risk; (2) require approval at the national level for studies exceeding a specific risk level; or (3) preserve the status quo and allow IRBs to determine acceptable risk levels. If the decision to limit risks is made, consideration should be given to providing more specific definitions than exist in current policy provisions on minimal risk and minor increase over minimal risk.

Maintaining Acceptable Risk-expected Benefit Ratios in the Research Process

In the initial review process, IRBs evaluate a research proposal's risks and expected benefits based on predictions of subject response. In many cases, a range of responses among subjects will be predicted. In some cases, predictions may prove inaccurate as research progresses, for some or even all subjects. As a result, subjects' health status and experiences must be evaluated on an ongoing basis to ensure that subjects can be removed if risks become excessive.

The need for subject monitoring is widely acknowledged. The Common Rule directs IRBs to ensure that "[w]hen appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."[163] Commentators also refer to the importance of monitoring.[164] The major question is how to implement this task. A central issue is whether, and if so, when, monitoring should be conducted by a person independent of the research team.

After evaluating human subject protections in schizophrenia research conducted at the University of California at Los Angeles (UCLA), the U.S. Office of Protection from Research Risks (OPRR) required the institution to "establish one or more independent Data and Safety Monitoring Boards ... to oversee [DHHS]-supported protocols involving subjects with severe psychiatric disorders in which the research investigators or co-investigators are also responsible for the clinical management of subjects."[165] The institution was directed to submit to federal officials a proposal on creating and operating the monitoring boards.

Detailed provisions on monitoring are included in Loma Linda University IRB guidelines on psychopharmacology research in which placebos are administered. Investigators must specify how often subjects will be assessed for deterioration or improvement during studies. Validated quantitative instruments must be used for assessment and subjects must be withdrawn if their condition deteriorates to a level "greater than that expected for normal clinical fluctuation in a patient with that diagnosis who is on standard therapy," if they exhibit previously specified behaviors indicating possible danger to self or others, or if no signs of improvement in their condition are evident after a specified time.[166]

Other documents assign monitoring responsibility to the incapable subject's representative as well. According to the Belmont Report, the representative "should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest."[167] The Maryland draft legislation directs subject representatives to "take reasonable steps to learn whether the experience of the individual in the research is consistent with the expectations of the legally authorized representative at the time that consent was granted."[168]

The general policy question is whether research team members and subject representatives can provide sufficient protection to incapable subjects. Research team members face a conflict between protecting subjects and maintaining the study population.[169] It is unlikely that subject representatives will be present during every part of an incapable subject's research involvement; in addition, lay persons might not recognize every indication of increased risk to subjects. Federal policy should provide guidance to IRBs on potential approaches to monitoring harms and benefits to individual subjects and criteria for determining when the involvement of an independent clinician is needed.[170]

162 High, et al., supra, 72. Another statement questions the assumption that a national review body would be particularly qualified to determine "whether the research in question is indeed extremely important to society or to a class of patients—sufficiently so that standard research norms could be put aside." Keyserlingk, et al., supra, 335.

163 Sec. ___.111(a)(6).

164 See, e.g., Appelbaum, supra, 4 (noting importance of close monitoring to detect early symptoms of relapse so that medication can be resumed to minimize deterioration); Keyserlingk, et al., supra, 324 (researchers "must have in place at the start the needed mechanism to monitor subjects, not only as regards the research question, but also in order to identify and prevent unanticipated complications and harms, both physical and psychological").

165 Office for Protection from Research Risks, supra, 27.

166 Orr, supra, 1263.

167 *Belmont Report*, supra, 6.

168 Office of Maryland Attorney General, supra, 16.

169 In the UCLA schizophrenia research, subjects received clinical care from psychiatrists who also were co-investigators for the study. There was concern that such a conflict of interest could lead psychiatrists to be insufficiently responsive to signs of possible relapse in patient-subjects.

170 See Shamoo and Sharev, supra, S:29 (researchers and IRBs should be held accountable for monitoring to ensure welfare of subjects protected; physician not associated with research or institution where research conducted should help decide whether subjects' interests served by continued participation).

Subject Representation in Research Design and Review

Increased subject representation in the review and conduct of research is another commonly-endorsed strategy for improving research decisions affecting persons with mental disabilities. Representation is generally viewed as a means of enhancing the likelihood that decisions will be responsive to the interests of affected groups.

The Common Rule directs IRBs frequently reviewing research involving a vulnerable subject group to consider including as reviewers persons with knowledge of and experience working with the relevant subject group. The current provision is advisory only; moreover, it refers to the involvement of expert professionals, not persons representing vulnerable subject groups.

After evaluating schizophrenia studies at UCLA, the OPRR directed the School of Medicine's IRB to "engage one or more subject representatives as IRB members who will assist the IRB in the review of issues related to the rights and welfare of subjects with severe psychiatric disorders."[171] This requirement was imposed even though the IRB already had a psychiatrist and a psychologist as members.[172]

New federal policy creating an exception to informed consent requirements for certain research in the emergency setting directs IRBs approving such research to arrange for consultation "with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn."[173] The regulations also instruct IRBs to ensure that plans for and results of such studies be disclosed to the relevant communities.[174]

A third relevant development is the increased involvement of affected persons in the planning of clinical research on their conditions. The phenomenon first arose in the context of HIV research; it is now evident in other areas of clinical research as well.[175] It would be possible for federal policy on research involving persons with mental disabilities to promote the involvement of subject representatives in planning clinical studies of the relevant conditions.

If enhanced subject representation is adopted as a policy goal, several issues merit consideration. First, should policy set forth specific qualifications for representatives of affected groups? Should policy include a preference for persons diagnosed with the relevant condition? Under what circumstances may family members or members and employees of advocacy organizations act as representatives? Should investigators be required to demonstrate to IRBs that representatives of the affected group were consulted in the planning process? Specific responses to these issues would assist IRBs asked to implement federal policy concerning this relatively unexplored area.

Conclusion

The aim of this analysis has been to highlight the important issues and concepts meriting enhanced attention in federal research policy and to describe various reforms endorsed in the literature. An improved federal policy would address, through regulation or enhanced guidance and education for IRBs and investigators, the following matters:

- identification of the population of persons with mental disabilities at risk of decisional incapacity; and
- appropriate standards and procedures for determining which individuals are capable of independent decisions to enter and to remain in a research study.

For individuals identified as incapable of independent decision making, the following topics need attention:

- identification of a proper surrogate decision maker;
- screening, education, and substantive decision-making standards for surrogate decision makers;
- definition of subject assent and determination of when it is required;
- definition of subject objection and determination of when it rules out subject participation;
- the role and significance of research advance directives;
- the acceptable risk-expected benefit ratios for research involving incapable subjects;
- the definition of any designated limits on risk for research involving incapable subjects;
- standards and procedures for waiving the customary limits on acceptable risk (e.g., with explicit prior consent, consent of previously designated surrogate, or permission of national advisory body); and
- monitoring procedures to ensure continued consent, assent, absence of objection, adherence to

171 Office for Protection from Research Risks, supra, 21–22.
172 See also Shamoo and Sharev, supra, S:29 (IRBs reviewing proposals to involve mentally disabled subjects should include at least two patient-representatives).
173 21 CFR 50.24 (a)(7).
174 Id.
175 See Erikson, "Breast Cancer Activists Seek Voice in Research Decisions," *Science* 269 (1995): 1508.

advance directive terms, and adherence to permissible risk-expected benefit ratio.

Provisions on consumer representation in IRBs and in planning and conducting research on affected populations should also be considered.

PAPER THREE

RELATIONAL ETHICS AND RESEARCH WITH VULNERABLE POPULATIONS

Celia B. Fisher, Ph.D.
Professor
Director of the Doctoral Specialization
in Applied Developmental Psychology
Fordham University
Bronx, New York 10458
Telephone: (718) 817-3793
Fax: (212) 759-2009
E-mail: Fisher @ Murray.Fordham.edu

This work benefited from the insightful comments of Bart Collopy, Gary Fisher, and Margaret Walker.

Researchers applying the scientific method to describe, explain, and enhance the status of individuals with physical, psychological, and social vulnerabilities are encountering ethical dilemmas to which current federal regulations offer incomplete answers. In such work, scientific and ethical duties often appear to have mutually exclusive goals. Whereas scientific responsibility involves a search for truth through experimental controls, ethical duties are directed toward protecting participant welfare through means that often seem to jeopardize such controls (Fisher, 1993). When the goals of science and ethics appear to conflict, investigators studying vulnerable populations draw upon their own moral compass, the advice of colleagues, and recommendations of institutional review boards (IRBs) to make decisions about ethical procedures that have immediate and possibly long-term impact on participants, their families, and the communities they represent.

Since 1974, the federal government, through regulations requiring the establishment of the institutional review board (IRB) system, has formally recognized the inadequacy of ethical procedures which rely solely on the professional judgment of individual scientists (Benson and Roth, 1988). However, ethical evaluations drawn from the consensus of IRB members can also represent a restricted moral view. IRBs typically include ethicists, academic scholars, practitioners, and scientists who judge the ethicality of a research proposal through the application of federal and professional guidelines, abstract moral principles, and values situated within the cultures of academia, institutionalized medicine, or science. The perspectives of those who participate in research are typically given only superficial consideration through the appointment of a community member who cannot realistically represent perspectives of the diverse individuals who will be called upon to participate in various research projects conducted by members of the institution. Children and adolescents at psychosocial or physical risk, individuals from diverse economic and cultural backgrounds, and adults with cognitive deficits react differently to controlled procedures, and their perspectives and the perspectives of their family members can differ from those of well-meaning IRB decision makers.

Public reactions to past and recent revelations concerning the government-sponsored Tuskegee Syphilis Study (Jones, 1993), the human radiation experiments (ACHR, 1996), and the NIMH Violence Initiative (Leavy, 1992) have lead to

concerns that current federal guidelines do not adequately protect the interests of our most vulnerable citizens and that diminished public trust in human subjects research may jeopardize research participation. In response to public concern, the President has appointed the National Bioethics Advisory Commission to review the adequacy of current federal guidelines for the protection of human subjects. This paper argues that to insure such protections are adequate, revised research regulations need to reflect a relational approach that encourages moral discourse between scientists and participants as an essential means of constructing the best scientific and ethical procedures possible within each unique research context.

Philosophical Premises Guiding Ethics-in-Science Decision Making

Consequential and Deontic Frameworks

Since the Nuremberg Code (1946), federal regulations (DHHS, 1991) and professional guidelines for research (e.g., American Psychological Association [APA], 1992), have primarily drawn upon the utilitarian or consequential meta-ethical position (Beauchamp, Faden, Wallace, and Walters, 1982) to solve ethical problems when actions that would protect the rights and welfare of research participants threaten the internal validity of an experiment. According to utilitarianism, the morally right action is the one that produces the most pleasing consequences (Mill, 1861/1957). Applied to ethics-in-science decision making, when a conflict between scientific rigor and participant welfare arises, the investigator's obligation to a small group of research participants may be superseded by her or his responsibility to produce reliable data that can potentially provide future benefits to members of society at large or to the participants' particular social group. Utilitarianism thus encourages a value structure in which potential benefits of science to society can receive higher moral priority than concrete and measurable risks to research participants.

Although consequentialism does not rule out consideration of participant values about, and idiosyncratic sensitivity to, specific types of harm and benefit, in practice those adopting this framework conceptualize risk and benefit as tangible entities with universal value subject to rational analyses by those other than the participant. Utilitarianism can thus promote an ethical orientation in which an abstract risk/benefit calculus guides moral action independent of the particular values and priorities a subject might place on the specific risks and benefits under consideration.

Equally important in philosophical circles, but less pervasive in ethics-in-science decision making, is the deontological approach in which the moral rightness of an action is evaluated without regard to the consequences and is carried out only if one would will that that action should be universal law (Kant, 1785/1958; Levine, 1986). Following deontic moral premises, an investigator would never treat a participant simply as a means to advance scientific knowledge and would only select research procedures she or he could apply across all research contexts. The Kantian tradition's inherent respect for the dignity of persons would appear to encourage scientists to incorporate participant perspectives into their ethical decision making. In practice, however, its focus on the universality of moral principles, and its indifference to particular relations and particular persons (Carroll, Schneider, and Wesley, 1985; Williams, 1981), often leads investigators and IRBs to believe they can determine which research procedures are ethical without consulting members of the population under study.

Although both utilitarianism and deontology are important philosophical resources for ethics-in-science decisions, applied in isolation from a participant's own understanding of the research context, these moral frameworks have the potential to minimize a scientist's special relationship, and subsequent moral obligations, to individual research participants, fostering a psychological distance between scientist and subject (Fisher, 1994).

A Relational Ethic Derived from a Justice-Care Perspective

Moral arguments for the duty to consider participant perspectives in ethics-in-science decision making derive from a synthesis of principle-based justice ethics and relational-based care ethics. The justice perspective emphasizes moral agency based upon principles of mutual respect, beneficence, and fairness (Kohlberg, 1984). It stresses impartiality and distance from both the scientist's own interests and her or his connectedness to participants. The ethics of care emphasizes the duty to interact with research participants on their own terms in response to their needs (Gilligan, 1982). It stresses attention to the interpersonal situation and a narrative of relationships that extends over time.

In recent years there has been growing recognition in philosophical and scientific circles that morality based on justice can and does coexist with morality based on interpersonal obligations (Baier, 1988; Dillon, 1992; Higgins, 1989; Killen, 1996; Waithe, 1989). For example, efforts have been made to integrate the two perspectives into a single moral orientation toward individual identity. Those advancing the justice perspective have traditionally taken individual identity as fundamental, viewed care as a choice, focused deliberations on how one can fulfill obligations to others without violating their autonomy, and emphasized the development of moral injunctions to protect identity. In contrast, those advancing the care perspective have traditionally taken relationships as fundamental, viewed care as an obligation, focused on how one can achieve individual freedom without violating moral obligations to others, and stressed the construction of moral injunctions to protect relationships (Clement, 1996). By integrating the two philosophical orientations, a justice-care position assumes:

(a) individuality is a product of ongoing interactions between a person and her or his social environment; (b) respect for individuality need not threaten a sense of community; and (c) one cannot care for others without recognizing and being responsive to their individuality.

Research Vulnerability as a Relational Construct

A justice-care orientation conceptualizes vulnerability as a relational construct. Research vulnerability is defined in terms of a susceptibility to harm that does not rest solely upon the physical, psychological, or social characteristics that society views as disadvantageous, but upon the degree to which an individual's welfare is dependent upon the specific actions of scientists within a specific experimental context. In relational ethics, the obligation to protect the vulnerable also resides within the context of dependency and not in the charitable inclinations of the moral agent (Goodin, 1985). From this perspective both the specific susceptibility to research risks and the specific ability of scientists to help alleviate these risks defines an obligation that is not voluntary but morally binding (Goodin, 1985).

When an individual labeled by society as vulnerable is the focus of scientific inquiry, the investigator must consider the special life contexts that render this person more or less susceptible to the harms associated with recruitment procedures and participatory requirements for each particular experimental design. For example, susceptibility to coercion and exploitation may be a particular risk for those whose age, mental status, or sociopolitical standing have limited their experience in making independent choices or for whom acquiescence to authority has been a means of survival. It is not unusual for individuals with mental retardation to assume permission from a nondisabled guardian is required when they seek or are offered treatment (Ficker-Terrill and Rowitz, 1991; Ellis, 1992). For these persons, recruitment and consent procedures drawing upon institutional authority or the influence of legal guardians may increase their vulnerability to undue persuasion and involuntary participation. On the other hand, relationships between vulnerable persons and their family members, practitioners, or community leaders may be a positive life feature that investigators can draw upon to reduce susceptibility to research risk.

A relational concept of vulnerability also implies harm is not predetermined. From this perspective, protecting the vulnerable entails reducing if not eliminating the probability of threatened harms (Goodin, 1985). As a consequence, morally responsible scientists must take actions which go beyond simply protecting cognitively impaired persons from *established risks* associated with research participation. They must be willing to reconfigure experimental procedures to reduce or eliminate research vulnerability. This may include re-conceptualizing traditional assumptions regarding the standards by which an individual is considered competent to give informed consent and the role of guardians in consent decisions. It may also include new ethical responsibilities, including an obligation to educate prospective participants about concepts associated with the conduct of human subjects research and to inform them of the value orientations driving the research. From a relational perspective, the investigator sees such efforts not in terms of paternalism (Goodin, 1985), but as contextually defined obligations of the research contract.

Principles, Consequences, Community, and Care

A justice-care perspective accepts *respect, beneficence, justice,* and *integrity* as fundamental ethical principles that guide the moral actions of scientists. The translation of these principles into moral actions is not, however, assumed to be achieved simply through a scientist's moral reflections, but must derive from expressions of mutual accommodation among scientist, participant, and caring others integrated into concrete practices (Ricoeur, 1990; Widershoven and Smits, 1996). In addition, connectedness with, and caring for, those who participate in research need to be viewed as moral ends in their own right, rather than simply as a means to facilitate recruitment or maintain participant cooperation.

While accepting the deontic principle that research participants should not simply be used as a means to achieving research goals, relational ethics conceives personhood and autonomy as social constructions which can best be respected through mutual understanding and dialogue between scientist and subject. Respecting research participants thus involves responding to them on the basis of their own self-conceptions. A justice-care perspective proposes such ethical principles as beneficence, respect, and justice can and should guide research design and ethics-in-science practices, but that the investigator's interpretation of these principles should not be prioritized over the moral perspectives of participants and their families.

A justice-care perspective includes an evaluation of the moral rightness of ethics-in-science decisions in terms of consequences. However, relational ethics also draws attention to contextual factors that may influence how a specific moral goal may be achieved and perceived. Such factors include the recognition that scientists and participants may differ in their understanding of the rightness of the consequences of a particular form of scientific inquiry. A relational approach to ethical decision making also rejects sole reliance on a rational calculation of risk to benefits, recognizing that scientists and prospective research participants may differ in how they evaluate particular harms and goods, and whether or not they view the weighing of costs and benefits itself as a morally right action.

Ethical relationalism is not ethical relativism. An emphasis on the contextual nature of ethical judgments based upon scientist-participant dialogue is not meant to imply an ethical relativism. Relational ethics does not assume basic foundational moral principles can be derived from group consensus. It sees

embeddedness within a moral community composed of scientists, participants, and their families as an essential starting point but not an end point in the search for the good (MacIntyre, 1984). Thus, the exchange of views between scientist and participant is aimed at illuminating rather than eliminating the moral values of each and creating a research enterprise that can accommodate rather than subjugate these values. As discussed more fully below, *participant perspectives must inform but not dictate a scientist's moral judgments.* Similarly, the value orientations of scientists can not be perceived to outweigh those who will be the focus of scientific inquiry. When applying a relational ethic, an investigator must be prepared to abandon a research project if its implementation compromises or usurps scientific, participant, or community values.

Relations between partners, not strangers. Relational ethics draws upon features of communitarianism (Rawls, 1971). It promotes reliance on compassionate and reciprocal empathy for the feelings of others and encourages scientists and prospective participants to uphold the common good rather than individualistic notions of the good life (Prilleltensky, 1997; Sugden, 1993). Rawls (1971) proposes that just actions in a society composed of members with different levels of resources and power can be guided by imagining oneself in an "original position" behind a veil of ignorance that would conceal one's actual social status. However, as Toulman (1981) points out, a system of justice based upon imagining a veil of ignorance may well be fair, but will also be an ethics for relations between strangers. In relational ethics, such imaginings, if based solely upon rational and abstract reasoning abilities, are seen to result in false perceptions irretrievably embedded in the rational scientist's own subjectivity. At its very core, relationalism assumes that the ability to understand the perspective of individuals who differ in life experiences, world views, needs, power, social status, culture, and material and personal resources requires a process of bidirectional teaching and learning. This dialectic is operationalized in investigator-participant co-learning procedures wherein the moral perspective of prospective participants is viewed as an essential element of ethics-in-science decision making.

Relationalism and Participant Perspectives

A relational ethic based upon a justice-care perspective (Farr and Seaver, 1974; Sullivan and Dieker, 1973; Veatch, 1987; Wilson and Donnerstein, 1976), supports several moral arguments for including the views of prospective research participants, their families, and their communities in ethics-in-science decision making (Fisher and Fyrberg, 1994; Hillerbrand, 1987; LaFromboise and Foster, 1989; Ponterotto and Casas, 1990). First, formulating regulations and ethical judgments solely on the bases of opinions expressed by experts in the scholarly community and IRB members risks treating subjects as "research material" rather than as moral agents with the right to judge the ethicality of investigative procedures in which they participate. Second, failure to consider prospective participants' points of view encourages singular reliance on scientific inference or professional logic that can lead to research procedures causing significant participant distress. The University of California IRB approval of consent procedures that failed to disclose the full nature of experimental risk involving medication withdrawal from participants with recent-onset schizophrenia (OPRR, 1994) is an unfortunate example of what happens when ethics-in-science decisions are not based upon honest and open dialogue among scientists, prospective participants, and families.

Third, failure to draw upon participant perspectives can also lead to the rejection of potentially worthwhile scientific procedures that participants and their families would perceive as benign and/or worthwhile. For example, in the every day practice of science, investigators often find that guidelines designed to protect vulnerable children from experimental psychopharmacological treatments inadvertently create institutional obstacles that limit participants' autonomy and access to research protocols that may advance scientific understanding and treatment of their disorders (Jensen, Hoagwood, and Fisher, 1996). Fourth, consistent with the community consultation model advanced by ethicists and investigators concerned with ethical practices and policies for clinical research on HIV/AIDS and other life threatening and potentially socially stigmatizing disorders, engaging prospective participants' partners in the design and implementation of research: (a) assures adequate consideration of the ethical values of beneficence, respect, and justice; and (b) increases the probability of community support and cooperation (Levine, Neveloff Dubler, and Levine, 1991; Melton, Levine, Koocher, Rosenthal, and Thompson, 1988).

Relational Ethics and Co-Learning

For the past two decades, ethical decisions regarding research with human subjects have been guided by the three fundamental principles set forth by the *Belmont Report* (DHEW, 1978): *respect for persons, beneficence, and justice.* Although few dispute the importance of these principles, there is no consensus on how to prioritize one's obligations when specific ethical problems place the principles in conflict. From a relational standpoint, achieving such consensus might actually decrease the adequacy of moral procedures. Consensus among IRBs, bioethicists, and investigators risks promoting universal application of a presumed hierarchy of values across contexts differing in their moral requirements that would reflect the values of the scientific and scholarly communities without consideration of participant values. Co-learning approaches can help situate decisions surrounding conflicting ethical principles within specific research contexts and the perspectives of the specific

population considered for investigation.

A major assumption of relational ethics is that co-learning enhances the moral development of scientists and participants through a better understanding of the reciprocal relationship between the participant's expectations and the researcher's obligations. Relational ethics views scientist and participant alike as moral agents joined in partnership to construct research goals and procedures that produce knowledge carrying social value and scientific validity. In viewing autonomy as a social construction, it proposes that respect for personhood must be rooted in scientist-participant dialogues aimed at discovering shared and unshared values in a process of mutual influencing through which fair and caring ethical procedures are derived.

Teaching and Learning

A relational ethic seeks to develop methods of ethics-in-science decision making sensitive to both the justice-based dimension of equality and inequality and the care-based dimension of attachment and detachment (Clement, 1996). It assumes both scientist and participant come to the research enterprise as experts: The researcher brings expertise about the scientific method and extant empirical knowledge base and the prospective participant brings expertise about the fears, hopes, and wishes the community brings towards the prospect of research.

A cornerstone of relational ethics is that the roles of teacher and student are assumed by both investigator and participant throughout the process of exchanging views. For example, to begin a dialogue by asking prospective participants open-ended questions concerning research ethics is sometimes problematic since it asks individuals to provide spontaneous and decontextualized responses to moral questions which require informed deliberation on issues of scientific concern that most participants have not previously considered. Investigators can use co-learning procedures to share with prospective participants their views on how and why it is important to apply the scientific method to examine questions of societal import and to debates underlying areas of current ethical concern. In turn, the prospective participants, their families, or community representatives can apply their moral perspectives to critique the scientific and social value of a proposed study and share with investigators the value orientations guiding their reactions to the planned procedures.

Through the uncovering of common and unshared dimensions of ethical attitudes toward the integrity of scientific research, co-learning joins scientist, prospective participants, and community members in partnership to discover previously unidentified areas of moral concern and to construct a scientific enterprise based upon mutual respect, accommodation, and trust. Researchers employing co-learning welcome differing points of views as checks against the risk of confusing scientific self-interest with social beneficence. They forge ongoing partnerships with prospective participants, gaining community input at the design, implementation, interpretation, and dissemination stages of research (Higgins-D'Alessandro, Fisher, and Hamilton, 1998).

Debriefing as Part of the Ongoing Process of Co-Learning

A foundational assumption of relational ethics is that co-learning is an ongoing process involving scientist and community members in moral discourse throughout each step of human subjects research including: the research design, informed consent, project implementation, data interpretation, and knowledge dissemination phases. It therefore requires greater attention to debriefing procedures, an ethics-in-science practice that has received scant attention outside of ethical discourse on deceptive research practices. Debriefing has been viewed traditionally as a unidirectional activity that allows the scientist to correct any misconception or supply information, purposely withheld, in a sensitive and educational manner so that the participant can understand and accept the reasons offered, and be satisfied with the experience (Keith-Spiegel and Koocher, 1985). As a consequence, in practice, especially in non-treatment research, debriefing is typically conducted in a cursory fashion, void of an exchange of views, sometimes consisting simply of a promise (often unfulfilled) to send participants a summary of the findings when the research is completed.

From a relational standpoint, debriefing is a critical phase during which the congruence between the participant's expectations and the scientist's obligations, presumably obtained during informed consent, can truly be assessed (Scott-Jones and Rosnow, in press). Debriefing thus needs to be constructed as a bi-directional activity in which investigator and participant openly share their views on: (a) the nature of and reaction to the research experience; (b) the adequacy of information provided during informed consent; and (c) the scientific validity and social value of the data collected. From this exchange, participants become more educated critics and consumers of scientific knowledge and investigators become more educated about participant perspectives that can improve future ethical procedures, research design, and interpretation and communication of research results.

Confidentiality in Research with Vulnerable Populations: A Case Example of Co-Learning

The principle of *respect* has generated numerous ethical guidelines for protecting participant privacy through the maintenance of confidentiality. Intricate procedures have been developed for keeping data sheets free of identifying information and for keeping records secure. Maintaining confidentiality presents few ethical challenges when science is characterized by laboratory studies devoid of information about individual differences or when individuals with

previously identified disorders are the focus of study. The ethical obligations are more complex when scientists study the probability of impairment in populations judged to be at risk for disorders or health-compromising behaviors. Such studies have the potential to tap previously unidentified sources of psychopathology, developmental delay, cognitive deficits, abuse, addictions, criminal activities, and other socially stigmatizing characteristics and behaviors (Fisher, 1993, 1994; Fisher and Rosendahl, 1990).

Does an investigator have a moral duty to help a research participant if a previously unidentified problem is revealed during the course of research? Does this moral obligation override the duty to protect participant confidentiality? The scientific community has traditionally been reluctant to act upon information about individuals uncovered during the course of nonintervention research out of a healthy skepticism that inferences drawn from tests designed to evaluate differences between groups of individuals may not have diagnostic validity when applied to a particular research participant (Fisher and Brennan, 1992). A second source of reluctance is scientists' awareness that sharing information with someone who can help the research participant can sometimes create stressful or harmful consequences for the participant, especially if such individuals react to information with punitive measures (Fisher, 1993).

A third element of caution against acting when research-derived information indicates that participants are in jeopardy is rooted in the scientist-citizen dilemma (Veatch, 1987). Acting to help a research participant may threaten the internal validity of an experiment (especially in longitudinal designs) or jeopardize the trust and participation of others involved in the research (Fisher and Brennan, 1992; Fisher, Higgins, et al., 1996; Fisher, Hoagwood, and Jensen, 1996). Applying the rule-utilitarian framework, when a conflict emerges between participant welfare and scientific rigor, investigators have often valued the production of well-controlled data that can benefit society over their duty to facilitate or procure services for individual participants.

Adolescent Perspectives on Risk and Confidentiality

The study of risk in adolescent populations highlights ethical issues surrounding confidentiality, both because of the potential dangers the risks pose to each particular teenager's well being and because of this age group's ambiguous status with respect to decisional capacities (Holder, 1981; Koocher and Keith-Spiegel, 1990; Melton, Koocher, and Saks, 1993). Research on risk-related characteristics or behavior can reveal a particular adolescent participant may have: suicidal ideation, is engaging in health compromising behaviors, is involved in illegal and/or harmful behaviors, or is living in abusive circumstances. An implicit assumption underlying the failure to assist adolescents who indicate potential problems during the course of risk research is that teenagers value autonomy and would feel betrayed by an experimenter disclosing confidential information to protect them. Blind faith in this assumption has prevented scientists from asking two critical questions: *What moral role does an adolescent research participant expect of an investigator and what are the consequences of failing to fulfill this role?*

Applying a co-learning procedure, my colleagues and I (Fisher, Higgins, et al., 1996) asked these questions of high school students living in a low-income urban environment. Students (who self-identified as predominantly Hispanic) were provided with a brief overview of the scientific method and scientists' concerns regarding confidentiality. They were then asked to give opinions concerning different ethical strategies an investigator could follow if during the course of research an adolescent participant indicated she or he was in danger or engaged in high-risk behaviors. The investigator could: (1) keep the information confidential and take no action; (2) talk to the teenager and assist her or him in finding a referral source; or (3) tell a parent or another concerned adult. To avoid imposing our own evaluations of risk severity, we asked the adolescents to rate their perceptions of how problematic they considered the following: use of alcohol, illegal drugs, and cigarettes; physical and sexual abuse; suicidal ideation; sexually transmitted diseases; truancy; vandalism; theft; violence; and shyness.

Influencing the Lives We Examine

> *"Those of us who study lives are aware that we influence the lives we examine—perhaps very little, perhaps a great deal" (Josselson, 1996, p. 80).*

Perhaps, not surprisingly, adolescents of all ages viewed self-referrals most favorably. However, probably the most important finding of this co-learning approach was that teenagers often viewed the maintenance of confidentiality negatively, especially in situations in which an investigator learns that a research participant is a victim of, or engaged in, behaviors adolescents themselves perceive as problematic. Students' responses thus indicated that *they saw the investigator as having a moral role in relationship to their problems.* The advocacy role that teenagers assumed was a scientist's obligation was thus in direct contradiction to the role of impartial observer assumed by the majority of investigators currently conducting adolescent risk research.

A process of co-learning can illuminate the impact of both action and inaction on the life trajectories of those studied. The responses of adolescents alerted us to the disconcerting probability that even when teenagers have been promised confidentiality under traditional informed consent procedures, they nonetheless expect to be helped when they tell an adult interviewer they are a victim of violence or involved in high-risk behaviors. An investigator's failure to help a teenager may have

an iatrogenic effect on how the teenager conceptualizes her or his own behaviors and the fiduciary responsibility of adults. Adolescents may interpret the scientist's lack of action as an indication that their problem is unimportant, appropriate services are unavailable, or that knowledgeable adults can not be depended upon to help children in need (Fisher, 1993, 1994; Fisher, Higgins, et al., 1996). Thus, the preservation of confidentiality in adolescent risk research in particular and research with other vulnerable populations in general, assumed by many scientists to be a moral good, may in some cases actually result in harm.

Avoiding the Fallacy of "Is to Ought"

In working with vulnerable populations, ethics-in-science decisions must reflect a balance between the need for communion between scientist and participant and the obligation of individual moral agency. Relational ethic's emphasis on autonomous mutual accommodation guards against the temptation to use the co-learning process to follow the fallacy of "is to ought" (Sidgwick, 1902). The fiduciary nature of the scientist-participant relationship obliges the investigator to take ultimate responsibility for decisions that impact the rights and welfare of research participants. Accordingly, prospective participant perspectives must inform, but not dictate, the scientist's ethical decisions (Fisher and Fyrberg, 1994). *In developing ethical procedures for human subjects research, scientists must assume the responsibility to apprehend and respect the views of research participants without relinquishing their obligation to apply their own knowledge, training, and values to the pursuit of the moral act.*

For example, although they rated sexually transmitted diseases (STDs) as a serious problem, most teenagers we interviewed did not believe an investigator should report STDs to concerned adults. While providing teenagers with a referral to a health clinic may respect their autonomy, given the life-threatening nature of some of these diseases, an investigator has to evaluate teenagers' preferences against the ability of those in this age group to understand the personal implications of the disease, adolescents' ability to obtain appropriate assistance in this circumstance, and the risk to their health if they do not follow through on the referral and the problem remains unreported.

Constructing ethical procedures based upon mutual accommodation. How does a relational ethic address conflicts between the principles of respect and beneficence? Instead of simply complying with or overriding the adolescents' preferences, a relational-based approach calls for the development of ethical procedures that can accommodate (a) the scientist's fiduciary responsibility to protect participant autonomy and welfare and produce reliable information according to accepted principles of research practice; (b) the adolescents' expectations for confidentiality and concern; and (c) the participants' and guardians' right to know the exact nature of the investigator's confidentiality and reporting policy.

In this specific situation, an understanding of adolescent and guardian expectations, combined with a recognition of the investigator' fiduciary responsibility, leads to the following guidelines for confidentiality and disclosure procedures in adolescent risk research:

- Prior to initiating a study, the investigator should determine the adequacy of school and community services for the risk behaviors and disorders under investigation, the general ability of prospective participants at different stages of adolescence to utilize and benefit from these services with or without parental involvement, and the extent to which different reporting options conducive to the participants' ability to use existing services sustains or impairs the scientific validity of research procedures.
- The investigator then engages a small sample of prospective participants and their guardians in discussion regarding the available reporting options or draws upon previously acquired information on adolescent and guardian perspectives.
- Based upon this information, the investigator selects the reporting and referral procedures that meet the adolescents' and guardians' expectations of the scientist's role responsibilities, serve the teenage participants' autonomy and welfare, and preserve the scientific integrity of the study.
- During the recruitment phase of the study, both guardians and adolescents are informed about the specific confidentiality, referral, or reporting procedures to be implemented. This insures that either can decline to give their permission/assent for participation based on full knowledge of how the investigator will respond to risk information derived during the course of research.
- In addition, in recognizing that many adolescents' assume that scientists have a moral obligation to assist participants who are at developmental risk, irrespective of the confidentiality or reporting procedures selected for the study, a list of neighborhood agencies specializing in the problems under investigation is provided to all those contacted, regardless of whether or not they choose to participate in the study.
- If during the course of the study, an adolescent participant meets conditions for referral or reporting, the course of action outlined during the consent procedures are reviewed with the teenager, and then implemented.

- At the completion of the study, participants are asked to evaluate the adequacy of the ethical procedures and guardians and participants are provided with a general summary of the scientific and ethical aspects of the study. These last steps allow for continued mutual evaluation and potential adjustment of future procedures.

Questioning Value Assumptions and Striving for Common Conceptions of the Good

In the construction of its professional authority, the science establishment has endorsed a set of ethical codes to police itself and allow others to police its members. These standards can be said to largely reflect Eurocentric, rational-deductive, libertarian conceptions of the good (Prilleltensky, 1997) which, preserved in federal regulations and professional codes, become moral premises not amenable to challenge. The establishment's definition of the good is embodied in assumptions guiding scientific conduct (Beauchamp, et al., 1992; Freedman, 1975; Rosenwald, 1996; Veatch, 1987), among them:

- knowledge gathering is a fundamental and unconditional good;
- knowledge generated by the scientific method is and should be value free;
- scientists are entitled to use humans as material for their pursuits;
- respect, beneficence, and justice are guiding moral principles for ethical decision making in human subjects research;
- cost-benefit analysis is an acceptable basis for deciding how to prioritize these moral principles and for guiding ethical decision making;
- informed consent is the primary means of ensuring participants are not victims of an imbalance in favor of greater risks than benefits;
- the right to make autonomous decisions regarding research participation is dependent upon the ability to weigh the risks and benefits of the experimental procedures;
- principles of beneficence and justice can be subordinated to the principle of autonomy reflected in informed consent policies;
- the absence of harm justifies the absence of benefits if it leads to scientifically valid information; and
- science-in-ethics decision making is the province of those with professional authority, be it scientists, bioethicists, IRB members, or policy makers.

Relational ethics poses several interrelated questions about these traditional value premises: Do the values embodied in current professional codes and federal regulations reflect the moral visions of those asked to participate in research? Do scientists and participant groups have different conceptions of the good life and therefore different evaluations of the ethical procedures aimed at producing knowledge to achieve the good? Do standards of competency for consent to research decisions place an unjust burden on those with identified mental impairments? Would some individuals who consent to research participation on the basis of information describing the immediate purpose and nature of a study, decline to consent if they knew the value orientations driving the scientific and ethical procedures? Should scientists be required to communicate their conception of the good and have their values exposed to participant evaluation? These questions take on ethical urgency when applied to research with persons with cognitive deficits, individuals not old enough to have the legal right to consent to research, and members of historically oppressed populations.

Advocates for those who because of age or impairment have traditionally been denied the right to consent to research, have begun to challenge traditional standards for judging the moral agency of those legally defined as incapable of consent. For example, with the advent of de-institutionalization and the principle of normalization into human services (Lindsey and Luckasson, 1991; Wolfensberger, 1972), regulations for Intermediate Care Facilities (Conditions of Participation, 1988) and recent court decisions guaranteeing the right of persons with mental retardation to make their own treatment decisions (*Rennie v. Klein,* 1982; *Rogers v. Okin,* 1982), a diagnosis of mental retardation is no longer accepted as a presumption of incompetence to consent to or refuse treatment (Dinnerstein, 1994). Similarly, state laws have increasingly granted adolescents the right to make decisions concerning treatment for venereal disease, drug abuse, or emotional disorders without guardian permission (Fisher, Hatashika-Wong, and Isman, 1999; Holder, 1981). However, federal guidelines regulating the rights of these individuals in research have been vague in the case of teenagers, and not formally articulated in the case of individuals with cognitive deficits (Fisher, Hoagwood, and Jensen, 1996; Bonnie, 1997). In the absence of clear guidelines, individuals who have not reached the age of legal maturity, or who because of disability do not have the legal right to make autonomous decisions, have lost their claims to the moral authority to make decisions about research participation.

Advocates for the rights of historically oppressed groups are increasingly drawing attention to the possibility that established Eurocentric views of science may not be universal. Some

argue that the value placed on the control and manipulation of variables may reflect a materialistic, individualistic, power dynamic inconsistent with the values of spirit, collectivity, and harmony inherent in many ethnic minority cultures (Greenfield, 1994; Marcus and Kitayama, 1991; Parham, 1993; Triandis, 1990). Ethnic minority scholars are also espousing widely held minority community beliefs that their members have been "raped" by white researchers who engage in research without understanding or caring for those they study, who use minority members as bargaining chips for the receipt of large federal grants, and who treat them as the "human equivalent of lab rats" (Mio and Iwamasa, 1993; Parham, 1990; Ponterotto, 1993).

Challenging Scientistic Assumptions

Is All Knowledge Worth Pursuing?

Science has traditionally attached ethical significance to methods but not topics (Rosenwald, 1996). This stance reflects two assumptions inherent in a scientistic philosophy: (a) the pursuit of knowledge is good regardless of its social and ethical implications, and (b) consideration for the practical consequences of research will inhibit scientific progress and academic freedom (Scarr, 1988). From this perspective, statements in the final paragraph of a journal article stating the limited generalizability of one's work to social application provide sufficient ethical safety mechanisms and/or alleviate the investigator of further moral responsibility against society's (mis)use of the products of her or his work (Fisher, et al., 1997; Prilleltensky, 1997).

From a relational perspective, research is embedded in valuational contexts that make it impossible to claim the existence of value-free information (Prilleltensky, 1997). Thus, a counterpoint to the scientistic view is that all research is value-laden and sociopolitical in nature (Kurtines, Azmitia, and Gewirtz, 1992). This is particularly true when individuals with cognitive deficits and minority group members are the focus of study (Sampson, 1993; Zuckerman, 1990). In a society in which persons with cognitive impairments see their rights diminished through protectionist laws and members of historically oppressed communities have their rights degraded through discriminatory laws and practices, scientists must recognize that any research on these and other politically vulnerable communities can directly impact public attitudes and policies directed toward research participants and the populations they represent (Fisher, et al., 1997). That policy makers and nonscientist citizens "are not likely to make the distinction between scientific theory and what seems to be its political implications, or between generalizations based on population statistics and their applications to individual members of a given group" (Zuckerman, 1990, p. 1301), argues for the importance of integrating participant perspectives into ethics-in-science decision making.

Group stigmatization. One community concern receiving little attention in ethics-in-science discourse is whether group stigmatization should be considered in determining risks to participants. Failure to give ethical attention to group depreciation as a research risk is rooted in the scientific ethos which considers research morally permissible if the risks of the procedures are "reasonable" in relation to the benefits hoped for (Beauchamp, et al., 1982). The "reasonableness" of risk has typically been determined by members of the majority establishment who, by definition of their intellectual, age, or racial caste status, may overestimate the value of research and underestimate the risks of community stigmatization. According to Cassell (1982), if harm/benefit cannot be accurately predicted it should not be applied. This may be especially true for the ethical evaluation of research on minority persons or those with diminished legal rights, when they or their families do not have a voice in evaluating the "reasonableness" of collective risks and benefits.

Many researchers have yet to recognize that racism and other prejudices are not just abstract theoretical ideas, but rather real conditions of discrimination and oppression in the lives of ethnic minority individuals and those labeled as having cognitive deficiencies (Sue, 1993). Accordingly, failure to consider group stigmatization as a potential cost of research participation may be asking politically disadvantaged members of society to unjustly bear research risks. A relational ethic calls for researchers adhering to Eurocentric, scientistic philosophies to question their individualistic and rational-deductive values and consider the diverse world views held by members of ethnic minority and cognitively vulnerable communities.

In moving from a "discourse of power of the majority" to a new form of dialectics between investigators and communities (Ponterotto and Casas, 1990; Ivey, 1987), the science establishment must be prepared to ask questions that may challenge foundational premises of scientism: Should government and IRBs provide assurance of protection from group stigmatization and personal harm to physically, cognitively and politically vulnerable participants? Should the risk of group stigmatization be communicated to participants and their families during informed consent procedures? Is collective stigmatization a moral prohibition?

Re-evaluating the Ethical Significance of Research Benefits

Secular scientific thinking holds an instrumental view of reality. It values self-directed rational planning, self-determination, and autonomy. The notion of the good is constantly filtered through these values. In ethics-in-science decision making, the scholarly community grants moral priority to the ability to weigh the costs and benefits of an experiment, but does not challenge whether a society based upon such calculations is worthwhile. A relational ethic emphasizes the

importance of considering the authenticity of the cost-benefit analysis to the moral lives of prospective research participants. For example, might some adults with mental retardation prefer to avoid unpleasant side effects associated with experimental treatments for behavioral disorders, rather than take the chance that their behavioral problems might or might not be reduced by research participation? Are some individuals from historically oppressed populations unwilling to engage in any research which may risk additional group stigmatization?

Questioning the moral value of the cost-benefit analysis. The acceptance of the balance of risks and benefits as a primary means of ethical justification implies that beneficence, the moral obligation to protect the welfare of research participants, does not take priority over other moral values in ethical decisions for human subjects research. Some have questioned whether efforts to ameliorate potential harm to vulnerable populations is sufficient ethical justification for human experimentation. In human subjects research it is often considered morally sufficient to conduct an experiment if the participants are in no worse condition at the end than they were at the beginning of a study. This emphasis on the principle of nonmaleficence—to do no harm—has lead to the acceptance of an "ethical minimalism" (Rosenwald, 1996) in which research participants are rarely direct beneficiaries of the knowledge they helped produce. Such research is said to be valuable if it is conducted according to accepted scientific standards of reliability and control and assumed to have social value. When conducting research with historically stigmatized populations, investigators need to be sensitive to how evaluations of social benefits are culturally determined and pose the question: Within whose historical tradition is this knowledge valued? (Bermant, 1982).

Justice in its narrower sense is understood to be what is fair and equal, and the just person is the person who takes only her or his proper share. When research offers no direct benefits to a participant or her or his community, how do we determine what is the scientist's proper share? Casas (1990) criticizes current ethical guidelines for human subjects research for their emphasis on avoidance of harm rather than promotion of benefit to the community under investigation. Casas argues that an emphasis on harm avoidance is an insufficient ethical justification for conducting research on vulnerable communities because it shifts the ethical burden away from the investigator's obligation to demonstrate that research will result in any good and towards the participant who must demonstrate that they may be harmed. Casas' comments raise the provocative possibility that the cost/benefit calculus, a traditionally cherished means of evaluating ethical actions, may not be an acceptable method of moral analyses for individuals holding values outside the Eurocentric and scientistic conceptions of the good.

Incentives for research participation. The absence of participant input on the risks and benefits of research inducements can also lead to unfair practices. When applied to studies on impoverished, institutionalized, or otherwise vulnerable populations, the decision to provide inducements creates a tension between compensating individuals fairly for their time and coercing them to assume extraordinary burdens because they need the income (Levine, 1986). Unfortunately, little consensus exists about what defines due and undue incentives for research participation (Macklin, 1981).

Offering incentives should serve the principle of justice, by enabling a balanced sampling of individuals from all segments of society and equitable distribution of both the burdens and benefits of research participation (Fisher, 1993; Levine, 1986). However, varying economic circumstances can lead to varying perceptions of monetary inducements. To insure that consent to participate in research is rational and voluntary, investigators and IRBs have warned against inducements that might coerce individuals with limited economic power to participate in scientific procedures to which they might not otherwise consent. Unfortunately this approach sometimes leads to situations in which legal minors, adults with mental retardation, or persons from lower socioeconomic backgrounds are provided smaller compensation than economically advantaged individuals engaged in similar types of research activities.

When is consideration of the economic, intellectual, developmental, or political status of individuals with respect to research inducements *justice* or *discrimination*? Who should decide? One response to this dilemma is to view research in terms of the justice of exchange and the selection of incentives as a means of establishing equality between goods exchanged. The goods that participants bring to the research arena include: (a) the characteristics essential to answering a research question; (b) the ability to engage in the experimental procedures; and (c) the motivation to participate honestly and to the best of their ability. Scientists bring to the research partnership: (a) the knowledge and training needed to construct experimental problems of scientific and societal import; (b) the ability and responsibility to protect the rights and welfare of participants during the implementation of these procedures; and (c) the willingness to share the benefits of research with participants and/or society.

To determine a just exchange of research goods, investigators can consult with prospective participants and their advocates to determine the market value of the time, skill, and effort required for participation within the context of the nonmonetary goods they may receive from research participation (e.g., individual or community benefits of research-derived knowledge). Inducements based upon this information can be set at levels sufficient to attract the desirable number and diversity of research participants (Levine, 1986). Such an approach reflects the position that economic justice belongs to the domain of obligation rather than charity (Goodin, 1985).

The Sociopolitical Nature of Ethnic Minority Research

> *"Concepts of racial inferiority form what Horace Mann Bond called "a crazy-quilt world of unreality" in a society that proclaimed equality, opportunity, and democracy as goals while it "brutalized, degraded, and dehumanized" African Americans "by every instrument of the culture" (Tyack, 1995, p. 6).*

Racism in American society has a long history marked by social and political constructions of differences governed by the political and social interests of the ruling racial caste (Miles, 1989). Race-based research can and has been used to justify segregation, political subordination, and hostile and demeaning stereotypes (Laosa, 1984; Tyack, 1995). To many members of racial and ethnic minority groups, federally funded research represents another arm of a powerful racial caste system.

Although the recent federal regulation that requires justification for failing to include women and minorities in research is laudable (DHHS, 1994), this policy does not address, and may even perpetuate, the questionable scientific validity and ethicality of classifying humans into different "races" and the practices of power and subordination that such classifications represent in the United States (Tyack, 1995). In contemporary science, terms such as "race" and "ethnicity" are used categorically with little scientific basis outside of historical folk beliefs based upon pre-colonial era thinking about the inherent superiority and inferiority of populations along genetic lines (Chan and Hune, 1995; Essed, 1991; Fisher, et al., 1997; Stanfield, 1991). Use of racial labels to categorize research participants enables investigators to leave monolithic racial stereotypes unquestioned and avoid examining the personal significance of these terms for research participants, scientists, and members of society (Cocking, 1994; Fisher, et al., 1997; Oboler, 1995; Ogbu, 1994; Stanfield, 1993). Socially constructed racial labels can strip participants of their personal identity by studying them only in terms of racial or ethnic categorizations (Heath, 1993). In their rush to label ethnic minority participants, researchers apply categories that may not reflect how individuals see themselves.

Funding for research on ethnic minority populations is often driven by economic and political concerns (e.g., urban crime, welfare dependency) framed within the cultural lens of nonminority political leaders. Research designed to address minority "problems" may be viewed very differently by white researchers and the minority communities they wish to study. Desegregation policies (Tyack, 1995), the *Bell Curve* debate and associated IQ-based tracking movements in American education (Herrnstein and Murray, 1997; Jensen, 1991; Laosa, 1984), the Tuskegee syphilis study and government radiation experiments which misinformed research participants about information directly relevant to their health (Jones, 1993; ACHR, 1996), the NIH-initiated studies on the biological bases of violence (Leavy, 1992), and the California Adolescent Family Life Program's study of sexual abuse in African-American and Latin-American adolescent mothers (Fisher, et al., 1997) are examples of sociopolitically driven experimentation on racial/ethnic minorities that have undermined trust in scientists as guardians of ethical treatment when prospective participants are minorities (Fisher, et al., 1997).

Who Speaks for Ethnic Minority Communities?

Some minority scholars have expressed the view that white researchers do not understand the sociopolitical nature of research involving questions of oppression, discrimination, prejudice, racism, and dominate-subordinate relations (Sue, 1993). They argue researchers seeking to study minority communities, including investigators who are themselves members of the ethnic group(s) to be studied, should routinely seek advice of community leaders (J.F. Jackson, M.H. Bennett, J. Dent, H. Fairchild, R. Jones, and P. Rhymer-Todman, personal communication, January 21, 1993). In response to these concerns, social scientists investigating high-risk behaviors in ethnic minority youth have formed community advisory task forces comprised of ethnic minority scholars, practitioners, and community members charged with assisting in the development of culture-fair research procedures and adequate informed consent and debriefing procedures (Fisher, Hoagwood, and Jensen, 1996).

Relational ethics requires investigators to guard against another form of paternalism: The unwarranted assumption that opinions of minority scholars and community leaders reflect or override those of the less educated and more vulnerable community members who may be the target of investigation. In response to concerns regarding the controversial NIH Violence Initiative (Wheeler, 1992), a panel of African-American leaders was appointed to review the scientific adequacy and potential for group stigmatization and harm that would result from government-sponsored research on pharmacological approaches to stemming the tide of urban violence. However, absent from the dialogue was the voice of African-American women and men living in impoverished ghetto communities, whose sons, based on current statistics, have a devastatingly high probability of entering the juvenile justice system before they reach adulthood (Wordes, Bynum, and Corley, 1994).

Federal guidelines that encourage the inclusion of guardians of prospective participants might have situated the ethical issues raised by the government initiative within the real-world concerns and needs of those who would be most directly impacted. For example, how would these individuals have weighed the risk of group stigmatization against the chance that experimental treatment might help them protect their sons from the sobering picture of adolescent risk characterizing their communities? How might an understanding about their

fears, hopes, and dreams for their children have influenced the research plans and goals supported by the initiative? How might an honest dialogue between scientists and the parents of prospective participants have shaped the recruitment procedures, experimental design, and dissemination plans in ways that might impact positively on the reactions of those later recruited for participation in the studies?

From a relational perspective, investigators conducting multicultural research need to insure scientific and ethical procedures are derived from dialogue among scientists, community leaders, and representatives of the ethnic minority individuals who will directly participate in the research. Moreover, investigators need to insure discussions are bidirectional, and that ethics-in-science decision making derived from such discourse is based upon respect and mutual accommodation, rather than compromise and coercion.

White Racial Identity and the Cultural Lens of Ethnic Minority Research

From a relational perspective, a scientist's identity is in part defined by the participants studied. When members of ethnic minority groups are the focus of scientific inquiry, investigators should approach all research projects with the assumption that racial/ethnic bias is inherently present (Atkinson, 1993). A relatively ignored basis of unintentional racism is failure of white investigators to consider the impact of their own racial identity on what research problems they choose to examine and the research methodologies they select (Ponterotto, 1993). According to Helms (1993), an inherent and sometimes unconscious facet of white racial identity is that white members of society are born the benefactors and beneficiaries of racism. Their attempt to deny, repress, or distort this fact can lead to research supporting racist ideologies. From this perspective, racism in research can only truly be overcome after white researchers attempt to become aware of their role and status in a racist society and work to develop non-racist definitions of whiteness. In relational ethics, this goal can only be achieved through honest, caring, and ongoing engagement of minority members in dialogue on value assumptions driving race-relevant research.

Research implications of Helms' stages of white racial identity. Helms' model of white racial identity includes six stages of increasingly complex racial conceptualizations. In the first stage, "contact," a white researcher is considered naïve to the sociopolitical implications of race in this country and erroneously assumes that data from research on predominantly white samples pertain to people of all races. Researchers operating at this level may focus their investigations on social characteristics such as income, education, and employment status rather than factors associated with minority status (e.g., discrimination) on the unsupported assumption that racial group differences disappear when ethnic groups are of similar demographic backgrounds (Fisher, et al., 1997; Slonim-Nevo, 1992).

In Helms' second stage, "disintegration," an investigator becomes aware of race-related moral dilemmas and becomes ambivalent about the inclusion of racial/ethnic minorities in research. This may lead to unrealistic expectations for standards in research excellence applied only to minority group investigations, resulting in a paucity of studies directly relevant to the concerns of ethnic-minority communities. For example, members of grant review panels operating at this level may give lower priority scores to research on newly immigrated, lower-income, Spanish-speaking populations if the proposed study does not include comparison groups defined by various combinations of individuals of different immigration histories, income levels, and language orientations. Such decisions can undermine research on ethnic minorities when there is a lack of sufficient numbers of individuals representing each of these groupings, when individuals who meet certain group criteria are non-representative of Spanish-speaking residents of the United States, or when the rationale for inclusion is based upon empirically unsupported assumptions that these factors comprise independent influences on behavior.

In attempts to deal with the personal disorientation emerging in the second stage, Helms describes a third level of white racial identity development, "reintegration." In this stage, white researchers may seek re-equilibration by idealizing white culture as a standard for behavioral norms. This can lead to the assumption that ethnic minority research is only valuable when whites are used as a control group, leading to comparative methodologies, which in turn result in deficit-oriented approaches to understanding ethnic-minority behaviors and mental health issues (e.g., Banks, 1993; Graham, 1992; McAdoo, 1993).

At Helms' next level, "pseudo-independence," white researchers substitute the ethnocentrism of the earlier stages for a liberalism that seeks to explain away racial-group differences in terms of cultural disadvantage, rather than looking equally at both minority and white behaviors. This can lead to research supporting the paternalistic view that ethnic minorities lack the ability or fortitude to play a role in alleviating adverse conditions impacting their lives (Parham and McDavis, 1987). Research influenced by this level of white racial identity development may also include assessments of acculturation (adaptation to white social values) as an indicator of psychological adjustment, when in fact some newly immigrated participants may experience the transfer of culture as a source of intrapsychic and intrafamilial stress (e.g., Cooper, 1994; Gil, Vegas, and Dimas, 1994; Szapocznik and Kurtines, 1993), and traditional values or a bicultural orientation may in fact serve as buffers against psychological distress (Berry, 1980; Bettes, et al., 1990; LaFromboise, 1988). In the absence of information about what elements of majority culture are

harmonious with the basic values and characteristics of specific ethnic communities, white researchers operating at this level of racial identity development risk legitimizing social prejudices into presumably value free "adaptive" and "maladaptive" categories of racial behavior (Fisher, et al., 1997; Takanishi, 1994; Tharp, 1994).

According to Helms, those scientists attaining the fifth level of white racial identity, "immersion-emersion," attempt to re-educate themselves and others by incorporating an understanding of white culture and racist sociopolitical history in studies on both minority and white behaviors. This can include scientific attention to the impact of racial discrimination in employment, housing, educational, and legal institutions as factors influencing family socialization patterns and physical and psychological well-being (Boykin and Toms, 1985; Fisher, et al., 1997, Gaines and Reed, 1995; Johnston, O'Malley, and Backman, 1993; Sue, 1991). Such endeavors will fail to provide adequate explanation of factors influencing ethnic-minority well-being if they do not incorporate the perceptions and understanding that minorities have of their own social realities, including perspectives of their immigration and life in the United States.

In Helms' final stage, "autonomy," white scientists, willing to abandon the benefits racism has provided them, recognize the implicit cultural assumptions in their work and the need not to impose these assumptions on other racial groups. From a relational perspective, researchers can not develop a mature white racial identity without giving ethnic minority members a voice in the scientific enterprise designed to determine their identity and subjectivity (Fisher, et al., 1997; Sampson, 1993). Incorporation of ethnic minority perspectives in white researchers' exploration of their own racial biases may challenge the extent to which their world view and conception of the good is sufficient or even appropriate for studying racially diverse populations.

Relational Ethics and Informed Consent

Treating Adults with Cognitive Impairments as Members of the Moral Community

The scholarly and legal establishments have traditionally defined partners in the moral community as "rational" persons with whom one can have a shared understanding about what constitutes a moral action in a given situation. The "rational person" orientation has elevated certain levels of abstract thinking to standards by which moral agency is judged. In the scientific community, adaptation of the utilitarian philosophy has led to ascribing what might be considered exultant status to the ability to weigh the costs and benefits of research. For adults with cognitive impairments who may not make decisions based upon rational calculation, valuation of cost-benefit analysis as a standard of moral agency can deprive them of liberty of action and consensus making—considered to be the rights of personhood.

The ability to rationally manipulate the costs and benefits of research and arrive at a "reasonable" outcome of choice is the most cognitively complex of several psycho-legal standards of consent capacity (Appelbaum and Roth, 1982). The ability to respond to requests to participate in research can be also be evaluated at levels requiring less abstract reasoning skills including: (1) expressing a choice concerning participation; (2) demonstrating a factual understanding of the risks, benefits, and alternatives associated with a research project; or (3) indicating the ability to appreciate the implications of the above factors to one's own circumstance and the voluntary nature of participation (Appelbaum and Roth, 1982). Holding persons to a standard which requires the calculation of costs and benefits poses legal and ethical problems because it is difficult to demonstrate that a person's preference is directly related to the rational she or he may give, and rejection of an individual's rational can justify widespread substitute decision making for those with cognitive impairments (Roth, Meisel, and Lidz, 1977).

All persons with mental disabilities are unique individuals. Those in the mild and moderate classifications of mental retardation and those with non-acute psychiatric disorders can often speak intelligibly, comprehend the speech of others, and reason, and many have more in common with those with typical mental abilities than with those classified with severe or profound mental retardation or acute psychosis. However, many have characteristics, educational backgrounds, and social experiences that can negatively impact their ability to make decisions affecting their lives. These can include deficits in basic knowledge, difficulty with abstract reasoning and in foreseeing the long-term consequences of a present act, denial of disability, reduced ability to make and/or communicate a reasoned choice, limited experience in making independent choices, or difficulty in delaying gratification (Ellis, 1992, Evans, 1981; Hayden, et al., 1992; Hill and Lakin, 1986; Wikler, 1996; Zetlin and Turner, 1984). The ethical challenge for scientists is to balance the obligation to respect the right of those with cognitive deficits to be treated as members of the moral community, with the need to ensure that ill-informed or incompetent decisions will not place their welfare in jeopardy (Ellis, 1992; Grisso, 1986; Lidz, et al., 1984).

Are standards of consent capacity fairly applied? Since the decisionmaking styles of those with*out* identified mental disability are rarely evaluated, some have warned that adults with intellectual impairments may be unfairly held to a higher standard of competency than commonly applied to the general population (Lidz, Meisel, et al., 1984; Morris, et al., 1993). Defining consent competency simply, in terms of higher-level abstract reasoning skills, does not do justice to the complexity of human judgment as situated in a person's experiences,

emotions, needs, and patterns of practical life (Merleau-Ponty, 1945; Widdershoven and Smits). Scientists recognize the role of affective and practical factors in the decision making of those with*out* mental impairments, and respect their "non-rational" preferences to decline research participation.

Consider, for example, persons with diagnosed disorders not considered mentally incapacitating who are invited to participate in a study to determine the efficacy of a psychopharmacological agent that may potentially reduce symptoms of their disorder. They have the right to refuse to participate if they do not want to subject themselves to the experimental medication's side effects (e.g., nausea, dry mouth, headaches), despite the fact that in objective terms such side effects pose "minimal" risk with the potential benefits of symptom reduction outweighing the temporary physical discomfort. This is not the case with individuals with mental deficits who, by being presumed incompetent, must demonstrate a capacity to make rational decisions, especially when their wishes are inconsistent with conventional wisdom (Drane, 1985; Grisso, 1986; Lidz, et al., 1984; Roth, et al., 1977).

The moral claims of adults with cognitive deficits. What moral claims do adults with mental retardation have on science? From a relational perspective, their claims are no different from those with typical intelligence. They have the right to assume that scientists are obligated to communicate with them honestly, to develop procedures that do them no harm, to act to protect their right to autonomy and privacy, and to treat them fairly. The special cognitive status of adults with mental deficits does mean that procedures to insure that these claims are met require special efforts. Such special efforts may include the use of proxy consent if: (a) standards of consent capacity are applied equally to those with and without mental retardation; (b) guardian consent is used to protect the personal rights and welfare of the prospective participant rather than the interests of science; and (c) the adult with mental impairment sees proxy oversight as a legitimate and/or desirable means of protecting her or his interests.

Relational ethics recognizes that in some research contexts denying cognitively impaired individuals, especially those in institutional settings, the protection of guardian consent may result in unfair outcomes. Their limited abstract reasoning skills, restricted knowledge base, and lack of experience and opportunity to make autonomous decisions, may in some contexts make the cognitively impaired particularly vulnerable to coercion and exploitation. Despite these vulnerabilities, it is difficult to justify current ethical procedures that do not require a person's assent along with guardian permission or that allow proxy consent to override an individual's objections to research participation.

For example, the principle of justice calls for a re-evaluation of scientists willingness to rely on proxy consent for research with only a minor increase over minimal risk that holds out no potential benefit to a cognitively impaired individual, but which might provide general information about her or his condition (Bonnie, 1997). Individuals without mental disorders have the right to consent or dissent to requests to participate in research that may generate information pertinent to their future welfare or the welfare of others. It is inherently unfair to require those with mental disabilities to participate in research that may benefit members of their social group, when that same requirement is not made of those with typical intelligence.

For experimentation on mental disability, the science establishment has also condoned proxy consent over participant objections for research holding out direct benefit to the individual, especially when no other treatments are available (Bonnie, 1997). However, accepting this violation of participant autonomy rests on a false distinction between non-therapeutic and therapeutic research. First, all knowledge generated by science, including basic research, can potentially lead to application. Second, by definition, therapeutic research does not guarantee benefits and, in fact, can pose greater risk to the participant because of the side effects of the experimental manipulation or the deprivation of treatment if one is assigned to a non-treatment control group. Consequently, to give investigators and guardians greater power in overriding the objections of vulnerable individuals in treatment research does not have a convincing moral basis and is unjust if the dissent of those without cognitive disabilities is considered inviolate.

Informed consent as a process of justice and care. Relational ethics emphasizes attention to both the person and the context in which research will be conducted. Accordingly, when working with adults with identified cognitive impairment, it is incumbent upon the investigator to justify the standard of consent that will be required for each experimental procedure and the specific role that proxy consent should play in the informed consent process. This justification should be based upon an understanding of the characteristics, life experience, knowledge base, and attitudes toward proxy consent of the individuals who will be recruited for participation. Such understanding should be achieved through ongoing dialogue with prospective participants, their families, and advocates. Engaging prospective participants and their legal guardians in discussion regarding consent decisions can also help determine how proxy consent, when necessary, can reflect both the participant's wishes and her or his best interests?

From a relational perspective, the responsibility to meet a selected standard of consent should not rest solely on the intellectual capacity or prior experience of a person with a cognitive impairment. Rather, investigators should seek to reduce the participant's vulnerability to research risks by providing information essential for a knowledgeable decision to be made in a format that is conducive to the prospective participant's learning abilities. Many people with longstanding

cognitive impairments are used to other people making decisions and may not understand or have experience applying the concept of autonomy. For these individuals, the concept of voluntary choice may be an important element of the informed-consent dialogue. In addition, investigators should be required to develop consent procedures sensitive to the ways in which those with cognitive impairments may express their desire not to participate in a study (e.g., physical or verbal signs of anxiety or fatigue, body movements indicating a desire to leave the situation, verbal expressions of distress).

Relational ethics and advance directives for research. As advance directives for health care have become increasingly accepted in society, some have suggested that similar directives by those with advancing cognitive impairment can enhance substitute decision making for research participation once an individual's mental capacity has been compromised. Several scholars have provided excellent overviews of the ethical issues associated with using advance directives for research (Moorhouse and Weisstub, 1996; Sachs, 1994). Among the problems inherent in issuing and following advance directives is that neither the individual, in the early stages of increasing mental disability, nor those who will serve as her or his legal guardians can know with certainty how the prospective participant will think and feel in a deficient state (Moorhouse and Weisstub, 1996). In the face of such uncertainty, protectionist policies precluding research with the cognitively disabled and paternalistic approaches taking consent authority away from the participant, are equally undesirable. Rather, from a relational perspective, despite limitations in foreseeing future reactions, the prospective participant is still the most expert in envisioning how she or he would respond to experimental procedures in an eventual state of cognitive impairment.

Persons with advancing cognitive impairments can not make decisions regarding future research participation in isolation. The process of obtaining ethically acceptable advance directives requires a series of ongoing co-learning experiences among scientists, the prospective participant, and substitute decision maker. This process, like that of obtaining informed consent, must insure that participant decisions are free of coercion and exploitation. This means that statements precluding participation in research are presented as equally acceptable directives.

During the co-learning process:

- Investigators provide the prospective participant with information about the nature and rationale for different types of experimentation, the associated risks and benefits typically associated with various types of studies, as well as what is known about her or his future state of cognitive impairment. Information about experimentation must be specific enough to allow an individual to assent or dissent to different types of research (e.g., descriptive or intervention research, greater than minimal risk, physically invasive versus behavioral).
- Prospective participants provide the investigator and future substitute decision makers with information that helps them understand: (a) the participant's value system; (b) the way she or he evaluates pain, discomfort, and embarrassment; (c) her or his views on altruism; and (d) other aspects of the person's character and perspective that will allow legal guardians to approach consent decisions from the participant's perspective.
- Future guardians must also be encouraged to share with prospective participants their moral philosophies on consent-relevant dimensions so that both can decide whether or not the advance directives can be carried out in a manner that honors both the participant's and the substitute decision maker's value orientations.

As in research with persons already identified as cognitively impaired, there is no ethical justification for overriding an advance directive that indicates dissent to participate in research. However, from a justice-care perspective, advance directives which do not rule out participation in specific types of studies do not replace the moral decisionmaking responsibility of the legal guardian. The fiduciary nature of legal guardianship obliges substitute decision makers to take ultimate responsibility for deciding the extent to which research participation protects the rights and welfare of those who have placed their trust in them. Thus, a substitute decision maker's dissent should override advance directives that appear to grant consent to research participation. The advance directive process should provide a sufficient understanding of the participant's character and values to assist the guardian in making consent decisions that most closely represent the prospective participant's past wishes and protect the participant's current best interests.

Consent Policies and Participation Rates for Research with Minors

Informed consent has been seen by many as the primary mechanism for respecting the rights and protecting the welfare of research participants. Children and most adolescents do not, however, have the legal capacity to consent, may lack the cognitive capacity to comprehend the nature of experimental procedures, or perceive they lack power to refuse participation (Fisher and Rosendahl, 1990; Keith-Spiegel, 1983; Koocher and Keith-Spiegel, 1990; Levine, 1986; Melton, et al., 1993; Thompson, 1990). To insure that more vulnerable persons with diminished autonomy have their rights as autonomous agents protected, federal regulations (DHHS, 1991) and professional codes (e.g., American Psychological Association, 1992; Society

for Research in Child Development, 1993) require both guardian permission and assent from the adolescent before a teenager can participate in research.

Statements regarding confidentiality policies for research on adolescent risk. Informed consent procedures need to provide individuals and their guardians with all information that might affect their willingness to participate in research, including the potential risks of participation. In consent practices for adolescent risk research, one risk often overlooked—or intentionally not included because investigators worry that it may be a disincentive to participation—is the possibility that the researcher will disclose confidential information because of state laws (e.g., in the case of suspected child abuse), institutional policies (e.g., harm to self or others), or ethical standards set by IRBs or the investigator's own moral compass (e.g., illegal substance use or abuse, sexually transmitted diseases). Applying a co-learning procedure, Colleen O'Sullivan and I examined whether disclosure policies stated in informed consent forms would deter parental and adolescent agreement to participate in research on different adolescent risk behaviors (O'Sullivan and Fisher, 1997). Contrary to assumptions held by many investigators, the attitudes expressed by this sample of predominantly white suburban parents and their teenagers suggested that for some risk contexts confidentiality policies may actually be a deterrent to research participation.

In our examination of prospective participant opinions, a majority of parents indicated they would refuse to grant permission for their teenager to participate in investigations of peer harassment, child maltreatment, suicide, sexually transmitted diseases, and violent behavior if they were informed that investigators would neither discuss the problem with the teenager nor report the problem to a concerned adult (O'Sullivan and Fisher, 1997). Moreover, both parents and high school students indicated they would agree to participate in research on physical and sexual abuse, suicide, and sexual harassment if the investigator had a policy of informing parents if any of these risk factors were a problem for the adolescent. Parents and adolescents also indicated they would consent to participation in studies on other risk factors (e.g., substance use, shyness, truancy, stealing, and vandalism) if they knew that the investigator would discuss the problem with the teenager and assist him or her in getting help.

Information gained from this study underscores the value of obtaining the views of prospective participants and their guardians about different confidentiality and disclosure policies. This information challenges traditional investigator biases which assume that consent forms which include notice that an investigator will refer adolescents found to be in jeopardy for services or report their problem to a concerned adult participants will reduce participation rates. The views expressed by parents and teenagers suggest that alternatives to confidentiality policies may actually increase participation in some types of studies and points to the importance of telling individuals and their guardians about disclosure policies during informed consent procedures.

Questioning the use of passive consent as a means of increasing participation in research with children and adolescents. The cost-benefit calculus has often been applied unjustly to decisions to waive the requirement for parental permission and guardian consent when research involves ethnic minority participants. To insure the rights of those who do not have the legal capacity to consent, federal regulations (DHHS, 1991, 46.408a; OPRR, 1993) require the permission of legal guardians, as well as the assent of the minor, before a child can participate in research. In some situations, however, federal regulations (DHHS, 1991, 46.408[c]) allows parental permission to be waived when data are collected anonymously and questions are assumed to be noninvasive and non-harmful or when such consent may jeopardize the minor's welfare. When guardian consent is waived or when minors are wards of the state, federal regulations (46.408[c] and 46.409 [2.b]) require that an advocate for the minor verify the minor's understanding of assent procedures, support her or his preferences, ensure that participation is voluntary and that the minor can terminate participation, assess reactions to planned procedures, and ensure that debriefing is appropriate (Fisher, 1993; Fisher, Hoagwood, and Jensen, 1996; OPRR, 1993).

Federal guidelines 46.408[c] also allow for waiver of guardian consent in an unfortunately gray area defined in federal regulations 46.116[c.2] and 46.116 [b.3] as "research that cannot be practically carried out without the waiver or alteration." These regulations can lead to an abuse of participant rights in situations where the investigator successfully argues that obtaining parental permission is a legitimate "practical" reason for waiving the consent requirement. Ethnic minority children, especially those living in economically disadvantaged or non-English speaking communities, are particularly vulnerable to scientific exploitation supported by conventional justifications for consent waivers. Investigators often find recruitment in these neighborhoods difficult. In such instances, some have condoned the use of "passive consent" procedures (sending home a letter to parents asking for a response only if the guardian does not wish their child to participate) as an acceptable means of protecting child welfare. Middle class majority populations are not immune from the use of passive consent procedures, especially when school principals or administrators in children's psychiatric centers, out of paternalism or convenience, support or encourage its use.

It has been argued that passive consent is not an ethical alternative to active guardian consent because its use creates an unjust situation in which certain populations are disproportionately deprived of the protections afforded by parental and guardian consent (Fisher, 1993; Fisher, et al., 1997; Nolan, 1992). I would also argue that the science establishment's

acceptance of passive consent as a tool of convenience to enhance participation rates reflects the scientistic assumptions that knowledge gathering is a fundamental and unconditional good and that scientists are entitled to use humans as material for their pursuits. As a consequence, underlying ethical justifications for the use of passive consent is the implicit assumption that a caring and knowledgeable guardian would perceive the research as important and desirable for her or his child. This assumption leads to the damaging inference that parents who do not return consent forms either lack the knowledge to appreciate the importance of the research or are unconcerned about their child's welfare (Fisher, 1993).

No empirical data exist to support these assumptions. Such views fail to consider that parents may decide not to return consent forms because they do not approve of the goals or methods of the research, are generally suspicious of scientific research, or are concerned that the signing of any form may trigger inquiries from immigration, welfare, or other government agencies. In the absence of knowledge derived from scientist-community dialogues on the potential threats of passive consent to participant autonomy and adolescent welfare, unwarranted assumptions regarding community attitudes toward informed consent procedures risk substituting investigator paternalism for parental permission.

Conclusion: Power and Partnership

Relational ethics draws our attention to the interpersonal nature and obligations inherent in the scientist-participant relationship. It expands the traditional universalistic, principle orientation of ethics-in-science decision making to include the importance of intersubjectivity, particularity, and context, and moves scientists toward a reinterpretation of their own moral agency (see Smith, 1985; Walker, 1992). A relational perspective also recognizes power-asymmetry as an inherent feature of human subjects research.

The scientist-participant relationship is not purely contractual because the scientist has directive power that the participant does not have and because the hypothesis may not be known to the participant. Most prerogatives lie with the researcher. A scientist has the prerogative to select who will be recruited for research and the question under investigation. The participant has the prerogative to decline research participation or withdraw once consent has been granted. An investigator can come back and ask a person to participate in an extension of the research or a second study, but the participant does not usually have the prerogative to ask for additional scientific assessments of treatment efficacy or knowledge generation once a study is completed. The command performance for the participant is to apply her or his best efforts to follow the experimental protocol during the study at the direction of the scientist. The command performance of the scientist is to protect the scientific and ethical integrity of the study before, during, and after experimentation—however, the investigator's responsibilities are not commanded by the participant, but by the scientific establishment and the investigator's IRB.

When working with individuals identified as vulnerable, the responsible scientist needs to insure power differentials are not a product of the participant's special circumstance. Context-derived power asymmetries can occur when guardian consent is given higher priority than participant assent simply because of an individuals physical, psychological, or social status. Power asymmetries are also magnified when the experimental arrangement itself increases participant dependency. This can occur, for example, when an individual with cognitive disabilities or inexperience in challenging authority freely assents to participation, but is not aware of her or his right to withdraw participation, does not know the actions she or he would take to withdraw, or believes that she or he would do so at great cost. Potentially destructive power asymmetries also emerge when science is used as a tool of subordination to legitimize oppressive policies (Prilleltensky, 1997).

Those who seek greater symmetry in power relationships emphasize that each party must derive something out of the relationship and be able to exercise discretionary control over the resources prized by the other (Goodin, 1985). However, these resources must be used to enhance, not compromise, the ethical and scientific integrity of experimentation. Relational ethics recognizes both scientists and participants can misuse their influence to compromise the autonomy of the other: Scientists can use their status and control of resources to coerce participant compliance in treatment research that the participant may view as harmful, unjust, or unworthy. Participants or their community representatives can exploit the science establishment's dependency upon their cooperation to coerce investigator compliance in research practices that compromise scientific validity. In relational ethics, the development of ethical procedures must derive from mutual accommodation rather than coercion.

Although power relationships between scientist and participant may not be truly symmetrical, they can be complementary. Such complementarity must be based upon trust that each party will work to understand and respect the value orientations of the other. Relational ethics views an action as unethical if it violates the moral values of either the scientist or participant. If co-learning discourse reveals that mutual accommodation can not take place, the investigator must be willing to abandon a particular research plan. The argument is that to truly accept a relational model, one must value the moral claims of both investigators and research participants. Scientific procedures gain moral legitimacy only if they are the product of autonomous solutions which do not require compromises that would coerce, exploit, or deprecate the values

of either party. In a justice-care based approach, ethics-in-science decision making is based upon respect and mutual accommodation between scientist and participant, rather than compromise and coercion.

Relational ethics encourages scientists to engage research participants as partners in creating experimental procedures reflecting both scientific and interpersonal integrity. It does not seek to encourage federal regulations that shackle science or that promote protectionist policies that create research orphans out of vulnerable populations. Rather, a relational perspective should serve as a guide for moral discourse that moves science toward an orientation of the good life lived with others in social conditions that are just (Widdershoven and Smits, 1996). Scientific ethics is a process which draws upon investigators' human responsiveness to those who participate in research and their awareness of their own boundaries, competencies, and obligations. If becoming a moral subject is the critical moral task for all individuals (Smith, 1985), then recognizing that morality is embedded in the investigator-participant connection is the essential moral activity of science.

References

Advisory Committee on Human Radiation [ACHR]. *The human radiation experiments: Final report of the president's advisory committee*. New York, NY: Oxford University Press, 1996.

American Psychological Association. "Ethical principles of psychologists and code of conduct," *American Psychologist* 47 (1992): 1597–1611.

Applebaum, P.S. and Grisso, T. "Assessing patients' capacities to consent to treatment," *New England Journal of Medicine* 319(24) (1998): 1635.

Aronson, E. and Carlsmith, J.M. "Experimentation in social psychology," in G. Lindzey and E. Aronson (eds.). *The Handbook of Social Psychology* Vol. 2, pp. 1–79. Reading, MA: Addison-Wesley, 1968.

Atkinson, D.R. "Who speaks for cross-cultural counseling research?" *The Counseling Psychologist* 21 (1993): 218–24.

Baier, A.C. "The need for more than justice," in M. Hanen and K. Nielsen (eds.). *Canadian Journal of Philosophy* Supplementary, Vol. 13. Canada: University of Calgary Press, 1988.

Banks, J.A. The canon debate, knowledge construction, and multicultural education. *Educational Researcher* 22 (1993): 4–16.

Baumrind, D. "Research using intentional deception: Ethical issues revisited," *American Psychologist* 40 (1985): 165–74.

Beauchamp, T.L., Faden, R.R., Wallace, R.J., and Walters, L. "Introduction," in T.L. Beauchamp, R.R. Faden, R.J. Wallace, and L. Walters (eds.). *Ethical Issues in Social Science Research* (pp. 3–39). Baltimore, MD: Johns Hopkins University Press, 1982.

Benson, P.R. and Roth, L.H. "Trends in the social control of medical and psychiatric research," *Law Mental Health* 4 (1988): 1–47.

Bermant, G. "Justifying social science research in terms of social benefit," in T.L. Beauchamp, R.R. Faden, R.J. Wallace, and L. Walters (eds.). *Ethical Issues in Social Science Research* (pp. 125–144). Baltimore, MD: Johns Hopkins University Press, 1982.

Berry, J.W. "Acculturative stress: The role of ecology, culture and differentiation," *Journal of Cross-Cultural Psychology* 5 (1980): 382–406.

Bettes, B.A., Dusenbury, L., Kerner, J., James-Ortiz, S., et al. "Ethnicity and psychosocial factors in alcohol and tobacco use in adolescence," Special Issue: Minority children. *Child Development* 61(2) (1990): 557–65.

Bonnie, R.J. "Research with cognitive impaired subjects: Unfinished business in the regulation of human research," *Archives of General Psychiatry* 54 (1997): 105–111.

Boykin, A.W. and Toms, F. "Black child socialization: A conceptual framework," in H. McAdoo and J. McAdoo (eds.). *Black Children: Social, Educational, and Parental Environments* (pp. 32–51). Newbury, Park, CA: Sage, 1985.

Brabeck, M.M. "Introduction: Who cares?" in M.M. Brabeck (ed.). *Who Cares? Theory, Research, and Educational Implications of the Ethic of Care* (pp. xi–xviii). New York: Praeger, 1989.

Carroll, M.A., Schneider, H.G., and Wesley, G.R. *Ethics in the Practice of Psychology*. Englewood Cliffs, NJ: Prentice-Hall Inc., 1985.

Casas, J.M. "Ethical imperatives in multicultural counseling." I.J.G. Ponterotto (Chair), *The white American researcher in multicultural counseling: Significance and challenges.* Symposium presented at the 98th Annual Convention of the American Psychological Association, Boston, MA, August 1990.

Casas, J.M. and San Miguel, S. "Beyond questions and discussions, there is a need for action: A response to Mio and Iwamasa," *The Counseling Psychologist* 21(2) (1993): 233–39.

Cassell, J. "Does risk-benefit analysis apply to moral evaluation of social research?" in T.L. Beauchamp, R.R. Faden, R.J. Wallace, and L. Walters (eds.). *Ethical Issues in Social Science Research* (pp. 144–62). Baltimore, MD: Johns Hopkins University Press, 1982.

Chan, K.S. and Hune, S. "Racialization and panethnicity: from Asians in American to Asian Americans," in W.D. Hawley and A.W. Jackson (eds.). *Toward A Common Destiny: Improving Race and Ethnic Relations in America* (pp. 205–36). San Francisco: Jossey-Bass Publishers, 1995.

Clement, G. Care, *Autonomy, and Justice. Boulder*, CO: Westview Press, 1996.

Cocking, R.R. "Ecologically valid frameworks of development: Accounting for continuities and discontinuities across contexts," in P.M. Greenfield and R.R. Cocking (eds.). *Cross-cultural Roots of Minority Child Development* (pp. 393–410). Hillsdale, NJ: Lawrence Erlbaum Assoc., 1994.

Cole, E.B. and Coultrap-McQuin, S. "Toward a feminist conception of moral life," in E.B. Cole and S. Coultrap-McQuin (eds.). *Explorations in Feminist Ethics* (pp. 1–11). Bloomington, IN: Indiana University Press, 1992.

Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded, 45 CFR Subchapter E Part 483. *Federal Register* 53 (107) (1988): 20448–20505.

Cooper, C.R. "Cultural perspectives on continuity and change in adolescents' relationships," in R. Montemayor, G.R. Adams, and T.P. Gullotta (eds.). *Personal Relationships During Adolescence* (pp. 78–100). Thousand Oaks, CA: Sage Publications, 1994.

Daniel, J.H. "Exclusion and emphasis reframed as a matter of ethics," *Ethics and Behavior* 4 (1994): 229–35.

Davis, K. The sociology of parent-youth conflict. *American Sociological Review* 1 (1940): 523–37.

Department of Health and Human Services. Title 45 Public Welfare, Part 46, *Code of Federal Regulations, Protection of Human Subjects* (August 1991).

Department of Health and Human Services. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, *Federal Register* 59 FR 11146 (March 1994).

Dillon, R. "Care and respect," in E.B. Cole and S. Coultrap-McQuin (eds.). *Explorations in Feminist Ethics* (pp. 69–81). Bloomington, IN: Indiana University Press, 1992.

Dinnerstein, R.D. "Revising the consent handbook: From consent to choice," *AAMR News and Notes* 7 (1994): 1,4.

Drane, J.F. "The many faces of competence," *Hastings Center Report* (April 1985): 17–21.

Ellis, J.W. "Decisions by and for peoples with mental retardation: Balancing considerations of autonomy and protection," *Villanova Law Review* 37 (1992): 1779–1809.

Essed, P.J.M. *Understanding Everyday Racism*. Newbury Park, CA: Sage, 1991.

Evans, D.P. *The Lives of Mentally Retarded People* (1983).

Farr, J.L. and Seaver, W.B. "Stress and discomfort in psychological research: Subject perceptions of experimental procedures," *American Psychologist* 30 (1975): 770–73.

Fisher, C.B. "Integrating science and ethics in research with high-risk children and youth," *SRCD Social Policy Report* 7 (1993): 1–27.

Fisher, C.B. "Reporting and referring research participants: Ethical challenges for investigators studying children and youth," *Ethics and Behavior* 4 (1994): 87–95.

Fisher, C.B. and Brennan, M. "Application and ethics in developmental psychology," in D.L. Featherman, R.M. Lerner, and M. Perlmutter (eds.). *Life-span Development and Behavior* (pp. 189–219). Hillsdale, NJ: Lawrence Erlbaum Associates, 1992.

Fisher, C.B. and Fyrberg, D. "Participant partners: College students weigh the costs and benefits of deceptive research," *American Psychologist* 49 (1994): 417–27.

Fisher, C.B., Hatashita-Wong, M., and Isman, L. "Ethical and legal issues in clinical child psychology," in W.K. Silverman and T.H. Ollendick (eds.). *Developmental Issues in the Clinical Treatment of Children and Adolescents* (pp. 470–86). Boston, MA: Allyn and Bacon, 1999.

Fisher, C.B., Higgins, A., Rau, M.B., Kuther, T., and Belanger, S. "Referring and reporting research participants at-risk: Views from urban adolescents," *Child Development* 1996.

Fisher, C.B. Hoagwood, K., and Jensen, P.S. "Casebook on ethical issues in research with children and adolescents with mental disorders," in K. Hoagwood, P.S. Jensen, and C.B. Fisher (eds.). *Ethical Issues in Mental Health Research with Children and Adolescents* (pp. 135–238). Mahwah, NJ: Lawrence Erlbaum Associates, 1996.

Fisher, C.B., Jackson, J.F., and Villarruel, F. "The study of African American and Latin-American children and youth," in R.M. Lerner (ed.), W. Damon (series ed.). *Handbook of Child Psychology: Vol. 1. Theoretical Models of Human Development* (5th ed.) (pp. 1145–1207). New York, NY: Wiley, 1997.

Fisher, C.B. and Lerner, R.M. "Foundations of applied developmental psychology," in C.B. Fisher and R.M. Lerner (eds.). *Applied Developmental Psychology* (pp. 3–20). New York: McGraw-Hill, 1994.

Fisher, C.B. and Murray, J.P. "Applied developmental science comes of age," in C.B. Fisher, J.P. Murray, and I.E. Sigel (eds.). *Applied Developmental Science: Graduate Training for Diverse Disciplines and Educational Settings* (pp. 1–22). Norwood, NJ: Ablex, 1996.

Fisher, C.B. and Rosendahl, S.A. "Psychological risks and remedies of research participation," in C.B. Fisher and W.W. Tryon (eds.). *Ethics in Applied Developmental Psychology: Emerging Issues in an Emerging Field* (pp. 43–60). Norwood, NJ: Ablex Publishing, 1990.

Freedman, B. "A moral theory of informed consent," *Hastings Center Report* 5 (1975): 32–39.

Gaines, S. Jr. and Reed. E. "Prejudice from Allport to DuBois," *American Psychologist* 50 (1995): 96–103.

Gibson, M.A. and Ogbu, J.U. *Minority Status and Schooling: A Comparative Study of Immigrants and Involuntary Minorities*. New York, NY: Garland Press, 1991.

Gil, A.G., Vega, W.A., and Dimas, J.M. "Acculturative stress and personal adjustment among Hispanic adolescent boys," *Journal of Community Psychology* 22 (1994): 43–54.

Gilligan, C. *In A Different Voice.* Cambridge, MA: Harvard University Press, 1982.

Goodin, R.E. *Protecting the Vulnerable*. Chicago, IL: University of Chicago Press, 1985.

Graham, S. "Most of the subjects were white and middle class: Trends in published research on African Americans in selected APA journals, 1970-1989," *American Psychologist* 47 (1992): 629–39.

Greenfield, P.M. "Independence and interdependence as developmental scripts: Implications for theory, research, and practice," in P.M. Greenfield and R.R. Cocking (eds.). *Cross-cultural Roots of Minority Child Development* (pp. 1–37). Hillsdale, NJ: Lawrence Erlbaum Associates, 1994.

Grisso, T. *Evaluating Competencies*. New York, NY: Plenum Press, 1986.

Harding, S. *Whose science? Whose knowledge?* Ithaca, NY: Cornell University Press, 1991.

Hayden, M.F. "Placement practices in specialized foster homes and small group homes for persons with mental retardation," *Mental Retardation* 30 (1992): 53.

Heath, S.B. "Race, ethnicity, and the defiance of categories," in W.D. Hawley and A.W. Jackson (eds.). *Toward A Common Destiny: Improving Race and Ethnic Relations in America* (pp. 39–70). San Francisco, CA: Jossey-Bass Publishers, 1995.

Helms, J.E. "I also said, 'White racial identity influences white researchers,'" *The Counseling Psychologist* 21 (1993): 240–41.

Herrnstein, R.J. and Murray, C. *The Bell Curve: Intelligence and Class Structure in American Life.* New York, NY: Free Press, 1994.

Higbee, K.L. Millard, R.J., Folkman, J.R. "Social psychology research during the 1970's: Predominance of experimentation and college students," *Personality and Social Psychology Bulletin* 8 (1982): 180–83.

Higgins, A. "The just community educational program: The development of moral role-taking as the expression of justice and care," in M.M. Brabeck (ed.). *Who Cares? Theory, Research, and Educational Implications of the Ethic of Care* (pp. 197–215). New York, NY: Praeger, 1989.

Higgins-D'Alessandro, A., Fisher, C.B., and Hamilton, M.G. "Educating the applied developmental psychologist for university-community partnerships: The Fordham model," in R.M. Lerner and L.A.K. Simon (eds.). *Outreach Universities for America's Youth and Families: Building Community Collaborations for the 21st Century.* New York, NY: Garland Publishing, Inc., 1998.

Hillerbrand, E. "Philosophical tensions influencing psychology and social action," *American Psychologist* 42 (1987): 111–18.

Holder, A.R. "Can teenagers participate in research without parental consent?" *IRB: Review of Human Subjects Research* 3 (1991): 5–7.

Ivey, A.E. "The multicultural practice of therapy: Ethics, empathy, and dialectics," *Journal of Social and Clinical Psychology* 5 (1987): 195–204.

Jensen, A.R. "Spearman's g and the problem of educational equality," *Oxford Review of Education* 17(2) (1991): 169–87.

Jensen, P.S., Hoagwood, K., and Fisher, C.B. "Bridging scientific and ethical perspectives: Toward synthesis," in K. Hoagwood, P.S. Jensen, and C.B. Fisher (eds.). *Ethical Issues in Mental Health Research with Children and Adolescents* (pp. 287–98). Mahwah, NJ: Lawrence Erlbaum Associates, 1996.

Johnston, L.D., O'Malley, P.M., and Bachman, J.D. *National Results on Drug Use from Monitoring the Future Study, 1975-1992, Vol. I: Secondary School Students.* Rockville, MD: National Institute on Drug Abuse, 1993.

Jones, J.H. Bad blood: *The Tuskegee Syphilis Experiment* (Rev.ed.). New York, NY: Free Press, 1993.

Josselson, R. "Introduction," in R. Josselson (ed.). *Ethics and Process in the Narrative Study of Lives* (pp. xi–viii). Thousand Oaks, CA: Sage Publications, 1996.

Kant, I. *Foundations of the Metaphysics of Morals*. Indianapolis, IN: Bobbs-Merrill, 1959/1785.

Keith-Spiegel, P.C. "Children and consent to participate in research," in G.P. Melton, G.P. Koocher, and M.J. Saks (eds.). *Children's Competence to Consent* (pp. 179–211). New York, NY: Plenum, 1983.

Kinzie, J.D., Fredrechson, R.H., Rath, B., Fleck, J. and Karls, W. "Posttraumatic stress disorder among survivors of Cambodian concentration camps," *American Journal of Psychiatry* 141 (1984): 645–50.

Kohlberg, L. *Essays on Moral Development*. San Francisco, CA: Harper and Row, 1984.

Kohlberg, L. *Essays on Moral Development: Vol. II. The Psychology of Moral Development*. San Francisco, CA: Harper and Row, 1984.

Keith-Spiegel, P. and Koocher, G.P. *Ethics in Psychology*. New York, NY: Random House, 1985.

Killen, M. "Justice and care: Dichotomies or coexistence?" *Journal for a Just and Caring Education* 2 (1996): 42–58.

Koocher, G.P., and Keith-Spiegel, P.C. *Children, Ethics, and the Law*. Lincoln, NE: University of Nebraska Press, 1990.

Kurtines, W.M., Azmitia, M., and Gewirtz, J.L. *The Role of Values in Psychology and Human Development*. New York, NY: Wiley, 1992.

LaFromboise, T. "American Indian mental health policy," *American Psychologist* 43 (1988): 388–97.

LaFromboise, T.D., and Foster, S.L. "Ethics in multicultural counseling," in P.B. Pedersen, J.G. Draguns, W.J. Lonner, and J.E. Trimble (eds.). *Counseling Across Cultures* (3rd ed.) (pp. 115–36). Honolulu, HI: University of Hawaii Press, 1989.

Landrine, H. and Klonoff, E.A. "The African American acculturation scale: Development, reliability, and validity," *The Journal of Black Psychology* 20 (1994): 104–127.

Laosa, L.M. "Social policies toward children of diverse ethnic, racial, and language groups in the United States," in H.W. Stevenson and A.E. Siegel (eds.). *Child Development Research and Social Policy,* Vol. 1, (pp. 1–109). Chicago, IL: University of Chicago Press, 1984.

Laosa, L.M. "Population generalizability, cultural sensitivity, and ethical dilemmas," in C.B. Fisher and W.W. Tryon (eds.). *Ethics in Applied Developmental Psychology: Emerging Issues in an Emerging Field* (pp. 227–51). Norwood, NJ: Ablex Publishing, 1990.

Leavy, W.E. "Struggle continues over remark by mental health official," *New York Times*, March 8, 1992, p. 34.

Levine, C., Neveloff Dubler, N., and Levine, R.J. "Building a new consensus: Ethical principles and policies for clinical research on HIV/AIDS," *IRB: A Review of Human Subjects Research* 13(1–2) (1991): 1–17.

Hill, B.K. and Lakin, K.C. "Classification of residential facilities for individuals with mental retardation," *Mental Retardation* 24 (1986): 107.

Levine, R.J. *Ethics and Regulation of Clinical Research* (2nd Ed.). Baltimore-Munich: Urban and Schwarzenberg, 1986.

Lidz, C., Meisel, A., Zerubavel, E., Careter, M., Sestak, R., and Roth, L. *Informed Consent: A Study of Decision-making in Psychiatry*. New York, NY: Guilford, 1984.

Lindsey, P. and Luckasson, R. "Consent screening interview for community residential placement: Report on the initial pilot study data," *Mental Retardation* 29 (1991): 119–24.

Manning, R. "Just caring," in E.B. Cole and S. Coultrap-McQuin (eds.). *Explorations in Feminist Ethics* (pp. 45–54). Bloomington, IN: Indiana University Press, 1992.

Markus, H.R. and Kitayama, S. "Culture and the self: Implications for cognition, emotion, and motivation," *Psychological Review* 98(2) (1991): 224–53.

MacIntyre, A. "The virtues, the unity of a human life, and the concept of a tradition," in M.J. Sandel (ed.). *Liberalism and its Critics* (pp. 125–8). New York, NY: New York University Press, 1984.

McAdoo, H.P. " The ethics of research and intervention with ethnic minority parents and their children," in C.B. Fisher and W.W. Tryon (eds.). *Ethics in Applied Developmental Psychology: Emerging Issues in an Emerging Field* (pp. 273–84). Norwood, NJ: Ablex Publishing, 1990.

McAdoo, H.P. *Family Ethnicity: Strength in Diversity*. Newbury Park, CA: Sage Publication, 1993.

McCarthy, E.D. *Knowledge as Culture: The New Sociology of Knowledge*. New York, NY: Routledge, 1996.

Melton, G.P., Koocher, G.P., and Saks, M.J. (eds.). *Children's Competence to Consent*. New York, NY: Plenum.

Melton, G.B., Levine, R.J., Koocher, G.P., Rosenthal, R., and Thompson, W. C. "Community consultation in socially sensitive research: Lessons from clinical trials of treatments for AID," *American Psychologist* 43 (1988): 573–81.

Merleau-Ponty, M. *Phenomenology of Perception*. Paris: Gallimard, 1945.

Mill, J.S. *Utilitarianism*. New York, NY: Bobbs-Merrill, 1957/1861.

Miles, R. *Racism*. London: Routledge, 1989.

Mio, J.S. and Iwamasa, G. "To do, or not to do: That is the question for white cross-cultural researchers," *The Counseling Psychologist* 21 (1993): 197–213.

Moorhouse, A. and Weisstub, D.N. "Advance directives for research: Ethical problems and responses," *International Journal of Law and Psychiatry* 19 (1996): 107–141.

Morris, C.D., Niederbuhl, J.M., and Mahr, J.M. "Determining the capability of individuals with mental retardation to give informed consent," *American Journal on Mental Retardation* 98 (1993): 263–72.

Noddings, N. *Caring: A Feminine Approach to Ethics and Moral Education*. 1984.

Nolan, K. "Assent, consent, and behavioral research with adolescents." *AACAP Child and Adolescent Research Notes,* Summer 1992, 7–10.

Nuremberg Code. *Journal of the American Medical Association* 132 (1946): 1090.

Oboler, S. *Ethnic Labels, Latino Lives: Identity and the Politics of (Re)presentation in the United States*. Minneapolis, MN: University of Minnesota Press, 1995.

Office for Protection from Research Risks, Division of Human Subjects Protections. *Evaluation of Human Subject Protections in Schizophrenia Research Conducted by the University of California, Los Angeles.* Los Angeles, CA: University of California, 1994.

Ogbu, J.U. "From cultural differences to differences in cultural frame of reference," in P.M. Greenfield and R.R. Cocking (eds.). *Cross-cultural Roots of Minority Child Development* (pp. 365–92). Hillsdale, NJ: Lawrence Erlbaum Assoc., 1994.

O'Sullivan, C. and Fisher, C.B. "The effect of confidentiality and reporting procedures on parent-child agreement to participate in adolescent risk research," *Applied Developmental Science* 1 (1997): 185–97.

Parham, T.A. Do the right thing: Racial discussion in counseling psychology. In J. G. Ponterotto (Chair), *The White American Researcher in Multicultural Counseling: Significance and Challenges*. Symposium presented at the 98th Annual Convention of the American Psychological Association, Boston, MA. August 1990.

Parham, T.A. "White researchers conducting multicultural counseling research: Can their efforts be "mo betta"?" *The Counseling Psychologist* 21 (1993): 250–56.

Parham, T.A. and McDavis, R.J. "Black men, an endangered species: who's really pulling the trigger?" *Journal of Counseling and Development* 66 (1987): 24–27.

Pedersen, P. "The multicultural dilemma of white cross-cultural researchers," *The Counseling Psychologist* 21 (1993): 229–32.

Ponterotto, J.G. "White racial identity and the counseling professional," *The Counseling Psychologist* 21 (1993): 213–17.

Ponterotto, J.G. and Casas, J.M. *Handbook of Racial/Ethnic Minority Counseling Research*. Springfield, IL: Charles C. Thomas, 1990.

Prilleltensky, I. "Values, assumptions, and practices: Assessing the moral implications of psychological discourse and action," *American Psychologist* 52 (1997): 517–35.

Rawls, J. *A Theory of Justice.* Cambridge, MA: Harvard University Press, 1971.

Rennie v. Klein, 462 F. Supp. 1131 (1978); modified, 476 F. Supp. 1294 (1979); stay denied, 481 F. Supp. 552 (179); modified and remanded, 653 F.2d 836 (1981); vacated and remanded, 50 YSLW 3998.27 (1982).

Rogers v. Okin, 478 F. Supp. 1342 (1979); affirmed in part, reversend in part, vacated in part, and remanded 643 F.2d 650 (1980); vacated and remanded sub.nom Mills v. Rogers 457 U.W. 291 (1982); Certified questions answered sub. nom.

Rogers v. Commissioner of Mental Health, 390, Mass. 489 (1982).

Ricoeur, P. *The Self As Other*. Paris: Editions du Seuil, 1990.

Rogler, L.H. "The meaning of culturally sensitive research in mental health," *American Journal of Psychiatry* 146 (1989): 296–303.

Rose, H. *Love, Power, and Knowledge*. Bloomington, IN: Indiana University Press, 1994.

Rosenwald, G.C. "Making whole: Method and ethics in mainstream and narrative psychology," in R. Josselson (ed). *Ethics and Process in the Narrative Study of Lives*, Vol. 4 (pp. 245–73). Thousand Oaks, CA: Sage Publications, 1996.

Roth, L.H., Meisel, A., and Lidz, C.W. "Tests of competency to consent to treatment," *American Journal of Psychiatry* 134:3 (1977): 279–83.

Ryu, J.P. and Vann, B.H. "Korean families in America," in M.E. Procidano and C.B. Fisher (eds.). *Contemporary Families: A Handbook for School Professionals* (pp. 117–34). New York, NY: Teachers College Press, 1992.

Sachs, G.A. "Advance consent for dementia research," *Alzheimer Disease and Associated Disorders* 8 (1994): 19–27.

Sampson, E.E. (1993). "Identity politics: Challenges to psychology's understanding," *American Psychologist* 48 (1993): 1219–30.

Sarason, S.B. "If it can be studied or developed, should it?" *American Psychologist* 39 (1984): 477–85.

Scarr, S. "Race and gender as psychological variables: Social and ethical issues," *American Psychologist* 43(1) (1988): 56–59.

Scott-Jones, D. "Ethical issues in reporting and referring in research with low-income minority children," *Ethics and Behavior* 4 (1994): 97–198.

Scott-Jones, D. and Rosnow, R.L. (in press). "Ethics and mental health research," in H. Friedman (ed.). *Encyclopedia of Mental Health*. New York, NY: Academic Press.

Sears, D.O. "College sophomores in the laboratory: Influences of a narrow data base on social psychology's view of human nature," *Journal of Personality and Social Psychology* 54 (1986): 515–40.

Seigfried, C.H. "Pragmatism, feminism, and sensitivity to context," in M.M. Brabeck (ed.). *Who Cares? Theory, Research, and Educational Implications of the Ethic of Care* (pp. 636883). New York, NY: Praeger, 1989.

Sidgwick, H. *The Methods of Ethics*. Indianapolis: Hackett Publishing, 1981/1907.

Slonim-Nevo, V. "First premarital intercourse among Mexican American and Anglo American adolescent women: Interpreting ethnic differences," *Journal of Adolescent Research* 7(3) (1992): 332-351.

Smetana, J.G., Killen, M., and Turiel, E. "Children's reasoning about interpersonal and moral conflicts," *Child Development* 62 (1991): 629–44.

Smith, R.L. "Feminism and the moral subject," in B.H. Andolsen, C.E. Gudorf, and M.D. Pellauer (eds.). *Women's Consciousness, Women's Conscience* (pp. 235–50). Minneapolis, MN: Winston Press, 1985.

Society for Research in Child Development [SRCD]. Ethical standards for research with children. *SRCD Directory of Members* (pp. 337–39). Author. 1996.

Spelman, E. "On treating persons as persons," *Ethics* 88 (1977): 150–61.

Stanfield, J.H. II. "Racism in American and other race-centered societies," *International Journal of Comparative Sociology* 32, (1991): 243–60.

Sue, D.W. *Counseling the Culturally Different: Theory and Practice*. New York, NY: Wiley, 1981.

Sue, D.W. "Confronting ourselves: The white and racial/ethnic-minority researcher," *The Counseling Psychologist* 21 (1993): 244–49.

Sugden, R. "The contractarian enterprise," in D. Gauthier and R. Sugden (eds.). *Rationality, Justice and the Social Contract: Themes from Morals by Agreement* (pp. 1–23). Ann Arbor, MI: The University of Michigan Press, 1993.

Sullivan, D.S. and Deiker, T.E. "Subject-experimenter perceptions of ethical issues in human research," *American Psychologist* 28 (1973): 587–91.

Szapocznik, J. and Kurtines, W.M. "Family, psychology, and cultural diversity: Opportunities for theory, research, and application," *American Psychologist* 48 (1993): 400–407.

Takanishi, R. "Continuities and discontinuities in the cognitive socialization of Asian-originated children: The case of Japanese Americans," in P.M. Greenfield and R.R. Cocking (eds.). *Cross-cultural Roots of Minority Child Development* (pp. 351–62). Hillsdale, NJ: Lawrence Erlbaum Associates, 1994.

Tharp, R.G. "Intergroup differences among Native Americans in socialization and child cognition: An ethnogenetic analysis," in P.M. Greenfield and R.R. Cocking (eds.). *Cross-cultural Roots of Minority Child Development* (pp. 87–105). Hillsdale, NJ: Lawrence Erlbaum Associates, 1994.

Thompson, R.A. "Vulnerability in research: A developmental perspective on research risk," *Child Development* 61 (1990): 1–16.

Toulmin, S. "The tyranny of principles," *Hastings Center Report* 11(6) (1981): 31–39.

Triandis, H.C. "Cross-cultural studies of individualism and collectivism," *Nebraska Symposium on Motivation* 37 (1989): 41–133.

Tyack, D. "Schooling and social diversity: Historical reflections," in W.D. Hawley and A.W. Jackson (eds.). *Toward A Common Destiny: Improving Race and Ethnic Relations in America* (pp. 3–38). San Francisco, CA: Jossey-Bass Publishers, 1995.

Veatch, R.M. *The Patient As Partner*. Bloomington, IN: Indiana University Press, 1987.

Waithe, M.E. "Twenty-three hundred years of women philosophers: Toward a gender undifferentiated moral theory," in M.M. Brabeck (ed.). *Who Cares? Theory, Research, and Educational Implications of the Ethic of Care* (pp. 3–18). New York, NY Praeger, 1989.

Walker, M.W. "Moral understandings: Alternative "Epistemology" for a feminist ethics," in E.B. Cole and S. Coultrap-McQuin (eds.). *Explorations in Feminist Ethics* (pp. 165–75). Bloomington, IN: Indiana University Press, 1992.

Wheeler, D.L. "Ambitious federal plan for violence research runs up against fear of its misuses," *The Chronicle of Higher Education*, November 4, 1992, pp. A7, A9.

Widdershoven, G.A.M. and Smits, M. "Ethics and narrative," in R. Josselson (ed). *Ethics and Process in the Narrative Study of Lives*, Vol. 4 (pp. 274–87). Thousand Oaks, CA: Sage Publications, 1996.

Wickler, D. "Paternalism and the mildly retarded," in R. Sartorius (ed.). *Paternalism* (pp. 83–94). Minneapolis, MN: University of Minnesota Press, 1983.

Williams, B. *Moral luck*. Cambridge, MA: Cambridge University Press, 1981.

Wilson, D.W. and Donnerstein, W. "Legal and ethical aspects of non-reactive social psychological research: An excursion into the public mind," *American Psychologist* 31 (1976): 765–73.

Wolfensberger, W. *The Principle of Normalization*. Toronto: National Institute of Mental Retardation, 1972.

Wordes, M., Bynum, T.S., and Corley, C.J. "Locking up youth: The impact of race on detention decisions," *Journal of Research in Crime and Delinquency* 31(2) (1994): 149–65.

Zetlin, A. and Turner, J.L. "Self-perspectives on being handicapped: Stigma and adjustment," in R. Edergerton (ed.). *Lives in Process: Mildly Retarded Adults in A Large City* (pp. 93–120), publisher?, 1984.

Zuckerman, M. "Some dubious premises in research and theory on racial differences: Scientific, social, and ethical issues," *American Psychologist* 45 (1990): 1297–1303.

PAPER FOUR

CRITICAL ISSUES CONCERNING RESEARCH INVOLVING DECISIONALLY IMPAIRED PERSONS

Jonathan D. Moreno, Ph.D.

Introduction

This is a working paper prepared by staff to the Human Subjects Subcommittee of the National Bioethics Advisory Commission (NBAC). At the request of the subcommittee, the paper attempts to set out the critical issues facing the commissioners concerning the recruitment and participation in clinical research of those who are decisionally impaired. The critical issues considered in this working paper are as follows.

- Should the individual's informed consent always be required for research participation?
- Should individuals be able to execute substantive advance research directives?
- Should the patient's legally authorized representative be empowered to make research participation decisions, and on what basis should he or she decide?
- Should legally authorized surrogates be empowered to make research participation decisions, and on what basis should they decide?
- Should those who are decisionally impaired, and at high risk for decisional incapacity, be excluded from research?
- Should the patient who decides to participate in research be required to have appointed a legally authorized representative to make subsequent *medical care* decisions?
- Should those who are decisionally incapacitated be excluded from research?
- Should research involving the decisionally impaired or incapacitated be limited to that which is relevant to a medical problem from which the patient is suffering?
- Should investigators be required to notify individuals that they have been found to be decisionally inacapacitated and that they are to be entered into a research project without their consent?

- Should consent auditors ever be required?
- Should "reconsent" procedures ever be required?
- Should "wraparound" studies ever be required?
- Should placebo arms ever be prohibited?
- Should the NBAC promulgate new regulations concerning the participation in research of those who are decisionally impaired, or should it rather offer guidance for potential subjects, their physicians, clinical investigators, institutional review boards, and other policymaking bodies?

Should the individual's informed consent always be required for research participation?

The Nuremberg Code is perhaps the most important touchstone of research ethics. The first sentence of the Code states that "[t]he voluntary consent of the human subject is absolutely essential."[1] As the field of medical ethics has grown, some distinguished commentators have continued to defend the view that no research is permissible without the subject's informed consent. They point out that scientific progress is morally optional, while respect for human beings and their self-determination is not.

Yet research with children and other populations has continued and flourished in the half century since Nuremberg. These practices have been justified by seeking what many regard as the moral equivalent of subject consent, including parental permission and subject assent where feasible. A further justification is that significant benefits to many individuals would have to be foregone if the consent requirement were strictly interpreted, but few have found strict interpretation of the consent requirement to be morally obligatory. Various standards and procedures have been established to protect the well-being of subjects. It is also often noted that, since treatment of individuals for disease must continue, far more harm would be done through the widespread clinical use of modalities that had not been subjected to controlled study.[2]

Instead, conditions have been placed on research with those who cannot give their own consent. If research with children and others who lack decisionmaking capacity can be ethically acceptable, then presumably research with the decisionally impaired, who may have various levels of decisionmaking capacity, can also be done in a way that is ethically acceptable.[3]

Foremost among the conditions that may be imposed on research with those who are decisionally impaired or incapacitated is the gradually higher level of scrutiny that is accorded research proposals as the risk-benefit ratio becomes less favorable. Conditions may be imposed concerning not only acceptable levels of risk, but also through recruitment and selection of subjects, study design, consent processes, and independent monitoring.

Should individuals be able to execute substantive advance research directives?

Some persons whose decisionmaking capacity is currently intact may be able to anticipate a period of incapacity, perhaps extending for the rest of their lives. Various neurodegenerative diseases have this kind of course, including Alzheimer's. By the time an individual's disease has progressed to a stage that is of research interest, he or she may no longer be capable of granting an informed consent. In theory, the individual may make both substantive and procedural arrangements, while capable, to enable study participation after a loss of decisionmaking capacity. An outstanding issue is whether such arrangements are acceptable approximations of the gold standard of ethical research enrollment, the subject's contemporaneous informed consent.[4]

A substantive advance research directive would specify a research project or projects that an individual would be prepared to enter, should he or she lose capacity. These advance directives would be roughly equivalent to living wills for standard treatment. States would presumably need to pass legislation recognizing such devices. One question is whether federal regulations should recognize research advance directives and take them into account in rules concerning subjects who may lose their decisionmaking capacity before they can enter or complete a study.

The idea of an "advance directive for research" appears to be consistent with our society's dominant philosophical beliefs about control over one's body and with other practices. Some argue that, just as individuals may donate their remains to medical schools and laboratories, so they should be permitted to commit themselves to a research project as living subjects while they still have the ability to do so. This argument seems to gain strength when the anticipated research participation holds some prospect of benefit to the incapacitated subject.[5]

1 Rebecca Dresser, "Research Involving Persons with Mental Disabilities: A Review of Policy Issues and Proposals," contract paper for National Bioethics Advisory Commission, 1997, p. 5. Relevant portions of this paper will hereafter be cited in footnotes as Dresser, followed by the manuscript page number.

2 Dresser, p. 6.

3 Dresser, p. 8.

4 Dresser, pp. 41–51.

5 Dresser, pp. 51, *passim*.

But potentially beneficial research for those who are incapacitated is the exceptional case; few studies offer even a remote chance of benefit. Many contend that it is exploitive to permit people, hoping desperately for a return to lucidity and health, to make such a commitment, often well in advance of the actual research intervention. They note that one's views about continued medical procedures may change as one's illness progresses, perhaps without the opportunity to review a research living will once it has been executed. Further, how can it be decided when the experimental involvement should cease, especially in studies that did not offer benefit to the subject in the first place?

If the idea of an advance directive for research is nevertheless attractive because of its consistency with our other values, such as the protection and promotion of patient autonomy and the advancement of medical knowledge, some conditions could be placed on its use. For instance, research advance directives might only be valid when the research presents some prospect of patient benefit, and strict time limits could be imposed that require active renewal of the living will. Another option is to require the appointment of a legally authorized representative to make a decision about stopping participation in the study, as a condition of validity of the advance directive for research.

There is another objection to research advance directives that is rather different from those mentioned above and that many find decisive. The incapacitated patient may be aware of being subjected to various experimental procedures, but be unable to understand their significance or appreciate that they had been consented to in advance. A person with waxing and waning awareness, often highly medicated and perhaps physically restrained, could experience study procedures as quite disturbing, and even as a kind of torture. To minimize this possibility, careful protections would need to be constructed, including perhaps the advance appointment of an alternative decision maker who could stop study participation at the least sign of subject distress.

Should the patient's legally authorized representative be empowered to make research participation decisions, and on what basis should he or she decide?

In anticipation of a period of incapacity, many individuals have appointed others to make treatment decisions on their behalf. The authority to appoint such representatives, who are often called health care agents, has been recognized in the laws of many states, technically known as the "durable power of attorney" (DPA). In general, the health care agent is obligated to make medical decisions that are in accord with the patient's previously expressed wishes, or, if those wishes are unknown to the agent, consistent with the patient's expressed values. Failing that, the health care agent should make decisions that advance the patient's medical best interests.[6]

Many have advocated extending this legal authority to enable the representative to make research participation decisions. There are several situations in which such an arrangement has practical appeal. Often individuals "fail" standard therapy but are incapable of deciding about trying to take advantage of a medication or device still under study. Or a person may not have anticipated becoming ill and, suddenly incapacitated, may have had no time to consider whether some experimental treatment might be preferable to a standard therapy. Or an individual may become decisionally incapacitated in the course of medical care without having considered the next step in his or her treatment. Finally, some may find donating their body to a research project to be a highly desirable and satisfying way to exit, but, rather than leave this to chance, wish a representative to identify a worthwhile scientific effort taking place at the time of death.

In one important sense, the power to appoint a "research agent" is an expression of the patient's self-determination, for which all sorts of provisions are currently made in the delivery of health care. If individuals are empowered to identify those whom they wish to speak for them in making decisions about recognized medical interventions, then why not extend this authority to emerging medical alternatives?

One important difference between reliance on health care agents in the standard treatment setting and in the research setting is that recognizing the authority to decide about someone else's care seems to be more easily justifiable when there is good reason to believe that the intervention will be in that person's interest. Experimental procedures or maneuvers are not undertaken with the primary goal of subject benefit, but rather are intended to help advance knowledge about the problem motivating the study. Allowing other persons to decide about making someone an experimental subject, even when the individual in question has authorized them to do so, is a qualitative departure from ordinary DPA arrangements. Such decisions may entail considerable risks with little likelihood of substantial benefit.

Though great deference is given to individual self-determination in our political system, there does seem to be a legitimate societal interest when a private arrangement may present significant harm to the individual initiating it, in the absence of a reasonable prospect of offsetting advantages. Weighing against this societal interest is the possibility that greater medical knowledge may accrue to society in permitting these arrangements to go forward in spite of their risks. In some cases, the rejection of those who would make themselves

6 Dresser, pp. 29–36.

available for research through an agent could significantly hamper studies of the condition that led to the person's current incapacity.

A balance might be struck by limiting the conditions under which the health care agent's authority would be valid. For instance, studies that present no prospect of direct benefit to the subject, but entail significant risk, could be ineligible for enrollment via a DPA. Studies that entail minimal risk could be regarded as consistent with a patient's best medical interests and therefore permissible, even though they do not advance those interests.

Alternatively, a representative's decision could be subject to review to establish that it is consistent with what is known about the patient's wishes. But (short of intervention by a court of law), it is not at all clear how such a challenge could be warranted, especially if the patient leaves no written statement about his or her attitudes toward research. How should other responsible parties, like researchers and IRBs, assess whether the patient's representative, in enrolling the patient in research, is truly acting in accordance with the patient's wishes and values? Unlike treatment DPAs, one test that would have very limited applicability is the best interests of the patient. Since studies are not designed to satisfy individual subjects' medical interests (though that may be a happy by-product of a study), to say that a study is in a person's best interests, especially when that person no longer has capacity, is often going to be far-fetched. For many, this limitation on objective review of a representative's decisions is important enough to reject procedural arrangements.

In partial amelioration of this problem, at least from the standpoint of potential harms to subjects, a warning to representatives might be appropriate in some cases. For example, legally authorized representatives could be informed of the possibility that the research would add to the patient's risk of harm or discomfort. Were such information made part of the process, the difference between the expected course with and without research should be clearer to the lay person representing the decisionally incapacitated person.

Procedural advance directives, like DPAs, offer at least two advantages over substantive research advance directives. The first is that they are far more flexible than statements about preferred or permissible interventions. The second advantage, and one especially pertinent to patients who suffer from some degree of decisional impairment, is that it may be much easier to designate a representative whom one trusts than to assess the relative risks and benefits of a research study. Thus, it may be argued, if one wishes to grant patients the right to research participation when they no longer have decisionmaking capacity, then the approach that is most reliable concerning their expressed choice is probably the procedural one. However, it must be granted that there is little evidence for this argument, however intuitively plausible it may seem.

One objection to research DPAs is also an objection to research advance directives and, indeed, to any study participation by the decisionally impaired: that the disoriented patient-subject may feel imprisoned and forced to undergo procedures without understanding, even though they have been authorized by the legally authorized representative. This could be a terrifying, nightmarish experience for a decisionally impaired person. Although a procedural advance directive may reduce this risk, it remains a serious concern and may require more than one protective mechanism for the impaired subject.

Should legally authorized surrogates be empowered to make research participation decisions, and on what basis should they decide?

Usually people who lose decisionmaking capacity have not created an advance directive. Sometimes members of their family or other caretakers are identified as suitable surrogates in granting permission to enter them into research. But these arrangements have, at best, an uncertain legal standing. Regulations could recognize state legislation that established in the law what is now a matter of common practice by granting "natural" surrogates (such as family members or close friends) a specific role in the research recruitment process for decisionally impaired persons.

An obvious objection to such arrangements is that, unlike a representative appointed by the patient in advance, the surrogate's standing as a substitute decision maker may arise only from the law. To many the moral basis for the surrogate's authority appears inadequate, especially in the research context, because he or she has not been selected by the potential subject. According to many bioethicists, surrogates are supposed to act on the patient's behalf in accordance with their "substituted judgement." But there is no guarantee that even a close relative is aware of the patient's preferences or values with respect to standard medical treatments, let alone research participation, or even that the surrogate will act on those preferences or values if they are known. A surrogate may only be able to decide based on the patient's medical best interests. A "medical best interests" standard will not apply to studies that offer no prospect of direct benefit to the subject.

However questionable the legal basis of this process, a large number of research subjects have been recruited through identification of a surrogate and restrictions on these measures would constitute a severe blow to a great deal of research on diseases that involve cognitive disabilities. And many studies do hold out the prospect of direct benefit, including the use of new drugs and medical monitoring. One option would be to recognize in regulation the role of surrogates in research that involves only procedures that are potentially beneficial to the subject, or that entail no more than minimum risk.

Should those who are decisionally impaired and at high risk for decisional incapacity be excluded from research?

In the final analysis, both substantive and procedural advance directives for research are at best problematic. The underlying difficulty is that, unlike the usual medical circumstances for which these legal devices have been designed, in a research context the individual is giving himself or herself over, in advance, to an enterprise that is likely to be of benefit only to the society at large, through the advancement of medical knowledge.

Considering the inherent limitations of measures intended to enable the incapacitated research subject to continue to have a voice in his or her treatment, it may be argued that those who are at greatest risk of decisional incapacity should simply be excluded from research. Were the assessment of risk for loss of decisional capacity required prior to enrollment in a study, the remaining subjects would be those who are less likely to require the application of substantive or procedural advance directives, though these devices might still be a condition of study participation.

There are several objections to a rule-out procedure based on the prospect of a potential subject's losing decisionmaking capacity. First, although the prospect of decisional incapacity is often clear, especially in progressive diseases or when a patient is going to be heavily medicated, in many cases the loss of capacity is not so predictable. Second, however one weighs the importance of advancing medical knowledge, prohibiting research on those most likely to lose capacity would create a significant obstacle to the study of some diseases in their most debilitating stages. Third, some research may be concerned with determining at what dosage a drug impairs cognitive function, an issue that could be of great importance to preventing future patients from losing their decisionmaking ability. Fourth, the proposed exclusion would not avoid instances of uncertainty about the meaning of a substantive advance directive or the propriety of a decision made by representative empowered through a procedural advance directive.

Nonetheless, the idea that ethical problems raised by incapacity should be avoided if possible has intuitive force. One approach could be to require that a research project begin by enrolling those least likely to lose their decisionmaking ability during the study period, and that the selection of at-risk subjects be justified by the particular goals of the study. A different approach would look again to the risk-benefit ratio, excluding prospective subjects from certain studies depending on their likely ability to make future decisions, as well as the anticipated level of risk.

Should the patient who decides to participate in research be required to have appointed a legally authorized representative to make subsequent *medical care* decisions?

Apart from decisions having to do specifically with continuing study participation, medical decisions must often be made while a patient is enrolled in research. To avoid confusion about who is authorized to make medical care decisions if the subject loses capacity, investigators might be required to ensure that all subjects have a legally authorized representative. In some jurisdictions this may require that the subject appoint a health care agent prior to enrollment in a study.

From the researcher's standpoint, it also seems prudent to ensure that a patient with a decisional impairment not be left without a representative to make health care decisions; such a representative could help the study team avoid problems if treatment issues arise. However, there may be confusion about the limits of the representative's authority, since it may not extend to issues having to do with the research itself. For example, conceivably the patient's medical care representative could decide that continued participation in a current research project is incompatible with the patient's medical well-being and could have the power to remove the patient from the study, but lack the power to enroll the patient in a different research project.

Should those who are decisionally incapacitated be excluded from research?

One way to avoid the practical and philosophical problems with justifying research with those who are no longer able to consent would be to exclude such individuals from being part of research. A wholesale exclusion from research of those who lack decisionmaking ability would square with the letter of the Nuremberg Code, but would not be consistent with research practices even in the decades since the code was written. In general, it is thought that ethical research with human subjects who cannot give informed consent can be and has been conducted, especially if some form of advance directive or surrogate decision making arrangement is in place. Several subsequent ethics guidelines (including those of the Helsinki declarations of the World Medical Association and the Council for International Organizations of Medical Science) have endorsed research with those unable to consent under certain conditions. Recent scholarship indicates that even the Nuremberg Code itself was not intended to refer to clinical research with those who are ill, but to research with normal subjects.

Furthermore, though it is controversial, the recently authorized exception to informed consent requirements for certain emergency research is a greater departure from the Code's voluntary consent requirement than any contemplated herein concerning research with those who are decisionally incapacitated. A primary consideration in the creation of the narrow exception to the federal rules was the need for improvements in the care of emergent, life-threatening conditions. A similar argument can be mounted on behalf of the improved treatment of those who are or are at risk for a loss of decisionmaking ability.

Should research involving the decisionally impaired or incapacitated be limited to that which is relevant to a medical problem from which the patient is suffering?

Some "vulnerable" or "special" populations are currently accorded a particular protection in the regulations to ensure that they are not unfairly burdened with involvement in research simply because they are easily available. Thus, prison research is to be limited to conditions that especially affect that population. Considering that the decisionally impaired are often not only institutionalized but may also be unable to speak for themselves, their position bears earmarks of special vulnerability. One important justification for involving those with decisional impairments in research is the need for progress in the treatment of certain diseases. In order to thwart the temptation to engage them in research simply because they are more available than others, it may be appropriate to restrict research involving decisionally impaired persons to that which is relevant to conditions responsible for the impairment itself. A less restrictive rule would limit research to that which is relevant to conditions that tend to afflict those who are decisionally impaired.

Should investigators be required to notify individuals that they have been found to be decisionally inacapacitated and that they are to be entered into a research project without their consent?

To be found decisionally incapable and then enrolled in research according to alternative decisionmaking arrangements is to have certain of one's rights curtailed, however justifiable the curtailment research may be. Some argue that whenever an individual is found to be decisionally incapable, the individual should be put on notice of this finding, especially when it could have important consequences for the individual's medical treatment, as in the case of enrollment as a subject.[7]

Such an notification process will often be an empty ritual. Worse, a requirement that implies a duty to so inform those who are in an advanced stage of dementia prior to research involvement could well contribute to undermining health professionals' respect for the regulatory system. Nevertheless, to be unaware that one has been found decisionally incapable is to be deprived of the opportunity to seek review and perhaps of the right to judicial intervention. The implications of such a determination, including the loss of control over one's own person, are among the most serious one can imagine for a liberal, democratic society.

Rather than require that all individuals who have been found to be decisionally incapacitated be informed of that finding prior to their enrollment in a study, such a rule may be limited to those potential subjects who show any signs of consciousness. The notification would also enable the patient to assent to his or her research role, by no means a trivial recognition of individual dignity.

Should consent auditors ever be required?

The consent auditor is one device that has frequently been suggested as an additional procedural protection in the recruitment of research subjects who may be decisionally impaired. The consent auditor, who is not a member of the study team but perhaps a member of the IRB or an institutional ethicist, witnesses the consent process and then either certifies the consent as valid, or informs the principal investigator that an individual is not able to give valid consent.[8]

The consent auditor may be adopted as an alternative or as a complement to the blanket notification requirement discussed above. Rather than requiring researchers to engage in what will often be an empty ritual, consent auditors could be required for potential subjects who have conditions associated with a decisional impairment. A system of audited consent will require a substantial investment by research institutions. The requirement may be limited to studies that have certain characteristics, such as those that involve greater than minimal risk and/or those that do not hold out the prospect of direct benefit to the subject.

Should "reconsent" procedures ever be required?

Studies with those who are decisionally impaired may take place over extended periods. One of the essential conditions of ethical research is continued voluntary participation, but those who are deeply involved with and dependent upon the health care system may not feel able to disenroll from a study. A

7 Another way to express this issue is whether the assent of incapable subjects should be required. Dresser, pp. 36–40.

8 Dresser, pp. 22–25.

requirement for periodic "reconsenting" would help ensure that a patient's continued involvement is truly voluntary by giving "permission" to leave the study. Such a requirement would also provide the occasion to reassess decisionmaking capacity, and it could trigger an advance directive or surrogate arrangement. Reconsent mechanisms conform with the spirit of informed consent as a process rather than a single event, and with the view of human research participants as collaborators rather than as passive subjects.[9]

Reconsenting is, however, another labor-intensive measure that would add to the cost and complexity of the human research system. Yet a number of long-term studies already include such a procedure. A reconsent requirement could be attached to certain studies depending on their length and the condition of the individuals to be included, such as those with progressive neurological disorders.

Should "wraparound" studies ever be required?

With or without a decisional impairment, many who are ill and candidates for a research study can suffer from the "therapeutic misconception," the notion that the research maneuvers or procedures might be of personal benefit even though that possibility has clearly been ruled out in the consent process. One way to deal with the therapeutic misconception is to incorporate a non-research or "wraparound" phase into the project, one that provides the subject with some beneficial intervention independent of the study itself.

A serious problem with a wraparound phase is that it may shift the balance in the opposite and equally problematic direction of the therapeutic misconception, by providing an inappropriate incentive to study participation in order to derive the benefits of a recognized therapeutic strategy without payment. On the other hand, wraparounds could be suitable follow-ups to certain kinds of research that involve the provocation of symptoms.

Should placebo arms ever be prohibited?

Many decisional impairments are associated with psychiatric disorders that can be managed symptomatically with neuroleptic medication. When a known risk of placebo is the return of symptoms, it may be argued that it is unethical to include a placebo arm. Thus, some contend that new drug investigations should be controlled by measures against standard therapy, in spite of the methodological shortcomings of such designs.

A basis for excluding placebo arms in particular studies could be an individualized assessment that concludes that certain patients would be at high risk for relapse if their current therapeutic regimen was discontinued, that a "drug holiday" is not contemplated for this patient apart from enrollment in a study, and that standard therapy is generally considered effective if not ideal. However, any change in human subjects regulations concerning permissible research design should presumably accommodate other federal requirements for drug approval.

When drug-free research is conducted (whether as part of a "blinded" placebo-controlled study or otherwise), it is important to follow patient-subjects who are at risk for relapse. Presumably, under current regulations for "vulnerable" subjects, IRBs should take such arrangements into account when evaluating research proposals. One regulatory option is to require investigators to explain how they propose to monitor subjects for symptom relapse in studies with a drug-free component that enroll decisionally impaired individuals with a history of psychiatric disorders.

Should the National Bioethics Advisory Commission promulgate new regulations concerning the participation in research of those who are decisionally impaired, or should it rather offer guidance for potential subjects, their physicians, clinical investigators, institutional review boards, and other policymaking bodies?

The desirability of governmental regulation depends not only on the importance of the policy enunciated or the practices addressed, but also on the rules' ultimate efficacy. Presumably, the least formal measures taken by governmental entities are the preferred ones, so long as those measures are consistent with achieving the important societal goals that have been identified. Many who are familiar with the current federal regulations concerning human subjects research complain that they are already unjustifiably complex and bureaucratic. Some of those engaged in research on conditions related to decisional impairment are fearful that further regulation affecting these populations will unnecessarily retard scientific progress and stigmatize individuals who may be suitable subjects.

But many others note that, in spite of the imperfections of the current regulations, the period since their enactment has been largely free of the sorts of large-scale controversies that helped give rise to them. It may also urged that the issues discussed in this working paper illustrate some of the shortcomings of the common rule. The commission will need to determine whether issues concerning the decisionally impaired in research are of such a magnitude that new regulations are required, or whether some or all of the reforms it may determine are indicated could be advanced through another mechanism, such as a statement of recommendations for relevant parties.

9 There are related suggestions. See Dresser, pp. 26–27.

PAPER FIVE

COMPETENCY TO DECIDE ON TREATMENT AND RESEARCH

The MacArthur Capacity Instruments

Elyn R. Saks

Introduction

The issue of competency to decide on treatment and research has come center stage in the arena of bioethics. With the advent of the doctrine of informed consent came attention to both the quality of the doctor's informing and the quality of the patient's understanding. Since World War II, moreover, concern about the ethics of doing medical research on human subjects, particularly vulnerable subjects, has led commentators to focus on competency to consent. Finally, since the 1970s, many courts, first on federal and now on state law grounds, have granted competent psychiatric patients the right to refuse treatment absent an emergency. Indeed, probably the vast majority of treatment competency hearings today arise out of efforts to medicate psychiatric patients.[1]

Courts and commentators have struggled with the test for competency in this setting. Unfortunately, courts typically cite language that often obscures more than it helps, seldom engaging in illuminating analysis. Commentators have done better. The premier work on competency to make treatment and research decisions has come out of the MacArthur network on law and mental health.[2] The MacArthur researchers, in particular, Paul Appelbaum and Thomas Grisso, have operationalized three research instruments to measure four capacities involved in treatment competency and have studied

---

[1] The Supreme Court's decision in *Zinermon v. Burch*, 494 U.S. 113 (1990), made this issue important in the context of *consent* to treatment as well as refusal, in particular, consent to voluntary psychiatric hospitalization.

[2] The literature contains studies of only a few other treatment capacity/competency instruments—my research has uncovered four. See, e.g., C. Dennis Barton, Jr., Harminder S. Mallik, William B. Orr, and Jeffrey S. Janofsky, "Clinicians' Judgment of Capacity of Nursing Home Patients to Give Informed Consent," *Psychiatric Services* 47 (1996): 956 (Hopkins Competency Assessment Test [HCAT]); Jeffrey S. Janofsky, Richard J. McCarthy, and Marshal F. Folstein, "The Hopkins Competency Assessment Test: A Brief Method for Evaluating Patients' Capacity to Give Informed Consent," *Hospital and Community Psychiatry* 45 (1992): 132 (HCAT); Gary N. Sales, "Assessing Competency" (letter), *Hospital and Community Psychiatry* 43 (1992): 646 (discussing article on HCAT); Michael Lavin, "Assessing Competency" (letter), *Hospital and Community Psychiatry* 43 (1992): 646–47 (same); Jay Englehard, "Assessing Competency," *Hospital and Community Psychiatry* 43 (1992): 647 (same); Graham Bean, Shizuhiko Nishisato, Neil Rector, and Graham Clancy, "The Assessment of Competence to Make a Treatment Decision: An Empirical Approach," *Canadian Journal of Psychiatry* 41 (1996): 85 (Competency Interview Schedule [CIS]); Graham Bean, Shizuhiki Nishisato, Neil Rector, and Graham Clancy, "The Psychometric Properties of the Competency Interview Schedule," *Canadian Journal of Psychiatry* 39 (1994): 368 (CIS); Daniel C. Marson, Lawrence Hawkins, Bronwyn McInturff, and Lindy E. Harrell, "Cognitive Models that Predict Physician Judgments of Capacity to Consent in Mild Alzheimer's Disease," *Journal of American Geriatrics Society* 45 (1997): 458 (testing of Alzheimer's patients based on vignette procedure intended to identify incompetency based on Roth, Meisel, and Lidz' discussion of different standards in "Tests of Incompetency to Consent to Treatment," *American Journal of Psychiatry* 134 (1977): 279; Daniel C. Marson, Heather A. Cody, Kellie K. Ingram, and Lindy E. Harrell, "Neuropsychologic Predictors of Competency in Alzheimer's Disease Using a Rational Reasons Legal Standard: A Prototype Instrument," *Archives of Neurology* 52 (1995): 955 (same instrument); Daniel C. Marson, Anjan Chatterjee, Kellie K. Ingram, and Lindy E. Harrel, "Toward a Neurological Model of Competency: Cognitive Predictors of Capacity to Consent In Alzheimer's Disease Using Three Different Legal Standards," *Neurology* 46 (1996): 666 (same instrument); Daniel C. Marson, Lauren Hawkins, Bronwyn McInturff, and Lindy E. Harrell, "Cognitive Models that Predict Physician Judgments of Capacity to Consent in Mild Alzheimer's Disease," *Journal of American Geriatrics Society* 45 (1997): 458 (same instrument); Daniel C. Marson, "Determining the Competency of Alzheimer Patients to Consent to Treatment and Research," *Alzheimer Disease and Associated Disorders* 8 (1994 Supp.): 5 (same instrument); and Atsuko Tomada, Takahio Sumiyama, Kazumi Tsukada, Tatsuro Hayakawam, Kimimori Matsubara, Fusako Kitamura, and Roshinori Kitamura, "Validity and Reliability of Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory," *Journal of Clinical Psychology* 53 (1997): 443 (Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory [SICIATRI]). I focus here on the MacArthur instruments because they appear to be the most carefully constructed, best studied, and most discussed in the literature.

the instruments in their application to patients and control groups. They have also produced a treatment capacity measure that can be administered in the clinic.[3] Their work has been impressive indeed; they have given us a set of generally well-designed instruments that have achieved high reliability, can be administered with relative ease, and have been studied in interesting and informative ways.

The three research instruments are: (1) the Understanding Treatment Disclosures (UTD) instrument, which measures understanding;[4] (2) the Perceptions of Disorder (POD) instrument, which measures one's appreciation of disclosures about illness and treatment as they apply to one's own situation;[5] and (3) the Thinking Rationally About Treatment (TRAT) instrument, which measures one's reasoning skills as one decides about a hypothetical treatment dilemma based on one's own condition.[6] A subset of the latter test is a question which measures one's ability to express a choice.

Appelbaum and Grisso argue that the three instruments measure capacities relevant to different standards of legal competency found in the case law and statutes.[7] They distinguish between capacity and competency—"capacity" refers to abilities relevant to performing a task, while "competency" is a legal judgment that one has sufficient abilities to perform the task—and say that their instruments measure only capacities.[8] The term "impaired" means that the subject scored two standard deviations below the mean of those studied.[9]

The researchers have recently designed a treatment capacity instrument, to be used for actual evaluations rather than research purposes (the MacArthur Competence Assessment Tool-Treatment, or MacCAT-T).[10] The MacCAT-T incorporates many of the questions found in the research instruments, while being more economical to administer and tailoring the questions to the person's particular situation. The investigators do not suggest that MacCAT-T scores translate directly into competency or incompetency findings (although those who score average or better on all the tests are said to be likely to be competent).[11] Clinical judgment is required to make these findings.

This paper seeks to evaluate the MacArthur instruments with a view to understanding their implications for assessing the competency to participate in research of vulnerable psychiatric patients. This assessment takes place against the background of some of the important normative issues that arise whenever one selects a competency instrument. The paper begins by describing the three MacArthur instruments in greater detail. It then sketches a framework for thinking about the normative questions raised by any competency instrument, discussing the implicit judgments the MacArthur investigators smuggle in, despite protestations that they have not addressed these issues and absent an effort to justify the choices. The paper then evaluates the MacArthur instruments in light of the normative framework, focusing on both the classification schema itself and specific features of each instrument. The evaluation leads into a discussion of the issues involved in importing these treatment instruments into the research context—as well as additional normative issues raised in this context. The paper concludes by addressing the dilemma of what IRBs should require of their investigators in this regard: first, should researchers be required to evaluate competency when recruiting subjects for research? And second, should they be required to use particular instruments to do so? A call for further research will end this section.

My conclusions? First, adopting any standard or instrument to assess capacity/competency will involve normative considerations. The MacArthur investigators have arguably omitted an essential step in developing their instruments. Second, the implicit judgments that the MacArthur investigators do make may strike the wrong balance between autonomy and

---

[3] The MacArthur researchers have written a number of articles describing their development of the three MacArthur research instruments and the treatment of the competence instrument (MacCAT-T), as well as their application to patient populations and matched controls. See, e.g., Paul S. Appelbaum and Thomas Grisso, "The MacArthur Treatment Competence Study I: Mental Illness and Competence to Consent to Treatment," *Law and Human Behavior* 19 (1995): 105; Thomas Grisso, et al., "The MacArthur Treatment Competence Study II: Measures of Abilities Related to Competence to Consent to Treatment," *Law and Human Behavior* 19 (1995): 127; Thomas Grisso and Paul S. Appelbaum, "The MacArthur Treatment Competence Study III: Abilities of Patients to Consent to Psychiatric and Medical Treatment," *Law and Human Behavior* 19 (1995): 149; Thomas Grisso and Paul S. Appelbaum, "A Comparison of Standards for Assessing Patients' Capacities to Make Treatment Decisions," *American Journal of Psychiatry* 152 (1995): 1033; Jessica Wilen Berg, Paul S. Appelbaum, and Thomas Grisso, "Constructing Competence: Formulating Standards of Legal Competence to Make Medical Decisions," *Rutgers Law Review* 48 (1996): 345; and Paul S. Appelbaum and Thomas Grisso, "Capacities of Hospitalized, Medically Ill Patients to Consent to Treatment," *Psychosomatics* 38 (1997): 119. They have also recently published a book on the MacCAT-T: Thomas Grisso and Paul S. Appelbaum, *Assessing Competence to Consent to Treatment* (Oxford University Press, 1998). And they have an article in press on the application of their instruments to the research context. See Jessica Wilen Berg and Paul S. Appelbaum, "Subjects' Capacity to Consent to Neurobiological Research," in *Ethical Issues In Psychiatric Research: A Resource Manual on Human Subjects Protection* (Harold Alan Pincus, Jeffrey Lieberman, and Sandy Ferris, eds.) (forthcoming in American Psychiatric Association). Finally, they have copies of their manuals for the different instruments, see note 4–6 and 10 below, which are essential reading for anyone interested in their instruments. Finally, there has been considerable literature discussing the MacArthur instruments, most prominently, the articles in *Psychology, Public Policy, and Law* 1, vol. 2.

[4] The best way to understand the MacArthur instruments is to look at the manuals for the different instruments. For the UTD, see Thomas Grisso and Paul S. Appelbaum, *Manual for Understanding Treatment Disclosures* (1992) (available on request from authors).

[5] See Paul S. Appelbaum and Thomas Grisso, *Manual for Perceptions of Disorder (POD)* (1992) (available on request from authors).

[6] See Thomas Grisso and Paul S. Appelbaum, *Manual for Thinking Rationally About Treatment* (1993) (available on request from authors).

[7] See, e.g., Berg, Appelbaum, and Grisso, supra note 3, 363; Appelbaum and Grisso, *Hospitalized and Medically Ill Patients*, supra note 3, 121; and *MacArthur I*, supra note 3.

[8] See, e.g., Grisso and Appelbaum, *Assessing Competence,* supra note 3, 11.

[9] See, e.g., Berg, Appelbaum, and Grisso, *Constructing Competence*, supra note 3, 373. In this chapter I use the terms "competency," "capacity," and "impaired" in the same way.

[10] See Thomas Grisso and Paul S. Appelbaum, *MacArthur Competence Assessment Tool-Treatment (McCAT-T*) (1995) (available on request from authors).

[11] See, e.g., Grisso and Appelbaum, *MacCAT-T,* supra note x, 17.

paternalism. Both of these conclusions are equally applicable to the treatment and research contexts, and are important for the National Bioethics Advisory Commission to consider in assessing what to require of IRBs in regard to competency evaluations in the research context.

The Nature of the MacArthur Treatment Instruments

Before evaluating the MacArthur instruments, let us consider in more detail what they do, and what studies of their application have revealed about different groups of people. The UTD measures the subject's understanding of treatment disclosures about the illness he suffers from and its treatment.[12] Form disclosures were devised for schizophrenia, depression, and ischemic heart disease (angina). Each disclosure, using language understandable at the junior high level, consists of five simple paragraphs briefly describing the illness and its treatment.

The first paragraph speaks of the illness itself, as well as of two common symptoms of the illness ("schizophrenia is a mental disorder. People with schizophrenia often have unpleasant experiences, called symptoms. For example, they . . . may hear voices talking about what they are doing, even when there are no other people around").[13] The second paragraph talks about treatment, how it is administered, and what is required of the patient for it to be effective ("fortunately, schizophrenia can be treated with medicine. . . . But if patients stop taking this medicine, their symptoms may come back"[14]). The third speaks of the potential benefits of the treatment ("the medicines used to treat schizophrenia help many patients to think more clearly. They often stop the frightening voices that some patients with schizophrenia hear"[15]). The fourth paragraph speaks of the potential side effects of the treatment ("the medicine might make patients restless or cause their muscles to tighten up"[16]). The fifth paragraph speaks of alternatives, benefits of the alternatives, and potential problems with the alternatives ("there is also psychotherapy [to help treat schizophrenia]. . . . This talking therapy may help patients better understand themselves and their feelings. But psychotherapy alone does not usually help with schizophrenia by itself. . . . [it] is most helpful when the patient is also taking medicine"[17]).

The UTD is administered in three forms. First, the patient is read the entire disclosure and asked to paraphrase what has been said (with questions prompting him if need be). Second, the patient is read each element of the disclosure in turn, and after each element is read, is asked to paraphrase what has been said. Third, the same element disclosure format is followed, except the patient is asked, after each element, whether a statement read is "the same as or different from" what has been said.

Patients receive points depending on how much they have remembered and (presumably) understood. For example, if two symptoms of schizophrenia have been disclosed, a patient will receive a full score on that issue if he repeats or paraphrases those two symptoms. He will also receive a maximum score if he includes those two but adds others that were not disclosed to him. He will receive no credit if he remembers none of the symptoms or, interestingly, if he brings up other symptoms—even if they are bona fide symptoms of schizophrenia—that he did not hear in the disclosure (and he does not additionally mention disclosed items).

The POD measures people's appreciation of their illness and its treatment: it requires them to apply general information to their own situation.[18] There are two subtests, the Non-Acknowledgment of Disorder (NOD) subtest and the Non-Acknowledgment of Treatment Potential (NOT) subtest. The first measures the patient's failure to acknowledge his diagnosis, the severity of his condition, or the symptoms he has been demonstrating. "Objective" measures of these three are provided by the diagnosis given in the patient's medical chart, the severity of his symptoms as measured by the Brief Psychiatric Rating Scale, and the symptoms recently reported in his medical chart.

The NOT measures patients' failure to acknowledge the potential value of treatment for their illnesses even when successful treatment is likely. It focuses on the extent to which patients believe (1) any treatment might be of benefit to them, (2) medication specifically might benefit them, and (3) the course of improvement is likely to be lessened absent treatment. If they fail to acknowledge the potential benefits of treatment, they are provided a hypothetical premise that logically nullifies their reasoning (e.g. "imagine that a doctor tells you that there is a medication that has been shown in research to help 90 percent of people with your problem, *even people who had not gotten better with any other medication*[19]). Non-acknowledgment is scored only if the patient fails to acknowledge the potential benefits of treatment under the hypothetical condition. The NOT does not assess whether patients would

[12] The source for these claims about the UTD is the *UTD Manual*. See supra note 4.
[13] *Manual for UTD*, supra note 5, 24.
[14] Id.
[15] Id.
[16] Id.
[17] Id.
[18] The source for these claims about the POD is the *POD Manual*: See supra note 5.
[19] *POD Manual*, supra note 5, 54.

agree to the medication—just whether they believe it might be of possible benefit.

There are three additional elements of the POD that contribute to no subscale; they have been included for exploratory reasons only. These items assess patients' acknowledgment of potential side effects of medication generally, their perceptions of the beneficence of the hospital staff, and their perceptions of their own need for hospitalization.

The third instrument, the TRAT, measures patients' ability to think rationally about treatment.[20] The instrument gives a vignette including information about a disorder, various treatment alternatives, and their probable risks and benefits. It then asks the subject to recommend one of the treatments to a friend with the relevant illness, and to describe the reasons for the selection. The patient's reasoning is then scored for various cognitive activities that are considered important to making a decision. A second set of procedures examines more formal cognitive functions with relevance for decision making.

The cognitive functions identified are "seeking information" (tendency to seek information beyond what is provided); "consequential thinking" (consideration of consequences of treatment alternative when deciding whether to accept or reject it); "comparative thinking" (simultaneous processing of information about two treatment alternatives, such that they are considered in relation to each other); "complex thinking" (attention to the full range of treatment alternatives); and "generating consequences" (generation of potential real-life consequences of the liabilities described in the informed consent disclosure, such as effects of a side effect of medication on ability to perform job functions).

In the second part of the TRAT, three additional cognitive functions are measured independent of the vignette: "weighting consequences" (tendency for consistent application of preferences); "transitive thinking" (assessment of relative quantitative relationships between several alternatives based on paired comparisons); and "probabilistic thinking" (ability to distinguish correctly the relative values of percentage probabilities).

All of the abilities measured on the two parts of the TRAT were derived from discussions in the literature of essential reasoning abilities. Presumably they are measured in a different way given the constraints of the vignette procedure.

The way the vignette abilities are scored is by presenting the vignette to the patient, asking her if she needs further information, and asking her to choose one of the alternatives and to give her reasons for doing so. She is then asked for further reasons, as well as for her least preferred choice and her reasons for that. Scoring occurs by seeing how many of the kinds of cognitive operations identified earlier occur. For instance, did the patient compare risks and benefits of the alternatives with each other?

The way the three further abilities are scored is by presenting the patient with a series of questions that tap into those abilities. For instance, to test probabilistic thinking the patient is told that some event has a 90 percent probability of occurring and is then asked if he thinks it likely to occur.

Finally, the TRAT has a question that measures the patient's ability to "express a choice." A full score is received if the patient unambiguously chooses an option, and partial credit is received if the patient chooses two or no alternatives, but chooses one alternative during a "repeat" inquiry.

Early indications are that two of the cognitive operations—weighting consequences and seeking information—are frequent outliers, and when factor analyses are performed with these subscales removed, they produce two very consistent factors: consequential, comparative, and complex thinking on the one hand, transitive and probabilistic thinking together with generating consequences on the other.

Formulating these instruments to measure capacities relevant to competency has been an impressive achievement. The instrument designers have also done a large-scale, multicenter study evaluating the reliability and validity of the instruments.[21] The instruments have done well on such indicators. In addition, the study has enabled the researchers to draw certain important conclusions about different populations of patients. The research design was to study populations of patients diagnosed with schizophrenia, depression, and ischemic heart disease, and to match the patients on various measures (e.g., age, race, gender, socioeconomic status) to a sample of community nonpatients.

The results are intriguing. The most important is that a significant proportion of patients and nonpatients, in all categories, scored in the nonimpaired range, although the schizophrenic patients did the least well. "Impaired," as noted, was defined as two standard deviations below the mean for the aggregate of everyone studied, patients and nonpatients alike. Given this definition, approximately 25 percent of the schizophrenic patients scored in the impaired range on each of the three principal instruments, and approximately 50 percent scored in that range if the scores on the different instruments were aggregated. But this means, of course, that approximately 50 percent scored reasonably well.

The researchers noted that their study probably understated the impairment in the group of patients studied, because probably the most disturbed patients were not deemed suitable for participation by their treaters. One could, however, look at the matter another way. The study looked only at recently hospitalized patients who were likely to be in the throes of the most acute phase of their illness. One would want a study of these patients much later in their hospital stay

[20] The source for the claims below is the *TRAT Manual*, supra note 6.

[21] See Grisso and Appelbaum, *MacArthur III*, supra note 3, for the findings described below.

as well—the study did look at them a little later—in order to judge the capacities of hospitalized schizophrenics. And a study evaluating schizophrenics in different settings, such as day hospitals, community mental health centers, and group homes, would probably have found a much higher percentage of patients scoring in the nonimpaired range. These patients, of course, also have to make treatment decisions. Moreover, insofar as schizophrenia is a chronic illness, studying schizophrenics' decisionmaking abilities should include them; they may be displaying some symptoms even when not hospitalized. In short, many if not most patients—even those with the most severe psychiatric disorder—are quite capable of making their own decisions. Beliefs otherwise may reflect bald prejudice.

The second important finding of the study was that the three different instruments seemed to be picking out different patients. While the UTD and the TRAT somewhat tracked each other, the POD was not correlated with either of the former two at all.

The final instrument that these researchers have designed is the MacCAT-T.[22] The MacCAT-T incorporates many of the questions found in the research instruments, while being more economical to administer and tailoring the questions to the patient's particular situation. On the normative matters, the researchers have pointed out that the research instruments pick out different groups of people as impaired, and therefore ought all to be used in the MacCAT-T. This is a policy choice which we will consider below.

Quantitatively, the researchers consider two alternatives: using a fixed level of performance as a basis for a finding of competency—say understanding, appreciating, and reasoning about 75 percent of the information provided; or varying the level based on the net balance of expected benefits and risks of the patient's choice compared to the alternatives (i.e., requiring more capacity for more problematic decisions). The researchers seem to prefer the latter, although they do not clearly take a position in this work. I consider the issue of varying the level of competency required depending on the decision below.

Finally, qualitatively, the researchers note that some items of information to be understood, appreciated, and reasoned about may be much more important than others. Decisions about the weight to be given to each item are of great importance in formulating a competency standard.

The MacCAT, then, is an instrument, unlike the three research instruments, which can be used to aid clinical evaluators in a determination of legal competency. It does not definitively answer what level of impairment should equal incompetence. And its authors recommend that the instrument be used in conjunction with a clinical evaluation that takes into account such things as contextual variables. Nevertheless, it, like the research instruments, is an important contribution to the literature on competency.

Normative Judgments Required When Designing Competency and Capacity Instruments

While the MacArthur investigators claim that they have left open the normative questions in designing their instruments[23]—a claim I question below—the adoption of any standard or instrument for capacity and/or competency requires careful normative analysis.[24] The most critical normative issue facing any designer of a capacity and/or competency instrument is how to strike the balance between autonomy and paternalism. It may be true that bioethicists have moved beyond this simple dichotomy in many areas. But in the arena of assessing competency, this conflict remains the most critical. Competency standards are the mechanism by which we draw the line between those who will be permitted to exercise their autonomy and those who will be treated paternalistically.

Of course, it is at best incomplete to say that we strike the balance in our society between autonomy and paternalism by holding that competent patients, and competent patients alone, are given the right to exercise their autonomy. For this simply pushes back the question: how we define competency is itself the pivotal determiner of how that balance is struck—requiring much in the way of competency favors paternalistic interests and vice versa.

Perhaps more important, the definitional question replicates within itself autonomy/paternalism concerns. The MacArthur researchers recognize that the issue of when to decide for a patient and when to allow him to decide himself raises an important autonomy dilemma. We are concerned about allowing people choice—say of treatment or participation in research—when it is appropriate to do so. But the researchers do not seem to recognize that the very definition of competency requires us to decide how much latitude we will give

---

22 The source for the claims below is the *MacCAT-T Manual*, supra note 10.

23 See, e.g., Thomas Grisso and Paul S. Appelbaum, "Values and Limits of the MacArthur Treatment Competence Study," *Psychology, Public Policy, and Law* 2 (1996): 167–70.

24 Since my writing of this chapter, the MacArthur researchers, Thomas Grisso and Paul Appelbaum, have published a book, *Assessing Competence to Consent to Treatment* (Oxford University Press, 1998), supra note 3, which bears on this critique. In this book, the researchers lay out the kind of normative analysis that the competency evaluator, using the MacCAT-T, must go through. In a sense, however, their treatment is not all that helpful. The main thing they say is that a competency judgment must balance autonomy and paternalism, a value about which there is much more to say than this in describing an instrument. They also say that the balance may change when a decision is more or less consequential. They do not fully explain either why we should have such a sliding-scale competency standard (see below) or why they study the abilities they study or decide to draw the line where they do. Moreover, they neglect some of the additional normative dimensions involved in adopting a competency standard (see below).

the decision maker to exercise in selecting a method of decision making. Are intuitive methods adequate? Must decision makers compare all alternatives? A most important subset of this issue is how much scope we will give decision makers to select the version of the truth they will embrace.

What does this all mean? In adopting a competency standard, we must be mindful of several important problems. First, we want to protect the vulnerable who are unable to decide for themselves (our "paternalism interest"); this translates into a careful inquiry into what abilities are essential for making decisions. Second, an important purpose of our doctrines regarding competency—which must therefore be reflected in the standard we adopt—is to protect the unconventional (our "autonomy interest"). Third, we must be mindful of the discovery of psychoanalysts, psychiatrists, and psychologists that irrationality in decision making is really quite pervasive: people misunderstand statistics, overvalue vivid memories, form somewhat distorted beliefs about their doctors as a result of transference, and so forth.[25] This requires us to question whether we want to find many more people incompetent than our current practices do—to encompass all of these people who are mildly irrational. If we do not make this normative choice, it requires us to be very careful not to find incompetent those who are mentally ill[26] but really suffering from no more irrationality in the relevant regard than many people. To do otherwise is to mistake the floridness of many of the patient's symptoms for sufficient decisional impairment and therefore to stigmatize the mentally ill unnecessarily (our "nondiscrimination interest").

These, it seems to me, are some of the normative parameters in terms of which we must measure a competency standard and its implementing instrument. Concretely, what this means is that we must justify which abilities we require for competency, as well as the level of these abilities which we require. Are these abilities, with this level of performance, really necessary, and if so why? Or are they nice, but inessential, much as speaking a foreign language with a good accent is inessential to basic communication? Even if we think them arguably important, do we trench too much on patient autonomy by requiring them? And if their absence or impairment is widespread, do we risk discrimination by applying them only to the mentally ill? In short, deciding on the abilities and levels are thoroughly normative endeavors.[27] The choices will be manifest in the kinds of abilities chosen; the skill level in the tests of those abilities chosen (e.g., the reading level in the UTD); and the level of performance required in order to be deemed competent.[28]

Can the MacArthur researchers avoid criticism of their instruments by claiming that they have not made normative choices—an argument they have made in the *Law, Psychology, and Public Policy* issue devoted to their research?[29] In my view, they cannot. It is true that they avowedly leave some choices open: how deficient must one be to be incompetent (vs. "impaired")? But they have also made certain other choices—and these choices must be justified. For instance, they do set a level at which "impairment" is found. In addition, in their discussion of the MacCAT-T (admittedly at a time after they invoked the shield of supposed normative-lessness), they suggest that a particular score should, whatever else we decide, definitely lead to a competency finding. Further, they suggest that we should probably adopt a variable competency standard depending on a cost-benefit judgment about the patient's choice.[30] These are not pure, value-free statistical questions, but rather normative choices.

Perhaps most important, the MacArthur researchers point out that the three main research instruments seem to be picking out different populations of patients, so that a treatment capacity instrument (their MacCAT-T) should aggregate the three measures. This judgment presupposes that all the skills measured by the three instruments are important to competency—something which is not at all obvious and needs to be justified.[31]

---

[25] See, e.g., Sigmund Freud, *The Psychopathology of Everyday Life* (1901) (standard ed., vol. VI, 1986); Jay Katz, *The Silent World of Doctor and Patient* (The Free Press, 1984); Daniel Kahneman, "New Challenges to the Rationality Assumption," *Journal of Institutional and Theoretical Economics* 150 (1994): 18; Donald A. Redelmeier, Paul Rozin, and Daniel Kahneman, "Understanding Patients' Decisions: Cognitive and Emotional Perspectives," *Journal of the American Medical Association* 270 (1993): 72; and Amos Tversky and Daniel Kahneman, "Rational Choice and the Framing of Decisions," *Journal of Business* 59 (1986): S251.

[26] Although "mental illness" is a contested term, I use the term here in roughly the same sense as it is used in *The Diagnostic and Statistic Manual of Mental Disorders, Fourth Edition* (American Psychiatric Association, 1994). I do not, in this work, address the many difficult issues that surround the notion of mental illness.

[27] In saying this I do not mean to suggest that choosing a competency standard is *completely* normative, just that it is *in large part* normative. Choosing such a standard also depends on empirical findings, such as what impairments lead to substandard decisions, what abilities people actually use when they are deciding, and how psychiatric impairments can impact decisional ability.

[28] There are other normative issues also raised by competency standards, for instance, in the research context, where other values (e.g., the progress of science) are involved. In addition, the question of whether we should adopt a sliding-scale competency approach cries out for further analysis. I discuss some of these issues below when we turn to the research context.

[29] See supra note 3. They have also discussed this issue in other publications, e.g., Berg, Appelbaum, and Grisso, *Constructing Competence*, supra note 3, 375–90. Here the authors discuss the kinds of normative issues that must be addressed to adopt a competence standard, conceding that their instruments do not address these issues.

[30] See, e.g., Berg, Appelbaum, and Grisso, *Constructing Competence*, supra note 3, 385–87; Grisso and Appelbaum, *Assessing Competence,* supra note 3, chapter 7.

[31] See, e.g., Berg, Appelbaum, and Grisso, supra note 3, 380–81. Indeed, the authors suggest that there are *empirical* grounds to aggregate the standards because they pick out different groups. Actually, however, it is a *normative* issue whether we should aggregate the standards given that they pick out different groups, depending on whether we think the capacities judged are important to competency.

Indeed, even by proposing the research instruments the MacArthur researchers make normative choices.[32] True, the instruments measure only "capacities," and not "competency." But why would one measure these particular capacities unless one thought them relevant (critical?) to competency? One could also measure foreign language skills, but no one would bother to measure these skills in a capacity instrument administered in one's own language that was designed to be significant for measuring treatment competency. Simply by selecting the abilities measured, and measuring them down from and up to certain levels, the MacArthur researchers are making normative choices. Once again, these choices must be justified.

(In addition, as a practical matter many future competency administerers may mistake the nature of certain of the instruments—thinking that "impairment" simply translates into "incompetency" or imagining that the standard given for "clearly competent" on the MacCAT-T should divide the competent from the incompetent. It would be interesting to try to judge how often these instruments are being used in current practice, and whether such mistakes are being made.)

The absence of normative justification is the most important flaw in the MacArthur instruments. (It is difficult to imagine leaving a harder task to the evaluator on the streets, so to speak.) Below, I evaluate the instruments by suggesting that they may strike the balance in the wrong place—without myself undertaking the sustained normative evaluation that would fully establish the point. I intend to do so in future work. Until that time, one might see my critique and proposals as the kind of critique and proposals one would make if one very much valued autonomy. Still, undertaking the appropriate normative justification is the biggest challenge facing future scholars.

Evaluating the MacArthur Instruments

Problems with the MacArthur Scheme

Although it is not clear until one reads through the questions in the instruments themselves, the UTD is what I have elsewhere called a "pure understanding" standard, while the POD is what I have elsewhere called a "naive understanding and belief standard."[33] By a pure understanding standard, I mean that what is assessed is whether the patient comprehends what the caregiver tells him without necessarily believing it,[34] while by an understanding and belief standard I mean that what is assessed is the adequacy of the beliefs the patient forms (such as standard is "naive" to the extent it rests on the notion that truth is easy to discern). The UTD looks, in particular, at pure understanding of general information about an illness and its treatment, while the POD looks at naive understanding and belief concerning the illness and the treatment that the patient applies to himself.

Why do I argue that the UTD measures pure understanding? First, the questions in the UTD ask the patient not to tell the evaluator what is the case, what she believes, or even what the evaluator believes; they ask, instead, only what the evaluator says. This suggests that the UTD is not measuring beliefs, even only fairly obvious beliefs such as what someone else purports to believe. Rather, it is measuring simply the ability to say back what has been said.

Second, the questions in the third part of the UTD ask whether a statement is the "same as or different from what has just been said." Once again, not belief but comprehension is being measured. Indeed, if the patient says that a proposed statement is "true," rather than "the same," he is corrected, because that is not what is being tested.

Third, the researchers distinguish between the UTD and the POD on the basis that the former identifies what the patient *knows* while the latter identifies what he *believes*. In at least one common philosophical tradition, knowing implies believing, and so is not something less than believing as suggested by the researchers here. Still, what the researchers seem to want to get at is clear—the difference between grasping some information and truly believing it. This is precisely the difference between abilities measured by the pure understanding and those measured by the understanding and belief standards

If I am correct in my assessment of what these MacArthur instruments are measuring, the next question becomes whether the precise distinction they draw makes sense, and the answer is that the distinction is problematic. The problem with the MacArthur schema is that it incorporates two distinctions—pure understanding vs. understanding and belief on the one hand, and general information vs. specific information on the other—in a way that does not cover the entire field. While it does cover pure understanding of general information and understanding and belief of specific information, it omits pure understanding of specific information and understanding and belief of general information. Put

---

[32] The researchers say that they have based their instruments on standards found in the courts. But the language the courts have used is most ambiguous and does not clearly lead to the investigator's selection of measures. For instance, some courts speak about the rationality of the patient's choice. See, e.g., *Osgood v. District of Columbia,* 567 F. Supp. 1026, 1031 (D.C. Cir. 1983); *In re* Mental Commitment of M.P., 500 N.E. 2d 216 (Ind. Ct. App. 1986); and *United States v. Charters*, 829 F. 2d 479, 496 (4th Cir, 1987). But is this meant to imply a judgment about the reasonableness of the outcome (the so-called "reasonable result standard")?; about the intactness of the patient's reasoning processes (e.g., what is measured by MacArthur's TRAT)?; or about the soundness of the beliefs underlying the patient's choice (e.g., what is measured by MacArthur's POD)? The language of the courts is simply very unclear in many instances. For a discussion of the lack of clarity of the courts' statements on this matter, see Elyn R. Saks, "Competency to Refuse Treatment," *North Carolina Law Review* 69 (1991): 945, 977–84. In addition to this problem, relying on the courts is no substitute for one's own normative analysis—and is itself a normative choice.

[33] For this distinction, see Elyn R. Saks, *Competency to Refuse Treatment*, supra note 32, 952–53, 955–56.

[34] Compare the difference between the sentence, "he understands the theory that the fittest survive"—which does not require that he believe it—with the sentence, "he understands that the fittest survive"—which does require that he believe it.

differently, only two of the four cells generated by these two distinctions is covered.

The problem is that pure understanding is relevant as to both general information and information as applied to the patient's situation; and adequate beliefs are important both as to the general information and the information as applied to the patient's particular situation. If this is so, the critical division should be between a standard requiring only comprehension and one requiring belief, and not between a standard involving understanding of general information and belief about information as applied to one's own case.

In my view, the best solution, then, is to preserve the distinction between pure understanding and understanding and belief standards, but discard the distinction between general information and information as applied to oneself; the latter distinction is a red herring. Otherwise, the instruments do not cover the entire field.

Evaluating Whether the General Capacities Picked Out by the MacArthur Instruments are Necessary to Competent Decision making

In my view, the capacities the MacArthur instruments treat as essential are necessary, but perhaps not sufficient, to adequate decision making; I discuss below whether the level of abilities the MacArthur instruments pick out is plausible.[35] I understand the essential abilities to be: pure comprehension of relevant information; the ability to assess evidence and form appropriate beliefs about that information; the ability to reason with that information; and the ability to evidence a choice. All of these abilities can be normatively justified as necessary for competent decision making.

Why is pure understanding required? Comprehension of relevant information is a sine qua non for a person's assessing that information as it bears on how the patient should decide. To see that a competency standard should require pure understanding, consider the following thought experiment. John is a captive faced with two contraptions between which he understands that he must decide, on pain of death. One of the contraptions will torture him and the other will grant his every wish. John cannot tell from looking at the contraptions what they will do, and he cannot understand his captors' explanation of them because it is in a foreign language.

It seems plausible to say that John is incompetent to decide between the two contraptions—with one reservation. We may want to reserve the term "incompetent" for people who are not simply ignorant. Although well-known philosophers have justified paternalism in the face of ignorance (recall, e.g., John Stuart Mill's broken bridge example), the law may prefer to reserve the term incompetent for those who lack abilities, perhaps as a function of their mental illness, and not simply knowledge. There may be practical reasons for doing this—e.g., we often do not know the truth, so we want assurances that the person is under some disability and so likelier to be self-deceived. These practical concerns may not speak to what we would do if we *could* always know the truth; perhaps in an ideal universe, all ignorance would amount to incompetency. Whatever we decide in the real world, surely most people would want, in our example above, to be disabled from deciding for themselves, and to have benign and knowledgeable others decide for them.[36]

Indeed, we do not need fanciful thought experiments to recognize the importance of pure understanding: imagine being asked to make any important decision the implications of which are described in a foreign language. One is simply not in a position to decide in that case. Pure understanding, then, is a prerequisite for competency.

Yet Pure Understanding, while necessary, is not sufficient. The ability to assess evidence and form appropriate beliefs is also necessary; MacArthur's inclusion of this ability in one of its capacity instruments makes eminent sense. Consider our example again. If the captive comprehends his captor's information, but does not credit it at all—say because he believes the captor is delusional—he is not even going to advert to the information in making his decision. Because making a decision in one's best interests requires assessing how those interests are likely to be affected, the patient must be able to form adequate beliefs in order to be a competent decision maker.

We can think of the matter yet another way. Decisions are based on desires[37] and beliefs; one desires x, and believes that y is the way to get x, and thus one decides to y. Believing y is the way to get x, in turn, requires other subsidiary beliefs. A deficiency in one's beliefs may therefore severely affect one's decisionmaking capacity. (How deficient is too deficient is, of course, another question—one which I shall address below.) One forms beliefs as a result of assessments of the evidence, so that the skill tapped here is the ability to assess evidence; and this skill is clearly needed in some degree or another for competency.

But pure understanding and the ability to assess evidence are also arguably not enough; one needs also to be able to reason with some degree of intactness. Reasoning allows one to put together the information one has purely understood and, having assessed, has formed beliefs about. Consider, at its simplest, the practical syllogism recited above. If one knows that one desires x and one believes that y is the way to get x (and say

[35] Thus, while the MacArthur instruments measure *capacities*, and not competency, they are clearly intended to aid in yielding judgments, after appropriate normative choices are made, about competency. As a result, it is perfectly appropriate, as I do here and in the next sections, to assess them in terms of whether they are useful or problematic as tools for measuring competency.

[36] The typical consequence of a finding of incompetence is that others are permitted to decide for one—either one's family, a guardian, the court, or one's doctors.

[37] One could also speak of "wants" or "preferences" here. Nothing of importance, in this context, turns on which term we use.

that not doing y will guarantee not getting x), and if one then concludes to not y on the basis of deficient reasoning,[38] one has clearly not made a competent choice to not y. Some level of reasoning ability is required. Thus the MacArthur instruments' inclusion of a measure of this makes sense.

Should evidencing a choice also be considered a necessary skill for making a competent choice? There are two possibilities here. If making a competent choice means (in part) expressing a choice, then the answer is obviously yes; so much is a tautology. If, on the other hand, making a competent choice can include going through intact decisionmaking processes without necessarily telling anyone what one has chosen, then the answer is obviously no. Take a person who is paralyzed and unable to communicate. He may very well decide, after careful consideration, that he would like some procedure done. Suppose that by any (other) measure we could formulate he would be deemed competent. Does his inability to say what he wants make him incompetent? If not, making a choice and showing one's choice are two different things.

Two views are possible, then—evidencing a choice is prima facie evidence of one's competency that triggers an inquiry or is actually itself necessary for one's competency-—and it is not important which view we choose, since in either case the ability must be assessed. Thus, the subtest in the MacArthur instruments measuring evidencing a choice seems justified.

While all the abilities the MacArthur instruments target are arguably necessary for competency, are there others they have omitted? For instance, practical syllogisms also refer to the person's desires; so perhaps one must be able to identify one's desires. Indeed, perhaps one must make a choice that is *true* to one's desires. More robustly (and relatedly), perhaps one must be oneself so that one can be true to oneself and one's values. Other noncognitive abilities should also arguably be required—for instance, that one not be under the sway of internal compulsion.[39]

The MacArthur instruments omit any mention of these abilities and, to the extent we think them important, the instruments are lacking. I myself have doubts at least about our ability to identify such deficits reliably—but it is clearly an open question whether we should want to try to test for them.

If the MacArthur instruments plausibly pick out abilities that any competent decision maker must have, at least formulated at a high level of abstraction, do they set the level of abilities required paying sufficient regard for the various other values involved in designing competency instruments? We now turn to that question, as well as to other questions about the specific instruments.

Assessing the Individual Instruments and the Balance Struck Among the Values Implicated by Competency Instruments

Assessment of the UTD

The UTD is a well-crafted instrument, with two qualifications. First, it seems that the UTD may handle, in the wrong way, information relevant to the patient's decision which he acquired apart from the disclosure. The patient receives no points if she mentions even real symptoms that were not part of the current disclosure. Second, the UTD may both overmeasure and undermeasure pure understanding.

The UTD's treatment of extra-disclosure information makes sense up to a point. We arguably want the patient to listen to and understand what he has been told. If he cannot do this, he cannot assimilate (and eventually assess) information which we believe to be relevant to his decision.

On the other hand, proper respect for unconventionality might counsel us to allow the patient completely to diverge from what he has just been told, provided he recites true information. Patients may get just as good information—or better information for their situation—from other sources. They should arguably be entitled to choose what information is important to them, and they clearly purely understand that information.

Indeed, the patient may have *better* information relevant to his decision than that which the researcher has given him. What may be most salient about schizophrenia to *him*, for instance, may not be the voices mentioned in the disclosure, but the disorganization of his thinking process. So *that* is what he recites as a symptom of schizophrenia.

On this view, then, patients do seem to have the requisite ability stated at a high enough level of generality. Indeed, requiring them to understand the particular information disclosed may not be necessary for them to be able to make decisions; it may not disserve our interest in protecting the vulnerable to fail to so require. It takes choice away from patients to require them to purely understand just certain information, thus disserving our autonomy interest.

In fact, it may be the case that the UTD requires a specificity of information that is not necessary if a patient is to be capable of decision making.[40] It is arguable that all a patient needs to

---

[38] I mean to indicate by "deficient reasoning" the faulty syllogism itself—"if I y, I can get x, I want x, therefore I will not y."

[39] A number of commentators have addressed the need for such abilities. See, e.g., President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions* (1982); Ruth Macklin, "Treatment Refusals: Autonomy, Paternalism, and the 'Best Interests' of the Patient," in D. Pfaff (ed.). *Ethical Questions in Brain and Behavior* (1983); Paulo, Bursztajn, and Gutheil, "Christian Science and Competence to Make Treatment Choices: Clinical Challenges in Assessing Values," *International Journal of Law and Psychiatry* 10 (1987): 395. I myself am skeptical about incorporating them in an incompetency standard. See Elyn R. Saks, "Competency to Refuse Psychotropic Medication: Three Alternatives to the Law's Cognitive Standard," *University of Miami Law Review* 47 (1993): 689.

[40] I am now suggesting not just that it requires patients to understand *this specific information* as opposed to that, but *specific information* as opposed to *general*.

understand to make a treatment decision is that, as a result of mental illnesses, people feel distress and suffer certain disabilities; that there are treatments such as medication for the illness; and that the medication can help people with the distress and/or disability but might have some unpleasant consequences of its own.[41] Patients must have a "ballpark" sense of the seriousness of the condition described, as well as the risks and benefits of the treatment; but perhaps ballpark generalities are enough.

Even if we wish for patients to understand only what they have just heard, patients may not understand well enough that they are to repeat just that. They may have heard "there are symptoms of schizophrenia, including x, y, and z," and appended in their mind some others they know only too well. They may think that what is important to understand is that there are unpleasant happenings associated with schizophrenia, and not the particular ones the researcher has mentioned.

So, at the very least, subjects should be instructed that it is necessary to mention all of the items on the list and only those items. Those who nevertheless give "extra-disclosure" information should be warned that this is not the information wanted. Subjects may still recite extra-disclosure information—they may have source amnesia, as it were—while understanding both in-disclosure and extra-disclosure information perfectly well; but we may want to be sure patients understand the disclosed information, and so we should arguably not be overly concerned with false positives.

There remains another more serious problem with the UTD: it may overmeasure and undermeasure pure understanding.[42] To do well on the UTD, one must be able to attend, process, record, retain, and recite back the information provided. Being able to attend and process information are clearly important for (pure) understanding. But being able to record, retain, and recite back are not necessarily so. Thus the UTD may measure abilities not essential to pure understanding.

Conversely, a person who is able to recite back—which is all the UTD arguably asks a person to do—may not have (purely) understood anything he has heard. A parrot can recite phrases back with no understanding at all. One suggested modification of the UTD?—in the section asking whether a statement is the same as one made in the disclosure, use sufficient numbers of statements that are equivalent in meaning but use completely different words.[43] (Of course there may be people who understood the original information but not the equivalent statements; but no measure can be perfect.)

The UTD, then, is an impressive instrument: it does a good job spelling out the items of information, for the three relevant diagnoses, that patients ought to understand; it explains this information with a simple enough vocabulary that most people should be able to understand it; and it tests understanding of these items of information in several different ways, thus allowing patients full scope to demonstrate what they have learned in the best way they can. On the other hand, the UTD has some problems. It may set the level required for being unimpaired too high by requiring disclosed rather than extra-disclosure information or information at a higher level of generality. In addition, it may not require enough in the way of understanding inasmuch as it tests essentially recall and repeating ability rather than understanding. Finally, difficulties remembering may not disable someone from making an adequate decision, provided he remembers enough at the moment of decision to process all the relevant information. Despite these difficulties, the UTD has many virtues.

Assessment of the TRAT

Requiring highly developed reasoning ability—e.g., knowledge of all the rules of logic, absence of any strong emotions influencing a decision, etc.—is problematic for a number of reasons, and we shall have to assess whether the TRAT does so.

First, it is unclear that pure or pristine reasoning plays an essential role in all effective decision making; intuitive, idiosyncratic processes actually may improve decision making in some cases. (Consider cases in which people dream of solutions to difficult mathematical problems.) Thus, fully intact reasoning may not be necessary for adequate decision making (recall our example of the good accent). Concerns about protecting the vulnerable, then, may not be implicated. Moreover, what qualities of reasoning are "good" may be open to dispute, so that to require some particular form of reasoning may be to discriminate against unconventionality.

Perhaps most important, even generally effective decision makers who clearly have the ability to form accurate beliefs misuse statistics, misunderstand probabilities, and accord undue weight to vivid examples. They also may be affected profoundly by irrational and unconscious factors. Thus, unless we are to declare most people incompetent, to so declare only the mentally ill who exhibit these deficiencies amounts to prejudicial discrimination.

Requiring some reasoning ability, on the other hand, seems to make sense, as I argued above: if one does not know how to put

---

41 I am not suggesting, of course, that doctors be required to make disclosures about the patient's illness and its treatment at such a high level of generality in an actual informed consent process—just that patients need to take in no more.

42 Indeed, it bears noting that all of the MacArthur measures may be overrating incompetence to the extent that low scores may reflect things other than incapacity—e.g., motivational/compliance problems, cultural issues around openness to one's doctor, and articulateness, to mention a few.

43 As written now, the sentences that are not "the same as" those given are in different language, but the sentences that are "the same" are in very closely similar language. Someone who didn't understand the meaning of the sentences could get a high score simply by saying "different" when none of the same language was used. For some examples of these sentences in the case of schizophrenia, e.g., *UTD Manual,* supra note 4, 30–33.

together the information one has understood, so to speak, one will not be able to reach the right conclusion. The question is how much reasoning ability should be required. Does the TRAT set the right level?

In one way, the TRAT does seem to require the presence of fairly basic abilities. For instance, in testing the understanding of probabilities, it requires only the understanding of a grossly obvious inference. One problem with the TRAT, on the other hand, may be that it does not justify requiring all of these abilities it tests for—or rather, giving better scores the more abilities there are in evidence. A particular decision, for instance, may involve only two alternatives; what, then, is the relevance of (say) transitive thinking, or of complex versus comparative thinking in that case? More important, a patient might not engage in many of these cognitive functions because, for her, one consideration is decisive; she may (say) so disvalue a risk of one of the alternatives that thinking consequentially is all she needs to do to choose between two alternatives—particularly since she may trust her doctor not to propose otherwise horrendous alternatives.

On the other hand, it may be that evidencing all the TRAT abilities puts one in a better position to decide by giving one more options. If one asks for further information, for example, of if one considers unstated consequences of the choices, one may be in a better position to decide. The question is whether this added strength of one's decisionmaking process is really necessary to competent decision making.

Another problem with the TRAT may be its requirement that one evidence all of these other functions; they may be occurring at an implicit level. For instance, a patient who says I want x and not y because I am terribly frightened of the significant seizure risk carried by y—my dad died in a car accident when I was three as a result of a seizure—will often have gauged that x does not carry such a seizure risk (or anything equally abhorrent to the patient). If she has not done so, her decision making is arguably deficient. But she may well have done so and may simply not *say the words* "and I have compared x to y and x does not have any such abhorrent consequences to me."

If this is right, there is at least a problem with the TRAT, i.e., that it is difficult to test for the different functions. Perhaps instead of simply asking for reasons, the patient, once having given a reason, should be asked *directly* if he compared y to x and, if so, what in the comparison led to his choice? On the other hand, this approach may be too leading. I leave to psychometricians the task of arriving at effective, nonleading ways of eliciting this information.[44]

In short, the TRAT does an impressive job in identifying reasoning abilities, arguably necessary for competency, and testing for them in a reasonable way. It nevertheless suffers from two problems. First, it may sometimes require abilities that do not really add, in a given case, to the patient's decisionmaking process. Second, it may underestimate how often those cognitive processes are actually occurring, while the patient is simply not saying the magic words. Nevertheless, the TRAT remains an impressive instrument for the reasons given above.[45]

Assessment of the POD

The POD, as will be recalled, measures a patient's appreciation of her or his illness as well as of the potential benefits of treatment. The ability it taps is the ability to assess evidence; and so the quality of the patient's beliefs is at issue. While an ability to assess evidence is important, the POD requires too high a level of that ability—and too high a level in a context when we sometimes cannot even decide what a high level is. In my view, the POD is seriously flawed and needs to be radically revised.

Deciding what beliefs a patient must have to be deemed competent is fraught with danger. Since decisions take effect in the world, we want the patient to come to accurate beliefs about the world. The problem is that it is—more often than we like to think—an open question what is true; very few beliefs are completely indisputable. This means that requiring particular beliefs may not further our interest in protecting the vulnerable; if the beliefs we require are wrong, we are not putting the patient in a better position to decide. We should not say the patient is incompetent—indeed, if most of us are wrong, the patient may in fact be super competent.

Perhaps, more important, freedom includes freedom to decide what is true no less than what is good. If we require particular beliefs, we prevent the patient from pursuing the truth according to her or his own lights. There may be some limits on what patients can believe. But too stringent limits severely curtail patients' freedom to be unconventional in their pursuit of truth. And once again, patients may turn out to be right.

In addition, we must be mindful of the fact that many people have distorted beliefs and make decisions on the basis of those beliefs. Unless we want to call many, if not most, people incompetent, we are discriminating against the mentally ill if we disable them on the basis of many of their distortions.

There is a range in the kinds of beliefs we can require or proscribe. The POD is at the far end of the range: patients must, essentially, believe what their doctors believe about their illness

---

[44] The issue raises the same kinds of value questions we have seen earlier: not asking may underestimate competence while asking, inasmuch as it is leading, may overestimate it. Which kind of error we fear most—abrogating autonomy unnecessarily or failing to protect—will determine our choice of test.

[45] A submeasure on the TRAT looks at whether the patient meets an "evidencing a choice" standard. I quarrel with this measure's marking the patient down for only unequivocally making a choice on a second inquiry. Cannot people take time to make up their minds?

and treatment. This cannot be a correct standard. Given the many contested things in our society, an individual doctor cannot be held out as the final authority on truth. What would become of second opinions if doctors were?

Let us look at the submeasures of the POD in a little more detail. The NOD (Non-Acknowledgment of Disorder) measures appreciation of one's illness. One receives a full score if one accepts the diagnosis one's doctor has given one; judges one's illness as severe as a particular measure of symptom severity does; and accepts the symptoms reported in one's chart.

The first two are problematic. One's doctor may be wrong about one's diagnosis. To put this in a more technical way, the NOD is limited by the reliability and validity of psychiatric diagnosis. In fact, doctors disagree quite often about a particular patient's diagnosis. They often disagree about the category of illness (e.g., psychotic disorder vs. mood disorder vs. personality disorder). They sometimes disagree about whether a patient even has a significant illness.

A single individual cannot be made the final authority on truth.[46] Indeed, the patient may be quite willing to believe an earlier doctor's diagnosis or even that he is seriously ill; but if he disagrees with this particular diagnosis, he is counted impaired on this measure of the NOD.[47]

The second measure of the NOD asks whether the patient rates his symptoms as severe as the Brief Psychiatric Rating Scale does. This measure also makes little sense. First, the patient may be the most important judge of how severely ill he *feels*. Second, even if the question is how severe his illness is on some common metric, how shall we expect patients to know that metric? This is a comparative judgment which patients are not in a good position to make. A result that diverges from the scale is not a profound distortion of reality. Finally, as with the first measure of the NOD, this measure is limited to the extent that the severity ratings of the Brief Psychiatric Rating Scale are not highly reliable and valid.

The third measure of the NOD is more acceptable. It asks whether patients acknowledge the presence of symptoms mentioned in their chart. Many of these symptoms will be grossly demonstrable. If a patient denies that he has just been frenetically pacing, or hasn't slept in days, he is severely distorting reality. Some symptoms, of course, involve more interpretation. Is the patient agitated? Maybe not for him. Other symptoms essentially duplicate the illness question; patients cannot deny they are ill and admit to hallucinations and delusions, so-called, although they can admit they are seeing, hearing, and believing things that others do not. Framing the question in terms of whether patients are experiencing "delusions" or "hallucinations" should therefore be off limits.[48]

The NOT (Non-Acknowledgment of Treatment Potential), which measures acknowledgment of treatment potential, is also problematic. The NOT requires one to accept a good prognosis with treatment if it exists; a good prognosis in particular with medication if it exists; and a worse prognosis without treatment. As will be recalled, if the patient has reasonable grounds to disagree with the doctor's judgment, a hypothesis nullifying his premise is presented and he is asked again his beliefs. ("Imagine that a doctor tells you there is a medication that has been shown in research to help 90 percent of people with your problem, *even people who had not gotten better with any other medication*."[49])

The NOT is problematic once again because the doctors may simply be wrong about one's particular likelihood of benefiting from treatment and declining without it. For instance, some patients may become demoralized and depressed at the need to take medication and essentially stop trying, just as some may regress in hospitals and never want to leave. It may be indisputable how patients on average do with and without a particular treatment. But averages don't speak to this particular patient, and he may be *right* that he will be in the 10 percent that do not respond to a particular treatment.[50]

Because no one can predict the future with complete confidence, it is problematic to require patients to form beliefs about a particular outcome they will experience in the future. Asking patients to understand what happens generally may make sense; asking them to believe that the general rule will apply to them does not have.

To look at this in another way, in essence the NOT measures optimism and pessimism. Many people are unduly optimistic or pessimistic about many things. Thus, in addition to requiring patients to believe things that may be false, and taking away their right to decide about truth as they will, the NOT requires patients (generally mentally ill people) to mani-

---

[46] I do not deny that doctors recognize that a differential diagnosis is based on uncertainty. But this recognition is not reflected in the POD, which simply assumes that the doctor's diagnosis is the measure of truth against which the patient's beliefs are to be assessed. If the patient disagrees with his doctor, then he is deemed "impaired" on the POD. The doctor's diagnosis is the "gold standard," and the patient's beliefs are only adequate for purposes of this measure of capacity if they agree with the doctor's beliefs.

[47] Unlike the research instruments, the MacCAT-T asks evaluators to assess the patient's reason for his denial; and the kind of reason given in the text would result in a full score. It remains the case that the research instruments are counting some people impaired who are arguably not in the least impaired. In addition, as we will discuss below, many of the reasons for denial, which I think should result in a nonimpaired finding, are counted as substantially diminishing capacity on the MacCAT-T.

[48] I also argue elsewhere that belief in a serious delusion distorts reality in a way that belief that it is *not* a delusion—is not a product of mental illness—does not. See Elyn R. Saks, *Competency to Refuse Treatment*, supra note 32, 991.

[49] *POD Manual*, supra note 5, 54.

[50] In the MacCAT-T, supra note 10, the MacArthur researchers allow a patient to get a full score if he says he expects to be in the bottom 10 percent because previous treatments have failed for him. But the patient may also have his own reasons—maybe even superstitious ones—for thinking that treatment will fail now and he will be in the bottom ten percent. Once again, he may be right—and many people are pessimistic about treatment (see below).

fest a trait—optimism or pessimism as the case may be—that many people do not.[51]

I have noted that there is a range in the kinds of beliefs we can require. At the far end is the naive view incorporated in the POD that we can require the patient to believe essentially what the doctor believes. This view is problematic, it seems to me, for all the reasons given above. At perhaps the other end of the range is the view that patients can believe anything but beliefs impossible in the nature of things. But quite apart from the fact that some philosophers will tell you that virtually anything, technically, is possible,[52] this view probably allows beliefs that are such a serious distortion of reality that we should not allow them. They are most probably wrong and are not widespread, so that ruling them out does not unduly infringe the right to be unconventional.

Within these extremes other standards are possible. Perhaps patients must believe what most doctors would believe about them. Or, so as to accommodate people who do not buy into the medical model,[53] perhaps they must believe what most *people* would believe. Or should it be "most rational or most reasonable people"? On the other hand, is this not just requiring patients to conform to norms? Perhaps we should try—if this is even possible—to characterize the standard in a way that does not refer essentially to majorities.

To my own way of thinking, we want a standard somewhere above a standard that proscribes only impossible beliefs and below a standard that makes doctors the final authorities on truth—somewhere, in other words, in the middle: patients cannot hold beliefs that obviously distort reality/are based on little evidence/are indisputably false/are patently delusional—we can choose the precise locution we wish. Perhaps referring to what most people would believe is the way to get at this; there may be others. The reader will recognize that I have evaluated the POD according to a kind of "patent distortion of reality" standard; I undertake to justify such a standard elsewhere.[54]

I want to conclude, however, by suggesting an idea that may be somewhat radical: that, according to such a standard, denial of mental illness often does not disqualify one from competency.[55] I hasten to add that I have no doubts whatsoever myself about the reality of mental illness and the severe suffering it causes. I subscribe completely to the medical model.[56] On the other hand, denying that one is mentally ill may have characteristics that should lead us to say that it should generally not go toward a finding of incompetency.

Let us consider why. First, a person denying he is mentally ill may simply not be willing to admit to something that is stigmatizing and carries negative consequences in our society. He may be frankly lying about what he thinks, or may be conflicted about what to think for these completely understandable reasons. In either case, a person trying to avoid the negative consequences of a mental illness diagnosis may be thought to be acting quite rationally in our society—and far from incompetently.

Second, even if the person cannot admit, even to himself, that he is mentally ill, he may be acting on the basis of a common, understandable, and often quite adaptive defense. Denial of difficult things is quite common. And so one might through denial be attempting to avoid the narcissistic injury of having a mental illness. People identify with—and accept ownership of—the contents of their mind; it is hard to believe that such an intimate part of oneself is diseased.

Denial is also understandable in a way that other primitive defenses may not be. People can perhaps understand another person's saying that she just can't fully believe that her daughter has died or that she herself has cancer; they do not in the same way understand a person's saying he just can't help believing that someone put a transistor in his brain.

In addition, denial can be very adaptive. There is evidence that seriously physically ill people live longer if they deny the seriousness of their illness.[57] And there are other less striking examples of the same kind of beneficial effects from denial. A person denying he is mentally ill might draw on resources he would be too discouraged to use if he admitted his illness.

Third, mental illness diagnoses are simply less certain than many, if not most, physical illness diagnoses. Unlike physical illnesses, where there can often be definitive physical findings that unequivocally establish the diagnosis, there are no physical tests for any nonorganic mental illness.[58]

---

[51] There are three additional measures on the POD that are equally problematic (although they do not contribute to the patient's score at present): the patient must acknowledge the side effects of the medication (maybe they don't and won't affect her); the patient must think her treaters have the benign motive of helping them (does it patently distort reality to believe that some do it for the money or prestige?); and the patient must acknowledge the need for hospital treatment (her doctor may be wrong—the patient may be one of the ones who regress in the hospital and one of the ones who rise to the demands of treatment in the community).

[52] Consider that skeptical philosophers doubt even the existence of the physical world as we know it. In my claim in the text I exclude, of course, logical truths.

[53] By the "medical model" I mean the views subscribed to by the medical profession on matters of health, illness, and treatment.

[54] This is the standard I propose in *Competency to Refuse Treatment*, supra note 32. I intend to explore this standard further in future work.

[55] I discuss this also in *Competency to Refuse Treatment*, supra note 32, 98–92, although my view since then has been tempered somewhat, see below.

[56] In this context, I mean by the "medical model" the model according to which mental illnesses are genuine illnesses, as much so as any physical illnesses, and therefore respond to treatments of various kinds. Mental illnesses are not simply "problems in living" or anything else that an anti-psychiatry person might say they are.

[57] See Saks, *Competency to Refuse Treatment*, supra note 32, 990, for some sources supporting this claim.

[58] To the extent that organic mental illnesses can be established by physical tests, patients should arguably have to accept them. This is one context, then, in which the analysis for, say, demented patients may be very different than the analysis for, say, schizophrenia.

It is interesting to speculate about what would become of this argument if a gene were discovered that was responsible for, or correlated with, mental illness. If this were the sort of gene that always resulted in the illness, and if the gene could be identified in a person by genetic tests, then that would offer an incontrovertible test for the presence of the mental illness, and what used to be called "functional illnesses," in this case, would be on the same footing as many organic mental illnesses are today.

Thus, even when there is considerable consensus among physicians about a particular person's diagnosis, it is *possible*, though perhaps not likely, that the consensus is mistaken. Consider seizures prior to the advent of EEGs; or lumps in the breast prior to the advent of biopsies. Physicians could have reasonable bases for diagnosing epilepsy or cancer; but they could always be wrong. In the case of the seizures, an EEG could establish, with some reliability, that there were no electrical charges firing and that hysterical seizures were the more likely diagnosis. Prior to EEGs, that judgment was much less certain.

In the same way, a person presenting with the symptoms of a psychotic disorder might not actually have a psychotic disorder; she might instead have what used to be called a "hysterical psychosis" or what might be called today a "factitious disorder with psychological symptoms." Alternatively, she could have a less serious diagnosis, such as obsessive-compulsive disorder with bizarre obsessional thoughts that she does not quite credit and that therefore should not be called delusions. Or perhaps she is frankly malingering for some reason we have not discerned. Even such serious disorders as schizophrenia are thought by many to be a collection of different conditions; and sometimes what looks like schizophrenia may not be an illness at all—or at least the illness doctors thought it was.

Thus, while psychiatrists may have reasons for preferring to say a person has a psychotic disorder, they can always be wrong. In the same way, physical illnesses, without clear physical findings, cannot be as certainly diagnosed as those with clear physical findings. A diagnosis of Gulf War syndrome, chronic fatigue syndrome, Epstein Barr virus, soft tissue damage, irritable bowel syndrome, even Crohn's disease, cannot be made as certainly as, say, a diagnosis of cancer.[59]

The point I am making is epistemological, not ontological. Again, I have no doubts about the reality of mental illness. In the same way, to say that we cannot definitively prove someone has soft tissue damage is not to deny that there is such an illness as soft tissue damage or that it can cause considerable pain and disability. The two issues are different.

Now the reader may object that I have established only that someone's belief that she is not mentally ill is not *impossible*, not that it does not patently distort reality. Some diagnoses of mental illness are simply pretty obviously true—the person has recurrent episodes, responds well to treatment, etc. But denial of mental illness may still often not patently distort reality because, coupled with the fact that the belief is not impossible, why the patient believes as she does given her evidence may be completely understandable. People often have a hard time accepting a mental illness diagnosis because they have felt the way they are feeling for a long time—the illness has come on so gradually or feels so appropriate to their current surroundings, that it feels a *part* of them. Why are they suddenly mentally ill? In addition, people often accept far more responsibility for their thoughts, feelings, and actions than they arguably should, so a patient may feel she has *chosen* to be the way she is. Her thoughts, feelings, and behaviors are not an illness, but a *choice*. (Compare the reasons people give for their behaviors that are clearly a response to posthypnotic suggestion.) In short, when a belief is possible, and when the belief does not wildly depart from the evidence the patient has, we should not deem the patient patently delusional.

Fourth, many members of society are skeptical about mental illness—or at least about whether particular behavior patterns or symptom constellations amount to an illness.[60] They may think that mental illness is a failure of will or consists of problems in living or is motivated by a desire to be cared for. They may attribute symptoms to stress and believe that the best response is coping with or avoiding the stress.

Many of these beliefs are not what we would call "enlightened." Some amount to frank prejudice, or are at least based on ignorance. But my point is that if these beliefs are not all that uncommon, then a particular patient's believing them does not represent a gross departure from ordinary ways of thinking. Once again, we don't want to single out only the mentally ill who hold certain beliefs when these beliefs are relatively widespread in society at large. In addition, that many people think this way is further reason to hold that the patient's belief in this nonimpossible belief is reasonable given his evidence and understandings of the world.

Fifth, I have suggested that it does represent a patent distortion of reality to deny that one is suffering from grossly demonstrable symptoms. But the patient who can admit that she or he is agitated, pacing, scared, or whatever, has every reason to accept treatment doctors say will help those symptoms abate. It is not clear that we need to make the patient admit to the illness; it is almost forcing a humiliation on the patient to do so. In the same way, a patient who admits to abdominal pain and all the symptoms of Crohn's disease, and understands that her or his doctor can recommend treatments that will help, need not admit to the disease to be in an adequate position to decide.

---

[59] It is worth mentioning that with any physical illness there are issues that may adversely affect our certainty about the diagnosis. How reliable is the test for the illness? Could anything have gone awry between the test and its interpretation (the "wrong blood" problem, if you will)? Even if the test is reliable, how valid is it in identifying symptoms? And how certain is it that these physical findings mean there is an illness? Cannot the patient admit that she has these physical signs, but deny that they amount to an illness—just deviant physical findings? Nevertheless, there are at least some tests for some illnesses that are extremely reliable and valid. In addition, it may be the right response here, too, that so long as one admits the symptoms, one doesn't have to take the next step and admit the illness. See below.

[60] The same is true of all physical illnesses; Christian Scientists don't subscribe to a medical model for any of them. Yet we would not say that denial of a frank cancer is not a serious problem. But I suggest that beliefs like these about mental illness are much more common than beliefs about physical illness. There just are not that many Christian Scientists.

Another point to bear in mind is that even certain doctors and psychologists have similar views about mental illness; Szasz, for instance, denies that any nonorganic mental illness is real. It would be surprising to discover an oncologist similarly denying the existence of cancer.

Perhaps, however, we should require more; patients need to accept not only that they are pacing, say, but that they have *some* condition, even if it is not the condition their doctors say they have. Or should we require patients to admit they have some condition that looks like schizophrenia and that most doctors would so diagnose and that is thought antecedently to be as likely to benefit from treatment as any other similar presentation. These claims are fairly indisputable in many cases—we don't need a physiological test to establish them. Thus, while a patient may not trust the individual doctor telling him about his diagnosis, he can and should trust the *DSM-IV*. In addition, these claims may be a necessary added ingredient before some will consent to treatment. I think it is a close call whether we require these additional beliefs or whether simply admitting to one's symptoms and one's doctor's belief in potential benefit of treatment is enough. An intermediate position would be to require patients to admit, simply, that "something's wrong."

All of this said, there are at least two tacks one could take: first, one could simply exclude most denial as a basis for an incompetency finding.[61] Alternatively, one could probe the denial further to see if the patient's reasoning is such that one can understand—see as somewhat reasonable—his denial. Perhaps he is not speaking honestly. Perhaps he is narcissistically wounded but, in his heart of hearts, knows the truth. Perhaps he thinks of his behaviors as his choice. Perhaps he holds widely held views about mental illness that lead him to think he is not really ill. In short, one would probe to see whether a given case of denial should be thought to amount to a patent distortion of reality. The implicit assumption is that if a belief is not impossible, then one must consider how plausible it is—and whether it is an understandable or common belief—to see whether the belief patently distorts reality.

One final point about denial: allowing denial to be a basis for an incompetency finding—and thus forced treatment—is in fact fraught with danger. Not only would it permit us to force treatment on an obsessive-compulsive person who denies that he is ill—and who among us is free of maladaptive personality traits?—but it would also allow us to characterize political dissidents as ill, and then to use their understandable denial that they are ill as a basis for their involuntary treatment, despite the fact that their denial is to be expected.

In addition to this central problem of treating denial in the wrong way, the POD may also, at times, *understate* the presence of incompetency by focusing too exclusively on disavowal of what one's doctor believes and not enough on the degree of distortion which the belief represents. Take the patient who admits he has the diagnosis his doctor says he has and agrees with his prognosis with and without treatment. This person would receive a full score on the POD. But suppose he also believes that he has the diagnosis his doctor says he has because aliens are manipulating his neurotransmitters from afar; and that taking the medication will enrage the aliens and cause them to destroy the earth—even though he thinks it will cure his illness. Again, this person would receive a full score on the POD. But is he really competent to refuse treatment? Do we not want to look for patently false beliefs and not just disagreement with what one's doctor says?

The POD, then, is a fundamentally flawed instrument. It naively requires patients to believe what their doctors believe, even though doctors-—certainly individually but maybe even collectively—can be wrong. It may also, at times, not only overstate but also understate the presence of incompetency by overlooking patently false beliefs that affect the patient's decision but do not involve denial. The POD should therefore be changed in one of two ways.

One way—pending normative argument for the appropriate level of impairment in assessing evidence—would be to design an instrument with different levels of the adequacy of one's belief. For instance, one could look at whether the patient denies what his doctor says; what most doctors would say; what most reasonable people would say; what is patently true; and what must be true. Future scholars would then establish which level of each belief to require. Another way is to tentatively adopt a particular level that one thinks is plausible. I myself think a level somewhere in the middle—a patently false belief standard, however characterized, looks likely to be correct. I intend to try to justify this level normatively in future work. In addition to either of these recommendations, one would want a method to probe the patient's reasons for her beliefs, so as to ferret out misconceptions at whatever level they may occur.

Assessment of the MacCAT-T

The MacCAT-T, as discussed earlier, is a streamlined version of the three research instruments described above. Therefore, many of the observations regarding the instruments described above also apply to the MacCAT-T. The MacCAT-T's "appreciation" component does try to acknowledge the difference between nonagreement that is nondelusional and has some reasonable explanation and nonagreement that is "based on a delusional premise or some other belief that seriously distorts reality and does not have a reasonable basis in the patient's cultural or religious background." But this effort is not entirely successful, inasmuch as the range of "reasonable explanations" given is quite narrow and, once again, only culturally or religiously sanctioned beliefs—conventional beliefs in that sense—are permitted to ground "reasonable" disagreements. Indeed, the MacCAT-T scores as "0" a patient's belief that his symptoms are related to circumstances other than a psychiatric disorder, such as stress or overwork. But the patient may be *right* or—

[61] The exception would be denial based on patently distorted beliefs, e.g., "little men in the sky are causing me to suffer to save the world."

given widespread beliefs in our society about psychological distress—is at least holding a *nonpatently* false belief.

The MacArthur Instruments Authors' Response to Similar Critiques of Their View

A 1996 symposium issue of *Psychology, Public Policy, and Law*, devoted to the MacArthur Treatment Capacity research instruments, contains a number of articles critiquing the POD on the basis of my work; Christopher Slobogin[62] does so in the most sustained way, but Susan Stefan[63] and Trudi Kirk and Donald Bersoff[64] critique the instrument on similar grounds as well.

The authors' response to the basic critique is severalfold.[65] First, they note that the critics all seem to want *some* measure of appreciation of illness and treatment to be included in a competency instrument, even if they object to the precise measure used. Second, they suggest that they may well not be all that far apart from the critics in the measure they want: they acknowledge that mere nonacknowledgment of one's disorder or of the realistic consequences of treatment is not enough to constitute incapacity, but the acknowledgment must be related to delusional thinking or other medical or psychological conditions that are responsible for a serious distortion of reality. They add that they accept the concept of a "patently false belief," provided it is not restricted to delusions but may also include nondelusional reasons for denying the existence of one's disorder, such as parietal lobe damage and intolerable anxiety related to recognition of the disorder. Third, they acknowledge that their *instrument* does not formulate a criterion for patently false beliefs, and suggest that it was difficult for them to operationalize this concept; they invite others to try. Finally, they note that the MacCAT-T requires clinicians to make a judgment about patients' reasons for denial of their symptoms in order to rate their appreciation. The requirement represents an effort to include the patently false belief component in the capacity standard; the authors thought it possible to do so only by relying on clinical judgment, at the cost of sacrificing some psychometric reliability.

The authors' response is helpful—and points to some recognition of the concerns that animate my argument—but is not completely satisfactory. Their first point is well taken: everyone weighing in on this issue does, and everyone should, care about beliefs the decision maker forms; they are simply extremely important to competency.

But I take issue with their second point—that their view is at all close to mine. They say they *want* to pick out only beliefs that seriously distort reality—which is important. But while I agree that there may be a variety of reasons for serious distortions of reality, such as anxiety or dissociation (although if the distortions are serious, don't they necessarily *amount* to delusions?), part of my point in discussing denial of illness has been that denial, at least of *mental* illness, is often *not* a sufficient distortion of reality to help justify a finding of incompetency.

The third point the authors make is that, although they approve of some notion like a "patently false belief" to help measure competency, they found it very difficult to operationalize such a notion, and therefore did not include it in their research instruments. They invite others to try to formulate a workable concept. It would be tempting to say that this notion would be fairly easy to apply; but given the authors' misunderstanding of what the terms mean in the case of denial of illness and treatment efficacy, that claim is rather hard to make. In any case, in future work I intend to undertake to operationalize this concept in collaboration with others skilled in test design.

Finally, the authors note that the MacCAT-T attempts to introduce the notion of a patently false belief by requiring examiners to assess the reasons for patients' denial. This is a step in the right direction, and I am pleased that the authors see a need to introduce such a concept. Given this approach, the most obviously well-reasoned bases for disagreement with one's doctor would not result in a finding of incapacity, as they currently do according to the POD. On the other hand, the reasons that the researchers *would* allow to justify disavowals are much more limited than makes sense; their exclusion for cultural and religious bases of distorted beliefs is also too narrow and they count beliefs that I would find acceptable as the most serious disavowals.

In short, the MacArthur researchers have not adequately answered some of the same types of criticisms leveled elsewhere, although they make a good faith effort to do so.

Concluding Evaluative Comments About the MacArthur Instruments

The MacArthur instruments identify the abilities necessary for competency, thus enabling us to protect the vulnerable; but they set the level of those abilities too high. The central failing of the instruments is insufficient attention to the need to protect unconventional behavior and to the pervasiveness of minor decisional impairment throughout the population as a whole.

The instrument designers recognize that competency issues involve normative judgments that balance freedom of choice and protection of the vulnerable. But they fail to recognize that

---

62 See Christopher Slobogin, "Appreciation" as a Measure of Competency: Some Thoughts About the MacArthur Group's Approach," *Psychology, Public Policy, and Law* 2 (1996): 18.

63 See Susan Stefan, "Race, Competence Testing, and Disability Law: A Review of the MacArthur Competence Research," *Psychology, Public Policy, and Law* 2 (1996): 31.

64 See Trudi Kirk and 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," *Psychology, Public Policy, and Law* 2 (1996): 45.

65 For the authors' response, see Thomas Grisso and Paul S. Appelbaum, *The Values and Limits of the MacArthur Treatment Competence Study*, supra note 23.

freedom of choice includes not only freedom to choose treatment (or no treatment) but also freedom to choose what skills to use in *deciding* about treatment. Most important, patients, within broad limits, should be given their choice of what to believe, no less than what to decide.[66] The patient's decision-making process, as measured by capacity and/or competency instruments, implicates the same normative issues as the patient's choice.

Importing the MacArthur Instruments into the Research Context

The MacArthur instruments were designed for measuring treatment capacity, but may well be of use in the context of consent to participate in research. To think about this issue we must ask, first, whether any abilities in addition to those the instruments assess are needed in the research context. Second, even over the range of abilities the instruments cover, certain adaptations may be necessary to tailor the instruments to the research context. Third, we must face additional normative issues.[67]

The answer to the first question is, arguably, yes. The patient asked to participate in research is serving the interests not only of himself but also of the researcher.[68] This means that the researcher may have something of a conflict of interest, and so perhaps cannot be counted on to be entirely benign. (I in no way think that researchers are selfish or malevolent; but unconscious motives for wanting to do their research may make them less reliable guardians of patients' interests.) It also means that, given the enormous transference patients bring to doctor/patient interactions, the patient may not be in a good position to protect himself—to make the best judgment for himself in the absence of a doctor whose job it is to make the best judgment for him.

Indeed, patients may have all sorts of unconscious reasons to consent to research when a doctor asks them to do so. I have mentioned transference—clearly the most powerful. Involved in this may be a desire to please the doctor, a desire not to be the object of her or his animus, a belief that the doctor offers protection from all harm, or a belief that the doctor *must* have only the patient's interests at heart. In addition, patients may believe that they will not get other therapeutic treatment if they are unwilling to participate, will get the best treatment only if they participate, or will be able to survive financially only if they are treated through a research protocol. Finally, the doctor may put some pressure on the patient to consent, and many people have a hard time saying no.

I recognize that patients suffer transference distortions in the treatment context as well. But again, the doctors' and patients' interests are largely the same in that context. Moreover, patients are likelier, in the research context, to want to decline participation, but feel they cannot. All of this at least suggests that we may want some measure of ability to protect oneself against pressure—to negotiate to protect one's own interests, or something of the sort—in a capacity/competency measure for consent to participation in research.

Second, the MacArthur instruments will need to be adapted in major ways to accommodate the research context. Under the UTD, they will need to include the most important information patients need to be able to (purely) understand. Most notably, the patients will need to understand that nontherapeutic research will not help them, how likely therapeutic research is to help them, and that the doctors have something of an interest in doing the research. Also, patients must understand their right to not participate in the research without incurring any penalties. In addition, patients may well want to understand the potential gains of the research in terms of increased knowledge—of what kinds and how much. Of course, patients will also need the usual disclosures describing the procedure itself and its potential risks. The UTD offers a good model for level of language comprehension to require and for different ways to test for understanding; but, once again, the actual content of the information will need to be adapted to the research context.

In the same way, the POD will have to be reformulated to ask about the patient's appreciation (belief formation) concerning these important things. As in the context of treatment, we arguably want patients to avoid believing only what is patently false. In nonobvious cases, a patient (who can resist pressure) who understands that a certain protocol is not designed to help him and probably will not help him may nevertheless optimistically hope it will; the point is, maybe the protocol *will* help him, even if there is little reason to expect so in advance.

On the other hand, if there is *no* chance the protocol will help, the patient must at least recognize that that is what his doctors think, and should perhaps be required to believe this himself. It all depends on whether this is one of those things on which doctors could be wrong.

---

[66] This is the most important failing of the MacArthur instruments because there may be broader agreement about what skills are necessary, at least at a high level of generality, to make decisions than about what beliefs one should embrace. In addition, our beliefs about the world are simply more important to us, and more important expressions of our person, than views about what skills to use in deciding.

[67] The MacArthur researchers have a book chapter in press that discusses adapting their instruments to the research context. See Jessica Wilen Berg and Paul S. Appelbaum, *Subjects' Capacity to Consent to Neurobiological Research*, supra note 3. They do not suggest that additional abilities may be required; they do acknowledge that the instruments must be adapted to this context—e.g., the UTD must disclose information appropriate to participation in research; and they point to the added value of increasing scientific knowledge. On the other hand, they once again do not answer the central normative questions, suggesting that we adopt a sliding-scale competency approach, so that each evaluator is free to draw the line between autonomy and paternalism as she or he sees best.

[68] Even in nontherapeutic research, the patient may have an interest in wanting altruistically to help others.

Of course, I am again proposing a kind of "patently false belief" standard, and one might reject that view. Another level of belief, required in this context, must then be proposed. Alternatively, the POD in the research context could include a number of different levels at which ideas must be appreciated.

The POD must not only include additional items for the patient to appreciate, and at the right level, but it must also omit items which seem irrelevant to the inquiry. For instance, denial of mental illness seems irrelevant to the case of a patient who consents to participate in research.[69]

Third, there are additional normative issues in the research context. These include whether the additional important value, in this context of advancing science, justifies a different balance in our assessment of competency, and whether it makes normative sense to require more ability here because consent is of more questionable value to the patient in the research context than in the treatment context.

I address only the second issue here. The question raises a broader question of whether we should vary our competency standard depending on the quality of the decision being made. Everyone agrees that if a task is more difficult, one must have additional abilities, or a higher level of the relevant abilities, or both, to perform it. The proposal here is different: that if a patient is making a good decision, we should require only a low level of competency, while if he is making a bad decision, we should require a high level. Here, the decision to participate in research is not so beneficial to the patient as the decision to consent to conventional treatment.[70]

The reason we might want to vary the level of competency is clear: if patients are about to choose something that will not help them and may harm them, we want to be very sure that they know what they are doing.

To my mind, however, there is a very serious conceptual problem with varying the level of competency: doing so is only a distant cousin to declaring people who make good choices competent and people who make bad choices incompetent—a practice roundly criticized. In essence, one sets up each individual evaluator as judge of the quality of the patient's decision, and allows *him* to substitute his judgment for the patient's. If the evaluator, for example, disvalues limitations on occupational functioning to a high degree, he may disable the patient, by varying the level of competency, from making a choice that risks such limitations in his occupational functioning. But what if the patient himself does not much care about this?

One response to this charge—although not entirely satisfactory—is that whatever level of competency we set we are balancing well-being against autonomy, so that striking the balance differently makes perfect sense when well-being is likely to be affected more seriously.

But there is a difference between saying that one must have certain abilities as a general matter in order to take responsibility for one's own choices, without scrutiny of particular choices, and saying that one must have *more* abilities when *we* judge one's *particular* choices bad. Arguably, competency doctrine does and should set the balance once, as it were, so as to avoid second guessing patients' decisions and setting someone else up as a judge of what is a good choice; isn't that up to the *patient*?

If we reject varying the level of competency based on how good a decision we think the patient is making, there may nevertheless be good reasons for requiring a higher level of competency in general in the research context. For instance, we may think that, as a risk-of-error matter, evaluators are likelier to have an interest in finding competency so that their patients will be able to consent to research that will help the researchers. We should err on the side of requiring a higher level of competency.

In addition, we may be concerned that the researcher cannot be counted on to be entirely well-motivated in recommending the particular research protocol; once again, the researcher doesn't completely have the patient's interests at heart. This matters here, not because we think the patient is making a bad choice, but because we expect him to play a larger role in evaluating the decision, and he may need more capacity for this evaluation.

What about the argument that research subjects do not lose much by not being permitted to participate in research, and may at times suffer injuries by participating, so we should set a high bar before we allow a vulnerable subject to participate? This is a slight variation on the "sliding scale" competency approach we have just discussed. Consenting to participate in research is not making an obviously good choice for oneself—and so we want one to know well what one is doing. In addition, one might argue that denying the person the choice to participate does not much harm him. Indeed, we might even think that many research subjects do *not* feel harmed when deprived of the right to make such choices, because they are likelier to be acquiescing in what their doctor wants than independently choosing to participate.

This suggestion has some merit, but does not seem to me to carry the day. Patients can desperately want to participate in therapeutic research when nothing else is helping them, and

---

[69] It is also arguably irrelevant to *consent* to nonexperimental treatment—though consent to such treatment is rarely questioned.

The MacArthur researchers, in their article on adapting their treatment capacity instruments to the research context, suggest that denial of one's illness should vitiate one's consent to participate in research. But it is unclear why this is so. Arguably, one need only believe that the researcher considers one a good subject, whatever one may believe oneself, in order to be able to consent to participate. Just as people can consent to participate in wholly nontherapeutic research, so they can consent to participate in what their doctors think is therapeutic research for different reasons than they are suggesting for participation.

[70] The reader will readily appreciate situations in which this is not true; but as a broad generality it seems sound.

indeed it may be the best choice for them to do so. They can derive great utility from the thought of helping others. And they can feel terribly demeaned when their choice is not respected.[71] Thus, it is not obvious that we should raise the bar for competency to participate in research.

Given all of these competing concerns, I am not sure how I come down on the controversy around sliding scale competency measures, although I am tempted by a single level of competency. At the very least, I believe that we should increase the level that we require of patients only in the most exigent circumstances: when their choice exposes them to a serious risk of very substantial, perhaps irreversible harm. This policy would avoid letting individual evaluators make normative judgments about their evaluee's choices.[72] Even then, I might call the impairment justifying overriding the choice in exigent circumstances something other than incompetency (perhaps impairment?), so as not to open the door to more manipulation of the concept. In addition, we may have reasons for thinking that competency should be understood in realist terms as either there or not there, and not variable according to context.[73]

In sum, how we eventually come down on this issue will require careful normative consideration, which I have not undertaken here. And this question must be answered before we definitively adopt a competency standard or measure.

What recommendations should the National Bioethics Advisory Commission make to institutional review boards regarding competency evaluations?

Two questions arise with respect to NBAC recommendations to IRBs: first, should researchers be required to evaluate competency when recruiting subjects for research? And second, should they be required to use particular instruments to do so? It seems clear that researchers should inquire into competency whenever there is reason to suspect it is not present. This is particularly so in the research context where consent is not obviously in the patient's interests. Perhaps there should be a presumption that hospitalized psychotic patients should be evaluated, although requiring evaluation of anyone with a chronic psychotic illness may underestimate competency in this population. However we draw the line, if there is reason to doubt a potential subject's competency, it should clearly be evaluated.

Then the question becomes how to evaluate it. What should the NBAC recommend, if anything, for IRBs to require of investigators who wish to perform research on vulnerable populations? One possibility is that IRBs might wish to require use of the MacArthur instruments with suitable adaptations. MacArthur seems the most promising instrument available, but if the criticisms presented here and elsewhere are sound, it is also flawed.

If the MacArthur instruments are required, IRBs must realize that it is *never* sound for investigators *simply* to use them without more. At the least, they must be adapted to the research context. Perhaps they should also be modified in the light of criticisms I and others have made.

Perhaps most important, because the MacArthur researchers have omitted the crucial normative judgments necessary before the instruments can be used, some effort must be made to justify the normative choices the evaluator wishes to apply. For there is a real danger that an investigator faced with a requirement to use the MacArthur instruments may simply adopt its definition of "impairment" as the cutoff point for incompetence, or decide that the line the MacArthur researchers say indicates clear competence should also be the line below which incompetence falls. The MacArthur researchers did not justify these normative choices, so that using these cutoff points, without normative analysis, is improper.

If all of this is so, IRBs could require, at the least, that investigators study the MacArthur instruments, as well as critiques of the instruments as given here and by other scholars. Alternatively, they could require some sustained analysis, submitted to the IRB, of why the investigators are making the normative choices they are making—as well as of their responses to other criticisms of the instruments. To my way of thinking, the second provides much better assurance that the required analysis is being performed, and that investigators are not simply adopting the MacArthur researchers' suggestions.

On the other hand, it may simply be too costly to require such analysis, and researchers on the street, so to speak, may not be very skilled at this kind of analysis. It is, arguably, not within doctors' and other scientists' expertise to engage in this kind of philosophical inquiry. Thus we should encourage scholars to

---

[71] I am not suggesting we should never let others decide for the incompetent subject—that is a whole other subject in itself; to the extent that we do, some of these reasons lose force.

[72] "This choice is somewhat problematic, so we raise the bar a little; that choice is very problematic, so we raise the bar a lot." Of course, in both cases the evaluator gets to say that — why a choice is problematic based on his own values rather than having a standard that speaks to the nature of the necessary harm as in the text.

[73] Competency, of course, depends on various capacities, which can be a matter of more or less. It is nevertheless arguably the case—although I am not completely persuaded by the argument—that what it is to be competent is invariant across contexts: one needs, say, to be able to do x percent of the tasks required to do a good job to be "competent" to do that job. Compare the case of what it is to be a "proficient interpreter." Some languages are harder than others to be an interpreter of; and certainly some interpreters do the job in a given language better than others; but we reserve the term "proficient interpreter" to people who get the translation right, or close to right, most of the time. If I am "competent to interpret from Spanish to English," I need have no greater interpreting skills than someone "competent to interpret from English to Italian." There is one skill level required. Of course, in extremely sensitive negotiations we may want someone with extremely high levels of "capacity"; but this person might be called "super-proficient," and not just "proficient," in being an interpreter.

engage in the hard analysis of the normative questions. On the other hand, investigators can hardly be expected to wait for this kind of analysis, especially if some consensus is required—research must go on.

There are ultimately only three possibilities:[74] require investigators to use MacArthur with suitable adaptations after at least considering problems with the instruments and choices that must be made in order to use them, and perhaps justify those choices in some sustained way; require investigators to use some other instrument—say an instrument of their own devising; or allow, instead of the use of instruments, clinical investigations of competency.

Which option IRBs should use depends on how problematic one finds the MacArthur instruments to be; how confident one is of the ability of investigators to moderate the problems; and whether one thinks more open-ended evaluation involves the same kinds of problematic normative judgments, but simply sweeps them under the table, possibly achieving less accuracy in the end. How to answer the question of what IRBs should require is difficult given the state of the art of capacity/competency instruments today. Further research is needed both on the substantive question of what one's instrument should look like and on the procedural question of what to do in the face of the problems identified in existing instruments.

Conclusion

The MacArthur instruments are an extremely important contribution to the literature on treatment capacity. I have suggested two essential problems. First, the instruments omit necessary normative evaluation and smuggle in certain judgments without justifying them. Second, in some cases, they arguably strike the balance between autonomy and paternalism in the wrong place. Future research must focus on remedying these problems. In particular, to the extent that the normative inquiry leads us to select a "patently false belief" standard to measure appreciation, effort must be made to operationalize such a standard. Notwithstanding the need for future research, the MacArthur instruments are an impressive achievement and will no doubt be a focal point for the debate on capacity/competency for many years to come.

[74] This is somewhat overstated: IRBs can not only require one of these three, but perhaps others as well. And there are variations on these choices: IRBs, instead of *requiring* investigators to do something, can *encourage* them to do it, or *assure* themselves that they are being mindful of it—and many more.