REPORT AND
RECOMMENDATIONS

RESEARCH INVOLVING THOSE INSTITUTIONALIZED AS MENTALLY INFIRM

THE NATIONAL
COMMISSION FOR
THE PROTECTION OF
HUMAN SUBJECTS
OF BIOMEDICAL AND
BEHAVIORAL RESEARCH

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DHEW Publication No (OS) 78-0006

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

February 2, 1978

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our "Report and Recommendations: Research Involving Those Institutionalized as Mentally Infirm." This is one of several topics of study identified in our mandate under Public Law 93-348, which directs the Commission to submit its reports and recommendations to the President, the Congress, and the Secretary of Health, Education, and Welfare. The Commission has previously transmitted reports and recommendations on "Research on the Fetus" (1975), "Research Involving Prisoners" (1976), "Psychosurgery" (1977), Disclosure of Research Information under the Freedom of Information Act" (1977) and "Research Involving Children" (1977).

In our deliberations concerning research participation by those institutionalized as mentally infirm, the members of the Commission have been concerned both for the protection of such vulnerable persons and for the recognition of their right to make decisions for themselves to the extent they are able. We have recognized, too, that protection of the mentally infirm requires that we learn more about their disabilities and how to treat them, and that research is necessary to the development of such knowledge.

Accordingly, the Commission has made recommendations (set forth at the outset of the accompanying report) establishing conditions under which research involving those institutionalized as mentally infirm may ethically be conducted. These recommendations would require that (1) no prospective subject who is institutionalized as mentally infirm should be approached to participate in research unless a person responsible for the health care of the subject has determined that participation would not interfere with such care, (2) persons who are institutionalized as mentally infirm and cannot give informed consent must not be involved in research unless it is relevant to their condition, and (3) no one should be involved in research over their objection unless participation may benefit the subject and is specifically authorized by a court of competent jurisdiction.

Our report also presents background material, including discussions of the ethical and legal issues, and a statement of the Commission's conclusions that led to its recommendations. Brief statements regarding particular points of individual dissent are also included. An appendix volume contains a number of papers, reports to the Commission and supplemental materials that were used in our deliberations.

The Commission appreciates this opportunity to be of service in establishing appropriate conditions for the conduct of an important area of scientific research.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

February 2, 1978

The Honorable Walter F. Mondale
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

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National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

February 2, 1978

The Honorable Thomas P. O'Neill, Jr.
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our "Report and Recommendations: Research Involving Those Institutionalized as Mentally Infirm." This is one of several topics of study identified in our mandate under Public Law 93-348, which directs the Commission to submit its reports and recommendations to the President, the Congress, and the Secretary of Health, Education, and Welfare. The Commission has previously transmitted reports and recommendations on "Research on the Fetus" (1975), "Research Involving Prisoners" (1976), "Psychosurgery" (1977), "Disclosure of Research Information under the Freedom of Information Act" (1977) and "Research Involving Children" (1977).

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Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

February 2, 1978

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our "Report and Recommendations: Research Involving Those Institutionalized as Mentally Infirm." This is one of several topics of study identified in our mandate under Public Law 93-348, which directs the Commission to submit its reports and recommendations to the President, the Congress, and the Secretary of Health, Education, and Welfare. The Commission has previously transmitted reports and recommendations on "Research on the Fetus" (1975), "Research Involving Prisoners" (1976), "Psychosurgery" (1977), "Disclosure of Research Information under the Freedom of Information Act" (1977) and "Research Involving Children" (1977).

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NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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INTRODUCTION

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in 1974 under the National Research Act (Public Law 93—348) to develop ethical guidelines for the conduct of research involving human subjects and to make recommendations for the application of such guidelines to research conducted or supported by the Department of Health, Education, and Welfare (DHEW). The legislative mandate also directs the Commission to make recommendations to Congress regarding the protection of human subjects in research not subject to regulation by DHEW. Classes of subjects that must receive the Commission's particular attention include children, prisoners and those institutionalized as mentally infirm.

The duties of the Commission with regard to research involving those institutionalized as mentally infirm are as follows:

> The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by . . . the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary [DHEW] and involving . . . the institutionalized mentally infirm to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study the Commission shall make such recommendations to the Secretary as it determines appropriate to assure that biomedical and

> behavioral research conducted or supported under programs administered by him meets the requirements respecting informed consent identified by the Commission.

This responsibility is broadened by a provision that the Commission make recommendations to Congress regarding the protection of subjects (including those institutionalized as mentally infirm) involved in research not subject to regulation by DHEW.

To discharge its duties under this mandate, the Commission studied the nature and extent of research in mental health and illness and retardation and the issues surrounding the participation in research of those institutionalized as mentally infirm. Commission members and staff visited a school for the mentally retarded and a large, urban mental hospital (both with research units) and talked with residents, staff, research personnel, members of the review committees, and administrators. Representatives from professional societies, federal agencies and public interest groups, as well as members of the public, presented their views to the Commission at a public hearing. The National Minority Conference on Human Experimentation, convoked by the Commission to assure that viewpoints of minorities would be expressed, made recommendations to the Commission on research involving those institutionalized as mentally infirm. The Commission also reviewed papers and reports prepared under contract, including papers on informed consent and a survey of actual review and consent practices in research involving institutionalized subjects. Finally, the Commission conducted extensive deliberations in public and developed recommendations on the participation of those institutionalized as mentally infirm in research.

The Commission's recommendations are set forth at the outset of this report, followed by chapters presenting background information, summaries of reports and views presented to the Commission, an analysis of the law with respect to research involving those institutionalized as mentally infirm, and an analysis of various ethical arguments. An appendix to this report contains the text of reports and papers prepared under contract, other materials reviewed by the Commission in the course of its study and deliberations, and a selective bibliography.

* * * * *

Definitions

The term "institutionalized mentally infirm" as used in Section 202(a)(2) of the National Research Act is defined to include "individuals who are mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution." Thus, the term "mentally infirm" was apparently intended to encompass a broad array of people who, because of cognitive or emotional handicaps, reside in institutions and are subject to institutional constraints. Several problems with this term should be noted.

First, the term "mentally infirm" is not in current clinical use.*

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* Many individuals who commented on DHEW's November 16, 1973 proposed policy objected to the use of the term "mentally infirm" because it reflects an antiquated notion of mental illness and its scope is unclear, e.g., some felt it included those incapacitated as a result of physical conditions. DHEW substituted the term "mentally disabled" in the proposed rulemaking of August 23, 1974.

There is no reference to it in the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association. Second, there is considerable debate about whether symptoms that may result in institutionalization are properly characterized as diseases or illnesses in the conventional sense, or whether they represent problems in social adaptation. Research findings and current theories of personal adjustment recognize an interaction between biological and environmental factors resulting in behavior that society defines as illness and disability. An alternative to psychiatric diagnoses, which assume a medical or disease model, is the view that disturbing behavior is more appropriately described in terms of the immediate antecedent and consequent conditions that evoke, reinforce and perpetuate that behavior. The use of the archaic term "infirm" is thus problematic since it implies limited physical functioning. Third, it is increasingly recognized that labelling may lead to stereotyped conceptions of people and their problems. Finally, it must be recognized that some persons are institutionalized as mentally infirm because of misdiagnosis or by error. Therefore, the Commission uses the term "those institutionalized as mentally infirm" to avoid endorsing any particular theory of cause or intervention.

The phrase "who reside as patients in an institution" refers, for the purpose of this report, to residents, either by voluntary admission or involuntary commitment, in public or private mental hospitals, psychiatric wards of general hospitals, community mental health centers, half-way houses or nursing homes for the mentally disabled, and similar institutions. It should be noted that such institutions may house individuals not mentioned specifically in the definition of the institutionalized mentally infirm, most notably alcoholics

and drug abusers. The Commission's recommendations are applicable to research involving such individuals when they are residents of such institutions.

National policies toward deinstitutionalization and the use of alternative treatment modalities have resulted in an increase in the number of mentally disabled persons who reside outside traditional institutions. Such persons may be discharged from institutions or may be on "leave" or "furlough" status. They may reside in foster homes, group homes or other facilities. If they remain on an institution's census and are therefore under the administrative responsibility of the institution, such persons are considered to be covered by the recommendations in this report.

RECOMMENDATIONS

The following recommendations are directed to:

The Secretary of Health, Education, and Welfare with respect to research that is conducted or supported under programs administered by DHEW and re-reported to DHEW in fulfillment of regulatory requirements; and

The Congress, with respect to research that is not subject to regulation by the Secretary of Health, Education, and Welfare.

RECOMMENDATION (1) RESEARCH INVOLVING THOSE INSTITUTIONALIZED AS MENTALLY INFIRM MAY BE CONDUCTED OR SUPPORTED PROVIDED AN INSTITUTIONAL REVIEW BOARD HAS DETERMINED THAT:

(A) THE RESEARCH METHODS ARE APPROPRIATE TO THE OBJECTIVES OF THE RESEARCH;

(B) THE COMPETENCE OF THE INVESTIGATOR(S) AND THE QUALITY OF THE RESEARCH FACILITY ARE SUFFICIENT FOR THE CONDUCT OF THE RESEARCH;

(C) APPROPRIATE STUDIES IN NONHUMAN SYSTEMS HAVE BEEN CONDUCTED PRIOR TO THE INVOLVEMENT OF HUMAN SUBJECTS;

(D) THERE ARE GOOD REASONS TO INVOLVE INSTITUTIONALIZED PERSONS IN THE CONDUCT OF THE RESEARCH;

(E) RISK OF HARM OR DISCOMFORT IS MINIMIZED BY USING THE SAFEST PROCEDURES CONSISTENT WITH SOUND RESEARCH DESIGN AND BY USING PROCEDURES PERFORMED FOR DIAGNOSTIC OR TREATMENT PURPOSES WHENEVER POSSIBLE;

(F) ADEQUATE PROVISIONS ARE MADE TO PROTECT THE PRIVACY

OF THE SUBJECTS AND TO MAINTAIN CONFIDENTIALITY OF DATA;

(G) SELECTION OF SUBJECTS AMONG THOSE INSTITUTIONALIZED AS MENTALLY INFIRM WILL BE EQUITABLE;

(H) ADEQUATE PROVISIONS ARE MADE TO ASSURE THAT NO PROSPECTIVE SUBJECT WILL BE APPROACHED TO PARTICIPATE IN THE RESEARCH UNLESS A PERSON WHO IS RESPONSIBLE FOR THE HEALTH CARE OF THE SUBJECT HAS DETERMINED THAT THE INVITATION TO PARTICIPATE IN THE RESEARCH AND SUCH PARTICIPATION ITSELF WILL NOT INTERFERE WITH THE HEALTH CARE OF THE SUBJECT; AND

(I) THE CONDITIONS OF ALL APPLICABLE SUBSEQUENT RECOMMENDATIONS ARE MET.

Comment: In this recommendation, the Commission establishes general conditions that should apply to the conduct of all research involving those institutionalized as mentally infirm. Subsequent recommendations impose additional conditions for different categories of such research. Comments on the individual sections of this recommendation follow.

(A) Research should be judged according to the methodology of the relevant discipline to assure that the proposed procedures are appropriate for obtaining the information sought in the research. The biomedical aspects of a research protocol should be evaluated according to the methodology of the relevant biomedical sciences, and the behavioral aspects should be assessed according to the methodology of the relevant behavioral sciences. Biomedical research methods or designs should not be imposed inappropriately on observational or behavioral research protocols or on the behavioral portions of protocols in—

volving both biomedical and behavioral approaches to an inquiry.

(B) The experience and expertise of the principal investigator and research staff should be such that they will be able to perform competently the procedures involved in the research and deal with any reasonably foreseeable adverse reactions that may arise in the course of the research. Also, the facilities where the research will take place should be adequate to meet any contingencies reasonably foreseeable in the conduct of the research and to assure the safety of the research subjects.

(C) Where appropriate, drugs, devices and behavioral interventions should be studied first in nonhuman systems (e.g., animals, tissue, cells) in order to obtain sufficient data to justify introduction into humans. In some instances (e.g., when the study involves cognitive functions or psychiatric conditions that have no parallel in animals, or when the research focuses on the nature and effects of institutionalization) it is clearly impossible to perform studies on animals. The investigator proposing a study that will involve those institutionalized as mentally infirm should document the performance of prior studies in nonhuman systems or indicate why such studies are not feasible or appropriate.

(D) In reviewing proposals to involve institutionalized persons in research, the IRB should evaluate the appropriateness of involving alternative, noninstitutionalized populations in the study instead of, or along with, the institutionalized individuals. Sometimes the participation of alternative populations will not be possible or relevant, as when the research is designed to study problems or functions that have no parallel in free-living persons,

(e.g., studies of the effects of institutionalization or studies related to persons, such as the profoundly retarded or the severely multiply handicapped, who are almost always found in residential facilities). There may be times when the research design requires the participation of both institutionalized and noninstitutionalized subjects. This might occur, for example, in studies to determine the effectiveness of a given therapeutic approach on both moderately and severely disabled individuals, or to compare the effect of a patient's residential situation on therapeutic response.

The IRB should determine whether the involvement of institutionalized individuals in the research would be exploitive, and the burden should be on the investigator to show that it is appropriate to involve such individuals in the research. General factors to be considered in assessing the appropriateness of conducting research in an institution include whether the research is relevant to the subjects' emotional or cognitive disability, whether individuals with the same disability are reasonably accessible to the investigator outside the institutional setting, and whether the research is designed to study the nature of the institutional process or the effect of some aspect of institutionalization on persons with a particular disability.

Length of stay in an institution should be extended for the purpose of participating in or completing a research project only if a subject knowledgeably agrees. The IRB should review with special care any proposal to institutionalize subjects or to extend their stay in an institution solely for research purposes, to determine whether the nature of the research in fact requires that it be conducted in such a setting. In making such a determination, the IRB should consider whether the facilities or personnel necessary to con-

duct the research or to protect the subjects' well-being are available only in an institutional setting, and whether, even if such is the case, part-time stay in a general hospital might suffice.

(E) In order to minimize the risk of harm or discomfort to which persons in institutions are subjected, it is important to design research so as to use materials (e.g., blood or urine samples) or information (e.g., measures of intellectual, psychiatric or neurological functioning) that are obtained for diagnostic or therapeutic purposes, whenever possible. Moreover, when additional information or procedures are required, the investigator should use the safest means of accomplishing the objective, consistent with the research goal, information requirements and time constraints.

(F) Adequate measures should be taken to protect the privacy of institutionalized subjects and to maintain the confidentiality of the data that are produced. The very fact of institutionalization, if divulged, may itself be harmful. Therefore, personally identifiable information should not be recorded, except as necessary, and such information should be coded as soon as possible so that the research records will not identify the subjects. Access to the code should be restricted to a "need to know" basis. Individually identifiable information should not be released to individuals unrelated to the research or the patient's treatment without written authorization of the patient or the patient's guardian of the person. Beyond this fundamental protection for all institutionalized subjects, further procedures for protecting confidentiality of particular data should be developed commensurate with the sensitivity of the information.

(G) It is the responsibility of the IRB to monitor the overall distribution of research burdens and benefits in the institution under its authority, and to guard against the inequitable distribution of either. Subjects in an institution should be selected so that any burdens of research do not fall disproportionately on those who are least able to make decisions regarding participation in research. Further, one group of patients should not be offered opportunities to participate in research involving procedures or therapies from which they may derive benefit to the unfair exclusion of other, equally suitable, groups of patients.

(H) The IRB should determine, for each protocol, the appropriate person from whom to request permission to approach prospective subjects. The purpose of this recommendation is to assure that the well-being of a patient is not adversely affected by the request to participate in research, and that participation does not interfere with patient care. In addition, the provision is designed to assure that patients do not become involved in research that would pose additional risk to them as a consequence, for example, of drug interactions with their medical therapy.

It is not necessary for the IRB to designate a particular individual to make the determination with respect to each patient, but rather the category of persons or relationship between the person making the determination and the patient. Where the proposed research involves mere observation, the superintendent of the institution or ward may be the appropriate person to give permission. Where the research involves some degree of risk, someone more immediately involved with the provision of care for the patients should be consulted. In some cases, a social worker or psychologist may be the most quali-

fied person; in other instances the IRB may determine that the investigator should request such permission from the physician of record.

When a potential subject's physician or therapist of record is involved in the proposed research, independent clinical judgment should be obtained regarding the appropriateness of including that patient in the research. This will avoid conflict of interest between the objectives of health care and those of research, while still permitting clinicians, who may be especially knowledgeable regarding promising avenues of research, to apply their expertise in both enterprises.

(I) Recommendation (1) sets forth general provisions that should apply to all research involving those institutionalized as mentally infirm. Subsequent recommendations provide additional conditions that must be met for the conduct or support of certain kinds of such research. Research protocols should satisfy the conditions of one or more of the subsequent recommendations, as applicable.

RECOMMENDATION (2) RESEARCH THAT DOES NOT PRESENT MORE THAN MINIMAL RISK TO SUBJECTS WHO ARE INSTITUTIONALIZED AS MENTALLY INFIRM MAY BE CONDUCTED OR SUPPORTED PROVIDED AN INSTITUTIONAL REVIEW BOARD HAS DETERMINED THAT:

(A) THE CONDITIONS OF RECOMMENDATION (1) ARE MET; AND

(B) ADEQUATE PROVISIONS ARE MADE TO ASSURE THAT NO SUBJECT WILL PARTICIPATE IN THE RESEARCH UNLESS:

(I) THE SUBJECT CONSENTS TO PARTICIPATION;

(II) IF THE SUBJECT IS INCAPABLE OF CONSENTING, THE RESEARCH IS RELEVANT TO THE SUBJECT'S CONDITION AND THE SUBJECT ASSENTS OR DOES NOT OBJECT TO PARTICIPATION; OR

(III) IF THE SUBJECT OBJECTS TO PARTICIPATION, THE RESEARCH INCLUDES AN INTERVENTION THAT HOLDS OUT THE PROSPECT OF DIRECT BENEFIT FOR THE INDIVIDUAL SUBJECT OR A MONITORING PROCEDURE REQUIRED FOR THE WELL-BEING OF THE SUBJECT, AND THE SUBJECT'S PARTICIPATION IS SPECIFICALLY AUTHORIZED BY A COURT OF COMPETENT JURISDICTION.

WHERE APPROPRIATE, THE INSTITUTIONAL REVIEW BOARD SHOULD APPOINT A CONSENT AUDITOR TO OBSERVE THE CONSENT PROCESS AND DETERMINE WHETHER EACH SUBJECT (I) CONSENTS, OR (II) IS INCAPABLE OF CONSENTING AND EITHER ASSENTS OR DOES NOT OBJECT, OR (III) OBJECTS TO PARTICIPATION.

Comment: For the purposes of this report, "minimal risk" means the risk (probability and magnitude of physical or psychological harm or discomfort) that is normally encountered in the daily lives, or in the routine medical or psychological examination, of normal persons. Thus, for subjects who are institutionalized as mentally infirm, routine examination procedures present no more than minimal risk if the likely impact of such procedures on them is similar to what would be experienced by normal persons undergoing the procedures. The IRB may determine that prospective subjects who are institutionalized

as mentally infirm are likely to react more severely than normal persons to certain routine procedures; in such instances, the procedures present more than minimal risk to the subjects. On the other hand, information that is known about certain subjects, or their prior experience, may establish that the risk presented to them by routine procedures is equivalent to what would be presented to normal persons. For each research protocol, the IRB must determine the degree of risk that would be presented to normal persons and then consider whether such risk is heightened by the illness or institutionalization of the prospective subjects or class of subjects.

The standard for "consent" by an institutionalized subject under this and the following recommendations is the general standard for informed consent (see the Commission's forthcoming reports on the ethical principles that should underlie research involving human subjects, and the performance of Institutional Review Boards). If the subject, because of illness or institutionalization, is incapable of giving informed consent to participate in research presenting no more than minimal risk, the subject's "assent" should be sufficient to authorize participation, provided the research is relevant to the subject's condition.

The Commission has chosen the term "assent" to describe authorization by a person whose capacity to understand and judge is somewhat impaired by illness or institutionalization, but who remains functional. The standard for "assent" requires that the subject know what procedures will be performed in the research, choose freely to undergo those procedures, communicate this choice unambiguously, and be aware that subjects may withdraw from participation. This standard for assent is intended to require a lesser degree of

comprehension by the subject than would generally support informed consent, and it is not related to judicial determination of incompetency or commitment status. Assent is not intended to serve as a substitute for informed consent, but rather as the applicable standard for agreement to participate where the subject is incapable of giving informed consent and certain other conditions are satisfied. Under Recommendation (2), those conditions require that the research be relevant to the subject's condition and present no more than minimal risk. Additional circumstances under which assent may authorize participation in research are set forth in the following recommendations.

Where the subject is incapable even of assenting, absence of objection should be sufficient to permit participation in research that is relevant to the subject's condition and presents no more than minimal risk.

If the subject objects to participation in research presenting no more than minimal risk, such participation may not be authorized except by a court of competent jurisdiction, and such authorization should not be sought except in cases where the research includes an intervention or monitoring procedure that is directly beneficial to the subject. The desires of a caring parent with respect to a subject's participation should be presented for the court's consideration.

The Institutional Review Board should determine whether it is appropriate to appoint someone to audit the process of consent to participation in research presenting no more than minimal risk. Such a person, or "consent auditor," should observe the consent process and determine on behalf of the Institutional Review Board whether each prospective subject consents, or, being incapable of

consenting, assents, or objects to participation in the research. The function of the consent auditor, whose appointment is discretionary under Recommendations (2) and (3) but mandatory under Recommendation (4), is discussed more fully in following comments.

RECOMMENDATION (3) RESEARCH IN WHICH MORE THAN MINIMAL RISK TO SUBJECTS WHO ARE INSTITUTIONALIZED AS MENTALLY INFIRM IS PRESENTED BY AN INTERVENTION THAT HOLDS OUT THE PROSPECT OF DIRECT BENEFIT FOR THE INDIVIDUAL SUBJECTS) OR BY A MONITORING PROCEDURE REQUIRED FOR THE WELL-BEING OF THE SUBJECTS) MAY BE CONDUCTED OR SUPPORTED PROVIDED AN INSTITUTIONAL REVIEW BOARD HAS DETERMINED THAT:

(A) THE CONDITIONS OF RECOMMENDATION (1) ARE MET;

(B) SUCH RISK IS JUSTIFIED BY THE ANTICIPATED BENEFIT TO THE SUBJECTS;

(C) THE RELATION OF SUCH RISK TO ANTICIPATED BENEFIT TO SUBJECTS IS AT LEAST AS FAVORABLE AS THAT PRESENTED BY ALTERNATIVE APPROACHES;

(D) ADEQUATE PROVISIONS ARE MADE TO ASSURE THAT NO ADULT SUBJECT WILL PARTICIPATE IN THE RESEARCH UNLESS:

(I) THE SUBJECT CONSENTS TO PARTICIPATION;

(II) IF THE SUBJECT IS INCAPABLE OF CONSENTING, THE SUBJECT ASSENTS TO PARTICIPATION (IF THERE HAS BEEN AN ADJUDICATION OF INCOMPETENCY, THE PERMISSION OF A GUARDIAN MAY ALSO BE REQUIRED BY STATE LAW);

(III) IF THE SUBJECT IS INCAPABLE OF ASSENTING, A GUARDIAN OF THE PERSON GIVES PERMISSION (IF A GUARDIAN OF THE PERSON HAS NOT BEEN APPOINTED, SUCH APPOINTMENT SHOULD BE REQUESTED AT A COURT OF COMPETENT JURISDICTION) OR THE SUBJECT'S PARTICIPATION IS SPECIFICALLY AUTHORIZED BY A COURT OF COMPETENT JURISDICTION; OR

(IV) IF THE SUBJECT OBJECTS TO PARTICIPATION, THE INTERVENTION HOLDING OUT THE PROSPECT OF DIRECT BENEFIT FOR THE SUBJECT IS AVAILABLE ONLY IN THE CONTEXT OF THE RESEARCH AND THE SUBJECT'S PARTICIPATION IS SPECIFICALLY AUTHORIZED BY A COURT OF COMPETENT JURISDICTION; AND

(E) ADEQUATE PROVISIONS ARE MADE TO ASSURE THAT NO CHILD WILL PARTICIPATE IN THE RESEARCH UNLESS:

(I) THE SUBJECT ASSENTS (IF CAPABLE) AND THE SUBJECT'S PARENT(S) OR GUARDIAN GIVE PERMISSION; OR

(II) IF THE SUBJECT OBJECTS TO PARTICIPATION, THE INTERVENTION HOLDING OUT THE PROSPECT OF DIRECT BENEFIT FOR THE SUBJECT IS AVAILABLE ONLY IN THE CONTEXT OF THE RESEARCH AND THE SUBJECT'S PARTICIPATION IS SPECIFICALLY AUTHORIZED BY A COURT OF COMPETENT JURISDICTION,

WHERE APPROPRIATE, THE INSTITUTIONAL REVIEW BOARD SHOULD APPOINT A CONSENT AUDITOR TO OBSERVE THE CONSENT PROCESS AND DETERMINE WHETHER EACH SUBJECT CONSENTS, OR IS INCAPABLE OF CONSENTING AND ASSENTS, OR OBJECTS TO PARTICIPATION, AND WHETHER THE PERMISSION

OF THE GUARDIAN OF AN ADULT SUBJECT, OR PARENT(S) OF A CHILD, WHO OBJECTS SHOULD BE SUPPLEMENTED BY COURT AUTHORIZATION.

Comment: Greater than minimal risk is permissible under this recommendation only if it is presented by an intervention that holds out the prospect of direct benefit to the individual subjects or by a monitoring procedure necessary to maintain the well-being of those subjects. Such risk is acceptable, for example, when all available treatments for a serious condition have been tried without success, and the remaining option is a new intervention under investigation. To be considered "direct," the possibility of benefit to the subject must be fairly immediate. The expectation of success should be well-founded scientifically in order to justify undertaking whatever risk is involved. It is also appropriate to involve institutionalized individuals in research when new biomedical or behavioral procedures under investigation present at least an equally favorable risk-benefit ratio as accepted therapeutic, diagnostic or preventive methods.

The IRB should evaluate research protocols of this sort in the same way that comparable decisions are made in clinical practice. It should compare the anticipated benefits of the intervention under investigation (including the monitoring procedures necessary for care of the patient) with those of available alternative methods for achieving the same goal, and should also consider the risk and possible benefit of attempting no intervention whatsoever. In evaluating anticipated benefits of such research, the IRB should consider only benefits that will in fact accrue to the subjects of the research, rather than to their caretakers. If the research also includes an investigative procedure that does not hold out the prospect of direct benefit to the subjects

and presents more than minimal risk, the research should be reviewed under Recommendation (4) with respect to such procedure.

An adult subject's consent or assent, under the standards described in the Comment to Recommendation (2), above, should be sufficient to authorize participation in research that is reviewed under Recommendation (3). If the subject is incapable of consenting or assenting but does not object to participation, the permission of a guardian should be required to authorize participation; mere absence of objection does not constitute sufficient grounds to proceed with research whenever that research presents more than minimal risk. If the subject is incapable of assenting and does not have a legally appointed guardian of the person, arrangements should be made for requesting the appointment of a guardian following a court hearing in which the potential subject is represented by a *guardian ad litem* and has the right to be present, to present witnesses, and to cross-examine witnesses. The patient may then be included as a research subject if the guardian gives permission. Alternatively, the court may specifically authorize such participation. It is the Commission's intent that guardianships established pursuant to this recommendation be limited, with authority extending only to the provision and continuance or withdrawal of permission for the subject's participation in the research. An official serving in an institutional capacity should not be considered a guardian for the purposes of these recommendations.

The objection of an adult subject should not be overridden unless a court of competent jurisdiction specifically authorizes participation and, in addition, the intervention expected to provide direct benefit to the subject is available only in the context of research. Such would be the case, for example,

with a new drug that the Food and Drug Administration restricts to controlled clinical trials until safety and efficacy have been demonstrated. This condition would not be satisfied by an intervention that the investigator, at his or her discretion, determines to make available only to participants in a research project. Further, in jurisdictions that grant institutionalized individuals an unqualified right to refuse therapy, their objection to participation in research will be binding.

Generally, a child capable of assenting should be asked if he or she is willing to participate in the research. A child should not be included over his or her objection unless there is court permission and, as with adult subjects, the therapeutic intervention being studied is available only in the context of research. The desires of a caring parent regarding a child's participation should be presented for the court's consideration.

The Institutional Review Board should determine whether it is appropriate to appoint an auditor to observe and assure the adequacy of the consent process for research reviewed under this recommendation. The IRB's determination should be based on the nature of the subject population and the risks that are involved. If there is a substantial question about the ability of the subjects to assent or there is a significant degree of risk involved in the research, the appointment of a consent auditor by the IRB would be appropriate.

The auditor should determine whether subjects consent, assent or object to participation in research. In some instances it may be appropriate for the auditor to observe the conduct of the research after a subject has assented, in order to determine whether the subject continues to assent. The auditor

should be responsible only to the Institutional Review Board with respect to such determinations and should not be involved (except in the capacity of consent auditor) with the research for which subjects are being sought. The auditor should be a person who is familiar with the physical, psychological and social needs of the class of prospective subjects, as well as their legal status.

In determining the ability of a subject to assent, the auditor should take into consideration not only the individual's ability to realize what procedures will be performed and to communicate a judgment regarding participation, but also the individual's length of stay in the institution and the opportunities that have been available during that period for making choices. Thus, the consent auditor should be sensitive to the effects of prolonged institutionalization on a person's ability to make choices regarding any aspect of his or her life.

RECOMMENDATION (4) RESEARCH IN WHICH MORE THAN MINIMAL RISK TO SUBJECTS WHO ARE INSTITUTIONALIZED AS MENTALLY INFIRM IS PRESENTED BY AN INTERVENTION THAT DOES NOT HOLD OUT THE PROSPECT OF DIRECT BENEFIT FOR THE INDIVIDUAL SUBJECTS, OR BY A MONITORING PROCEDURE THAT IS NOT REQUIRED FOR THE WELL-BEING OF THE SUBJECTS, MAY BE CONDUCTED OR SUPPORTED PROVIDED AN INSTITUTIONAL REVIEW BOARD HAS DETERMINED THAT:

(A) THE CONDITIONS OF RECOMMENDATION (1) ARE MET;

(B) SUCH RISK REPRESENTS A MINOR INCREASE OVER MINIMAL RISK;

(C) THE ANTICIPATED KNOWLEDGE (I) IS OF VITAL IMPORTANCE FOR THE UNDERSTANDING OR AMELIORATION OF THE TYPE OF DISORDER OR CONDITION OF THE SUBJECTS, OR (II) MAY REASONABLY BE EXPECTED TO BENEFIT THE SUBJECTS IN THE FUTURE;

(D) ADEQUATE PROVISIONS ARE MADE TO ASSURE THAT NO ADULT SUBJECT WILL PARTICIPATE IN THE RESEARCH UNLESS:

(I) THE SUBJECT CONSENTS TO PARTICIPATION;

(II) IF THE SUBJECT IS INCAPABLE OF CONSENTING, THE SUBJECT ASSENTS TO PARTICIPATION (IF THERE HAS BEEN AN ADJUDICATION OF INCOMPETENCY, THE PERMISSION OF A GUARDIAN MAY ALSO BE REQUIRED BY STATE LAW); OR

(III) IF THE SUBJECT IS INCAPABLE OF ASSENTING, A GUARDIAN OF THE PERSON GIVES PERMISSION (IF A GUARDIAN OF THE PERSON HAS NOT BEEN APPOINTED, SUCH APPOINTMENT SHOULD BE REQUESTED AT A COURT OF COMPETENT JURISDICTION).

THE SUBJECT SHOULD NOT BE INVOLVED IN RESEARCH OVER HIS OR HER OBJECTION.

(E) IF THE SUBJECT IS A CHILD, THE REQUIREMENTS OF THE COMMISSION'S RECOMMENDATIONS (5), (7) AND (8) ON RESEARCH INVOLVING CHILDREN ARE SATISFIED.

THE INSTITUTIONAL REVIEW BOARD SHOULD APPOINT A CONSENT AUDITOR TO OBSERVE THE CONSENT PROCESS AND DETERMINE WHETHER EACH SUBJECT CONSENTS, OR IS INCAPABLE OF CONSENTING AND ASSENTS, OR OBJECTS TO PARTICIPATION.

Comment: In determining whether an intervention presents only a minor increment over minimal risk, the IRB should consider the degree of risk presented from at least the following four perspectives: 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.

Individuals who are institutionalized as mentally infirm may participate in research presenting a minor increment of risk above minimal, even if there is no expectation that they will derive direct (*i.e.*, fairly immediate) benefit from such participation, provided there is good reason to believe the research will yield information of vital importance for the understanding of the condition for which the subjects have been institutionalized, or there is a possibility of remote benefit to the subjects, such as the eventual development of better treatment for their condition. In the former case, the expectation may be only the development of better methods of diagnosis or prevention, so that others who are at risk for the disorder, or a future generation of persons suffering from the disorder, will be the ones to benefit from the research.

An adult subject's consent or assent, under the standards described in the Comment to Recommendation (2), above, should be sufficient to authorize participation in research that is reviewed under Recommendation (4). If the subject is incapable of assenting but does not object to participation, the permission of a guardian of the person should be required to authorize participation. As noted previously, an official serving in an institutional capa-

city should not be considered a guardian for the purposes of these recommendations. A subject's objection to research that is reviewed under Recommendation (4) should be binding.

In its Report and Recommendations: Research Involving Children, the Commission recommended conditions that must be met before children may participate in research that involves more than minimal risk and a procedure from which the subjects are not expected to benefit. Such conditions include a limitation on the amount of permissible risk (a minor increment above minimal), a limitation on the nature of permissible risk (reasonably commensurate with experiences inherent in the subject's actual or expected medical, psychological or social situations), and specific provisions for the assent of the children and the permission of their parents or guardians. For this kind of research (i.e., where the subjects will derive no direct benefit as a result of participation), a child's objection to participation should be binding. (See Recommendations (5), (7) and (8) of the Commission's Report and Recommendations: Research Involving Children.)

For research that is reviewed under Recommendation (4), the Institutional Review Board should appoint an auditor to observe and assure the adequacy of the consent process. Whereas the appointment of an auditor is at the discretion of the IRB under the previous recommendations, it should be mandatory for research that presents more than minimal risk and does not hold out the prospect of direct benefit. The auditor should determine whether subjects are capable of assenting and do in fact assent to participate; where appropriate, the auditor should also observe the conduct of the research to determine whether the subjects continue to assent. The auditor should assure

that any objection by a subject is honored; there are no conditions under Recommendation (4) for overriding an objection. As stated previously, the auditor should be responsible only to the Institutional Review Board and should not be involved (except in the capacity of consent auditor) in the conduct of the research. (Further statements regarding the qualifications and function of the consent auditor are set forth in the Comment to Recommendation (3).)

RECOMMENDATION (5) RESEARCH THAT CANNOT BE APPROVED BY AN INSTITUTIONAL REVIEW BOARD UNDER RECOMMENDATIONS (2), (3) AND (4), AS APPLICABLE, MAY BE CONDUCTED OR SUPPORTED PROVIDED:

(A) AN INSTITUTIONAL REVIEW BOARD HAS DETERMINED THE FOLLOWING:

(I) THE CONDITIONS OF RECOMMENDATION (1) ARE MET; AND

(II) THE RESEARCH PRESENTS AN OPPORTUNITY TO UNDERSTAND, PREVENT OR ALLEVIATE A SERIOUS PROBLEM AFFECTING THE HEALTH OR WELFARE OF PERSONS INSTITUTIONALIZED AS MENTALLY INFIRM; AND

(B) A NATIONAL ETHICAL ADVISORY BOARD AND, FOLLOWING OPPORTUNITY FOR PUBLIC REVIEW AND COMMENT, THE HEAD OF THE RESPONSIBLE FEDERAL DEPARTMENT OR AGENCY HAVE DETERMINED THAT:

(I) THE CONDUCT OF THE RESEARCH WILL BE IN ACCORD WITH THE BASIC ETHICAL PRINCIPLES THAT SHOULD UNDERLIE THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS; AND

(II) ADEQUATE PROVISIONS ARE MADE FOR OBTAINING CON-

SENT OR ASSENT OF EACH SUBJECT OR PERMISSION FROM A GUARDIAN OF THE PERSON.

Comment: If an IRB is unable to approve a proposed research project under the conditions of Recommendations (2), (3) and (4), as applicable, in certain circumstances the IRB may nevertheless certify the research for review and possible approval by a national ethical advisory board and the head of the responsible department or agency. Such review is contingent upon an IRB's determination that the research presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of those institutionalized as mentally infirm, and that the provisions of Recommendation (1) are fulfilled. Thereafter, the research should be reviewed by the national board and head of department or agency, with opportunity for public comment, to determine whether the research is justified by the importance of the knowledge sought and is in accord with basic ethical principles that should underlie the conduct of research involving human subjects. Because of the importance of the ethical issues at stake, debate should be in a public forum, and conduct of the research should be delayed pending Congressional notification and a reasonable opportunity for Congress to take action regarding the proposed research.

The Commission believes that only research of major significance, in the presence of a serious health problem, would justify the approval of research under Recommendation (5). The problem addressed must be a grave one, there must be a reasonable expectation of developing needed scientific information, and an equitable method should be used for selecting subjects who will be invited to participate. The Commission believes that generally the authorization

requirements of Recommendation (4)(D) and (E) should prevail; however, the ethical advisory board may recommend otherwise if it feels that the importance of the research justifies such a recommendation and that basic ethical principles will not be violated by so doing.

CHAPTER 1. BACKGROUND

Mental illness. It is difficult to estimate the extent of mental illness in the United States. There is no national registry, and there are difficulties in distinguishing psychiatric disorders from problems in living. Most authorities state that about 10 percent of the people in this country experience an incapacitating episode at some point in their lives. Of course, the number of individuals handicapped at a given time is much lower. The most recent data (1973) indicate that about 2.5 percent of the U.S. population receives mental health treatment in a given year.[1]

There has been a radical shift of the locus of treatment over the past two decades. In 1955, 49 percent of patient care episodes were in state and county mental hospitals. By 1973, only 12 percent of the episodes were in such institutions, while 49 percent were provided through outpatient psychiatric services and 23 percent through community mental health centers.[2] The general decline in the number of hospital beds in the United States has been most pronounced for psychiatric beds. While two decades ago half of the nation's bed capacity was allocated to psychiatric patients, this proportion was reduced to 25 percent by 1974.[3]

The declining role of state and county mental hospitals is related not only to expanded use of outpatient treatment, but also to an increased reliance on nursing homes for those with long-term disabilities. From 1963 to 1969, the proportion of resident patients with mental disorders who reside in nursing homes, rather than in psychiatric hospitals, increased from 53 percent to 75 percent, and the trend presumably has continued.[4]

The majority of inpatient beds in psychiatric facilities are in state hospitals which, along with the few remaining county hospitals, account for 71 percent of these beds. Other facilities provide the following proportion of beds for inpatient psychiatric care: the Veterans Administration (10 percent), general hospitals (6 percent), residential treatment centers for emotionally disturbed children (5 percent), private/nonprofit psychiatric hospitals (4 percent), and federally funded comprehensive community mental health centers (3 percent).[5] In 1973, inpatient facilities cared for 1,679,608 psychiatric episodes.[6] Most people admitted to these facilities are between 18 and 64 years old.[7]

The following table shows the distribution of admissions by diagnostic category for 1971.[8]

Percent Distribution

	All Inpatient*	Public	Nonpublic
All Diagnoses**	100.0	100.0	100.0
Mental Retardation	1.2	1.7	0.3
Organic Brain Syndromes	6.3	7.0	4.8
Schizophrenia	27.0	31.0	18.5
Depressive Disorders	22.5	13.8	41.0
Other Psychotic Disorders	1.6	1.4	2.2
Alcoholism	15.8	20.0	6.6
Drug Abuse	5.1	6.2	2.6
All Other Disorders	18.6	16.3	23.4
Undiagnosed	1.9	2.6	0.6

* Excludes residential treatment centers for emotionally disturbed children and other multi-service facilities for which the demographic characteristics of admissions were not available.

** The diagnostic groupings used in this Table are defined in terms of the Diagnostic and Statistical Manual - DSM II, American Psychiatric Association, as follows: Mental Retardation 310-315; Organic Brain Syndromes 290, 292, 293, 294 (except 294.3), 309 (except 309.18, 309.14); Schizophrenia 295; Depressive Disorders 296, 298.0, 300.4; Other Psychotic Disorders 297, 298.1-298.9; Alcohol Disorders 291, 309.13, 303; Drug Disorders 294.3, 309.14, 304.

The roles of sex and race are suggested by the observation that males are admitted more often than females, and nonwhites at a higher rate than whites. Nonwhite males are admitted to public mental health facilities at a rate eight times that for white males. It can also be noted from the above table that people diagnosed as schizophrenic tend to be admitted to public facilities, while depressive patients are more often admitted to nonpublic hospitals.

Except for the residents of nursing homes, the duration of inpatient treatment has decreased dramatically. The median lengths of stay for public non-federal general hospitals, private and voluntary general hospitals, private mental hospitals, and Veterans Administration general hospitals, range from 7 to 24 days, while the median stay in state and county hospitals is 44 days. The latter facilities discharge over 75 percent of their patients within three months and over 85 percent by the end of six months.[9] It is clear that some stereotyped notions about the location and duration of psychiatric treatment no longer apply. Many variables account for these changes, including an emphasis on community-based services, the use of psychotropic medications, a recognition of the episodic nature of most illnesses, and a general liberalization of attitudes toward the care of the mentally ill.

Mental retardation. There are four to six million retarded persons in the United States. Although mental retardation occurs among all socioeconomic groups, it appears disproportionately more often among the socially and economically disadvantaged. More than 20 million family members are directly involved with retarded persons.[10]

Approximately 200,000 persons reside in 176 public institutions for the retarded, and 28,000 reside in 1,031 private facilities.[11] In addition, it has been estimated that 8 percent of nursing home residents are retarded, including 27 percent of those under age 65 who reside in skilled nursing homes.[12] There are 30,000 retarded persons in state mental hospitals.[13] They are predominantly mildly and moderately retarded adults, in contrast to residents of institutions specifically for the retarded, 70 percent of whom are severely or profoundly retarded. Half of those with severe and profound retardation have at least one additional handicap, and over a third have two or more additional handicaps.[14]

The number of institutions for the mentally retarded has increased at an accelerating pace as a consequence of federal legislation (Mental Retardation Facilities and Construction Act of 1962, P.L. 88-164). New facilities, however, are so much smaller than the older institutions that there has been an overall 10 percent decline in the total population of public residential facilities since 1970. This is a reflection of the "normalization" policy which asserts that most of the retarded can function in supervised community settings.[15] Progress is being made toward the national goal to deinstitutionalize about one-third of the retarded persons living in public institutions and return them to the community.[16] "Normalization" is the policy underlying many approaches to retardation including housing, employment, treatment and education, as well as standards for accreditation of facilities.[17]

Admission Procedures: Mentally Ill. Procedures for admission to institutions for the mentally ill vary from state to state. Admissions are desig-

nated as voluntary or involuntary. By and large, involuntary commitment occurs only after a judicial or administrative determination that an individual is dangerous to self or others, or is in need of treatment.[18] Involuntarily committed persons, because they have been deprived of liberty, are provided with some constitutional safeguards (for example, due process requirements such as periodic review), but their freedom of choice with regard to treatment may be substantially curtailed. Voluntary residents are presumed to have entered the institution on their own initiative or to have acquiesced to the judgment of others who have brought them to the institution, although some voluntarily admitted persons have agreed to institutionalization only when threatened with involuntary commitment. Voluntarily admitted persons usually must give notice to the institution before they may leave. They may have freedom to participate in treatment decisions.

Admission Procedures: Mentally Retarded. Admission procedures for the retarded also vary among states. In some states, admission procedures parallel those for the mentally ill. In others, the states take the position that they provide protective services for the retarded and thus do not require periodic judicial or administrative review for continued residence. The majority of institutionalized retarded persons are admitted without any legal proceedings; most enter a residential facility before their twenty-first birthday, most of them placed there by parents or guardians.[19]

The severely and profoundly retarded and the senile are more likely to be long-term residents than are those experiencing acute symptoms of mental illness. There are no data available on the average length of stay of retarded

residents in public facilities, nor are there data which show the extent to which discharged persons move to other kinds of institutions.[20]

Thus, mentally infirm persons may be institutionalized for short or long periods. Commitment is usually for an indefinite term. Increasingly, however, legal restrictions are being placed on the length of time an involuntarily committed person may be kept for care or treatment without periodic review and evaluation.

REFERENCES

1. National Institute of Mental Health, Draft Report: The Financing, Utilization and Quality of Mental Health Care in the United States, Washington, D.C., 1976 pp. 9-11.

2. Ibid., p. 22.

3. National Institute of Mental Health, Statistical Note 118, Washington, D.C., July 1975, p. 7.

4. National Institute of Mental Health, Draft Report, supra note 1, p. 23.

5. National Institute of Mental Health, Statistical Note 118, supra note 3, p. 1.

6. Ozarin, L.D., Redick, R.W., and Taube, C.A., A Quarter Century of Psychiatric Care, 1950-1974: a Statistical Review, Hospital and Community Psychiatry, Vol. 27:7, 1976, p. 517.

7. Ibid., p. 516

8. National Institute of Mental Health, Utilization of Mental Health Facilities 1971, DHEW #NIH-74-657, Washington, D.C., 1973, p. 28.

9. National Institute of Mental Health, Draft Report, supra note 1, p. 9.

10. President's Committee on Mental Retardation, Report to the President: Mental Retardation: Century of Decision, Washington, D.C., 1976, p. 7.

11. President's Committee on Mental Retardation, Mental Retardation: The Known and the Unknown, DHEW #OHD 76-21008, Washington, D.C., 1976, pp. 66-67.

12. General Accounting Office, Returning the Mentally Disabled to the Community: Government Needs to Do More, HRD-76-152, Washington, D.C., 1977 p. 11.

13. Ibid., p. 4.

14. National Association of Superintendents of Public Facilities for the Mentally Retarded, Current Trends and Status of Residential Services for the Mentally Retarded, Lakeland State School, Washington (mimeographed), 1971.

15. President's Committee on Mental Retardation, Mental Retardation: The Known and the Unknown, supra note 11, p. 66.

16. Ibid., p. 66.

17. Ibid., p. 73.

18. Brakel, S.J. and Rock, R.S., The Mentally Disabled and the Law, Chicago, University of Chicago Press, 1971, pp. 49-59.

19. Stone, A.A., Mental Health and the Law: A System in Transition, DHEW #(ADM) 75-176, Washington, D.C., 1975, p. 121.

20. President's Committee on Mental Retardation, Mental Retardation: The Known and the Unknown, supra note 11, p. 66.

Chapter 2. Nature of Research Involving Those Institutionalized as Mentally Infirm*

Research involving the mentally infirm is broad in scope, extending from cell physiology to social systems, from normal developmental processes to behaviors associated with specific disorders. The research may be biomedical, behavioral or biobehavioral. As in studies of normal functioning, the current trend is to focus on the interaction of physiological and behavioral processes. Studies involving those institutionalized as mentally infirm may involve interventions that benefit the subjects directly, may be designed to contribute knowledge about the class of subjects, or may be unrelated to the conditions of the mental infirmity. Even in research not involving procedures designed to provide direct benefit to the health or well-being of the research subjects, however, there may be incidental or indirect benefits.

Research that may benefit the subjects 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.

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* For fuller descriptions of research involving those institutionalized as mentally infirm see: National Institute of Health, Research in the Service of Mental Health: Report of the Research Task Force of the National Institute of Mental Health, DHEW #ADM-4-236, Washington, D.C., 1975.

Typical procedures for evaluating therapies include systematic observation of behavior; interviews or administration of questionnaires to residents, families, employers, etc.; psychological, educational and vocational testing; and the compilation of data regarding length of stay, duration of community care following discharge from resident services, and number of readmissions, as these relate to individual outcome. Evaluation of therapeutic procedures may also involve random allocation of subjects to treatments.

A sizable proportion of research involving those institutionalized as mentally infirm is designed to produce knowledge about various disabilities, the factors underlying or precipitating them, the accompanying biobehavioral changes, and their incidence or distribution. Biological aspects of such research may involve biochemical evaluation or analyses, such as comparison of metabolism or biochemistry of schizophrenics with that of normal or depressed persons, investigation of the role of neurotransmitters in psychoses, and attempts to identify biochemical defects hypothesized to be genetically transmitted. Procedures typically used in such research include the collection of urine, blood and spinal fluid samples. Behaviorally oriented research projects may investigate motor, perceptual or cognitive behavior of the mentally infirm as compared to normals, such as studies of maze performance, visual or auditory thresholds, sentence completion and recall of serial digits. Although such research may benefit the class of subjects in the long run, much of it does not provide any immediate benefit to the participating subject (except to the extent that additional attention, personal interaction and monitoring of progress is beneficial to institutionalized persons).

Other research involves evaluation of alternatives to institutionalization of the mentally infirm, such as outpatient treatment, half-way houses, community care and other community-support programs. Alternative modes of institutionalization, such as increased resident-staff interaction, are also studied. Such studies may provide direct benefit to the individual subjects or may benefit long-term residents indirectly by demonstrating the harmful effects of institutionalization and encouraging improvements in the organization or administration of institutional facilities or the development of alternative treatment settings.

A study conducted for the Commission by the Survey Research Center, Institute for Social Research, University of Michigan, collected data regarding risks and benefits in research involving the mentally infirm. The findings of the Michigan study are summarized in Chapter 4 of this report.

Chapter 3. Extent of Research Involving Those Institutionalized as Mentally Infirm

Most federally sponsored research on mental health and illness is supported or conducted by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and within that agency by the National Institute of Mental Health (NIMH). NIMH supported approximately 1,050 research project grants in fiscal year 1975, at a cost of $62.7 million. Sixty-five percent of these grants in fiscal year 1975 were devoted to problem-oriented research and 35 percent to basic research. The total support of NIMH intramural and extramural research grants and contracts for fiscal year 1975 was distributed as follows:

Research Focus	% Research Funds
Causes and prevention	63
Amelioration	19
Diagnosis and epidemiology	9
Services delivery	8
Dissemination and use of findings	2

Problem-oriented research included such areas as (1) diagnosis, description, etiology and treatment of major psychiatric disorders; (2) developmental and adjustment problems associated with divorce, aging, school and sexual development; and (3) mental health aspects of crime, poverty, urban living and delinquency. Basic research related to such areas as preclinical drug research and fundamental biological, psychological and sociocultural processes (see Figure 1, page 38).

In order to identify the extent of NIMH supported research with the institutionalized, NIMH searched its active project grants in five research support program areas (clinical research, applied research, psychopharmacology, epidemiology, and services development research) and found that approximately 100 projects of 500 in these areas involved an inpatient population in fiscal year 1975.[1]

The Veterans Administration (VA) is the next largest sponsor of mental health research involving the institutionalized and conducts the greatest number of research projects. VA support for research on mental illness was $6.3 million (less than 10 percent of the VA research budget) for fiscal year 1973. Of the approximately 700 research projects concerning mental health or illness conducted by the VA in 1973, 230 were directly related to the nonretarded mentally ill. Of these, 70 percent were behavioral (for example, studies of the effects of institutionalization, attitude and motivation assessment, and behavior modification using operant conditioning procedures), and 30 percent were biobehavioral (for example, drug studies, psychophysiological measures, sleep and EEG studies) (see Figure 2, page 39).[2]

Figure 3 identifies federal agencies, in addition to those discussed above, which conduct or support research relating to mental health and illness. The nature of research supported by other agencies does not differ, in any pertinent way, from that supported by ADAMHA and the VA.[3]

Most of the federally sponsored research relating to mental retardation is conducted by twelve Mental Retardation Research Centers administered by the National Institute of Child Health and Human Development (NICHD), and by Uni-

versity Affiliated Facilities administered by the Division of Developmental Disabilities with support from the Bureau of Education for the Handicapped (Office of Education) and from Maternal and Child Health Service (Health Services Administration). NICHD also supports biobehavioral and behavioral research not affiliated with the Centers. Research sponsored by the Mental Retardation Branch, NICHD, is summarized in Figure 4.[4] Of the $5 billion annually expended for programs serving the retarded, less than one and one-half percent, or $62 million, is spent on research.[5] The National Institute of Neurological and Communicative Disorders and Stroke and the Rehabilitation Services Administration also fund some retardation research. The total mental retardation research budget of DHEW was $31 million for 1973.

REFERENCES

1. Data on NIMH supported research was obtained from the National Institute of Mental Health, Program Analysis Branch.

2. Data was obtained from the Veterans Administration, Medical Research Information System, and from the National Academy of Sciences.

3. National Institute of Mental Health, Research in the Service of Mental Health: Report of the Research Task force of the National Institute of Mental Health, DHEW #(ADM) 75-236, Rockville, Maryland, 1975, pp. 54-57.

4. Data was provided by National Institute of Child Health and Human Development, Mental Retardation Branch.

5. Conley, R.W., The Economics of Mental Retardation, Baltimore, Johns Hopkins Press, 1973.

FIGURE 1
DISTRIBUTION OF BASIC AND PROBLEM ORIENTED RESEARCH
NATIONAL INSTITUTE OF MENTAL HEALTH – 1975

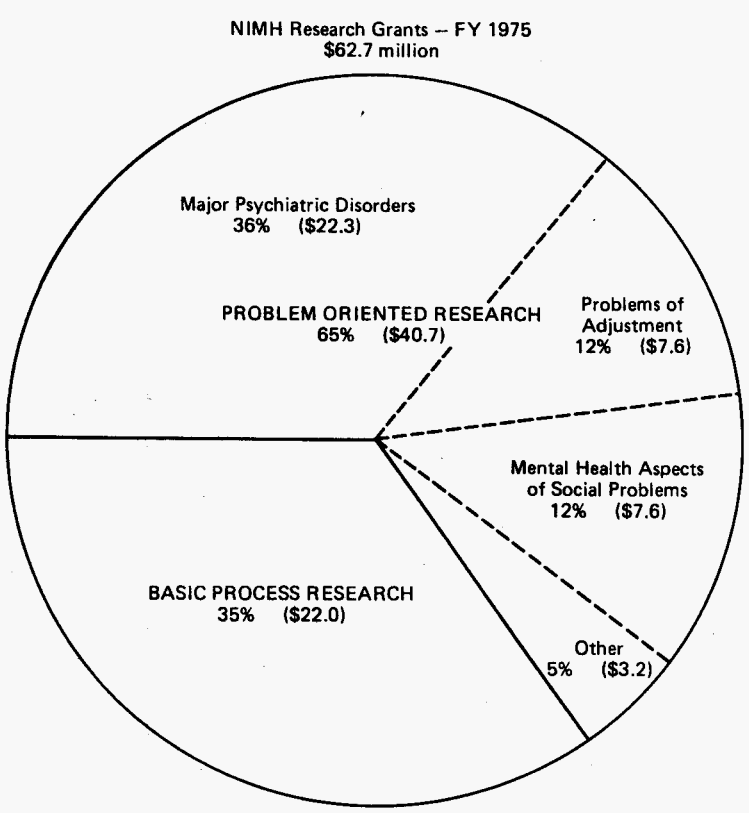


Fig. 1A

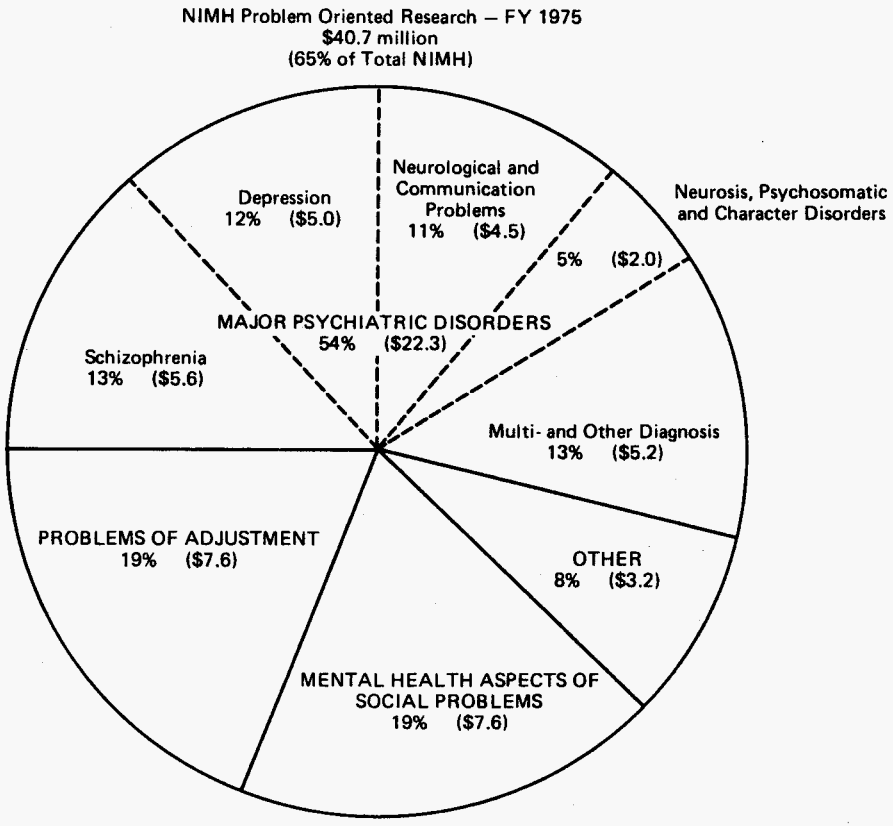
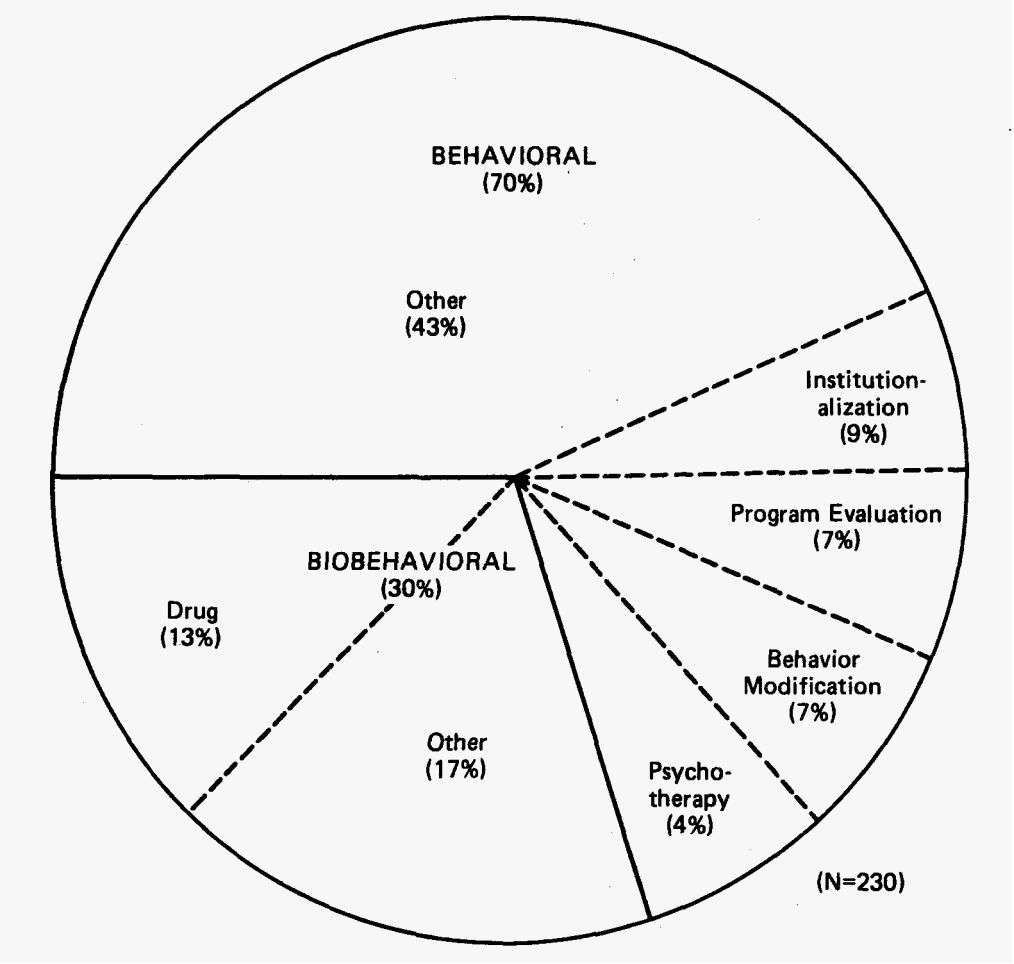


Fig. 1B

FIGURE 2
VETERANS ADMINISTRATION RESEARCH PROJECTS INVOLVING THE INSTITUTIONALIZED MENTALLY INFIRM

Fiscal Year 1974[1]



Behavioral: "Nonintrusive" behavioral research. The "other" category includes paper and pencil tests; interviews; questionnaires; measurements of attitude, motivation, mood, intelligence, aptitude, personality, etc.

Institutionalization: Research on the nature, process and effects of institutionalization.

Program Evaluation: Studies of rehabilitation or educational programs.

Behavior Modification: Projects utilizing behavior contingent management techniques.

Psychotherapy: Studies of the process and/or effects of therapeutic techniques.

Biobehavioral: Studies on psychophysiological and neuropsychological measures. The "other" category includes sleep, biofeedback, EEG, metabolism, etc.

1. Source: Veterans Administration

Reprinted from: National Institute of Mental Health, Research in the Service of Mental Health (1975), pp. 54-57.

Figure 3

1971 Extramural Projects Identified by the Smithsonian Science Information Exchange, as Relevant to NIMH Research
(Amounts in thousands, rounded)

	No.	Amount	Total 1971 Extramural Budget	Comments
National Institute of Mental Health	1,267	$73,669	$ 73.957	Note the close correspondence with internal NIMH figures for 1971.
National Institutes of Health (Total)	573	44,564	671,000 [a]	
National Institute of Child Health and Human Development	228	19,372	46,900	Program interests cover all human development, including population studies, pregnancy and birth, infant mortality; most pertinent to NIMH are studies in mental retardation, behavioral, cognitive, and social development, and social and intellectual aspects of aging.
National Institute of Neurological Diseases and Strokes	185	9,495	53,700	Program interests focus on neurological problems, epilepsy, cerebrovascular and muscular disorders; most pertinent to NIMH are studies of neural aspects of learning and behavior, and normal nervous system function.
National Heart and Lung Institute	25	2,794	109,800	Program interests cover cardiovascular and lung problems; most pertinent to NIMH are studies of behavioral aspects of hypertension.
National Institute of General Medical Sciences	16	2,537	77,800	Program interests center on noncategorical health research, such as biomedical technology and clinical studies of trauma, surgery, anesthesiology: most pertinent to NIMH are studies on genetics, endocrine functioning, and chemical correlates of memory.
National Eye Institute	51	1,970	19,200	Program interests focus on visual disorders: most pertinent to NIMH are visual perception studies and pyschophysiological investigations.
National Institutes of Health (Other)	68	8,386	364,200	
Maternal and Child Health Service	23	2,156	5,735 [b]	Research program centers on applied studies aimed at improving the health of children and mothers; pertinence to NIMH research is in general developmental area. MCHS is now a component of the Health Resources Administration.
National Center for Health Services Research and Development	21	1,933	47,000 [c]	Research program focuses on health services organization, delivery, and financing, consumer education, and data systems; relevance to NIMH derives from the extent to which general health delivery studies provide models for delivery of mental health services. NCHSR &D is now a component of the Health Services Administration.
Office of Education	24	8,052	61,262 [d]	SSIE reports an additional 760 projects, without dollar values. Research focuses on the full range of educational issues, including curriculum development and testing and innovations. Most pertinent to NIMH are projects on learning disabilities. Many OE research efforts have been transferred to the National Institute of Education.
Social and Rehabilitation Service	114	7,752	31,764 [d]	Research and development activities cover all aspects of welfare and social services: administration, service

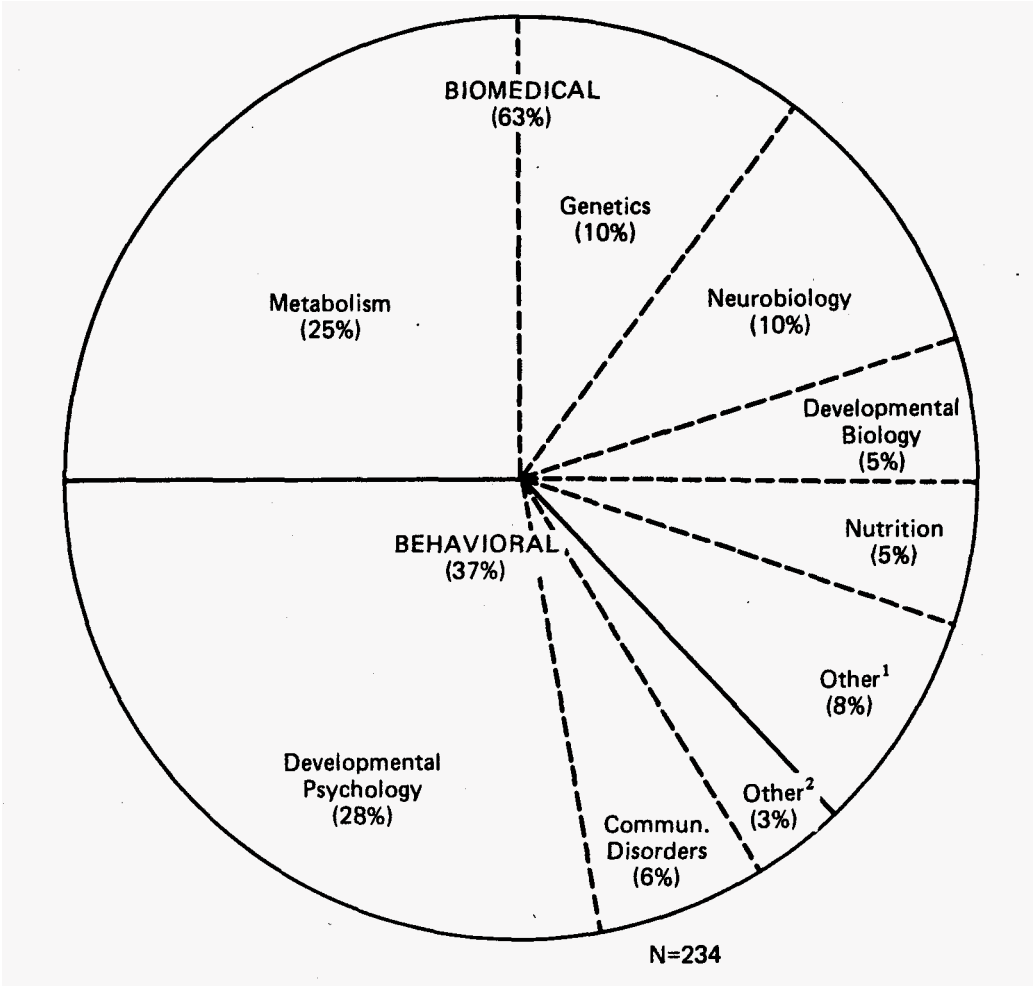
Figure 3 (con't.)

1971 Extramural Projects Identified by the Smithsonian Science Information Exchange, as Relevant to NIMH Research
(Amounts in thousands rounded)

	No.	Amount	Total 1971 Extramural Budget	Comments
				development and evaluation, quality and standards. Most pertinent to NIMH are projects on the special service needs of children, the aged, and other special groups.
Department of Defense	84	$ 5,161	$763,213[d]	SSIE information underestimates DOD research, since classified projects are not included. DOD research activities emphasize military technology, but some fundamental biological, and behavioral research is included. Also, there has been recent focus on drug addiction and rehabilitation studies.
USAF	17	1,318	530,377[e]	
USA	26	1,489	115,502[d]	
USN	41	2,354	117,334[d]	
Office of Economic Opportunity	46	21,366	57,187[d]	Large-scale demonstration and evaluation programs in poverty typify research here. Studies of delivering health services to the poor are most pertinent to NIMH.
Department of Justice	16	1,096	6,033[d]	In the Justice Department's Law Enforcement Assistance Administration, research and demonstration projects center on the reduction of crime; alleviating conditions which promote crime; intervening in criminal careers; etc. Most pertinent to NIMH are studies of the characteristics of juvenile and adult offenders, of release and probation techniques, and of drug abuse prevention. Research in the Bureau of Narcotics and Dangerous Drugs is also of relevance to NIMH.
National Science Foundation	531	13,405	60,750[f]	NSF supports a complete range of scientific endeavor in their psychology programs. The Division of Social Sciences and the Division of Biological and Medical Sciences support fundamental studies that are pertinent to NIMH research. Some projects in the international program (e.g., genetic studies of primitive populations) also are relevant to NIMH activities.
Division of Social Sciences	354	9,122	17,390	
Division of Biological and Medical Sciences	177	4,283	43,360	
Veterans Administration	—	$ —	$ —	The VA's research program is almost exclusively intramural; 5,283 research projects were conducted in VA installations in 1971. The SSIE search identified 980 studies as related to NIMH research. Projects in psychiatry, psychology, social work, and endocrine functioning are most pertinent to NIMH.
Private Nonprofit	240	20,308	—	Over 80 private nonprofit organizations supported at least one project identified as mental health related. An additional 44 projects were listed without dollar values.
State Governments	28	1,255	—	Additionally, SSIE includes 346 Stale government projects but has no information about costs. The National Association for Mental Health has begun and hopes to expand a project to assess State-supported mental health research more accurately.

[a] Source: National Indilutes of Health Basic Data 1972, p. 28.
[b] Source: DHEW Publication No. HSM 72-5002, p. 30.
[c] Source: NCHSR&D Focus, p. 8.
[d] Source: Federal Funds for Research Development and Other Scientific Activities (NSF publication 72-317, v. XXI), Table C-10.
[e] Total for USAF, USA, and USN only; does not include $235,234,000 and departmentwide defense agency expenditures.
[f] Total for individual project support in the Division of Social Sciences and Division of Biological & Medical Sciences only; does not include $113,810,000 of individual project support in other scientific fields. Source: National Science Foundation Annual Report, 1971 (NSF publication 72-1), p. 6-7.

FIGURE 4
NICHD, MENTAL RETARDATION BRANCH, RESEARCH PROJECTS (1975)*



1 Epidemiology, Infectious Disease, Teratology, Endocrinology, Toxic Agents, Ambulatory Pediatrics, Neonatology.

2 Behavioral Genetics, Behavioral Teratology, Social Psychology, Psychophysiology,

* Source: NICHD
N.B. No data is available on subject populations. Research participants may include normals, non-institutionalized, and institutionalized.

CHAPTER 4. SURVEY OF RESEARCH PROCEDURES, RISKS AND BENEFITS, INFORMED CONSENT AND REVIEW PROCEDURES

Research involving the mentally infirm was the subject of a report and supplementary information prepared for the Commission by the Survey Research Center (SRC) at the University of Michigan. This report was not confined to studies involving institutionalized persons, but included studies in which an investigator used a label such as mentally ill or retarded to describe those involved as research subjects. The data came from SRC's larger study of research involving human subjects, informed consent and review procedures at a probability sample of 61 institutions drawn from the more than 420 institutions that had Institutional Review Boards (IRBs) approved by the Department of Health, Education, and Welfare.* The SRC report on research involving the mentally infirm was based primarily on analysis of consent forms used in this research and interviews with 151 investigators, and 33 subjects, 12 other individuals who provided third-party consent on the behalf of subjects, and a representative of each of the 13 IRBs that reviewed research involving the mentally infirm between July 1974 and June 1975. With the exception of data from subjects and third-parties, SRC believed the data to be statistically representative of the population from which the sample was drawn.

Research involving the mentally infirm constituted nine percent of the research that was reviewed by the IRBs at the 61 institutions in the sample.

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* The study was confined to institutions from which DHEW had accepted a "general assurance" of compliance with DHEW regulations for protection of human subjects.

Sixty-four percent of the research involving the mentally infirm was reviewed by IRBs at institutions for the mentally infirm; the remainder was reviewed by IRBs at other institutions, primarily at medical schools and hospitals.

Approximately 60 percent of the studies involving the mentally infirm were behavioral. Most of these studies involved psychological or educational testing, interviews or questionnaires, or behavioral observation, but about 25 percent of the behavioral research entailed the study of an intervention of some kind (educational innovations, social or psychological therapies, or behavior modification). Biomedical research accounted for approximately a third of the projects involving the mentally infirm. Almost all of these projects involved the administration of drugs or the analysis of bodily fluids or tissue. Analyses of data or materials that had been obtained for other purposes accounted for the remaining small fraction (about seven percent) of the research involving the mentally infirm.

Subject Selection. Subjects of this research were generally selected because of their mental condition. The presence of a specific mental disorder was a selection criterion in 74 percent of the projects reviewed by IRBs in institutions for the mentally infirm, and in 94 percent of the projects in other institutions. In institutions for the mentally infirm, a diagnosis of psychosis was the most frequent selection criterion, being reported in half of the studies. Psychoses and neuroses were each a selection criterion in about a third of the studies in other institutions. Mental retardation was listed as a selection criterion in 13 percent of the studies involving the mentally infirm (although the retarded were subjects in 20 percent of the studies

involving the mentally infirm). In 13 percent of the projects involving the mentally infirm, the investigator did not mention mental condition of the subjects as a factor in subject selection; it is possible some of this research could have been conducted on other populations. In about one-fourth of the projects involving the mentally infirm, investigators involved their own patients in the research.

Risks and Benefits of Research Involving the Mentally Infirm. Investigators provided assessments of the probability and magnitude of the risks and benefits of their research. Most risks to subjects were described as pertaining to minor psychological stress, embarrassment or minor medical complications, and most risks were assessed as of "very low" probability of occurrence. Fewer than five percent of the studies involving the mentally infirm presented higher probabilities of more serious harms. More than one-third of the projects involving the mentally infirm were assessed by investigators as completely without risk.

In analyzing the risks of research involving the mentally infirm, studies that were expected to be beneficial to subjects were compared to studies in which no such benefits were expected. (Projects "expected to benefit subjects" were defined as those which investigators reported (a) to be conducted for the "primary purpose" of benefiting subjects or (b) to have a medium or high probability of benefiting subjects.) Just under half (46 percent) of the projects involving the mentally infirm were expected to benefit subjects. A larger percentage of the research conducted in institutions for the mentally infirm was expected to benefit subjects (49 percent) than was the research involving the

mentally infirm conducted in other institutions (40 percent). Investigators' assessments of most risks of research not expected to benefit subjects were substantially lower than for research in which benefit to subjects was expected. For example, in studies expected to benefit subjects, investigators reported a "very low" probability of "serious medical complications" in 15 percent of the studies and a "low" probability in an additional two percent of the studies. In studies not expected to benefit subjects, comparable figures were one percent for each category. Similarly, in studies expected to benefit subjects, investigators reported a "very low" probability of "serious psychological stress" in 14 percent of the studies and a "low" probability in an addittonal two percent. Comparable figures in studies not expected to benefit subjects were nine percent and three percent.

Informed Consent.* IRB requests that changes be made in consent procedures were relatively common in research involving the mentally infirm, occurring in about one-fifth of the projects. Consent changes were required less frequently (11 percent) in projects in institutions for the mentally infirm than in projects at other institutions (27 percent). Most of the consent changes pertained to consent forms rather than to the setting or circumstances under which consent would be obtained. Consent changes were requested most frequently in

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* Because the terms "consent" and "proxy consent" were used in the survey, they appear in this section. As is explained in the Commission's recommendations, the Commission has generally used the term "assent" to refer to the agreement to participate in research by an individual who is not competent to give legally effective informed consent. Similarly, the Commission has generally referred to "third-party permission," which it believes to be a more accurate term than "third-party consent."

studies that involved a behavioral intervention; the most frequent change in such projects was the requirement that consent be obtained in writing rather than orally.

Oral or written consent was sought in more than 80 percent of the projects involving the mentally infirm; the exceptions were reported to be due to (1) the investigator not having the names of subjects in a study of records, (2) consent having been obtained elsewhere, (3) the absence of risk, and (4) the IRB not having required it. In about one-third of the projects involving the mentally infirm, consent was obtained from a third party (or "proxy"); third-party consent was involved most frequently in research involving the retarded (80 percent) and was used most commonly in studies of behavioral interventions (59 percent). Third parties were usually parents, relatives or legal guardians. In institutions for the mentally infirm, consent by the subject's physician and by an institutional representative each occurred in one case (out of 83 studies). Courts provided consent in about three percent of the studies involving the mentally infirm. In projects in which third-party consent was used, consent was obtained only from the third party about twice as often as it was obtained from subjects as well as the third party. Most investigators reported that third-party consent served to protect subjects "very well" or "fairly well," but almost one-fifth of the investigators indicated otherwise. Reasons given included the third party's not being able to understand the research or not caring about protecting the subject's rights.

The major criteria for determining whether third-party consent would be used were the subject's age and degree of illness. When age was a criterion,

third-party consent was generally obtained for subjects 18 years or younger; the age below which consent was not obtained from subjects as well as third parties was about nine years. Degree of illness, rather than age or intellect, was usually cited as the criterion for a third party to provide consent. In studies in which subjects were the patients of a physician other than the principal investigator, approval for a subject's participation was obtained from the subject's physician in a majority of cases.

Although consent forms were used in more than 80 percent of the research involving the mentally infirm, these forms tended to be incomplete and difficult to read. On an index of six consent elements mentioned in DHEW regulations (45 CFR 46.103(c)) -- the purpose of the research, the procedures involved, the risks, the benefits, a statement that the subjects are free to withdraw from the research, and an invitation to ask questions -- only five percent of the forms from institutions for the mentally infirm and 21 percent of forms from other institutions were complete or nearly complete. Descriptions by investigators of the topics covered in oral explanations added only negligibly to the report of information transmitted to subjects or proxies.

Some elements appeared more frequently than others in consent forms. Most consent forms mentioned, at least briefly, the procedures and the purpose of the research. However, the benefits of the research (or the absence of benefits to subjects) were mentioned in only about half of the consent forms. There was no mention of risk (or absence of risk) on about 40 percent of the forms; of the studies in which risk was not mentioned either on the consent form or in the description of material presented orally to subjects and proxies,

almost two-thirds were described by investigators as entailing at least a "very low" probability of minor harm to the subject. The instruction regarding withdrawal was present in most forms, and an offer to answer questions appeared in more than half of the consent forms. A description of alternative treatments might have been expected in projects designed primarily to benefit subjects; however, alternatives were mentioned only rarely on consent forms in such studies.

The "reading-ease" of each consent form was measured using the Flesch Readability Yardstick.* The consent forms tended to be difficult to read. The "reading-ease" of most consent forms was comparable to that found in scholarly, academic material. Furthermore, medical and technical terms appeared in most consent forms, and very few of such terms were accompanied by a lay explanation. It is questionable whether many subjects or proxies would find these consent forms useful in making decisions regarding participation in research. No information is available on the degree to which the difficult language of the consent forms was mitigated by oral explanations in simpler terms.

Attitudes and Suggestions of Investigators. Most investigators conducting research involving the mentally infirm felt that the review procedure protects the rights of subjects and operates with reasonable efficiency, and a majority indicated that the review procedure improves the quality of research. However, some investigators found the review procedure to be an unwarranted

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* Rudolf Flesch, A New Readability Yardstick, Journal of Applied Psychology, Vol. 18, No. 3 June 1948, pp. 221-233. The "reading-ease score" is based on word length, i.e., the average number of syllables per 100 words, and sentence length, i.e., the average number of words per sentence.

intrusion on the investigator's autonomy and charged review committees with straying from their purpose, making judgments for which they are not qualitied, and impeding the progress of research. They offered suggestions for reducing "bureaucratic problems" such as the time-consuming nature of the review process, proposed that parts of the review process be eliminated (e.g., the review of research with little risk), proposed that IRBs should include more experienced investigators as members, and called for better communication between the IRBs and investigators. A small number of investigators called for the strengthening of the review process through, for example, more extensive follow-up on the conduct of research approved by the IRBs.

Attitudes and Suggestions of Subjects and Proxies. Only a limited number of subjects (33) and proxies (12) were interviewed, and they do not comprise a representative sample; thus, responses must be treated with caution. In general, these subjects and proxies indicated that they were satisfied with the clarity, sufficiency and accuracy of the information they had received regarding the research in which they were involved. About one-fourth would have liked more information. Several of the proxies indicated that the researchers had not explained the research to the subject, who did not have a good understanding of what was going on. Decisions regarding participation were apparently not difficult in most cases, with most respondents citing expectations of benefit to the subject as the reason for agreeing.

Approximately one-fourth of the respondents reported that unexpected difficulties had occurred as a result of the study. These difficulties included side-effects, physical discomforts and emotional problems. Several

subjects described these difficulties as "somewhat serious," and one described them as "very serious." On the other hand, more than two-thirds of the respondents said that the subject benefited from participation in the research, and most subjects reported that the actual experience of participating in the research was better than expected or the same as expected. More than two-thirds indicated willingness to participate in similar future studies. Reasons for not wanting to participate included the inconvenience involved, the lack of personal benefits, fear of side-effects, and belief that inadequate explanations were provided.

About half of the subjects or proxies offered suggestions. The most frequent suggestions concerned the desire for more or better information in the consent process and for more kindness and courtesy in the conduct of the research. A small number called for improvements in the risk/benefit ratio of research.

Chapter 5. Ethical Issues

The general purpose of research involving those institutionalized as mentally infirm is to increase knowledge about their disorders and institutionalization. The research often provides direct benefit to subjects, but some research may produce benefits for the subjects only in the future or may benefit only other persons at risk for, or suffering from, a mental disability. When there is a reasonable probability that the subjects will benefit, the research is generally considered justifiable. However, research in which procedures present no prospect of direct benefit to the subjects raises a variety of ethical problems about the protection and the rights of those institutionalized as mentally infirm and about the responsibilities of those charged with their care.

The application of basic ethical principles to research involving those institutionalized as mentally infirm suggests possible solutions to the ethical problems presented by this type of research. The Comnission has identified three such principles that should underlie the conduct of research involving human subjects: respect for persons, beneficence and justice.

Respect for Persons

The requirement to obtain informed consent from research participants is perhaps the least controversial and, some have argued, most significant ethical imperative incumbent upon investigators. This requirement has its moral basis in the principle of respect for persons. The function of informed consent is to respect the preferences and choices of the potential research

subject or, in other words, to respect individual autonomy. Even if others think that one's choice is foolish or wrong, they should also respect that choice. As John Stuart Mill put it:

> The only freedom which deserves the name is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it. Each is the proper guardian of his own health, whether bodily, or mental and spiritual.[1]

When individuals have diminished autonomy and may be unable to exercise their right to self-determination, the principles of respect for persons and beneficence both require that they be protected from harm. The principle of beneficence, which encourages avoidance of harm and promotion of good, underlies many models for third-party consent on behalf of incompetent subjects.[2] However, even with third-party consent, the principle of respect for persons requires consideration of how the incompetent person would have acted if able. If it is known that a person would have acted in a specific way, then a substitute decision maker may be required to act accordingly, thus respecting the choices that the person would have made. Robert Veatch argues that since some persons institutionalized as mentally infirm are intermittently competent, informed consent based on the right to self-determination would require that a "formerly competent patient's wishes clearly expressed while competent should be determinative when the patient is no longer competent."[3] This model of informed consent emphasizes respect for persons rather than beneficence, and seeks to broaden to the maximum extent possible the area in which autonomy should be operative.

Some have argued that research that does not hold out the prospect of direct benefit to subjects should never involve incompetent persons. Paul Ramsey, for example, has written that:

> Nontherapeutic, nondiagnostic experimentation involving human subjects must be based on true consent if it is to proceed as a human enterprise. No child or adult incompetent can choose to become a participating member of medical undertakings, and no one else on earth should decide to subject these people to investigations having no relation to their own treatment. That is a canon of loyalty to them. This they claim of us simply by being a human child or incompetent. . . .
>
> By insisting on a voluntary consent of the human subject for all experimentation, the Nuremberg Code seemed to rule out altogether nontherapeutic experimentation on children or the incompetent.[4]

This view has not gone unchallenged in ethical literature; moreover, the author of a memorandum to the war crimes court, from which the Nuremberg Code was derived, had originally proposed that:

> In the case of mentally ill patients, for the purpose of experiments concerning the nature and treatment of nervous and mental illness or related subjects, such consent of the next of kin or legal guardian is required; whenever the mental state of the patient permits (that is, in those mentally ill patients who are not delirious or confused), his own consent should be obtained in addition.[5]

Such a provision was not included in the final code, possibly because it did not apply to the specific cases under trial.

In the case of "beneficial research," Ramsey considers third-party consent a proper fulfillment of the obligation to protect vulnerable subjects, while in the case of "nonbeneficial research," he considers third-party permission

a breach of the duty to care and protect. It is not merely the exposure to possible risk that he finds unacceptable; rather, it is the violation of a perceived right to determine the extent to which we shall share ourselves with others. It is thus an alleged violation of respect for persons (by treating others as means only) that is morally unacceptable to Ramsey.

The most serious objection that can be raised regarding Ramsey's view is that those who refuse to consent to participation in research should be distinguished from those who are not able or legally qualified to consent. It is not a matter of serious controversy that those who are institutionalized as mentally infirm and refuse to participate in "nonbeneficial" research should not be involved. But Ramsey neglects to distinguish, within the class of persons unable to consent legally, between those unable to make any decision and those who are able to make choices and who clearly agree or object to participate in research.

Hans Jonas has injected another element of controversy into the discussion of research and respect for persons by suggesting that those persons most able to understand the nature of the research are most likely to be able to give adequately informed consent, and those persons least dependent or captive are most likely to give their consent freely.[6] However, one possible criticism of Jonas' selection criterion is that, if carried to its extreme, it could actually violate the principle of respect for persons. As the understanding and freedom of a class of subjects decreases, then additional safeguards may be imposed to insure that potential subjects' decisions, whatever they may be, are autonomous. Yet it should not be assumed that the "most

highly motivated, the most highly educated and the least 'captive' members of the community" are alone capable of making rational and autonomous decisions to participate in research. Such an assumption could unduly limit the choices of others.

Respect for persons means in part that people should be allowed to make and pursue their own decisions so long as basic conditions of information, communication and voluntariness can be met. For this reason, Jonas' proposed absolute prohibition on research that is unrelated to a patient's illness is also open to criticism. There may be some individuals institutionalized as mentally infirm who possess sufficient powers of understanding and are sufficiently free from coercion to give valid consent.

Beneficence

As previously noted, the principle of beneficence requires that subjects be protected from harm and that there be positive benefits from the research. This means that the possible good to be produced must justify the risk of harm to the subjects. Thus, beneficence requires a careful comparative analysis of possible harms to individual subjects and possible benefits either to the subjects or to others.

This application of risk/benefit analysis to the involvement of those institutionalized as mentally infirm raises no substantial controversy if applied exclusively to research involving interventions from which the subjects may derive direct benefit. The major controversies arise over the involvement of persons for whom the research holds out no immediate prospect of direct benefit.

Robert Veatch[7] and H. Tristram Engelhardt, Jr.,[8] both argue that because of certain minimal duties each of us owes to society, we may reasonably be expected to bear minor risks for the general welfare of all. Richard McCormick also emphasizes the duty to benefit others as the specific justification for research with subjects incapable of consent.[9]

Furthermore, 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. Moreover, it is sometimes unclear whether the subjects of a particular research project will derive some indirect or future benefit from their participation.

The ethical principle of beneficence thus provides several justifications for the general involvement of those institutionalized as mentally infirm in research; however, most who acknowledge the importance of the principle of beneficence are also careful to set limits to what it may justify. David Hume remarked, for example, that one is not obliged to do a small good to society at the expense of a great harm to oneself.[10] Applying the principle to the research context, Engelhardt and Veatch have attempted to outline the specific circumstances in which beneficence justifies participation.

Justice

Questions of justice relevant to the selection of subjects of research occur at two levels -- the levels of social justice and individual justice. Social justice demands a consideration of which classes of subjects ought and ought not to participate in research. Specific questions of social justice are: whether there should be an order of preferability in the selection of classes of subjects (e.g., adults before children, the competent before the incompetent), and whether those institutionalized as mentally infirm should be research subjects, and, if so, under what conditions they may be involved. Answers to these questions of social justice require a theory about how to distribute benefits and burdens to various social classes.

Individual justice demands a consideration of which individuals ought and ought not to participate in research. Thus, individual justice requires that after it has been determined that a particular class of subjects such as children or those institutionalized as mentally infirm may legitimately participate in research, it must be determined which specific members of the class may participate. Answers to the questions of individual justice require a theory about how to distribute benefits and burdens to particular individuals. Thus, in addition to a theory of social distributive justice, a theory of individual distributive justice is necessary.

Problems of social and individual justice are brought into sharp focus by the Willowbrook studies.[11] The first question, one of social justice, is whether research on an infectious disease should involve those institutionalized

as mentally infirm. The American Bar Association (ABA) Commission on the Mentally Disabled has recommended that:

> The proposed research should relate directly to the etiology, pathogenesis, prevention, diagnosis or treatment of mental disability, and should seek only such information as cannot be obtained from other types of subjects.[12]

The ABA Commission further concluded that involving institutionalized persons in research on the causes or treatment of infections such as hepatitis, which can be contracted by anyone, cannot be justified merely on the ground that such infections are widespread in some institutions. It said: "There is no acceptable reason why such research cannot be conducted with [noninstitutionalized] subjects who are free and fully informed." Although the ABA Commission does not attempt to justify its position on philosophical grounds, one could argue that the principle of justice, in a strict interpretation, requires that risks and burdens be distributed equally, so that no class of persons is unjustly required to bear an unequal distribution of burdens. If there are two classes of subjects, one of which is already severely burdened and the other of which is much less burdened, then in order to equalize the distribution of burdens, the latter class ought to accept any additional risks. Because those institutionalized as mentally infirm are already burdened by their disabilities, other less burdened classes of persons should accept the risks of research.

On the other hand, some theories would not prohibit participation of those institutionalized as mentally infirm in such research. One argument based on the considerations advanced by Engelhardt, Veatch and McCormick is the following:

All persons, insofar as they are members of a social community, have a duty to help others in that community. As an expression of common humanity, every person ought to benefit others and ought to be benefited by others. Because these reciprocal duties of beneficence apply to all persons, an enhancement of benefits for society as a whole will result. Thus, persons who are mentally infirm share to an equal degree with other persons this duty of beneficence; and it might even be argued that it would be a violation of their right to pursue their moral obligations if this class of individuals were categorically excluded from such participation. Research entailing only minimal risk could, according to this theory, legitimately involve those institutionalized as mentally infirm even if other subjects were available -- so long as there was equal involvement.

Assuming for the moment that an acceptable theory of social justice would justify at least limited involvement of those institutionalized as mentally infirm in research, it would then be necessary to determine those criteria that are relevant to selecting individual subjects. With respect to a specific research project, it might be asked whether certain persons institutionalized as mentally infirm, perhaps because of the nature of their infirmity, are more likely to be harmed by participating in the research than other individuals. It might also be the case that some persons who are mentally infirm have already participated in research and so should not be asked to participate again. If all persons have a duty of beneficence to help others, then it is morally relevant to know which individuals may have already fulfilled this duty.

The Conflict Between Autonomy, Justice and Beneficence

When the three ethical principles -- respect for persons, justice and beneficence -- come into conflict, one must be given priority over the others (unless some compromise is possible), and the priority that is established will determine how the related ethical problems are resolved.

Considering, first, possible conflicts between respect for persons and justice, one who gives absolute priority to respect for persons over justice would argue that there should be no restrictions on the types of research in which those institutionalized as mentally infirm should be allowed to participate, so long as they are able to give informed consent. The freedom to choose should not be restricted. In this view, problems about unfair distributions of burdens are not morally relevant, so long as individuals freely and knowledgeably choose to participate in the research, because the right to self-determination is so significant that it should not be restricted by a principle requiring equalization of burdens. In other words, even if a disproportionate number of persons institutionalized as mentally infirm choose to participate in research, one has no moral right to prevent them from doing so.

By contrast, those who give priority to justice claim that self-determination is important, but not absolute. Freedom of choice may be restricted legitimately when the demands of distributive justice so require. In this view, one must first develop a theory of distributive justice; then, persons will be granted the maximum autonomy consistent with the correct distributive principles. In other words, in order to avoid disproportionately unequal or

unfair distributions of research burdens, the right to exercise self-determination may be restricted, since the value of fairness has moral priority over freedom of choice.

Thus, when the research involves no direct benefit for the individual subjects and is not related to the prevention or amelioration of mental disability, justice may require that no one class of persons, such as those institutionalized as mentally infirm, may be disproportionately used as subjects. However, if participation in the research may benefit the subjects, or if the research is directly related to the prevention or amelioration of their mental infirmity, then the decision to participate ought to rest with the individual subject or his designated surrogate.

There may be conflicts related to the principle of beneficence. For example, conflicts between beneficence and respect for persons are at the root of the problem of paternalism. Paternalism is the doctrine that one is justified in interfering with a person's actions based on another's judgment about that person's own welfare or good. There is a wide divergence of opinion about the conditions, if any, under which paternalism is justified.[13] Those who emphasize the importance of autonomy argue, as does Veatch, that:

> Blocking of experiments in which there is free and informed consent solely on the independent grounds of paternalism seems rarely, if ever, justified.[14]

In this view, beneficence is rarely, if ever, a sufficient reason to limit a person's liberty, so long as the person is competent (and his actions do not cause harm to others). Even this view, however, is compatible with the belief

that a weaker form of paternalism that applies to persons whose choices are uninformed or nonvoluntary is justified. Thus, even those who stress autonomy may believe that paternalism is justified for individuals institutionalized as mentally infirm and who are incapable of meaningful consent or dissent. Others may go even further and argue for the general priority of the principle of beneficence over autonomy, believing that any person's autonomy may be restricted justifiably to prevent that person from undertaking actions that are unreasonably risky. Thus, the extent to which paternalism seems justified depends upon the relative priority one gives to autonomy and beneficence, and upon the way in which autonomy is conceived.

Serious ethical dilemmas are created by the conflicts between principles mentioned above. Most of the controversial ethical issues involving those institutionalized as mentally infirm could be structured in the form of such dilemmas. The resolution of those dilemmas requires striking a balance among competing ethical obligations.

REFERENCES

1. John Stuart Mill, On Liberty, Meridian Books, New York, 1962, p. 138.

2. John Robertson, Organ Donations by Incompetents and the Substituted Judgment Doctrine, 76 Columbia Law Review 48.

3. Robert Veatch, Three Theories of Informed Consent: Philosophical Foundations and Policy Implications, Submitted to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (February 2, 1976), Recommendation 13.

4. Paul Ramsey, The Patient as Person, Yale University Press, New Haven, 1970, p. 14 and The Enforcement of Morals: Nontherapeutic Research on Children, Hastinqs Center Report, August 1976, p. 21.

5. Leo Alexander, Psychiatry - Methods and Processes for Investigation of Drugs, Annals of N.Y. Acad. of Sci., Vol. 169, Art. 2, January 21, 1970, p. 350.

6. Hans Jonas, Philosophical Reflections on Experimenting with Human Subjects, Experimentation with Human Subjects, Edited by Paul Freund, George Braziller, 1969, pp. 18 and 20.

7. Robert Veatch, op. cit., esp. pp. 37f.

8. H. Tristram Engelhardt, Jr., Basic Ethical Principles in the Conduct of Biomedical and Behavioral Research Involving Human Subjects, Submitted to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (December 1975), esp. pp. 36f.

9. Richard A. McCormick, Proxy Consent in the Experimentation Situation, Perspectives in Biology and Medicine, Autumn 1974; Experimental Subjects -- Who Should They Be? JAMA, May 17, 1976; Experimentation in Children: Sharing in Sociality, Hastings Center Report, December 1976.

10. David Hume, Essay on Suicide, Moral Problems in Medicine, Edited by Samuel Gorovitz et al., Prentice-Hall, New Jersey, 1976.

11. The Willowbrook research is usefully described and discussed in Proceedings of the Symposium on Ethical Issues in Human Experimentation: The Case of Willowbrook State Hospital Research, Urban Health Affairs Program, New York University Medical Center, 1972.

12. Statement of ABA Commission on the Mentally Disabled Before National Experimentation Group, Mental Disability Law Reporter, Volume 1, Number 2, p. 156.

13. Gerald Dworkin, Paternalism, The Monist, January 1972. Joel Feinberg, Legal Paternalism, The Canadian Journal of Philosophy, Volume I, 1971; Murphy, op. cit.; Mill, op. cit.; H.L.A. Hart, Law, Liberty and Morality, Stanford University Press, Stanford, 1963; Tom L. Beauchamp, Paternalism and Biobehavioral Control, The Monist, January 1977.

14. Veatch, op. cit., p. 35. See also Engelhardt, op. cit., pp. 40-41.

Chapter 6. Legal Perspectives

Legal Effects of Incompetence and Institutionalization Generally

The law with regard to those institutionalized as mentally infirm is complicated and in transition, and the law regarding research with this population is sparse. Case law is meager, and most state legislatures have yet to address themselves to this area; yet the issues are important. Because institutionalized individuals have restrictions placed on their liberty, their ability to give voluntary consent is placed in doubt (as is the case with prisoners). Further, because most forms of mental illness and retardation are viewed as disrupting cognitive or affective functioning, there is concern whether persons suffering from these disabilities can consent to research, especially if it involves risk of harm. Therefore, consent of a third party is usually considered necessary and sufficient (as has been the case with children) for persons with diminished capacity to consent on their own.

Third-party consent, however, brings two principles of law into conflict. The first is the underlying premise of the informed consent doctrine, reflected in Cardozo's oft-quoted statement that "every human being of adult years and sound mind has a right to determine what shall be done with his own body"[1] The second is the *parens patriae* doctrine, expressing the state's traditional concern for those in need of special protection, primarily children and the mentally infirm. In furtherance of that concern, the state has attenuated or abolished for some individuals certain rights generally accorded others, including the right personally to consent (or refuse to consent) to medical care or participation in research.

It is difficult to present a clear view of the legal rights of persons institutionalized as mentally infirm because there is great disparity among the states, first, in defining incompetence, and second, in limiting or protecting the rights of individuals either judged to be incompetent or institutionalized without such an adjudication. Competency as a legal concept is multidimensional and arises in both the criminal and civil arenas. It takes many forms, and standards for determining competency may vary with the context in which it is judged, e.g., competency to stand trial, to plead guilty, to manage one's affairs, to form a contract, to make a will.

Competency to consent to participation in research may be viewed as a specific aspect of the ability to manage one's affairs. Incompetency in this broader setting generally results in the appointment of guardians to protect persons or their property. However, a survey of the 50 states and the District of Columbia reveals that statutory provisions for the adjudication of competency vary widely. Almost all statutes have what might be called a status component (i.e., some mental or physical condition) and a consequence component (i.e., a substantive standard). For example, appointment of a guardian may be permitted if the person is mentally ill (the status component) and is unable therefore to care for his physical well-being (the consequence component). Table One depicts the conditions required by statute in each jurisdiction for an adjudication of incompetency. Table Two summarizes the requisite substantive standard for each jurisdiction. Sometimes the substantive standard must be met in addition to proving that the status component exists; in a few jurisdictions, only the substantive standard need exist.

Many state statutes are irrelevant to the issue of competency to consent to research; they have provisions pertaining solely to property, estate and business affairs. Only those provisions relating to the ability to care for or make decisions concerning oneself, and perhaps those general provisions regarding the conduct of one's personal affairs, can be interpreted as applying to participation as a research subject.

Court definitions of competency also vary.[2] Some courts determine competency according to the capacity to reach a decision based on rational reasons, i.e., whether the person has the ability to understand the nature of the procedure, to weigh its risks and benefits, and come to a reasonable determination. Other courts determine competency according to the capacity to reach a reasonable result, i.e., one a reasonably competent person might have made. Thus, if a person makes a decision that may result in substantial damage to mental or physical well-being, the court employing this standard will consider that person incompetent. Finally, a minority of courts determine competency according to the capacity to make a decision. This approach avoids the difficulties inherent in evaluating whether a person's thinking is rational or irrational but precludes the apparent consent of those clearly out of touch with reality. According to this standard, a person is judged competent if he or she has sufficient understanding of the nature of the procedures, its risks and benefits, and possible alternatives. If so, any decision, provided there is a decision, would be honored.

Another problem area is the relationship between the commitment process and the adjudication of incompetency. Institutionalization and incompetence

are not necessarily synonymous; mere commitment of an individual to an institution does not necessarily mean that person is incompetent to consent, according to some state statutes and a number of courts.[3] Some states have statutes that presume that institutionalized persons retain certain rights, e.g. , the right to vote in Alaska, Georgia, Kentucky, Louisiana, Maryland, New Mexico, New York, South Carolina and South Dakota; the right to contract in Alaska, Kentucky, Louisiana and South Carolina; the right to marry in South Carolina; and the right to make a will in Georgia and South Carolina.[4] By contrast, other states provide that "commitment to a hospital for the insane pursuant to statute is equivalent to a prior adjudication of incompetency"[5] or apply blanket restrictions on the right of institutionalized persons to marry, vote, contract, drive or conduct their affairs, without any evidentiary hearing concerning the particular individual's ability to exercise those rights.

As a summary statement with regard to the relationship of institutionalization and competency, Allen, Ferster and Weihofen's conclusion of a decade ago is as applicable today:

> The effect in law of a hospitalization order on the competency status of a patient varies from state to state. In a few states the hospitalization order is also an adjudication of incompetency; in others, it results in at least presumptive incapacity; and in still others, there is a complete separation of hospitalization and incompetency. . . . In many states the effect of a hospitalization order cannot be determined from the written law, but the trend in legislation . . . has been toward the complete separation of hospitalization and incompetency.[6]

The disparity among the states regarding the effect on individual rights of institutionalization *per se* and of adjudication of incompetency is complicated further by very different approaches courts have taken in resolving questions regarding the relative rights of patients, guardians and the state in matters relating to biomedical and behavioral interventions. Although there has been a discernible trend in recent years for courts to protect the rights of mental patients in specific areas, that trend is obscure at best in cases most relevant to research (e.g., those involving the imposition of therapy, the transplantation of organs or tissue, sterilization and, in a very few cases, participation in research).

The Rights of Patients to Refuse Therapeutic Intervention

Generally, informed consent is necessary before physicians or therapists may perform procedures intended to benefit their patients. While the law usually permits third-party consent to these procedures on behalf of persons adjudicated as incompetent, a few states have passed statutes that specifically limit the performance of certain medical procedures without personal consent, and some courts have restricted the imposition of certain therapies on unwilling or nonconsenting patients. The most frequently regulated treatments are surgery, psychosurgery, "experimental" therapies and electro-convulsive therapy (ECT). In addition, developing case law has severely circumscribed the power of the state to sterilize involuntarily committed, incompetent persons without their consent, even though the procedure may be deemed therapeutic and in their best interest.

The requirement of personal consent appears related to the severity, intrusiveness, irreversibility and experimental (novel, untested) nature of the proposed interventions, regardless of whether or not they are viewed as beneficial. The outer reach of protection imposed under such conditions is found in Kaimowitz v. Department of Mental Health.[7] This case concerned a patient, committed to a state mental hospital as a sexual psychopath, who agreed to participate in research designed to study the effects of amygdalotomy (a form of psychosurgery) on aggressive behavior. The court held that the combined effects of institutionalization and the hazardous and unknown effects of the proposed operation precluded a finding of adequate consent by the patient. The "inherently coercive atmosphere" was said to prevent consent from being either "competent" or "voluntary," while the lack of scientific basis for predicting the outcome of such a novel procedure was said to render consent "unknowledgeable." The court also refused to acknowledge the validity of parental consent (which had also been given in this case) on the unelaborated ground that guardians may not consent to treatments to which the patient could not consent.

A number of courts have required a patient's consent prior to the administration of ECT. For example, in New York City Health and Hospitals Corp. v. Stein,[8] the court rejected the application of a director of a public hospital to perform the procedure without personal consent. Although the court noted that without the proposed treatment the patient's condition might become irreversible, it balanced this possibility against its concern that ECT was still "the subject of great controversy within the psychiatric profession, both as to its efficacy, and as to its dangers."[9] Of particular importance in

this case was the court's determination that although the patient still met the standard for involuntary commitment, she maintained the ability to consent or refuse to consent to such an intrusive form of intervention regardless of whether the court or the institutional staff agreed with the reasonableness of her decision. California, New York and Washington have enacted legislation to the same effect.[10]

Under certain conditions, especially when "experimentation" is involved, the administration of drugs to involuntarily committed mental patients without consent has also been prohibited. In Knecht v. Gillman,[11] a vomit-inducing drug, apomorphine, was injected into two unconsenting adults as part of an aversive conditioning program in the Iowa Security Medical Facility. Concluding that the purpose of administering the drug in this case had been disciplinary rather than as treatment, the court held that its administration to unwilling patients was a violation of the Eighth Amendment's prohibition against cruel and unusual punishment. It then indicated that administration of apomorphine would be permissible only if a physician certified that each patient knowingly and voluntarily consented, understood the risks and purposes of the procedure, and if consent could be revoked at any time. Similarly, in Mackey v. Procunier,[12] a prisoner, transferred to the California medical facility at Vacaville, alleged that his constitutional rights were violated by the administration of a drug (without his consent) causing temporary paralysis and inability to breathe, as part of psychiatric experimentation in aversive conditioning. The Ninth Circuit Court of Appeals held that proof of such allegations "could . . . raise serious constitutional questions respecting cruel and unusual punishment or impermissible tinkering with mental processes."[13]

The most widely known case in which experimentation with institutionalized mentally infirm subjects was an issue is Wyatt v. Stickney,[14] a far-ranging decision in which conditions at Alabama's institutions for the mentally ill and retarded were thoroughly scrutinized. Concluding that conditions in the facilities were so inadequate as to violate the residents' constitutional right to treatment, the court developed an extensive set of minimal standards to correct the deficiencies. Included in these standards was a provision declaring that mentally ill patients had "a right not to be subjected to treatment procedures such as lobotomy, electro-convulsive treatment, adversive [sic] reinforcement conditions or other unusual or hazardous treatment procedures without their express and informed consent after consultation with counsel or interested party of the patient's choice."[15] The court mandated that with regard to research:

> Patients shall have a right not to be subjected to experimental research without the express and informed consent of the patient if the patient is able to give such consent, and of his guardian or next of kin, after opportunities for consultation with independent specialists and with legal counsel. Such proposed research shall first have been reviewed and approved by the institution's Human Rights Committee before such consent shall be sought. Prior to such approval the Committee shall determine that such research complies with the principles of the statement on the Use of Human Subjects for Research of the American Association of Mental Deficiency and with the principles for research involving human subjects required by the United States Department of Health, Education, and Welfare for projects supported by that agency.[16]

In a companion decision concerning mentally retarded residents, the Wyatt court imposed the same restrictions on research, including review by the Human

Rights Committee and personal or third-party consent (depending on the capacity of the resident) before the use of behavior modification programs involving noxious or aversive stimuli. The court also held that ECT was to be considered an experimental technique and thus subject to the review and consent procedures prescribed for both research and aversive stimuli. Further, ECT could be administered only "in extraordinary circumstances to prevent self-mutilation leading to repeated and possibly permanent physical damage . . . and only after alternative techniques have failed."[17] Thus, even when the intervention in question is designed to benefit an incompetent patient, added layers of protection such as institutional and court review, or total prohibition, may be imposed when the proposed procedure is risky, invasive, noxious or permanent.

It appears that there is a recent trend, both judicially and legislatively, to guarantee patients the right to refuse hazardous or "experimental" therapies. The implications of this trend for research suggest a requirement to seek the affirmative consent of institutionalized patients prior to enrolling them in research involving therapeutic interventions, at least where any appreciable risk is involved.

The Rights of Guardians Regarding Interventions Not for the Benefit of the Incompetent

When the proposed intervention is not perceived as directly benefiting the incompetent subject, there are greater constraints on proceeding without the consent of the subject. In fact, it has been argued that third-party consent should be permitted only when the patient will derive direct benefit;

thus, theoretically, institutionalized persons considered incompetent could never participate in "nontherapeutic" endeavors. However, once again, there are few cases in this area.

The most commonly litigated situations concern sterilization and organ transplants. With regard to the former, for example, in Frazier v. Levi,[18] the mother of a mentally retarded woman with two illegitimate retarded children was denied permission to consent to sterilization of her daughter because there was no evidence that it was medically necessary and the woman herself lacked the mental capacity to consent, On the other hand, 24 states have laws permitting sterilization of persons with mental disorders in state institutions.[19] While the statutes vary in their provisions, most permit the institution superintendent to initiate a judicial or administrative proceeding to hear the matter, while some also permit relatives, guardians, physicians or state welfare boards to initiate a hearing. Most statutes provide notice to the persons to be sterilized and entitle them to an opportunity to be heard. Newer statutes amplify the procedural safeguards, and some even provide for either personal or third-person consent.[20] Proposed federal regulations would prohibit the performance of sterilization in DHEW programs for any mentally incompetent or institutionalized individual unless the individual has given a court-sanctioned informed consent; an alternative proposal would absolutely prohibit such sterilization on a mentally incompetent person.[21]

Although the cases are not uniform with regard to organ transplants, the decisions frequently rest on whether the court can find some benefit to the

incompetent donor. A Louisiana court in In re Richardson[22] refused to allow a kidney transplant from a mentally retarded child to his older sister arguing, by analogy to property rights, that a guardian is not permitted to make a donation that is not in the best interests of the incompetent. Finding no benefit to the child from the proposed bodily intrusion, it refused to recognize the validity of parental consent. On the other hand, in Strunk v. Strunk[23] a Kentucky court permitted a kidney transplant to an older brother from a severely retarded man who was institutionalized and incapable of consenting for himself. The court permitted the procedure by finding benefit in the avoidance of psychological injury, relying on psychiatric testimony that the death of the brother would have been traumatic for the incompetent. The court here also invalidated parental consent, however, finding authority for the operation in its equitable powers under the parens patriae doctrine.

The most publicized example of research involving the institutionalized mentally retarded is the hepatitis experiment at the Willowbrook State School in New York. The crowded and unsanitary conditions at Willowbrook, coupled with lack of training in personal hygiene, led to an epidemic of fecally-borne infectious hepatitis. In an attempt to develop a vaccine for the disease, researchers infected newly admitted retarded children whose parents had apparently consented to the procedure. All of the children risked serious illness, and many became sick. In subsequent litigation challenging the inhumane conditions and care of the residents generally, the court held that institutionalized retarded persons were constitutionally guaranteed protection from harm (as carefully distinguished by the court from the right to treatment).[24] Equating to some degree the rights of the institutionalized retarded

with those of prisoners, the court stated that as "Willowbrook residents are for the most part confined behind locked gates, and are held without the possibility of a meaningful waiver of their right to freedom, they must be entitled to at least the same living conditions as prisoners." [25] A consent decree was approved by the court in 1975 designed to insure enforcement of this right; included in that decree was an absolute prohibition against medical experimentation. [26]

In sum, the conditions under which a guardian may consent to the performance of a nontherapeutic medical procedure on an incompetent individual are not at all clear; and the law gives no guidance with respect to behavioral interventions. It is apparent, however, that where nontherapeutic biomedical procedures are permitted, additional layers of review may be imposed to evaluate the reasonableness of the guardian's consent.

The Right of the State to Impose Therapy

Under some conditions, the state may impose therapy on patients against their will. A significant case in point is Price v. Sheppard.[27] The plaintiff was committed to a state hospital as a "mentally ill-inebriate" upon petition by his mother. His diagnosis was changed subsequently to "simple schizophrenia" after he allegedly attempted to strangle one of the staff. After tranquilizers and antidepressants failed to reduce his assaultive behavior, ECT was then prescribed and the consent of the plaintiff's mother was sought prior to its administration. She refused on the advice of another psychiatrist, and drug treatment continued. When Price continued to be aggressive, the hospital administered shock treatments without either his con-

sent or that of his mother. Mrs. Price promptly filed a complaint, and the hospital defended its action on *parens patriae* grounds. While the court required judicial review with representation for the patient before invasive forms of treatment could be administered, it agreed that the state could make decisions regarding psychiatric treatment for those who were "presumptively, based on the fact of commitment on the ground of mental illness, . . . unable rationally [to] do so for themselves."[28] The court reached this conclusion notwithstanding a state statute to the effect that commitment was not a judicial determination of incompetency. The court reasoned, in a footnote, that because commitment required clear evidence that the person's ability to control himself, conduct his affairs and use good judgment was lessened to such an extent that hospitalization was necessary, the state was able to act for such an individual even in the absence of an adjudication of incompetency.

The crucial question in such cases is the extent to which a presumption of rationality and autonomy will be enforced. Clearly, any wholly arbitrary or unreasonable practice that permits nonconsensual invasion of one's body is unconstitutional. The question is whether the state merely needs to show a reasonable basis for its practice and demonstrate that its action is related to some legitimate state purpose, or whether courts will require that the state meet the more stringent test of demonstrating that it has some compelling (not merely reasonable) interest in interfering with autonomy, and can find no less drastic alternative for so doing.

Some Developing Options

Because existing decisional and statutory law provides no clear answer regarding the conditions under which those institutionalized as mentally infirm may be included in research, courts, commentators and legislators have proposed various means for balancing self-determination of the mental patient and the paternalistic role of the state in this area. Among the options proposed are the following:

1. Greater recognition of the concept of limited incompetency. One writer has suggested that "consent . . . should not depend upon the form of the patient's illness, but rather, should depend upon the effect the illness has on the patient's ability to understand the problems connected with his [participation]."[29] Washington's statute is an example of a law explicitly recognizing the concept of limited incompetency:

> [T]he court shall impose . . . only such specific limitations and disabilities on a disabled person to be placed under a limited guardianship as the court finds necessary for such person's protection and assistance. A person shall not be presumed to be incompetent nor shall a person lose any legal rights or suffer any legal disabilities as the result of being placed under a limited guardianship except as to those rights and disabilities specifically set forth in the court order establishing such a limited guardianship.[30]

Under this standard, persons institutionalized as mentally infirm would retain the right to consent or refuse to consent to research absent specific evidence concerning inability to exercise that right.

2. Strict limitation of the concept of incompetency. Some commentators have offered the more radical proposal that standards concerning competency

either be abolished or be established at a very low threshhold. For example, Friedman[31] suggests that the inquiry should go simply to whether the individual is willing to consent and is able to answer affirmatively or negatively. As long as both of those conditions exist, all answers should be honored despite the fact that they might have been evoked by reality distortions or stated in a perseverative, automatic manner.

Goldstein suggests a similar test, not as an option, but as a requirement:

> The burden in law for incompetence should be very high. No evidence other than a showing that the patient is comatose should ordinarily be accepted as proof of incompetence . . . . To accept proxy consent is to authorize invasions of persons and personality without regard to the wishes of the research subject -- that is to deny them freedom to choose without saying so.[32]

No courts have adopted either Goldstein's or Friedman's proposals. However, in Wyatt v. Aderholt[33] the court ordered that before an incompetent mentally retarded resident could be sterilized, a review committee must determine that the resident "formed, without coercion, a genuine desire to be sterilized,"[34] not that he or she understood the procedure and arrived at a "rational" decision.

3. Application of the doctrine of substituted judgment. There are times when personal consent is impossible or extremely difficult (e.g., with mute, unconscious or profoundly retarded subjects). Assuming that an intervention is warranted, third-party consent may be accepted on the theory that "such paternalism is justified by the fact that it is rational to choose to have

someone behave paternalistically toward us should we become incapable of looking out for ourselves." [35]

One traditional method of accomplishing this purpose is the doctrine of substituted judgment, a concept usually invoked in transfers of property. Under this rule, "the court may substitute its own judgment for the impaired judgment of the incompetent, if . . . the result achieved is what the incompetent almost certainly would have desired . . . ." [36] Particularly relevant is the criterion, first announced in a nineteenth century British case, Ex parte Whitbread, that the court act, "looking at what it is likely the Lunatic himself would do, if he were in a capacity to act . . . ." [37]

The substituted judgment doctrine can be distinguished from what has been called the benefit rule, commonly applied in the context of third-party consent to research and treatment. As the earlier summary of case law indicates, the benefit rule would preclude all research involving incompetent subjects unless the subjects would derive a benefit from their participation, even if competent persons in their position might have chosen otherwise. By contrast, the doctrine of substituted judgment would permit decisions to be made according to an incompetent person's conception of his or her interests, based on an actual indication in the past of a willingness to participate as a research subject or a communication of present willingness. This suggests that the substitute decision-maker should know the institutionalized person well enough to be able to discern such willingness.

TABLE 1

REQUIRED CONDITIONS FOR THE APPOINTMENT OF

GUARDIANS IN INCOMPETENCY ADJUDICATIONS

Definition of Terms

1. Mental Illness: includes such terms as mental disorder, mental disease, insanity and the outmoded term "lunacy" still used by 5 states.

2. Mental Retardation: includes mental deficiency, mental defective, and such outmoded terms as idiocy (9 states), imbecility (5 states), and feeblemindedness (1 state).

3. Terms Connoting MI or MR: some statutes used such vague terms that they are difficult to classify in the first or second column. They include mental infirmity, mental weakness, unsound mind, mental incapacity, mental disability, noncompos, want of understanding, deterioration of mentality. These may be taken to include both mental incompetency and mental retardation.

4. Mental Incompetence: the term is included here to indicate the circularity of some incompetency provisions. In these states incompetency is adduced by proof of mental incompetency.

5. Senility: includes terms such as age, advanced age, old age, extreme old age.

6. Physical Illness: includes physical incapacity, bodily infirmity, disease.

7. Drug Use: includes such diverse standards as chronic drug use, excessive drug use, drug addiction, drug dependence.

8. Alcohol Use: includes such diverse standards as habitual intoxication, chronic intoxication, drunkenness, inebriety, alcholism, excessive use of intoxicants.

9. "Spendthrift" provisions: allow for adjudication of incompetence when there is proof of "gaming," "idleness," "debauchery," "improvidence," or "vicious habits."

10. Other: this category includes catchall provisions (e.g., "and other causes") as well as unclassifiable conditions such as compulsory hospitalization, distracted person, imprisonment, confinement in mental institution for 1 year or more.

TABLE ONE
REQUIRED CONDITIONS FOR THE APPOINTMENT OF GUARDIANS IN INCOMPETENCY ADJUDICATIONS

Jurisdiction	Mental Illness	Mental Retardation	Terms Connoting MI or MR	Mental Incompetence	Senility	Physical Illness	Drug Use	Alcohol Use	Spendthrift	Other
Alabama	●	●								
Alaska	●	●			●	●	●	●		●
Arizona	●	●			●	●	●	●		●
Arkansas	●	●			●	●	●	●		●
*California										
Colorado	●	●			●	●	●	●		●
Connecticut		●	●							
Delaware	●		●		●	●				
Dist. of Col.	●		●		●	●				
Florida	●	●			●		●	●		●
Georgia	●	●		●						
Hawaii	●	●	●				●		●	●
Idaho	●	●			●	●	●	●		●
Illinois	●	●	●				●	●	●	
Indiana	●	●			●			●		
*Iowa										
Kansas	●	●			●	●	●	●		●
Kentucky	●		●		●	●				
Louisiana	●	●	●		●	●				
Maine	●	●	●		●	●			●	
Maryland	●		●		●	●	●	●		●
Massachusetts	●	●	●		●	●				
Michigan	●	●			●	●			●	
Minnesota			●		●			●		●
Mississippi			●							●
Missouri	●	●			●		●	●		●

*The statute indicates no status designation. California now views incompetency as a legal, not a medical disability, measured by functional inabilities.

TABLE ONE
REQUIRED CONDITIONS FOR THE APPOINTMENT OF GUARDIANS IN INCOMPETENCY ADJUDICATIONS

Jurisdiction	Mental Illness	Mental Retardation	Terms Connoting MI or MR	Mental Incompetence	Senility	Physical Illness	Drug Use	Alcohol Use	Spendthrift	Other
Montana	●	●			●	●	●	●		●
Nebraska	●				●				●	●
Nevada	●	●	●		●	●				●
New Hampshire				●					●	
New Jersey	●	●	●					●		
New Mexico			●					●		
New York	●				●			●		●
North Carolina	●	●	●					●		
North Dakota	●	●			●	●	●	●		●
Ohio	●	●	●		●	●		●	●	●
Oklahoma	●									●
Oregon	●	●	●		●	●				●
Pennsylvania	●	●			●		●	●		
Rhode Island	●	●	●				●	●	●	
South Carolina		●								
South Dakota	●			●		●				
Tennessee	●	●	●				●	●		
Texas	●	●						●		
Utah			●		●					●
Vermont				●					●	
Virginia	●	●								
Washington	●	●			●		●	●		●
West Virginia		●								
Wisconsin	●	●	●				●	●		
Wyoming	●	●			●	●	●	●		
Totals	**40**	**35**	**22**	**4**	**29**	**21**	**19**	**26**	**9**	**22**

TABLE 2

REQUIRED SUBSTANTIVE STANDARDS FOR THE APPOINTMENT OF

GUARDIANS IN INCOMPETENCY ADJUDICATIONS

Self	State
Lacks sufficient understanding or capacity to make (or communicate) responsible decisions concerning his person	Alaska, Arizona, Colorado, Idaho, Kansas, Maine, Maryland, Montana, North Dakota
Incapable of caring for (or taking care of) himself	Arkansas, Florida, Indiana, Iowa, Mississippi, Missouri, Texas, Vermont, Washington, Wisconsin
Incapable of taking proper care of himself	Ohio, Virginia
Incapable/Incompetent to manage his person	Illinois, Minnesota
Unable, without assistance properly to manage and take care of himself	Nevada, Oregon, Utah, Wyoming
Unable properly to manage and care for his person and in consequence thereof is in danger of becoming victim of designing persons	Delaware
Incapable of governing (or managing) himself	Connecticut, New Jersey, New York
Unable to care for his physical well-being	West Virginia
Unable properly to provide for his own personal needs for physical health, food, clothing or shelter	California
In danger of substantially endangering his health or of becoming subject of abuse by other persons or becoming the victim of designing persons	Delaware
Lessened or unacquired capacity to use customary self-control, judgment, and discretion in conduct of social relations as to make it necessary or advisable for him to be under care, supervision, guidance, or control	Louisiana
Incapable of managing himself independently and requires supervision and care (Mentally retarded only)	Maine
Unable to care for himself or manage his affairs and requires care, treatment, training in a developmental center (Mentally retarded only)	Tennessee
Incompetent to protect his rights	Maine

REQUIRED SUBSTANTIVE STANDARDS FOR THE APPOINTMENT OF GUARDIANS IN INCOMPETENCY ADJUDICATIONS

Property	State
Incapable of managing his property	Arkansas, Florida, Indiana, Iowa, Missouri, Oklahoma, Louisiana, South Dakota, Texas, Washington, Wisconsin
Unable, without assistance properly to manage and take care of his property	Nevada, Wyoming, Oregon, Utah
Unable properly to care for (or take care of) his property	D.C., Massachusetts, Mississippi, Ohio, Vermont
Unable to manage his property effectively	Maryland
Incompetent to have charge and management of his property	Nebraska
Unable properly to manage and care for his property and in consequence thereof is in danger of dissipating or losing such property or of becoming the victim of designing persons	Delaware
Incapable of managing or taking care of his estate	Georgia, Kentucky, Mississippi, South Carolina
Incapable of properly handling or managing his estate	Virginia
Incompetent to manage his own estate	Maine, Minnesota
Incompetent to have care, custody, manage-ment of his estate	Michigan
Lacks sufficient understanding or capacity to make or communicate responsible decisions concerning his estate	Kansas
Cannot effectively manage/apply his estate to necessary ends	Alaska

REQUIRED SUBSTANTIVE STANDARDS FOR THE APPOINTMENT OF GUARDIANS IN INCOMPETENCY ADJUDICATIONS

Personal and Business Affairs Generally	State
Incapable of managing his affairs	Connecticut, New Jersey, New York, Maine, North Carolina, Wyoming
Unable to manage his affairs effectively	Maryland
Unable to manage his affairs with prudence	New Hampshire
Lessened or unacquired capacity to use customary self-control, judgment, and discretion in conduct of his affairs as to make it necessary or advisable for him to be under care, supervision, guidance or control	Louisiana
Incapable of managing his affairs independently and requires supervision and care (mentally retarded only)	Maine
Unable to conduct his personal or business affairs (patients only)	New York
Unable to manage his business affairs	West Virginia
Incapable of managing his financial affairs	Texas
Substantially unable to manage his own financial resources	California

Family or Community (Spendthrift Provisions)	
So spends or wastes his estate as to expose himself or his family to want or suffering	Illinois, Maine, New Hampshire, Rhode Island
So spends or wastes his estate or injures his person as to likely expose himself or his family to want or suffering	Minnesota
So spends or wastes his estate as to expose his town to expense	Maine, New Hampshire, Rhode Island
Fails to provide for his family or other persons for whom he is charged by law to provide	Ohio
Liable to dissipate property or become victim of designing persons	Pennsylvania
Lack of discretion in managing benefits received from public funds	Nebraska

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Note: One state, Hawaii, has no substantive standard. Determinations are made, in part, by a review committee of the Dept. of Social Services.

Vermont also has a provision for voluntary appointment of a guardian for persons who deem themselves unable to prudently manage their affairs.

REFERENCES

1. Schloendorff v. Soc. of N.Y. Hosps., 105 N.E. 92, 93 (N.Y. 1914).

2. Friedman, Legal Regulation of Applied Behavior Analysis in Mental Institutions and in Prisons, 17 Ariz. L. Rev. 39, 77–80 (1975).

3. See, generally, Shapiro, Legislating the Control of Behavior Control: Autonomy and the Coercive Use of Organic Therapies, 47 So. Cal. L. Rev. 237, 308–309 (1974); Schoenfeld, Human Rights for the Mentally Retarded: Their Recognition by the Providers of Service, 4 Hum. Rights 31 (1974).

4. Annas, G., Glanz, L., and Katz, B., The Law of Informed Consent to Human Experimentation, a report prepared for the National Commission for the Protection of Human Subjects (1976).

5. Morris, Institutionalizing the Rights of Mental Patients: Committing the Legislature, 62 Calif. L. Rev. 957, 967 (1974).

6. Allen, R., Ferster, E., and Weihofen, H., Mental Impairment and Legal Incompetency, Prentice Hall (1968).

7. Civil No. 73–10433AW (Cir. Ct. Wayne Co., Mich., 1973).

8. 335 N.Y.S. 2d 461 (1972).

9. *Id.* at 464.

10. See Cal. Welf. & Inst'ns. Code §§ 5325(f) to (g) (West Supp. 1977); N.Y. Mental Hygiene Law § 15.03(b)(4) (1976); Wash. Rev. Code Ann. § 71.05.370(7) (1975).

11. 488 F. 2d 1136 (8th Cir., 1973).

12. 477 F. 2d 877 (9th Cir., 1973).

13. *Id.* at 878.

14. 344 F. Supp. 373 (M.D. Ala., 1972); 344 F. Supp. 387 (M.D. Ala., 1973); *aff'd. sub nom.* Wyatt v. Aderholt, 503 F. 2d 1305 (5th Cir., 1974).

15. 344 F. Supp. 373, 380 (M.D. Ala., 1972).

16. *Id.*

17. 344 F. Supp. 387, 401 (M.D. Ala., 1972).

18. 440 S.W. 2d 393 (Tex. Ct. Civ. App., 1969).

19. Gauvey and Shuger, The Permissibility of Involuntary Sterilization Under the Parens Patriae and Police Power Authority of the State, 6 Md. L. F. 109 (1976).

20. See, generally, Burgdorf and Burgdorf, The Wicked Witch is Almost Dead: Buck v. Bell and the Sterilization of Handicapped Persons, 50 Temple L. Q. 995 (1974).

21. 42 Fed. Reg. 62718, 62729 (1977). See also Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C., 1974).

22. 284 So. 2d 185 (La. App., 1973); see also, Lausier v. Pecinski, 226 N.W. 2d 180 (Wisc., 1975) (similar result in the case of a mentally ill, retarded adult).

23. 445 S.W. 2d 145 (Ky., 1969).

24. N.Y. State Ass'n. for Retard. Child., Inc. v. Rockefeller, 357 F. Supp. 752 (E.D.N.Y., 1973).

25. Id. at 764.

26. N.Y. State Ass'n. for Retard. Child., Inc. v. Carey, 393 F. Supp. 715 (E.D.N.Y., 1975).

27. 239 N.W. 2d 905 (Minn., 1976).

28. Id. at 911.

29. Note, The Involuntarily Confined Mental Patient and Informed Consent to Psychiatric Treatment, 5 Loyola of Chicago L. J. 578, 601 (1974).

30. Wash. Rev. Code Ann. § 11.88.010(2) (Supp. 1976).

31. Friedman, supra, note 2, at 80.

32. Goldstein, On the Right of the "Institutionalized Mentally Infirm" to Consent or Refuse to Participate as Subjects in Biomedical and Behavioral Research. Paper prepared for the National Commission for the Protection of Human Subjects (1976).

33. 368 F. Supp. 1383 (M.D. Ala., 1974).

34. Id. at 1385.

35. Macklin and Sherwin, Experimenting on Human Subjects: Philosophical Perspectives, 25 Case Western Reserve L. R. 434, 466 (1975).

36. Engel, Making Gifts from the Estate of an Incompetent: The Substitution of Judgment Doctrine, 9 Wake Forest L. Rev. 199, 200 (1973).

37. 2 Mer. 99, 102, 35 Eng. Rep. 878, 879 (1819).

Chapter 7. Site Visits

The Commission made site visits to the Fernald State School for the Retarded and the associated Eunice Kennedy Shriver Center in Waltham, Massachusetts, as well as to St. Elizabeths Hospital in Washington, D.C. Both are institutions for the mentally infirm at which research is conducted.

The Fernald School is a state institution for the mentally retarded which houses approximately 1,200 residents, 900 of whom are adults. The Shriver Center is a research unit which is independently incorporated but located on school grounds. In addition to research activities, the Center is involved in service and training programs for the school.

Research conducted at the school includes metabolic studies, behavior modification studies, sociological studies, evaluation of treatment, and neurological studies. A basic principle underlying research conducted at the school is that it must either be related to mental retardation (including etiology, care and treatment) or be directly therapeutic for the individual.

The Commission members toured the school and spoke at length with residents, parents of residents, primary care staff, research investigators and Institutional Review Board members. The Commission observed a behavioral treatment program in which self-abusive and severely retarded persons were positively reinforced for appropriate behavior.

The Commission learned that in Massachusetts retarded individuals over the age of 21 typically are in a consent limbo, in which they themselves are functionally incompetent to give informed consent and no guardian, with

authority to consent on their behalf, has been appointed by a court. This situation prevails even among retarded persons who are institutionalized. Other issues which emerged during the visit include problems with identifying the point at which innovations in training methods cease to be considered research and become accepted treatment practice, and the extent to which it is ethical not to conduct research when there is a clear need to improve the care and training of retarded persons, as well as to prevent retardation, and to prevent the deterioration which may result from an institutional setting.

St. Elizabeths is a federally owned hospital currently operated under the auspices of the National Institute of Mental Health. It houses approximately 2,700 patients, most of whom are involuntarily committed. The hospital treats approximately 3,000 out-patients annually and sees an additional 4,000 patients for screening or referral. To implement its objective of providing treatment for the mentally ill, the hospital conducts training and research programs.

At St. Elizabeths research is reviewed by the Research Review Executive Board, a policy-making body comprised of senior hospital staff, and the larger Research Advisory Panel which reviews individual protocols. Protocols are submitted by professional staff, trainees and outside investigators. The Review Board, as a matter of policy, construes the review process as educational for the investigator as well as to protect the research participants.

For review purposes, research is defined broadly at St. Elizabeths and includes observational, intervention, outcome and records studies. In actuality, very little research of any kind is being conducted; St. Elizabeth's staff re-

ported that in fiscal 1975, only 29 protocols (of 49 submitted for review) were approved. In discussions with research staff, the Commission learned that all research conducted at St. Elizabeths Hospital relates to mental health care or diagnosis including, for example, research to develop basic information about the metabolism and brain function of people with particular illnesses.

The Commission toured parts of the hospital including the community mental health center, a behavior modification treatment and research program, geriatric and youth units, the Forensic Program Division and the NIMH intramural research division.

All research participants in the William Alanson White Building (the principal research unit at St. Elizabeths) are voluntary patients who retain all their civil rights. The clinical and research staff must respect these rights, even when patients appear to be too disturbed to exercise them rationally. A voluntary patient who refuses treatment may be asked to leave the hospital, whereas an involuntary patient may be treated against his or her will.

During discussions with research staff, Commission members explored the impact of FDA regulations which require that most drugs be tested first on normal volunteers. The St. Elizabeths' staff expressed doubt that the major drugs currently used for treating psychiatric illnesses could be developed in the U.S. today, given such requirements.

Hospital staff viewed the presence of research as having a positive impact on patient care. Patients on research units benefit from the high staff-to-patient ratio, especially when the research involves careful monitoring of

biochemical interventions. However, a dilemma arises in the testing of new drug therapies because of possible interaction with drug treatment that the patient normally receives. If regular treatment is maintained concurrently with the experimental drugs, synergistic effects may result; but if regular treatment is withheld, regression may occur.

Commission members met with participants in psychopharmacological research to assess their understanding of the purpose and nature of the research, the voluntariness of their participation, and the extent to which they seemed able to give informed consent. In addition, the Commission asked research staff about the nature and meaning of the concept of informed consent for severely disturbed individuals. Investigators replied that informed consent, as generally understood, may be impossible for acute psychotics to give. The reality of this problem was apparent. Patients' thinking may be fragmented, and they may be suspicious or uncommunicative. On the other hand, depressive patients may be dependent upon others and may consent too freely. The Commission was urged to find a new way to conceptualize informed consent for research involving the institutionalized mentally infirm, taking into account potential impact on the physician-patient relationships.

Chapter 8. Public Hearing

On April 10, 1976, the Commission conducted a public hearing on the issue of research involving the mentally infirm. Summaries of presentations that were made to the Commission follow.

Roger Meyer, M.D. (Harvard Medical School), speaking for himself, said the current environment is hostile toward needed research in biology and behavioral sciences. He pointed out that to apply the notion of diminished capacity to give consent to all mentally disabled persons runs counter to modern concepts of mental illness and to court decisions which have restored their civil rights and limited judgments of incompetency. Issues of diminished capacity and guardianship should apply only following judicial determinations of incompetency. Another consent issue involves the concept of coercion as it relates to institutionalization. He submitted that coercion does not apply only to the mentally disabled, but to all chronically ill persons under the care of health professionals whom they trust, whether the persons are institutionalized or not.

Dr. Meyer cautioned that invoking the adversary process to protect research subjects may run counter to medical ethics and diminish accountability of professionals. Further, he said, consent negotiated with community groups is unworkable. Consent should be negotiated by the investigator with individual subjects. Dr. Meyer urged the Commission to address the need for research with the mentally disabled and to prepare a balanced current state of the art document that would include a review of consent issues and ethical implications of research.

Michael S. Lottman, J.D. (American Bar Association Commission on the Mentally Disabled (ABA/CMD)) supported the continuation of quality experimentation in mental disability under conditions that would prevent abuses. (The ABA/CMD defines "research" as any activity that places the subject "at risk" as defined by DHEW regulations, and distinguishes this from "behavior modification.")

The ABA/CMD would permit exposure of institutionalized mentally disabled research subjects to risk only when the proposed experiment is justified in terms of compelling societal interest and is conducted with scientific and procedural safeguards.

The ABA/CMD would allow nontherapeutic experimentation on the institutionalized only when certain conditions are met: (1) the protocol has scientific merit, verified by an independent multidisciplinary committee; (2) medical care, direct care and other institutional services are sufficient; (3) the experimentation will not reduce the amount or quality of therapy available to research subjects or to other residents; (4) the research poses no more than minimal risk; (5) the research is related to mental disability and seeks information that cannot be obtained from other subject groups; and (6) the information sought is of significance for the advancement of acknowledged scientific or medical goals.

With regard to nontherapeutic research, any objection, however expressed, by a competent or incompetent patient or resident should be an absolute bar to such individual's participation. Consent should be obtained, to the extent possible, from patients or residents competent to make such a decision, as well

as from such persons' guardians, if any. Nonobjecting incompetent individuals should be used as research subjects, with appropriate third-party consent, only in those rare instances where special necessity can be demonstrated for their participation.

Therapeutic experimentation would be permissible when the above conditions are met, with two major exceptions: (1) more than minimal risk could be imposed if absolutely necessary to preserve the life, health or physical safety of the research subject; and (2) given a high level of therapeutic justification, the objections of an incompetent (but not a competent) subject could be overridden with proper third-party consent and review procedures. (The term "therapeutic" must be strictly defined in terms of individual necessity and benefits.)

Philip Roos, Ph.D. (representing the National Association for Retarded Citizens (NARC)) addressed two issues: conduct of biomedical and pharmacological research in residential facilities for the retarded, and behavior modification research in such facilities. NARC is committed both to the protection of mentally retarded persons from exploitation and to encouraging research on prevention and amelioration of mental retardation. NARC's guidelines for research involving the retarded provide that: (1) biomedical research in residential facilities for the retarded must be directed toward retardation, be potentially therapeutic or, if nontherapeutic, pose no substantial danger to participants; (2) all such proposed research should undergo scientific review by an independent professional committee which should approve the project in writing prior to selection of subjects and should determine that another appropriate population is not available; (3) approved research should also be

reviewed by a "local committee on legal and ethical protection" (with "citizen" membership), which would provide written approval prior to selection of subjects; (4) the protection committee should also supervise and monitor consent procedures; (5) adequate medical facilities and supervision of participants by qualified clinical staff must be present; (6) multi-level continuous review should occur, and variations in procedures should be monitored; (7) the rights of individuals not to participate or to withdraw from research must be respected and protected; and (8) enforcement mechanisms must exist to assure that participants' rights are observed.

NARC approves the use of behavior modification procedures although there is concern about the specific programmatic procedures used and behavioral objectives that are selected. Therefore, NARC has developed specific guidelines for the use of aversive procedures and for selecting goals of behavior modification. In addition, NARC proposes that two independent review bodies be established to approve and monitor all behavior modification programs in institutions for the mentally retarded. Functions and procedures for these review bodies are described in Guidelines for the Use of Behavior Procedures in State Programs for Retarded Persons (NARC, 1975).

Dr. Roos also commented on the concept of competency. He said that competency is not an absolute dimension but is relative to a particular experiment. In each experiment, subjects should be questioned to see if they understand the research purposes and procedures. In addition, he proposed licensing of investigators and accreditation of institutions.

Johs Clausen, Dr. Philos. (Institute for Basic Research in Mental Retardation), speaking for himself, stated that aspects of federal protection regulations impede research in mental retardation. Regulations designed to protect subjects from physical risk, he said, should not be required for innocuous procedures. A realistic definition of risk is required. Written consent should not be required where no risk is involved; in such cases, research participants can be adequately protected by IRB approval.

Most of the research conducted by the N.Y.S. Institute for Basic Research in Mental Retardation entails no manipulation of behavior or administration of drugs. Nevertheless, detailed requirements for informed-consent have led parents and administrators to be very suspicious of the research and to see risk where it does not exist. Given this atmosphere, it is safer for them to refuse to allow retarded persons to participate. He observed that although the Institute was placed adjacent to Willowbrook Development Center in order to facilitate research with a population of retarded persons, the Willowbrook consent decree has made this impossible.

Neil Chayet, J.D. (Chayet and Sonnenreich), speaking for himself, said that the current protection system has created major barriers to research without really protecting the patient. It is erroneous to structure the issue in terms of individual rights versus research interests. Mr. Chayet criticized the concept of informed consent as outdated and overused. Emphasis on adherence to the letter of the law (e.g., preoccupation with written consent forms) often leads to disregard for the spirit of the law. DHEW consent regulations do not take into account "psychological factors" (e.g., full disclosure may not be in the patient's best interests).

For the mentally infirm, the legal presumption of competency is problematic since one cannot ordinarily act for another unless a determination of incompetency has been made and a guardianship established. It is difficult and costly to set up guardianships. The dilemma is that many mental patients are in need of treatment, are legally considered competent to consent, but in fact are unable to do so. To escape this dilemma, Mr. Chayet suggested that (1) the law must develop a set of criteria for determining competency to give consent; and (2) requirements for the consent process should be tailored to the nature of the research and the extent of subject involvement. For sociological research and noninvasive procedures (e.g., urine samples) IRB approval (assuming there exist adequate confidentiality provisions) ought to suffice. In projects that involve measurable risk of harm and where the patient is deemed incompetent either by current legal standards or in accordance with established criteria, a "patient-surrogate" should be utilized. In most cases, the surrogate, working with patients, physicians and researchers, should have ultimate legal responsibility for deciding upon the appropriateness of participation in research for the incompetent. The legal function of the surrogate would be to permit the conduct of research rather than to "consent" (in the legal sense). The patient-surrogates should be paid professionals who are caring, well-meaning persons.

The peer review system, including self-policing, should be strengthened, rather than externally imposing accreditation or licensing standards.

Sue Allen Warren, Ph.D. (testifying for the American Association on Mental

should reflect variations in degree of risk and benefit inherent in research. Review committees need guidance for determining what constitutes "risk." Excessive regulation of minimal or no-risk studies is counterproductive. Increased regulation makes research less attractive to investigators and thereby threatens to reduce research that is necessary to solve the problems of retardation.

The AAMD's Social and Legislative Committee believes that it is the obligation of scientists to conduct research and to protect research subjects. Retarded persons should be afforded special protections because of the likelihood that they are less competent to evaluate the consequences of their participation in research, and they are likely to live in situations in which they are identifiable and not free from coercion. However, institutionalized persons should not be categorically excluded from research that can be carried out with noninstitutionalized persons. In such cases, the degree of difficulty in conducting the research (including financial costs and incidence of disease in the two populations) is a relevant consideration in deciding whether or not to allow institutionalized persons to participate. Similarly, the institutionalized retarded should not be categorically excluded from research done in other residential facilities or schools. Such studies are justifiable provided there is: (1) minimal risk; (2) probability of "high yield"; and (3) "markedly improved efficiency from using this population in contrast to others." Mentally retarded persons may make important contributions to the welfare of the general public by their participation in research. When retarded persons participate in studies, the investigator should be particularly careful to attend to cues that indicate whether the retarded person is consenting to

participate or continue in research because of a felt coercion. It is particularly important that review groups help to safeguard rights of retarded research subjects, and that there are reviews of procedures to be used. Guidelines for review committees would be very helpful.

David Reiss, M.D. (George Washington University Medical Center), speaking for himself, supported an active, on-going review process, while recognizing that good review will be expensive and therefore require adequate funding. Review boards should not make *a priori* or indirect assumptions about a mentally impaired individual's competence to consent based upon supposed consequences of institutionalization or diagnostic categorization. Rather, review ought to focus upon the negotiation and consent process, considering the unique characteristics of the individuals involved, research setting, protocol, etc.

Dr. Reiss suggested that the ideally negotiated consent process should include: (1) patients in a group setting serving as advocates for one another; (2) a close working relationship with the patient's family so as to effectuate the right to withdraw from a study; and (3) a satisfactory end-phase consisting of follow-up and dissemination of research findings. He also suggested the following improvements in the research process: (1) emphasis on the positive function of review for the investigator seeking to act in an ethically and socially responsible manner; (2) expansion of the review format to include site visits, subject interviews, etc.; and (3) special attention to the composition and membership patterns of review boards.

Daniel X. Freedman, M.D. (representing the American College of Neuropsychopharmacology (ACNP)) urged that regulations be flexible enough to allow investi-

gators to conduct needed research in a wide variety of contexts, and said that there is need for continuing assessment of the effectiveness of regulations. Regulations must take account of the sequence of interactions involved in the research process, namely the dynamic interplay between researchers and practitioners. Excessive regulation tends to discourage researchers from undertaking formal research studies of observational or anecdotal findings reported by practitioners.

No blanket statements can be made about the competency of the mentally infirm to consent to experimentation because there is a wide range of capability. The problem of valid consent in the case of a patient whose lucidity varies can be overcome by the existence of a long-term, trusting relationship between physician-investigator and patient-subject.

Dr. Freedman stated that the objective of psychiatric research that employs new techniques and psychopharmacological agents is not to control minds but rather to extend the range of options available to disturbed people and thereby increase their degrees of freedom.

Robert Plotkin, J.D. (Mental Health Law Project), testifying for himself, stated that the mentally ill and retarded have a right to take advantage of and benefit from medical advances and therefore should not be categorically excluded from research. Because diminished capacity can negatively affect a person's ability to make responsible decisions, however, and because the institutionalized may be more vulnerable to coercion, special scrutiny is required for research involving these groups.

Mr. Plotkin recommended a two-step review process: (1) a review of the scientific soundness of protocols; and (2) a separate committee to scrutinize the involvement of particular subjects in scientifically-approved research. The second, "humanistic" committee would review the adequacy of consent and make an independent assessment as to whether or not the proposed research would be in the "best interest" of the individual subject. All proposed actions that pose potential harm to the subject must be reviewed, not merely those labeled "research" by an investigator. A national registry of protocols should be established.

Research may be undertaken inside an institution when it is intended to directly benefit the individual subject or to advance knowledge about the subject's disability, provided certain requirements are met, such as review and consent. Mr. Plotkin said, however, that research intended to advance general scientific knowledge should not be conducted on institutionalized mentally ill or retarded persons.

H. Carl Haywood, Ph.D. (representing the Division of Mental Retardation of the American Psychological Association) underscored benefits of research involving the mentally retarded and cautioned against generalizing from a few abuses to the whole research enterprise (e.g., prohibiting all aversive stimulation). Placing unreasonable restrictions on the ability of scientists to carry out research with human subjects constitutes, in itself, a systematic infringement upon the human rights of those same mentally retarded persons who might serve as participants in research by hindering the development of better services. Adding regulations increases the cost of doing research, which in turn reduces the volume of research conducted, given present funding trends.

An institution should never be accepted as the sole representative of the individual, regardless of his or her competence. Informed consent procedures should be overseen by a local review committee, especially because of the acquiescence response set found frequently in institutionalized persons. The frequency and duration of participation in research that might deprive a resident of rehabilitative programs should be considered by review committees in deciding whether or not to permit a project.

Jonathan D. Cole, M.D. (testifying for the American Psychopathological Association) suggested that protection regulations should reflect variations in the level of risk. For many minimal risk procedures, formal procedures for informed consent are unnecessary; rather, the patient's acquiescence should be adequate. Ground rules permitting "noninvasive" research in mentally impaired patients who are incapable of giving informed consent are particularly needed. The local review board should decide what level of consent, assent or acquiescence is appropriate, commensurate with the level of risk. For studies posing greater risk (e.g., phase II trials), informed consent should always be sought from the patient (most psychiatric patients are capable of giving informed consent), or if the patient is impaired, from the responsible relative.

Eleanor Kohn (testifying for the National Association for Mental Health, Inc. (NAMH)) stated that the incidence of mental illness and the degree of suffering it engenders can ultimately be diminished only by research into the causes, course and treatment of the diseases. Therefore, NAMH encourages research, provided proper safeguards (i.e., regulations no less stringent than the present DHEW regulations and the November 16, 1973 proposed DHEW policy)

are enforced. Protective guidelines should take into account the significant difference in types of research and be flexible enough to be appropriate to those important-differences. All review or protection bodies should include informed consumer representation.

Frederick K. Goodwin, M.D. (representing the National Institute of Mental Health) stated that research in the mental health field should be encouraged because the "knowledge base" is thin and the efficacy of many treatments has not been established. Any proposal for protecting human subjects must take cognizance of potential impact on the research enterprise, particularly effects on the physician-patient relationship. He warned that some mechanisms which have been proposed for protecting research participants run the risk of diluting the physician's sense of primary responsibility for the patient's well-being. Emphasis on the letter of the law can lead to violations of the spirit of the law. "Outside" individuals have a legitimate and useful role to play on review boards, but they should never come directly between physician and patient.

Dr. Goodwin expressed concern about singling out persons for special protection because they have a certain psychiatric diagnosis. Being a psychiatric in-patient, he said, is not necessarily associated with a decreased ability to consent.

Research unrelated to conditions of mental illness should not be categorically prohibited for institutionalized persons. In some studies, the effect of institutionalization is the subject of investigation. Involuntarily committed patients should not be categorically prohibited from participating in research

because there may be anomalies or conditions that are peculiar to the involuntarily committed.

Stewart Brown (representing the Pennsylvania Association for Retarded Citizens) stated that research should not be permitted on institutionalized retarded persons unless it is directly related to the individuals' condition or to mental retardation. Since April 1973, Pennsylvania has had a moratorium on human experimentation in state institutions for children, retarded persons and the mentally infirm because of "horrendous" institutional conditions. Past abuses indicate disregard for the health and safety of institutionalized persons by researchers. Disproportionate use of institutionalized retarded persons as subjects for research is both scientifically unsound, because of the skewed sample involved, and morally reprehensible.

Voluntary, informed consent of institutionalized persons is a misnomer, Mr. Brown said. Voluntariness is suspect because institutionalized persons are dependent upon the institution for life itself. "Informed" consent is dubious because institutionalized retarded persons are usually the most severely retarded persons, who often lack communicative skills.

Mr. Brown recommended that researchers should be qualified and licensed. A regulatory-type agency should enforce regulations and impose sanctions where violations are discovered. Facilities in which research is carried out should meet relevant JCAH standards.

Chapter 9. National Minority Conference on Human Experimentation

The National Minority Conference on Human Experimentation included three papers and two workshops that discussed research involving the institutionalized mentally infirm.

Henry W. Foster, M.D., in "Children and the Institutionalized Mentally Infirm," pointed out that the research community often falsely assumes a common national life-style in its research design. This would influence a definition of mental infirmity, though it would not present difficulties defining the institutionalized mentally infirm. Dr. Foster recommended that "for groups placed at greatest risk because of their 'captive state,' a moratorium be effected." He believes that those clearly incapable of providing voluntary informed consent constitute people at greatest risk, e.g., the functionally illiterate, the senile, those with poor command of the English language, and the mentally incompetent. Mental retardates, whether institutionalized or not, should not participate in any nontherapeutic research.

Crystall A. Kuykendall, Ph.D., in a paper on "Children and the Mentally Infirm," defined mental infirmity or mental retardation as "a condition of inadequately developed intelligence." She discussed sociopolitical influences on the concept of normalcy and the consequences of labelling as retarded those children who do not conform to majority culture norms. She reviewed the literature about negative effects of institutionalization such as deprivation of human dignity, stigmatization, and both physical and mental abuses, and summarized the rights of the handicapped, as determined by the courts. In addi-

tion, she surveyed alternatives to institutionalization, such as community care programs and the cascade system of educational alternatives. She recommended specific criteria for institutionalization, mechanisms to improve institutions, and procedures for "mainstreaming" all but the profoundly retarded. She did not deal specifically with research participation of those institutionalized as mentally retarded.

Jacquelyne J. Jackson, Ph.D., in a paper on "Informed Consent: Ethical Issues in Behavioral Research," said that informed consent procedures for the mentally infirm should include a determination by a panel, composed of a physician, a psychiatrist, a biomedical scientist and an attorney, that the individuals may participate in research without violation of their rights or, alternatively, that the potential benefit to the individuals or to the class of persons outweighs the harm. Concurrence from next of kin or appropriate legal guardian would be mandatory. When feasible in terms of mental status, institutionalized individuals should, in addition, provide their own informed consent.

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The recommendations of the National Minority Conference workshops on research involving the institutionalized mentally infirm include the following:

With respect to the selection of subjects: biomedical or behavioral research should not be conducted on the institutionalized mentally infirm unless the subjects have a relevant condition that requires treatment and may be ameliorated by the research, no acceptable alternative treatment procedures are

available, and the research cannot be accomplished outside the institutional setting. In addition, there should be safeguards against disproportionate use of certain groups as subjects, and the appropriateness of the institutionalization of research participants should be reviewed by two clinicians who are independent of the institution.

With respect to informed consent, the Conference recommended that persons should not be research subjects against their will, regardless of competency; participants should be able to obtain outside advice at no cost to themselves; evidence that informed consent guidelines are followed must be available to the public; two people who are unaffiliated with either the institution or the research should witness consent procedures; the consent form should specify the financial liability of the federal government in federally sponsored research; minor subjects who are at least seven years old should sign the consent form; and subjects should be given a copy of the consent form.

Other recommendations provided for protection of confidentiality, adequate disclosure (including results of other studies and the possibility of being a control subject), appropriate language and comprehension level of consent forms, and explicit notice of the right to withdraw at any time.

Recommendations concerning institutional review committees stipulated that a majority of the members should be community representatives who reflect the sociological characteristics of the subject populations. In addition, the committees should include representatives of consumers and former subjects, and the membership should rotate. Review of proposals should take into account risks and benefits, acceptability of the research procedures and subject selec-

tion. The committees should conduct periodic review of research and reevaluation of the subjects' institutionalization as well as monitoring the consent process and assuring feedback to subjects about the research.

Chapter 10. Deliberations and Conclusions

From a review of the pertinent literature and site visits to institutions for the mentally ill and the retarded, the Commission is profoundly impressed by the paucity of knowledge relating to the care and treatment of persons institutionalized as mentally infirm, and by the historical role of such persons as social outcasts. In no other area of the Commission's mandate has the need for research been so clearly manifest. So little is known about the factors that cause mental retardation and the conditions known as mental illness, that efforts to prevent such disabilities are in the primitive stages. This paucity of knowledge extends to all aspects of diagnosis, medical and behavioral therapy, and even routine care. There is widespread uncertainty regarding the nature of the disabilities, the proper identification of persons who are disabled, the appropriate treatment of such persons, and the best approaches to their daily care. Clearly, improvements are in order; and these improvements are strongly dependent upon research.

At the same time, the mentally infirm have long been victims of negative social responses ranging from outright fear and abuse, through isolation, neglect and abandonment. They have been placed in institutions usually far removed from sight or mind of the rest of society, making them vulnerable to exploitation. Only recently has society begun to recognize that the moral ideal of treating such persons with dignity means more than kindness; it has implications for the exercise of their civil rights.

Various proponents have different views on how best to help these individuals. Some emphasize protecting the institutionalized from exploitation and

abuse, and thus take a paternalistic stance. Others emphasize autonomy and urge that the rights of decision-making be restored to those institutionalized as mentally infirm. Each of these responses recognizes a legitimate claim of such persons upon the community; but the two may come into conflict. The Commission's debate involved, in large measure, attempts to reconcile differences of opinion among Commission members as to the proper balance between these two considerations. The different positions that were proposed, and the resolution of those differences, are described in the following discussion.

One primary consideration must be borne in mind: the class of people identified in the Commission's mandate as the "institutionalized mentally infirm" is not homogeneous. It includes the profoundly retarded, who may spend most of their lives in institutions, the senile, who will probably live out their lives in institutions, and individuals who enter such settings for short-term relief from crisis-induced stress or for periodic care of intermittent difficulties. Some members of the class of subjects under consideration are clearly competent, both functionally and in the legal sense, to make decisions regarding their participation in research. Others clearly are not. In addition, some patients retain a constant level of competency (or lack thereof) while others may fluctuate with respect to their capacity to understand information, to respond to the real world, or to communicate choices. Finally, the kinds of institutions in which such persons reside vary considerably. They include the large and dismal stereotype of the past, as well as small units such as half-way houses and community mental health centers, set within the community and not nearly so affected by isolation or impersonal care as the older institutions. Consequently, the Commission's recommendations provide a

certain amount of flexibility and room for judgment by local Institutional Review Boards in order to accommodate the diverse situations to which the recommendations must apply.

The issues surrounding the conduct of research involving those institutionalized as mentally infirm can be viewed in terms of a conflict between the obligation to develop better methods of diagnosis and treatment, and the duty to refrain from interventions that present unjustified risk, or exploit the vulnerability of patients. The problem facing the Commission, therefore, was to formulate recommendations that would permit the conduct of responsible investigations designed to improve methods of diagnosis, prevention and care of mental disabilities, and at the same time protect institutionalized individuals from unwarranted or unfair interference. The Commission's deliberations focused on three issues: (1) whether research involving this class of subjects must always be relevant to their condition or to some aspect of their institutionalization; (2) how to protect the autonomy of such individuals while still affording protection to those unable to protect themselves; and (3) how much risk is ethically permissible to ask such persons to assume for the benefit of others.

The question of relevance. There was a difference of opinion among Commission members as to (1) whether institutionalized individuals should participate in research when suitable noninstitutionalized subjects are available; and (2) whether institutionalized individuals should participate in research that is not relevant to their particular condition. Some members of the Commission felt strongly that an individual who is institutionalized as mentally

infirm should not participate, or be asked to participate, in research for which noninstitutionalized persons would be suitable subjects. The rationale for this position is twofold: first, that institutionalized individuals are particularly vulnerable to exploitation, and second, that they already carry burdens from their disability and their institutionalization, and it is therefore unjust to ask them to assume any additional burdens. It is feared that persons in institutions will be involved disproportionately and unfairly in research because they are convenient and because their presence in an institutional setting might reduce the expense of conducting research. Further, it was suggested that those outside the institution, although perhaps also burdened by disabilities, are likely to have caring persons to assist and protect them, if necessary. Therefore, some members of the Commission proposed that even for research that is relevant to a mental disability, selection of subjects should be limited to individuals who are not institutionalized, where possible.

On the other hand, some Commission members felt just as strongly that it is incorrect to assume that participation in research is always a burden or that being in an institution is always a damaging experience. They suggested that participation in research may have beneficial effects, such as interaction with people from outside the institution or, at least, additional attention. Research tasks may be interesting and a welcome change from the boredom of institutional life, although relief from boredom does not in itself justify participation in research. One Commission member also observed that deinstitutionalization of mental patients has resulted in the abandonment of many such persons to ghettos, where they have no one to look after their per-

sonal, health and social needs. Thus, they may be even worse off than those who remain inside the institutions.

The resolution reached by the Commission was (1) to put the burden on each investigator proposing to recruit subjects from an institution to justify the involvement of such subjects, and (2) to permit institutionalized individuals to participate in research that is not relevant to their condition only if they are capable of giving informed consent and the research presents no more than minimal risk. Justification of the involvement of institutionalized subjects should be based on such factors as the availability of suitable subjects outside the institution, the nature of the research, the risks and benefits involved, and the probable competence of the class of subjects who will be asked to participate. As the risk increases, justification in the way of relevance to the subjects' condition is required.

Protecting autonomy. Some institutionalized individuals are capable of giving a legally valid informed consent. Others, with diminished capacity, are able nonetheless to understand what they are being asked to do, to make a reasonably free choice and to communicate that choice unambiguously. The Commission has chosen to describe this ability as the ability to "assent," in order to distinguish it from the more considered judgments of those who are not impaired. A judicial determination of incompetency or involuntary commitment has no implication for the concept of "assent." The capacity to assent may be related, however, to the length of institutional confinement. An individual may be involuntarily committed to an institution, and even have been adjudicated incompetent, yet still be able to make a knowledgeable choice to

participate in research. On the other hand, an individual may have entered an institution voluntarily and never undergone incompetency proceedings, but after living for several years in an institutional setting may become quite incapable of making an autonomous choice. It is not uncommon for institutionalized individuals to do only as they are asked. There are two additional concerns that should be borne in mind. First, potential subjects may agree to participate in research out of fear that necessary services or attention will be withheld if such permission is denied. Second, when the research involves participation over an extended period of time, one cannot presume from initial assent that there will be continuing willingness to participate, and capacity to exercise the right to withdraw may fluctuate.

In view of the different factors that may impinge on a person's autonomy in an institution, there was some disagreement among Commission members as to where the presumption should lie regarding capacity to assent. Some felt that because individuals institutionalized as mentally infirm may suffer both from their disability and also from the effects of institutionalization, their capacity to assent is in doubt. Others felt that all individuals should be presumed to be capable of making decisions affecting their lives unless there is clear evidence to the contrary. All agreed, however, that the capacity to assent should be determined without reference to court adjudications or mode of admission. It was also agreed that assent or even lack of objection would be sufficient authorization for an individual institutionalized as mentally infirm to participate in research presenting no more than minimal risk, so long as the research is relevant to the subject's condition, and that assent would be sufficient for research involving an intervention from which

the subject is expected to derive direct benefit, and for research presenting no more than a minor increment above minimal risk and designed to yield important knowledge about the subjects' condition. For research in the last two categories, the permission of a legal guardian may also be required by state law.

The Commission also concluded that a consent auditor should be appointed for projects deemed by the Institutional Review Board to require additional protection of subjects (e.g., if the research presents more than minimal risk or if the capacity of the proposed subjects to assent is in doubt) and that the auditor, once appointed, should be available on a continuing basis to protect the rights and the interests of patients. Further, appointment of a consent auditor should be mandatory for all research presenting more than minimal risk and no prospect of direct benefit for the subjects. Observation of the consent process by an auditor who is independent of the research team will assist in assuring the adequacy of an authorization that is based on the subject's consent or assent.

A difficult question arose regarding the circumstances in which an individual's objection to participation in research might be overridden. Some Commission members felt that individuals lacking the ability to assent nevertheless should be permitted to exercise an absolute veto over participation in any research. Others felt that when the research involves a potential benefit for the subjects, a veto might be overridden if overriding a particular patient's objection is specifically authorized by a court. In response, it was suggested that the requirement of such a cumbersome procedure might deny

to many individuals the benefits of new treatments under evaluation, simply because of the time and expense involved in obtaining court permission.

Ultimately, the Commission recommended that an institutionalized person's objection to participation in research should be binding unless (1) the research involves an intervention that may directly benefit that person, (2) that intervention is available only in the research context, and (3) the subject's participation is authorized by a court.

Permissible risk. Occasionally, research is proposed that presents more than minimal risk and includes no procedures from which institutionalized subjects may derive direct benefit, but which nevertheless may provide important information about a specific disease or disorder from which they suffer. Some Commissioners felt that it is never justified to expose institutionalized patients to risk for the sole benefit of others, even if that benefit appears to be significant and probable. Others felt that the risk could be justified only if there were a remote possibility that the subjects, themselves, might eventually receive some benefit (if only in the far future). Still others would limit participation in such research to institutionalized individuals who are capable of consenting. Several Commission members suggested that if the proposed subjects are the only ones suitable for the conduct of the research, and thus in a position to make a unique contribution to the benefit of others, individuals incapable even of objecting might also be included in such research if the risk involved is not unreasonable.

The Commission concluded, after considerable debate, that individuals institutionalized as mentally infirm should be able to participate in research

presenting more than minimal risk and no direct benefit to them under very limited conditions: only a minor increment of risk (over minimal) may be presented, and the anticipated knowledge to be gained from the research must be of vital importance for the understanding of the condition for which the subjects have been institutionalized or be expected to provide some benefit for the subjects in the future. In addition, appropriate conditions for the consent or assent of the subjects must be met (including supervision of the process by a consent auditor) and no subject may be included in such research over his or her objection.

It is not possible for any set of recommendations to provide for all possible contingencies. Unusual circumstances may arise in which a research proposal presenting an opportunity to learn important information about a serious disorder may be designed in such a way that an Institutional Review Board will be unable to approve it under the standards recommended by the Commission. In such instances, the Commission believes that there should be an opportunity for debate at the national level and for public comment regarding the ethical acceptability of the proposal. This can be accomplished by forwarding such protocols to a national ethics advisory board for review. Further, because of the importance of the issues involved, the conduct of any research approved by such an advisory board and subsequently by the head of the responsible federal agency should be delayed to provide a reasonable opportunity for Congress to take action regarding the proposal.

Dissenting Statement of Commissioner Cooke

(Dr. Cooke voted against section (C) of Recommendation (4). His explanation of this dissent follows.)

Research in which there is more than minimal risk to a subject presented by an intervention that does not hold out the prospect of fairly immediate direct benefit or by a monitoring procedure that is not required for the well-being of the subject should not be performed unless, in addition to the requirements of sections (A), (B) and (C)(i) of Recommendation (4), the anticipated knowledge might reasonably benefit the individual subjects in the future (section (C)(ii)). There is no greater moral obligation for an institutionalized mentally infirm subject toward others of his disease class, present or future, than any other person in society, even though in biological terms there may be some closer relationship. Since it is accepted that normal persons should not be enrolled in nontherapeutic research with more than minimal risk unless they can give informed and meaningful consent, it is doubly unreasonable that the institutionalized mentally infirm should be so enrolled when society has had so much recent concern for their greater protection, and when they live in environments which seriously discourage any kind of decision making and the nature of their illnesses weakens their abilities to choose responsibly in most of life's usual situations.

To offer the choice of being a research subject to the institutionalized mentally infirm, who are inconsistent and eratic in behavior and limited in almost all the choices most normal persons experience daily, greatly exaggerates the psychic benefits of being a subject and projects on the institu-

tionalized mentally infirm values not generally considered important by most people in society.

Greater protection and concern for the institutionalized mentally infirm, not less, was an important reason for the formation of the National Commission. No evidence has been presented in our hearings that would reverse those concerns.

Dissenting Statement of Commissioner King

(Ms. King voted against section (B)(iii) of Recommendation (2) and sections (D)(iv) and (E)(ii) of Recommendation (3).)

I am dissenting from the Commission's requirement of court authorization in Recommendation (2)(B)(iii) and Recommendation (3)(D)(iv) and (E)(ii) to enroll an objecting subject in a research project. I should emphasize at the outset that any dissent must take into account at least two possible interpretations of these sections, since the Commission's reasons for this requirement are not easily discernible. I am, however, in disagreement with both interpretations.

I disagree with the Commission's recommendation, either because (1) a court should never be able to overrule the valid objection (by valid objection, I mean the knowing and understanding refusal by a patient of a possible benefit for whatever reason) of an institutionalized patient or (2) a court is not necessarily in the best position in all cases to determine the quality of an objection.

As pointed out in the legal chapter of the Commission's report, "it appears that there is a trend, both judicially and legislatively, to guarantee patients the right to refuse hazardous or 'experimental' therapies." If that is so, then it appears particularly absurd for the Commission to suggest or encourage a court to overrule a patients' valid refusal to participate in a research project.

Perhaps the Commission required court authorization to insure as fair and objective an assessment of the quality of the objection as possible. I certainly share the Commission's concern about insuring a fair and objective assessment of the quality of the prospective subject's objection. Most forms of mental illness and mental retardation are viewed as possibly impairing a patient's ability to make sound personal decisions. We should be concerned therefore about a subject's ability to refuse as well as to assent to participation in research activities. I differ with the Commission because I do not believe that a court is necessarily in the best position to make such an assessment.

There appears to me to be no reason to mandate court participation in every case where there is some behavior indicating an objection. By the time the matter comes before the court, the patient's original behavior might be radically different; thereby leaving the court with a skewed impression. Since the court would have to depend to a large degree upon institutional records and data in reaching a decision, it is not immediately apparent that its decision would be any fairer than that of a consent auditor or an Institutional Review Board (IRB), who would have a continuing relationship with the patient and the project.

The Commission has given the IRB the basic responsibility for determining the quality of a patient's assent, and provided that an IRB in its discretion could appoint a consent auditor to assist it in carrying out its responsibilities. It seems to me that the same process should be used to ascertain the quality of a patient's objection. If the IRB or consent auditor decides that there is a valid objection, that should end the matter. If a patient is determined to be incapable of either assenting or objecting to enrollment in a research project that seeks to directly benefit the patient, then an appropriate third party (someone other than an institutional guardian) can give permission or refusal. If a consent auditor and/or the IRB is not sure of the quality of the assent or objection, then the IRB can seek assistance from a court.

For the reasons stated above, I have serious concern about the Commission's requirement that court authorization be obtained before enrolling an objecting patient in a research protocol -- thus my votes against parts of Recommendations (2) and (3).

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