Informed Consent to Participation in Medical Research Employing Elderly Human Subjects

Robert L. Schwartz
INFORMED CONSENT TO PARTICIPATION IN MEDICAL RESEARCH EMPLOYING ELDERLY HUMAN SUBJECTS

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INTRODUCTION

The primary question facing researchers who intend to employ elderly human subjects is whether their subjects' advanced age requires that the protection of their autonomy be accomplished in some manner that is different from that employed to protect other subjects. Answering this question will require an analysis of whether elderly subjects have a greater or lesser interest in autonomy than do others who might be subjects in human research, and whether it is more or less important to protect them from potential research abuse. This article will suggest that the elderly may possess several attributes that require that they be employed as research subjects only when the selection process and research design compensate for those attributes.

The most troubling area for medical investigators who regularly employ elderly subjects is the propriety of conducting research upon patients suffering from senile dementia, particularly senile dementia of the Alzheimer's type. This devastating illness has developed a high political profile over the past several years, causing a great deal of research interest in and, more importantly, research funding for the study of this disease. As the elderly population continues to grow and develop into a powerful political lobby, the interest in senile dementia among the medical community will continue to increase. While the vast majority of the elderly do not suffer from senile dementia, most Alzheimer's patients are elderly. The presence of this disease affects the ability of its sufferers to give consent, and often renders it impossible to obtain consent that would be valid under standard accepted principles. On the other hand, the disease is a terrifying one, often research can be done only upon those suffering from the disease, and failure to do this research may condemn future generations to a devastation that could be overcome.

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I.

Although the institution of informed consent has been justified on many different grounds — it promotes trust and respect for the medical profession, for example — its principal purpose is the protection of the autonomy of those undergoing a medical procedure, and it is the primary social institution established to protect the autonomy of patients and subjects. The doctrine is explicitly founded upon the notions that what one does with one's body is a personal choice, and that the law, along with other social institutions, must act to protect that privacy interest. The doctrine of informed consent applies to everyone who may undergo any medical procedure, and it applies whether the procedure is denominated "treatment" or "research." In fact, it developed directly from the common law "consent" defense to a battery (any unconsented harmful or offensive touching) and thus applies to any physical touching of one person by another.

Of course, the doctrine of informed consent, as any other legal doctrine designed to protect freedom, has costs. Researchers view informed consent as a barrier to experimentation, if not an insidious plot designed to deny them the pursuit of their chosen profession. Indeed, the necessity of informed consent is a barrier to research in some cases; it makes almost all research slightly more inconvenient and it renders some research almost impossible. For example, if no proxy consent is available for the most se-

7. Id. Note that the distinction between treatment and research is not always clearcut. Indeed, it is likely that the vast majority of research done in the United States is viewed by the investigator as being, at least in part, therapeutic.
9. See Prosser, supra note 8, § 10 at 35, § 32 at 165.
12. Id.
verely ill and thus, at least for Alzheimer's patients, the most clearly incompetent, no research will be legally pursued to find treatment for the most severe type of dementia. The doctrine of informed consent, at least to the extent it does not permit proxy consent, would render that research impossible. The consequence of such a policy of informed consent might be that no course of treatment could be developed for this disease, and that consequence would surely be a serious and frightful one. On the other hand, if we do not respect the doctrine of informed consent, even for those suffering the most severe form of senile dementia, we will permit the medical conscription of the senile and approve a process that forces them to serve a progress they may neither desire nor care about.

The question is not whether we should draft subjects to serve medical progress but rather, who is a "true" volunteer? How certain must a researcher be that a subject truly wishes to participate in a research protocol before he accepts his consent? The answer to that question rests in the parameters of the doctrine of informed consent that will be applied to research subjects. That doctrine is itself a consequence of social policy that must weigh, on the one hand, the values of autonomy and clear affirmative consent, and, on the other hand, the value of research that may never be carried out if we require "perfect" consent from competent medically-trained subjects.

In weighing the value of research and the value of autonomy, this society has chosen to err towards protecting one's right to control one's own body. We are heirs to the Nazi experimentation, the Tuskegee Institute syphilis study, as well as the Jewish Chronic Disease Hospital cancer implant, and we can easily see the enormity of neglecting to protect individual subjects' autonomy. Alas, we never see the foregone results of research that was not undertaken. Those developments may have been especially significant in senile dementia of the Alzheimer's type, where the costs of the illness — in emotional, physical, and financial terms — are tremendous.

Balancing the interests in encouraging research and protecting individual autonomy is clearly a matter of social policy. As the Senate Committee on the Judiciary was told in 1974:

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14. Supra note 2, at 44-45.
15. 1 NUREMBERG CODE FOR TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW No. 10 XVI (1949).
16. JONES, BAD BLOOD (1982).
17. KATZ, supra note 5, at 9-65.
The problem of ethical experimentation is the product of the unresolved conflict between two strongly held values: the dignity and integrity of the individual, and the freedom of scientific inquiry. Professionals of many disciplines, and researchers especially, exercise unexamined discretion to interfere in the lives of their subjects for the sake of scientific progress. Although exposure to needless harm and neglect of the duty to obtain the subject's consent have been generally frowned upon in theory, the infliction of unnecessary harm and infringements on informed consent are frequently accepted in practice as the price to be paid for the advancement of knowledge. How have investigators come to claim this sweeping prerogative? If the answer to this question is that society has authorized professionals to choose between scientific progress and individual human dignity and welfare, should not 'society' retain some control over the research enterprise?¹⁹

In designing a doctrine of informed consent that gives proper weight to the subject's autonomy and to values of research, there first must be a determination of who is responsible for the development of social policy. Surely such policy decisions must not be left to investigators themselves, who are (and, perhaps, should be) prejudiced in favor of research. It would not be surprising if they considered their professional endeavor to be of even greater importance than would the rest of the community — after all, they have dedicated their professional lives to research.

There are, however, many other social institutions which contribute to the development of the requirements of informed consent, and, thus, to the balancing of the value of experimentation and the human dignity which might be put at stake by such experimentation. These institutions include the informal control of the medical profession's social customs, which are developed primarily in the realm of physicians providing therapy, not doing research.²⁰ In addition, formal policies emerge from hospital regulations.²¹ The restrictions this community places upon experimentation are the consequences of several of these institutions. For example, the consent requirements of the Food, Drug and Cosmetic Act are reflected in the regulations

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¹⁹. Individual Rights and the Federal Role in Behavior Modification, (Materials Relating to HEW Policies Concerning Behavior Research): A Study Prepared by the Staff of the Subcommittee on Constitutional Rights of the Committee on the Judiciary, United States Senate, 1974, at 109. This particular statement was provided by the Tuskegee Syphilis Study Ad Hoc Advisory Panel.

²⁰. Levine, The Boundaries Between Biomedical of Behavior Research and the Accepted and Routine Practice of Medicine, in The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research 1, 6-8 (1978).

²¹. LEVINE, supra note 6, at 259-91.
which establish institutional review boards. These regulations, in turn, give rise to hospital regulations and policies. All of these sources — the federal statute, the federal regulations, and the local institutional review board policies, along with the state law of informed consent and the informal social customs of local physicians — govern each case.

Obviously, the interests protected by the doctrine of informed consent need not be protected by the law alone. Perhaps the best way to serve the interests of the doctrine of informed consent would be to educate medical students so that they develop a high regard for the autonomy of their patients and subjects. Physicians and investigators have regularly complained that the legally imposed standards for informed consent are rigid, inflexible, and leave no room for discretion in an area that so plainly requires sensitivity to individual cases. The National Institutes of Health have convened a conference to discuss the developments of standards for investigators who seek consent for participation in research from subjects in protocols studying Alzheimer’s disease. To the extent that the standards provide successful informal control over those who would potentially abuse subjects, they will obviate the need for the formal development of a positive law of informed consent in this narrow area.

II.

The doctrine of informed consent requires that before any person be subjected to any medical procedure that person must be informed about the procedure and its alternatives, give voluntary consent to undergo that procedure, and be competent to give that consent. Without this consent, medical conduct, whether research or treatment, cannot be undertaken.

Although several early informed consent malpractice cases involved procedures described by courts as “experimental,” none of them involved

23. Blackwell, Drug Therapy — Patient Compliance, 289 NEW ENG. J. MED. 249, 252 (1973). See also Kaufmann, Medical Education and Physician-Patient Communication, in 3 MAKING HEALTH CARE DECISIONS, supra note 2, at 117-41 (app.); Oratz, Achieving Aesthetic Distance: Education for an Effective Doctor-Patient Relationship, 3 MAKING HEALTH CARE DECISIONS, supra note 2, at 143-73 (app.).
24. “The right to base one’s consent on proper information is effectively vitiated for those with fears, apprehensions, religious beliefs, or superstitions outside the mainstream of society.” McPherson v. Ellis, 305 N.C. 266, 273, 287 S.E.2d 892, 897 (1982).
25. NIH, Conference on Senile Dementia of the Alzheimer’s Type and Related Disease — Ethical and Legal Issues Related to Informed Consent, Bethesda, Maryland, Nov. 22-23, 1981.
26. See, e.g., NUREMBERG CODE, supra note 15. See also MAKING HEALTH CARE DECISIONS, supra note 2.
otherwise properly scientifically defensible research. In fact, litigation over informed consent has generally arisen out of instances of therapeutic treatment, not research. Thus, we ought to determine whether the doctrine of informed consent should be treated differently in a research context from the way in which it would be treated in the traditional therapeutic context.

Indeed, given the grand social function of medical research, one might argue that the doctrine of informed consent should be less strictly applied to research subjects than to patients seeking therapeutic treatment which has entirely private benefit. No legal authority has suggested that the social interests in having research performed make the doctrine of informed consent less significant in this context, however. In fact, the doctrine of informed consent may be of greater importance in the research context because there might be a greater potential for medical deviousness among researchers, and that might require the community to be more protective of subject autonomy.

There are four reasons for concluding that the doctrine of informed consent is a more necessary check against physician abuse in research than in therapeutic treatment. First, a physician may be more likely to be motivated to lie to get consent from a research subject than from a patient in therapy. While therapeutic treatment is in the interests of the patient, research is in the interest of the society — and in the interest of the physician, whose academic tenure and professional advancement may depend on running a research protocol with statistically proper subject participation. Any potential investigator misrepresentations can be limited by requiring that the subject’s informed consent be given in writing, and that the written instrument include all of the information necessary to make the consent “informed.” Indeed, federal regulations require that informed consent in the research context be obtained and reserved in writing, even though the common law does not require that informed consent for therapeutic treatment be in writing.

Second, the “therapeutic privilege” which permits physicians to omit otherwise necessary information from that provided to a patient when providing that information would be harmful to the patient, does not apply to pure research. Since pure research is not therapeutic, there is no reason for a therapeutic privilege. Third, we are skeptical of acts which appear to be motivated by unabashed altruism. A patient who consents to necessary

29. LEVINE, supra note 6, at 93, but see contra, at 94.
32. LEVINE, supra note 6, at 113.
medical treatment is perceived as doing that which any reasonable person would do; a person who consents to a medical process so that society’s knowledge can be enhanced is not perceived as acting quite so naturally. Thus, we view consent to participate in research as being more suspect than consent to therapy.

Finally, our recent history gives us more worry about the abuse of research than the abuse of medical therapy. There are few celebrated examples of medical bad faith in obtaining consent to therapeutical treatment; from the time of the Nazi atrocities (and the Tuskegee syphilis study) our history provides us with ample evidence of medical bad faith in obtaining consent to research.

There are additional reasons for being especially careful to protect the autonomy of subjects of research investigating diseases most common in the elderly — and especially senile dementia of the Alzheimer’s type. First, such research is likely to be wide ranging and unfocused. We do not know what Alzheimer’s disease is, and we cannot adequately measure its severity. It is difficult to tell when it is improving and when it is becoming worse. These difficulties are compounded by the fact that the earliest effectiveness trials of drugs designed to treat senile dementia will have to be conducted with human subjects. We may be able to learn about the side effects of proposed treatment by testing the drugs in laboratory rats, but it is unlikely that we will learn anything about the drug’s efficacy by applying it to senile laboratory animals.

Second, the treatment of senile dementia may already be overmedicalized and increased research in this area may only exacerbate the problem. Continuing focus on medical research to find a treatment for Alzheimer’s disease may create a core of specialists who feel obliged to provide medical treatment which is a severe intrusion on their patient’s autonomy and yet offers little in the way of comfort or cure. The existence of Medicare and other reimbursements for physician services makes it likely that private enterprise

34. See supra notes 19-21.
will rush to provide medical care that can be sold to the elderly population.\textsuperscript{38} For example, one would expect the drug companies to be willing to invest in research to develop drugs which could be approved for "selected symptoms in elderly patients . . . mood, depression, confusion, unsociability, and dizziness."\textsuperscript{39} Hydergin, for example, generated nineteen million dollars in sales in 1979 despite its novelty and highly controversial nature.\textsuperscript{40}

Physicians are willing to employ these minimally effective treatments for senile dementia because they allow the physician to do something to treat this terrifying disease. Both the physician and the patient’s family are more likely to believe that a senile patient is getting good medical care if something affirmative is being done, even if it is barely effective or completely ineffective.\textsuperscript{41} Of course, no therapy is harmless. Any treatment developed for Alzheimer’s disease is likely to have side effects. In addition, any treatment will impose another medical burden on a class already significantly burdened by medication and other regular medical treatments. This over-medication may mask other symptoms which would show the illness to be one of the reversible diseases often wrongfully diagnosed as senile dementia of the Alzheimer’s type.\textsuperscript{42} Some physicians estimate that 35% of those diagnosed as suffering from senile dementia are actually suffering from other diseases which could be medically treated.\textsuperscript{43} Finally, as the Public Citizen Research Group reported to the Psychopharmacologic Drugs Advisory Committee of the Food and Drug Administration meeting in March of 1981:

\begin{quote}
[T]hese drugs may give the doctor a false sense of security. Results of drug studies today make it questionable, at best, whether they offer any meaningful clinical benefits. Yet, as the British Medical Journal noted, ‘by making the doctor feel that he is doing something, the administration of these drugs may actually deflect from him the really important tasks: providing the patient and family with sympathy, practical advice and social support’.\textsuperscript{44}
\end{quote}

Just as the disease process being studied may affect our analysis of the importance of obtaining informed consent from potential subjects, so should the classes from which the subjects will be derived. The subjects of research

\begin{itemize}
\item \textsuperscript{38} \textit{Id.} See also Shoulson, \textit{Rational Pharmacotherapy in Dementia: Hazards of 'Vadodilator Therapy' in L. Lasagna, Controversies in Therapeutics} 368-73 (1980).
\item \textsuperscript{39} Statement of Eve Bargmann, M.D., before the FDA Psychopharmacologic Drugs Advisory Committee, Mar. 23, 1981.
\item \textsuperscript{40} \textit{Id.}
\item \textsuperscript{41} Schwartz, \textit{supra} note 37.
\item \textsuperscript{42} Jarvik \textit{supra} note 35.
\item \textsuperscript{43} Hollister, \textit{Are Drugs Useful for Treating Senile Dementia?} \textit{Controversies in Therapeutics, supra} note 38, at 362.
\item \textsuperscript{44} \textit{Supra} note 39 at 5.
\end{itemize}
In senile dementia will be cognitively or emotionally impaired, because that impairment is one of the defining characteristics of the disease. In addition, most of the subjects are likely to be elderly, and many will be institutionalized, either in nursing homes or in mental institutions. In fact, a great number of drug studies investigating potential treatments for senile dementia have been conducted among institutionalized patients.

The elderly, those suffering from senile dementia, and those institutionalized in nursing homes or in mental institutions are perceived as being sickly, unproductive, and unhappy. The stereotype of potential subjects for Alzheimer's disease studies would attribute to them very little reason to live. Because researchers may attribute a low value to the lives and health of these subjects, it may be especially important that we be vigilant in protecting their autonomy from intended or unintended abuse.

In determining how the doctrine of informed consent ought to be shaped in this area, we must recognize not only the tension between the interest in protecting the autonomy of subjects and the interest in curing a dreaded disease, but also the tension between protecting the autonomy of potential subjects by preserving their right to choose for themselves, and protecting the autonomy of those subjects by removing the subtle and unrecognized pressures and coercions that may dictate their choice. An elderly, ill, and institutionalized person may be losing control over most of the most commonplace activities of everyday life. Most of the autonomy that person retains may be invested in his control over his medical care. Indeed, it may be a much greater intrusion on that patient's autonomy to remove his power over his own medical care (and to remove his right to consent to be a research subject) than it would be to remove that power from another person who maintains control over other aspects of his life.

III.

For consent to be legally valid, it must be informed, voluntary, and given by a competent subject. The last section of this article explains the reasons for evaluating these requirements carefully where the medical conduct is re-
search rather than treatment. In this section, the article will briefly define each of those requirements and then attempt to determine whether the subject's status as an elderly person, as a senile dementia patient, or as a resident of a nursing home is relevant in analyzing whether that person's consent is properly informed and voluntarily given, and whether that person is competent to provide that consent.

Although the definition of what constitutes truly "informed" consent has been the subject of an extraordinary amount of academic writing and judicial evaluation,50 most courts now agree that the one giving consent must be provided with as much information about the proposed medical procedure, the alternative procedures, any research which is involved, and the risks and benefits of each of these, as a person in the position of the proposed subject would require in order to make a reasoned decision.51 Of course, the information that must be provided will vary from research protocol to research protocol, and from subject to subject within each protocol. In addition, the information may have to be presented to different subjects in different ways; the information has no meaning, practically or legally, if it is not presented in such a way that the subject actually does understand it.52 Providing too little or too much information may render the consent uninformed if it misleads the one whose consent is sought.53 For example, both failing to explain a likely outcome and explaining in great detail a very unlikely result may equally mislead the subject.54

The potential subject's status as an elderly person may affect the nature of truly informed consent.55 In addition, those studies indicate that older people have a slower reaction time and require more time to process complex information than do otherwise similarly situated younger people.56 Thus, even when an investigator might expect a younger person to be able to consent immediately upon hearing the risks and benefits of a medical procedure,

50. See the discussion of these definitions in Maisel & Kabnick, Informed Consent to Medical Treatment: An Analysis of Recent Legislation, 41 U. PIT P. L. REV. 409-10 (1980); A. RossoFF, Informed Consent (1981).
53. Pernick, supra note 8, at 71.
54. Id.
55. Horn, supra note 45. See also Botwinick, Behavioral Process, 2 Aging 1-18 (1975); Cohen & Wu, Language and Cognition During Aging, 1 ANN. REV. OF GERONTOLOGY & GERIATRICS 71-96 (1980); Craik, Age Differences in Human Memory, in HANDBOOK OF PSYCHOLOGY OF AGING 384-417 (J. Birren & R. Schale eds. 1977); Hiens & Fozard, Memory and Aging: Relevance of Recent Developments for Research and Application, 1 ANN. REV. OF GERONTOLOGY & GERIATRICS 97-120 (1980).
56. Ratzan, supra note 13; Lawton, supra note 48, at 5.
he ought to provide older people with more time to process that information. It may be important to temporarily separate the informing process from the consent process when those who are sought to consent are elderly, even if there is no need to do so under other circumstances.

Older people are more likely than others to have hearing or vision impairments, and thus any information provided to them ought to be offered by those sensitive to these potential difficulties. One with impaired vision ought not be asked to read and sign the fine print of a bureaucratically designed consent form. Similarly, the oral description of the risks and benefits of a particular procedure might be inappropriate for one with a hearing problem. Also, older people may be less familiar with bureaucratic requirements than are younger people and they may be less comfortable with formal written documentation than others would be. Obtaining truly informed consent from older people may require that the process be more informal, more personal, simpler, and more drawn out than it need be in other cases.

Finally, some substantive information that is highly significant to younger people may be irrevelant to those who are older. For example, the fact that a subject in a particular research protocol is exposing himself to a disease with horrible consequences after a forty-year latency period will be far less significant to someone who is ninety years old than to a twenty year old potential subject. In providing information to a subject of a research protocol, the investigator must determine what information will be significant to the potential subject, not what information would be significant to the investigator if he were to be a subject.

A proposed subject's status as a patient with senile dementia may also affect the nature of what constitutes truly informed consent. Memory loss is a symptom often associated with Alzheimer's disease. Informed consent has no meaning unless the proposed subject actually understands the proposed medical process and its risks, benefits, and alternatives at the time the consent is given. Thus, consent is not informed if it is given after the proposed subject has forgotten the risks and benefits that were described to him, even if he fully understood those risks and benefits at one time. Any research conducted upon senile subjects ought to be carefully monitored to assure that the consent is obtained when the proposed subject fully understands the risks and benefits.

Consent is voluntary only if it is provided freely, without undue inducement, without the fear of the deprivation of alternative treatments or any

57. Schwartz, supra note 37.
58. Id.
other reprisal, and without significant social pressures. Although no person can be free of all outside influence, consent is more likely to be truly voluntary when the effect of those pressures is minimized.

A patient suffering from senile dementia is likely to be very dependent on his family, physicians, and caretakers. This dependency which is like that suffered by others with serious illness, makes it much more difficult for him to provide truly voluntary consent. If the Alzheimer's disease patient believes that privileges might be limited or revoked or the quality of his care will be altered if he does not consent, his consent surely would not be voluntary.

The dependency which makes voluntary consent more difficult to obtain for senile dementia patients is exacerbated in the institutionalized and the elderly. Half of the institutionalized elderly need help in walking, bathing, toileting, and dressing. They are entirely dependent upon the nursing home administration for the most basic daily life functions. They are certainly good candidates for coercion by that administration. Indeed, they generally recognize that they have little control over their environment and their "learned compliance" may cause them to agree to anything apparently favored by those who control their lives. In addition, half of the institutionalized elderly have no living relatives, and a great number have very little social contact. Many may "volunteer" to participate in research so that they will have an opportunity for regular social contact with the investigator. Consent given by one who is desperate for that social contact is no less coerced than the consent that would be given by a prisoner hoping to be released early because of his participation as a research subject or the consent given by an involuntary resident of a mental institution hoping that his participation will cure him, thus making him candidate for release. Indeed, it is the apparent vulnerability of nursing home residents that led the Department of Health, Education and Welfare to include them as among those "Institutionalized as mentally disabled" for purposes of the proposed Regulations on Research Involving Those Institutionalized as Mentally Disabled. Of course, these regulations were never promulgated in final form. From the investigator's point of view, elderly nursing home residents are nearly perfect research subjects — they are easy to find, easy to control, and

59. TURNBULL, supra note 52, at 10-11.
60. Lawton, supra note 48.
61. Id. at 7.
63. Lawton, supra note 48, at 7.
64. See Proposed Regulations on Research Involving Those Institutionalized as Mentally Disabled, 43 Fed. Reg. 53950, 53954 (1978). These regulations were never adopted.
Informed Consent

Informed Consent is easy to follow. Their records are centrally maintained and easily accessed. The fact that they are so regularly sought out as research subjects, the fact that they are so convenient as research subjects, and the fact that they are under considerable pressure to participate as subjects when they are asked to do so ought to cause us to carefully scrutinize the voluntariness of their consent to participate in formal research.

There is no clear and generally accepted legal definition of competency for purposes of giving consent to a medical procedure. Every adult is presumed to be competent for all purposes unless he is shown to be otherwise. For that showing to have legal significance, generally it must take place in a judicial proceeding which results in a formal order. In most jurisdictions the courts will inquire as to whether the subject has the capacity to rationally perform, at some minimal level, the tasks expected of one carrying out the affairs of everyday life. If he possesses that capacity, he will not be declared incompetent for any purpose. If he does not possess that capacity, he will be declared incompetent for every purpose and a guardian will be appointed to act on his behalf. Mere residency in a nursing home is never sufficient to render one legally incompetent, and residency in a mental institution is generally insufficient to render one legally incompetent.

The law is slowly recognizing that it is senseless to require that competency determinations be "all or nothing" decisions which apply to the entire range of decisions one might be required to make. Obviously, one might be competent to understand some choices and make some decisions even if one cannot understand other choices and make other decisions. Thus, some jurisdictions, either by statute or judicial determination, permit individuals to be declared incompetent to make particular decisions and yet allow those individuals to maintain their right to make other kinds of decisions.

First, a subject's competency cannot depend on that subject's adoption of a socially preferred set of values. The mere fact that an older person, a senile person, or a person institutionalized in a nursing home has a different set of

65. Rosoff, supra note 50.
66. Id. at 234-36.
67. TURNBULL, supra note 52, at 6-8.
68. Id.
69. Id.
values from that person had when he was younger is not relevant to the
determination of whether that subject is incompetent. Older people may be
less risk (adverse) than younger people, for example, and that fact surely
should not affect their competence to make formal legal determinations.

In addition, older people may put a higher value on comfort and the
avoidance of inconvenience, and a lower value on avoiding life-threatening
illnesses or injuries than the rest of us. Indeed, some studies indicate that
older people apply problem-solving methods that are different from those
they applied when they were younger. These factors are not relevant to a
determination of their competency to consent to participation in research.

Of course, competency is always an issue when a prospective subject suf-
fers from senile dementia. The mental incapacity that may render one in-
competent is always present, in one degree or another, when senile dementia
is present. Generally, the more severe the disease the less likely it is that a
prospective subject will be competent to give consent. In any case, the men-
tally incapacitating consequences of senile dementia may vary from time to
time in a single patient. A patient who is occasionally competent can le-
gally give valid consent only if that consent is provided during a competent
period. Whether that consent is so durable as to be valid even when the
subject is no longer competent presents another, yet unresolved question.
Considerations of autonomy would seem to suggest that such a consent gen-
erally should survive subsequent incapacity of the patient.

Just as the law has reached no consensus on what constitutes competency,
it has similarly reached no consensus on who ought to make that determina-
tion, initially or eventually. Obviously, if the subject is incompetent he
must also be incompetent to determine his competency. The researcher
should not be allocated the authority to make that determination, because
the researcher has an interest in seeing that the research is done, and thus
finding the prospective subject competent if he would then consent, and in-
competent if he would not. The proposed but unadopted Regulation on Re-
search Involving Those Institutionalized as Mentally Disabled proposed that

72. Tibbles, Medical and Legal Aspects of Competency as Affected by Old Age in Spicker,
73. Rabitt, Change in Problem Solving Ability in Old Age in Handbook of the Psy-
choLOGY OF AGING, supra note 55, at 606-25.
75. Schwartz, supra note 37.
76. N. Reatig, New HHS Regulations and Psychiatric Research: Guidelines for Informed
Consent with Persons of Uncertain Competence. (Presented at the Symposium on the Future
of Psychiatric Research: Practical Problems at the Annual Meeting of the American Psychiat-
a "consent auditor" make this determination, and others have suggested that physicians independent of those doing the research make the determination. Until an alternative is developed, the current unwieldy legal requirement that each person be treated as legally competent unless that person is found to be incompetent by a court after a formal judicial hearing is likely to prevail. Further, until an alternative is adopted, researchers and physicians will continue to act at their peril when they obtain consent from either the subject or the subject's family if the subject is apparently incompetent but has not been declared legally incompetent.

IV.

If a proferred consent is not properly informed, that defect can be remedied by providing the prospective subject with proper information. If a proferred consent is not voluntary, that defect can be overcome by removing the coercion upon the subject. If the patient is not competent, however, there is no way to make the patient competent. Thus, when the competency element is the one that is lacking and only under those circumstances, the courts have sometimes permitted proxy consent to be offered by one authorized to act on behalf of the proposed subject. Unfortunately, perhaps, there is very little support in the law for the notion that anyone can act on behalf of an adult without having been appointed by a court to do so. Although the law does recognize a parent's right to act on behalf of a child, only a few states have statutorily extended that right to incompetent parents and spouses, and the case law in only a couple of states would permit such activity on behalf of an incompetent adult.

The purpose of allowing a parent to exercise proxy consent for a child is the preservation of that child's autonomy. Presumably, the good sense of the parent will allow that child to mature so that he too can exercise the autonomy of a competent adult. Obviously, that reason provides no basis whatsoever for allowing an adult to consent on behalf of an incompetent spouse, parent, or other relative. No one believes that one consenting to

77. Supra note 64.
78. Ratzan, supra note 13, at 38.
79. Rosoff, supra note 50. See also Annas, Glantz, & Katz, supra note 70; Turnbull, supra note 52.
80. Rosoff, supra note 50, at 233-45.
81. Id. at 187-210.
84. Id.
treatment for senile dementia is consenting to that treatment only so that the patient will regain his full and competent abilities to exercise his unfettered autonomy. For this reason, some have suggested that no proxy consent be permitted for research.\(^{85}\) On the other hand, that would accomplish very little. It would make some kinds of research — including research on those severely ill with senile dementia — impossible, and it would deny to many the opportunity to participate as a subject in an experiment just because they are incompetent. The proposed but unadopted Regulations on Research Involving Those Institutionalized as Mentally Disabled suggest that under some circumstances a "patient advocate" be able to exercise the power of consent on behalf of an otherwise incompetent patient, at least where that patient either "asserts" or does not apparently object to participation in the research.\(^{86}\) Others may object to the definition of the "patient advocate" because the term connotes someone who is an adversary to the medical authorities, and those who object may prefer the term "patient surrogate." In either case, the role of the one having authority to consent would be to determine whether the incompetent person, if competent, fully informed, and acting without coercion, would consent to participation in the experiment.\(^{87}\) If that person would do so then the advocate or surrogate would be able to consent (or, alternatively, must consent) also.

**CONCLUSION**

The primary purpose of the doctrine of the informed consent is to protect the autonomy of those who will receive medical treatment or will act as research subjects. While the necessity of acquiring consent may impede some types of research, the potential for investigator abuse of research subjects warrants an informed consent requirement that is at least as restrictive in a research context as it is in a purely therapeutic context.

The attributes found more frequently among elderly research subjects than among younger subjects — cognitive and emotional impairment, impaired vision and hearing, difficulty in resisting coercion, dependence on family and health care providers, acceptance of non-mainstream values, institutionalization in nursing homes — require that the doctrine of competent, voluntary, informed consent be especially carefully applied in research employing elderly subjects. While the precise requirements of competent, voluntary, and informed consent will vary from protocol to protocol and subject to subject, consent is more likely to be legally sound if (1) the sub-

\(^{85}\) Annas, Glantz & Katz, supra note 70, at 12.
jects of a research protocol are not limited to the elderly if others could also be employed as subjects without threatening the scientific integrity of the research protocol; (2) in research involving Alzheimer's disease, those with less severe dementia are preferred to those with more severe dementia as research subjects; and (3) those outside of nursing homes are preferred to those who are residents of nursing homes as research subjects.

The degree to which the preferences suggested here should be requirements depends on the value the community confers upon research among the elderly, those institutionalized in nursing homes, and the senile, and how important we view the protection of their autonomy to be. That balancing can be conducted informally by researchers themselves, or more formally through the explication of the common law of informed consent, the development of formal hospital policies, or the promulgation of federal regulations.