

Volume I, No. 1, “Conducting Medical Research on the Decisionally Impaired”

The National Bioethics Advisory Commission: Binding the Gaps in Human Subjects Research Protection
James F. Childress, PhD

In 1955, the National Bioethics Advisory Commission (NBAC) was created to make recommendations regarding bioethical issues arising from research on human biology. The NBAC must give first priority to two areas: the protection of the rights and welfare of human research subjects and issues concerning the management and use of genetic information. Furthermore, the NBAC is divided into two subcommittees, including the Human Subjects Sub-Committee and the Genetics Sub-Committee.

The author discusses the possible gaps that may exist in human subjects protection. Such an examination includes looking to Federal agency protection of human subjects, especially the Common Rule, which proscribes that federally conducted or sponsored research cannot proceed without institutional review board (IRB) approval. Furthermore, the author looks in to whether the Common Rule should be extended to Federal agencies that have not yet embraced it or to privately funded research.

In addition, the author notes that the Common Rule is implemented through IRBs. One important question is whether IRBs are properly guided and supervised, in order to properly execute the Common Rule. The author suggests the presence of other gaps in human subject research protections, such as gaps resulting from shifting paradigms of research. Also, the author notes a gap in compensation for research-related injuries, and a lack of public trust in researchers and research institutions.

Assessment of Capacity to Give Consent to Research Participation: State-of-the-Art and Beyond Evan G. DeRenzo, Ph.D., Robert R. Conley, M.D., and Raymond Love, Pharm.D.

This article focuses on the process of assessing the capacity of decisionally impaired individuals to give ethically and legally valid consent to research participation. The authors’ analysis focuses on three aspects of the issue: that the research community is beginning to acknowledge its inability to assess decisional capacity; that an old debate regarding who ought to participate or perform capacity assessments is being revived; and that additional assessment tools are necessary to supplement clinical judgment in evaluations of decisional capacity.

The authors then trace the historical factors which have contributed to the growing concern about impaired individuals’ ability to provide consent. In particular, the authors examine several studies which linked increases in disease severity to decreases in individuals’ ability to retain information about the consent process. These studies have illuminated a need to strengthen the research community’s ability to assess capacity to consent.

The authors also discuss the scholarly assessment of the capacity to consent. Such ethical literature balances increased protection of decisionally impaired individuals’ participation in research with the threat of exacerbating the stigmatization they already experience. The authors also consider other ethical discussions, including a feminist ethics analysis, which examines the effect of power differentials between doctor and patient, and how this effects the medical research environment. The authors then examine the progression of empirical studies concerning one’s ability to provide consent.

It is acknowledged that many more studies and discussions must take place before there can be a better understanding about assessing and individual’s capacity to provide valid consent. Finally, the authors state that decisionally impaired individuals need novel ways to assess the ability to consent to research participation, but they also need the continuation of research in order to aid in the treatment of their diseases.

Achieving Proper Balance in Research With Decisionally-Incapacitated Subjects: NAMI’s Perspectives on the Working Group’s Proposal.

Laurie M. Flynn
Ronald S. Honberg

Severe mental illness such as schizophrenia, manic-depressive illness, major depression and others, can be devastating for those who suffer them. These illnesses cause immense suffering and correlate to joblessness, homelessness, crime and suicide. While there have been few effective treatments in the past for such mental diseases, recent breakthroughs in understanding these diseases have offered new hope for people with these diseases to live a meaningful and productive life. These advances would not have occurred without the participation of individuals suffering from mental illnesses as human subjects in research. However, these individuals may not always be capable of understanding the nature of the research or the specific benefits and risks associated with the research protocols. Federal regulations do not adequately address these concerns.

In this article, the authors examine the ethical issues surrounding the research conducted on the mentally

ill. While the authors do not find outright ethical violations, they do believe that steps should be taken to better ensure that research subjects and their families adequately understand the nature, purposes, and procedures involved in research protocols. Furthermore, the authors discuss the possibility of limits on the types of research which should be conducted on individuals who may lack capacity to provide informed consent. The authors examine how the Maryland Attorney General's working group has addressed these concerns in their draft recommendations, with a particular emphasis on issues of concern to consumers and families. Part II of the article examines if research should be conducted on decisionally-incapacitated subjects at all. Part III discusses the subject's assent to participation by examining the case of *T.D. v. State of New York Office of Mental Health*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996), which raised the issue of surrogate consent procedures set forth in regulations. In Part IV, the authors discuss the absence of guidelines for researchers to use in assessing the capacity of research subjects. Finally, in Part V, the authors discuss the important role of IRB's for evaluating, monitoring, and overseeing research protocols involving the participation of decisionally-incapacitated individuals.

The authors conclude by restating that research represents the best hope for eradicating the suffering associated with severe brain disorders. Constraints and limitations on the way research is conducted means that not all individuals will derive direct benefits from their participation in research, and some individuals may be harmed. Federal regulations do not set forth requirements for protecting the rights and welfare of vulnerable and decisionally-incapacitated research subjects. The proposal developed by the Maryland Attorney General's working group seeks to develop standards that better protect these vulnerable research subjects, while not compromising the ability to conduct vitally important research. The proposal currently represents a significant step towards achieving this illusive balance.

Proxy Consents to Participation of the Decisionally Impaired in Medical Research – Maryland's Policy Initiative

Diane E. Hoffmann
Jack Schwartz

There is a demand for research subjects who are "decisionally impaired" – that is, incapable of providing informed consent to participation in medical research. Advertisements in area newspapers for such subjects suggest that "loved ones" may consent to participation in medical research for those who are unable to consent themselves. Furthermore, there is little Federal and state

law available that prohibits the "decisionally impaired" from participating in experimental research or which significantly limits the circumstances under which these individuals can participate in research.

This article discusses an effort in Maryland to decide whether proxies should have the authority to give consent for the "decisionally impaired" to participate in medical research. The article further examines Maryland's initiative to establish guidelines for research with those who lack decision-making capacity. In Part II, the authors examine the current legal uncertainty surrounding proxy consent for the "decisionally impaired." The authors analyze research-specific provisions and medical treatment statutes in both Federal and state law. In Part III, the authors identify the issues that lead up to the Maryland Policy initiative regarding proxy consent, and frame recommendations for giving proxy consent based on five factual scenarios.

The authors conclude by examining the next steps that the state of Maryland needs to take to ensure workable procedures and safeguards are in place for the participation of decisionally-impaired individuals in medical research. These steps include dissemination of reports recommending preliminary policy recommendations, providing public meetings so the community can comment on the policy recommendations, and asking the Attorney General to look for sponsorship of the policy recommendations in the Maryland General Assembly. With broad public participation, ideally the ultimate policy recommendation will reflect an appropriate balance between views of proponents and opponents of proxy consent.. The process and outcome may serve as a model for other states as they take up this important issue.

The Elderly Questionably Competent Client Dilemma: Determining Competency and Dealing With the Incompetent Client

Marilyn Levitt

Attorneys occasionally are confronted with a client who is questionably competent and seeking legal services. This article grapples with the practical and ethical issues which face an attorney in that situation. Of particular concern is the dilemma arising from the conflicting obligations of the attorney, particularly the extent to which the guidelines for dealing with questionably competent clients under the Model Rules of Professional Conduct and the Maryland Lawyers' Rules of Professional Conduct conflict with the attorney's duty of confidentiality and loyalty under those same rules. How is the attorney to determine the competency of a client who is not obviously incompetent, but rather questionably or partially incompetent? Further-

more, how is the attorney to proceed once a preliminary determination of incompetency has been made?

The first half of this paper, sections one and two, is concerned with the determination of competency. The first section discusses the attorney's obligations under the Model Rules and the Maryland Code. The second section discusses some practical considerations and methods for determining competency as suggested by legal and medical scholars. The second half of the paper, sections three and four, is concerned with the problems that arise once the attorney has made a preliminary determination of incompetency. Section three discusses the obligations and guidelines in the Model Rules and the Maryland Code for dealing with clients whom the attorney has determined to be incompetent. Section four examines recent relevant state and local ethics opinions, as well as opinions of the American Bar Association. Finally, survey results, presented in Appendix A to this article, illustrate how various Maryland attorneys deal with questionably incompetent clients. The survey addresses the manner in which attorneys determine competency, and the actions they take if they determine that a client is incompetent.

The authors concludes by arguing that attorneys should be able to contact other regarding questionably competent clients, without running the risk of violating that client's confidentiality. The lack of a consistent approach among attorneys, however, may be an indication of the individuality of each case or may indicate some confusion as to the attorney's duty to communicate and consult with the incompetent client. Recent guidance from the ABA Committee may help to resolve some of this confusion, and it is this author's hope that the results of the survey presented in appendix A will further highlight the alternatives which experienced attorneys find helpful.

Comments on the Second Report of the Maryland Attorney General's Research Working Group

Franklin G. Miller

The Maryland Attorney General's Research Working Group (Research Working Group), in its Second Report recommending legislation for regulating research with decisionally incapacitated individuals, has produced a path-breaking document. It makes a major contribution to the debate over a complex, difficult, and controversial topic.

In this article, the author comments on the recommended legislation, in which he draws from his own experience as being a member of the institutional review board for the intramural research program of the National Institute of Mental Health during the past six years. In Part II, the author examines the scope of the Working Group's

proposed legislation concerning decisionally incapacitated subjects. In Part III, the author comments on the draft legislation by examining the terminology of the legislation, research involving more than minimal risk, the scope of expected benefit research, and loss of decisional capacity during research.

The author concludes by recommending five changes to the proposed Maryland legislation governing research with decisionally incapacitated patients. One, the definitions should explain the role of the monitor and what is meant by a surrogate, distinct from a health care agent. Two, the sections stipulating what counts as more than minimal risk should be transformed into guidelines for IRBs to assess the risk level of prospective studies. Third, the misleading term "class" should be omitted from the provision stipulating the scope of "expected benefit research." Fourth, guidelines for research with subjects who have never had decisional capacity should be included. Lastly, the law should address substitute decision making for patients who lose decisional capacity in the course of research.

Regulation of Research on the Decisionally Impaired: History and Gaps in the Current Regulatory System
Jonathan D. Moreno, PhD

According to author Jonathan D. Moreno, the history of biomedical and behavioral research is void of any mention of its use of decisionally impaired individuals. In addition, neglect of the decisionally impaired population exists in the policy arena as well. The author's concern for these individuals' risk for involvement in research prompted this article, which charts the research regulation of this population. Part I describes how the author developed an interest in the decisionally impaired.

In Part II, the author discusses experimentation on patients who suffer from the disease being studied. For example, it was determined that the surgical removal of the prefrontal lobe abated anxiety and frustration in severely anxious or aggressive mental patients when performing complex tasks. As a result, lobotomy procedures became a popular method of treatment for such patients in the United States. The author also documented other types of therapeutic research such as shock therapy, moral treatment institutions and neuroleptic drugs.

Part III of the article discusses other forms of human research, in which the purpose is non therapeutic. This type of experimentation is intended neither to address the patient's condition nor to benefit the patient, but instead to determine the effect of a particular agent on the human body. The author notes that decisionally impaired individuals are often the subjects of such research because they are readily available. In Part IV, the author documents the history of regulation efforts on research involving the

decisionally impaired. The concern for regulation was generated by children in research, as well as human experimentation performed by Hitler's regime during World War II.

In Part V, the author next examines the contemporary debate, which involves a critique of the federal government's lack of guidance in its sparse regulation of this area. The author presents a paradox that pits the advancement of medical research against the need for stronger regulation in the area research involving the decisionally impaired. The author concludes with the acknowledgement that this research must continue, but in such a way as to minimize the undermining of human dignity.

Regulating Research With Vulnerable Populations: Litigation Gone Awry

John M. Oldham
Stephen Haimowitz
Susan J. Delano

Current litigation in New York challenges the Office of Mental Health regulations governing research with human subjects. The outcome of this litigation will ultimately determine whether research in New York may be conducted with children and with incapacitated adults, and under what circumstances. The repercussions may prevent numerous studies from going forward and ultimately put a halt to research that may have provided participants with access to effective treatment and significantly improved the well-being of other individuals suffering from mental illness and other cognitive impairments.

In this article, the authors discuss the consequences that the litigation in New York has had on research and treatment for the mentally impaired. The authors then compare the New York experience with the consensus building approach adopted in Maryland. In Part II, the authors lay out the background of the current status of litigation that effects research and treatment for the mentally impaired. The authors examine the history of research in the Office of Mental Health facilities, research regulations prior to 1990, the development of the 1990 regulations, and experience with those regulations. Part III discusses how research policy is set through litigation. The authors examine the New York case of *T.D. v. State of New York Office of Mental Health*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996). The authors discuss the Plaintiff's claim and how the court's reallocation of agency jurisdiction from one agency to another upset longstanding interagency coordination. The authors discuss further how the decision of the court misperceived the risks and benefits of the outcome of the litigation, which were based on hypotheti-

cal harms alleged by the plaintiff. Finally, the authors argue that the plaintiff combined rigid categories and exaggerated the risk involved in research to convince the court to invalidate the Office of Mental Health's research regulations. Lastly, in Part IV, the authors examine how the New York litigation has impacted research being conducted on the mentally ill.

The authors conclude that research must be done in a careful, thoughtful and heavily reviewed and scrutinized way. It must be done ethically and respectfully, attending to patients' rights. These critical concerns, however, must be integrated with the need to make available promising treatment for devastating illnesses as well as the need to continue the development of better treatments, which can only be discovered through research. A plan like the Maryland proposal accomplishes such a desirable balance. Unfortunately, the results to date of the court process in New York do not achieve this goal.

Diagnostic Evidence Admissibility and the Multiple Personality Disorder Defense

Sabra McDonald Owens

The growing recognition of psychiatric conditions resulting from childhood trauma has become a significant mental health issue of the 1990s. One such condition that has become significant in the legal community is Dissociative Identity Disorder (DID), better known as Multiple Personality Disorder. Over the last few decades, criminal defendants have increasingly raised insanity defenses based on DID in cases ranging from drunk driving to murder. While insanity defenses based on mental illness is common, defenses based on DID is unique because DID defendants argue that their various personalities should be granted separate legal status. Furthermore, expert testimony given to support or deny a diagnosis of DID come in a wide variety and is often controversial.

This article focuses primarily on DID in the criminal context, with examples and commentaries of civil cases provided in the footnotes. Part II of this article defines DID and the other Dissociative Disorders, and explains potential effects on behavior and mental state. Part III examines expert testimony and evidentiary admissibility standards. Part IV examines various types of forensic evidence presented in DID cases. Part V examines common areas of diagnostic controversy: malingering, misdiagnosis, and iatrogenesis. And, Part VI concludes that a wider variety of evidence should be admissible in DID cases because DID frequently results from severe and recurrent childhood abuse. In addition, there should be a rebuttable presumption of insanity for every identified and

confirmed criminal defendant with DID; resulting in acquittal and mandatory treatment until recovery occurs.

The author concludes by stating that because DID is often the result of childhood abuse, a wide repertoire of diagnostic evidence should be admitted when DID is alleged. While this type of evidence may be controversial, it can be counterbalanced with more generally accepted evidence if available. Enhanced admissibility of evidence, regardless of its origin, would support the concepts of fundamental fairness in multiple personality disorder cases.

Issues Raised by Research Using Persons Suffering from Dementia Who Have Impaired Decisional Capacity
Peter V. Rabins, MD, MPH

In his article, Peter Rabins argues that the decisionally impaired should not participate in research in the absence of special protective criteria. Such protection is necessary for these individuals because of their inability to provide informed, voluntary and competent consent to participate in human experimentation. Although the author identifies a variety of injuries and conditions that cause impaired decisional capacity, the article focuses on dementia.

The author justifies research into dementia because it affects 6-8% of people over age 65, and causes grave morbidities including hallucinations, aggressiveness, and depression. Such research is necessary, the author argues, because without it, questions regarding the onset, progression, symptoms and care of individuals with dementia would remain unanswered. However, added precautions are necessary with research on these individuals because of the decisional incapacity that often accompanies the disease. Studies have determined that some patients with dementia do have the capacity to consent to treatment, and this capacity has been extended to include participation in research.

Proxy consent is one possible protection for decisionally impaired individuals with dementia. The author explores the pros and cons of such a restriction on participation in research. Furthermore, the author examines the difficulty many researchers face in determining when a patient with dementia becomes decisionally impaired. Finally, the author states that individuals with dementia who are decisionally impaired should participate in research if there is a therapeutic benefit, and he or she has indicated consent to participation by proxy or otherwise.

In Harm's Way: Research Subjects Who Are Decisionally Impaired

Clarence J. Sundram

In this article, the author addresses the issue of biomedical research involving individuals with decisional impairments resulting from serious mental illness. The analysis begins with a discussion of the inequities suffered by the mentally ill as a result of their disease, including the issue of informed consent. The author provides a list of examples in which dangerous experiments were performed on mentally disabled individuals, a class of participants who bore a greater amount of research risk. Several legislative enactments, such as the American Medical Association's Statement of Principle of 1946 and the Nuremberg Codes of 1947, were aimed at balancing the distribution of research risk by regulating consent in experimentation.

The author next examines the inability of institutional review boards (IRBs) to adequately police research endeavors. The IRBs failure to properly regulate research stems from its failure to meet expectations, properly monitor of research being conducted, limited Federal oversight agencies, and the practice of research that is outside Federal regulations. The specifics of each of these failures is discussed in-depth by the author.

To remedy the problem, the author proposes three recommendations. First, he suggests a common body of rules which will apply to all human subjects research regardless of its source of funding. Second, it is recommended that the IRB process be more visible, as well as held accountable to a higher authority. Lastly, the author suggests that the research community should seriously reconsider whether there is any justification for non-therapeutic research on incapable individuals, who might be put at risk.

Protecting Vulnerable Research Subjects: Practical Realities of Institutional Review Board Review and Approval
Alison Wichman, MD

Institutions and researchers working with cognitively impaired research participants often face the challenge of balancing the progression of science with the need to protect the rights of human subjects. In this paper, the author discusses the role and responsibility of institutional review boards (IRBs), the policies used by IRBs when reviewing research involving cognitively impaired individuals, and suggests improvements in the protection of these subjects.

The current laws governing human subject research protection are found in the *Belmont Report*, establishes three ethical principles regarding human subjects: respect for persons, beneficence, and justice. The author discusses current regulatory requirements and the role of the IRB,

which is to protect the rights and welfare of the research subjects. When participating in research, vulnerable subjects must be accorded special protection. The author states such additional protection includes the maintenance of written policies or guidelines.

The author also focuses on the improvement of the IRB system. Although IRBs have significantly changed the face of research, the author suggests that the IRB system is in need of reevaluation. However, as the author discusses, the improvements that must be made to the IRB system must be accomplished based on the limited available knowledge. As a result, more research must be done on IRBs themselves.

