APPENDIX TO

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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This Appendix contains the papers, reports and certain other materials that were reviewed by the Commission during its deliberations on research involving those institutionalized as mentally infirm.

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APPENDIX

I. PAPERS AND REPORTS PREPARED FOR THE COMMISSION

1. Report on the Mentally Infirm . . . . . Survey Research Center
   University of Michigan

2. On the Right of the "Institutionalized Mentally Infirm" to Consent to or Refuse to Participate as Subjects in Biomedical and Behavioral Research . . . Joseph Goldstein, Ph.D., LL.B

3. The Law of Informed Consent in Human Experimentation: Institutionalized Mentally Infirm . . . . . George Annas, J.D., M.P.H.
   Leonard Glantz, J.D.
   Barbara Katz, J.D.

II. PAPERS PREPARED FOR THE NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION

4. The Rise of Drugs in Behavior Modification Programs. . . . . Rudy Lombard, Ph.D.

5. Informed Consent: Ethical Issues in Behavioral Research . . . . . Jackquelyne Jackson, Ph.D.

6. Ethical Issues on Mental Health Research from a Minority Perspective. . . . . Mary S. Harper, Ph.D.

7. Resolution and Recommendations on the Workshop on the Institutionalized Mentally Infirm

NOTE: Minority Conference papers on children and the institutionalized mentally infirm are included in the Appendix to the Commission's Report and Recommendations: Research Involving Children.

III. SUPPLEMENTAL RESOURCE INFORMATION

8. American Psychological Association, excerpt from Ethical Principles in the Conduct of Research with Human Participants, 1973.

9. Joint Commission on Accreditation of Hospitals, excerpts from Accreditation Manual for Psychiatric Facilities, 1972, and Standards for Residential Facilities for the Mentally Retarded, 1971.

10. DHEW, excerpt from National Standards for Community Mental Health Centers, 1977.

11. American Association on Mental Deficiency, excerpt from Consent Handbook, 1977.

12. Additional Readings

I

PAPERS AND REPORTS PREPARE FOR THE COMMISSION

REPORT ON THE MENTALLY INFIRM

Survey Research Center
University of Michigan
Arnold S. Tannenbaum, Ph.D.
and Robert A. Cooke, Ph.D.
Principal Investigators

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Research Involving the Mentally Infirm

The data of this report were obtained through interviews with 151 research investigators who have engaged in research involving the mentally infirm and with a very small number of subjects or their proxies. These projects come from our sample of 61 institutions having general assurance of compliance with DHEW regulations for the protection of human subjects. Projects involving the mentally infirm represent 11 percent of all of the research that passed through review boards between July 1974 and June 1975 (Table 1.1). Sixty four percent of this research was reviewed by boards at institutions for the mentally infirm and 36 percent by boards at other institutions, primarily at medical schools and at hospitals (Table 1.2).

The research investigators who have responded to our interviews are approximately 75 percent of the total number of such persons who were initially drawn in our sample. The representation of research investigators in our final sample corresponds reasonably well to our initial design. (A more precise statement concerning the reliability of all samples in the study will be presented in the final report.) The final sample of subjects, however, is very limited. We nonetheless report some of the opinions and suggestions obtained from these subjects or proxies in order to illustrate the reactions of some of these persons to the research in which they participated.

The report is divided into six sections. The first describes the types of research involving the mentally infirm in institutions for the mentally infirm and in other settings. The second concerns selection of subjects. The third section describes the risks and benefits of research as reported by researchers. The fourth section discusses informed consent and the fifth reviews the comprehensiveness and comprehensibility of consent forms used in research involving the mentally infirm. A sixth section presents the suggestions and opinions of investigators and some subjects/proxies. Accompanying the

report is an appendix which presents a large number of tables, most of which are summarized in the report.

Summary of Findings

Approximately 60 percent of the projects involving the mentally infirm were primarily behavioral. Biomedical research accounts for about a third of the research, and the remaining small percentage entailed secondary analyses.

Patients served as subjects in a majority of the projects reviewed at institutions for the mentally infirm as well as at other places. In a large majority of projects, investigators reported that subjects were selected because of a specific condition or characteristic.

The primary purpose of most of the research, according to investigators, was to benefit subjects directly or to benefit in the future persons with psychological or medical conditions similar to those of the subjects. Almost a third of the projects had primarily other purposes, such as contributing to scientific knowledge. In close to 90 percent of this latter group of projects, subjects were selected because they had a particular condition or characteristic.

According to investigators, the changes most frequently requested by review committees concerned procedures for obtaining consent, occurring in about a fifth of the projects. Consent procedures for behavioral interventions *were* more likely to elicit recommendations for change than were procedures for other types of studies, the most frequent change here being the requirement that written consent be obtained from subjects.

Oral and/or written consent was obtained in close to 80 percent of the

projects in which the mentally infirm participated. Approximately 35 percent of the projects employed proxy consent, although in the case of the mentally retarded, the percentage is closer to 80 percent. Parents, relatives, and legal guardians were the most frequent proxies. Most investigators felt that proxy consent protected subjects "very well" or "fairly well," but almost a fifth of the investigators indicated otherwise.

Consent forms showed varying degrees of completeness. The purpose of the research, procedures of the research, and/or the subjects' freedom to withdraw were mentioned in most but not all forms. Risks were mentioned in most of the forms used in projects, which, according to investigators, entailed some risk. Other elements were mentioned infrequently. An analysis of the readability of the consent forms suggests that most are at a difficult reading level.

Attitudes of investigators doing research on the mentally infirm were mixed. Most of the researchers felt that the review procedure protected the rights of subjects,, Nonetheless, up to half of the investigators indicated that the committee gets into areas not appropriate to its function, makes judgments it is not qualified to make, or impedes the progress of the research. Over half of the investigators offered suggestions or expressed concern about problems, such as the time-consuming nature of the process and the failure of the boards to discriminate between high risk and low risk research. Some of the small number of subjects and proxies whom we interviewed also offered suggestions, including the desirability of providing subjects with more information about the results of the research, and more concern on the part or researchers for the subjects as individuals.

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Robert A. Cooke, Ph.D., Study Director

Arnold S. Tannenbaum, Ph.D., Program Director

I. Types of Research (Tables I.3-I.9)

Approximately 60 percent of the projects involving the mentally infirm were behavioral and most of these included primarily psychological or educational testing, interviews or questionnaires, or behavioral observation. About 25 percent of the behavioral research entailed the study of an intervention of some kind, including educational innovations, social or psychological therapy, or behavior modification. Biomedical research accounted for approximately a third of the research projects involving the mentally infirm. These projects involved almost exclusively the administration of drugs or the clinical evaluation of bodily fluids (Tables I.3 and I.4). Secondary analyses represented the remaining small fraction (about seven percent) of research involving the mentally infirm. Most of these studies involved the use of existing data or records; a very small number involved the evaluation of bodily fluids or tissues which had been obtained for other purposes.

Investigators reported that about 10 percent of the drug studies involving the mentally infirm were done under an Investigational New Drug Application (INDA) from the FDA. Relatively few of these projects were Phase I or Phase II studies, according to investigators (Table I.5). In about half of the drug projects, investigators indicated that the drug administration would have occurred even if subjects were not participating in the project. Drugs were administered orally in about 85 percent of the drug studies and by injection in about 25 percent of these studies. (Some projects used more than one method of administration.)

The studies that entailed the analysis of bodily fluids included, in close to 90 percent of the cases, the examination of blood (data not shown). Urine was also obtained in about 40 percent of the studies in which bodily fluids were examined, and in all of these cases the urine was freely voided. According to investigators, the procedures used to obtian these fluids would have been employed

in about 30 percent of the cases even if the research had not been conducted.

The type of research reviewed at institutions for the mentally infirm is very much like that reviewed at other institutions, such as medical schools and hospitals (Table I.6).

According to investigators, review boards formally required a number of actions from researchers, primarily by requesting more information about the research or by asking for changes in the consent forms and procedures (Table I.7). Review boards suggested changes more often in the behavioral intervention studies than in the others, asking for more information in approximately 40 percent of them and modification of the consent procedures in about 30 percent. Boards also asked for more information concerning about a quarter of the biomedical projects and the non-intervention behavioral projects. Other requested modifications, such as those in scientific design, subject selection, risks, discomforts, and confidentiality, occurred relatively infrequently.

Changes also resulted from informal discussion between researchers and board members prior to the submission of the proposal. About two thirds of the investigators reported such discussion in connection with the behavioral intervention studies, about-half with secondary analyses, and a third with biomedical and other behavioral studies (Table I.8). Investigators reported making modifications in close to half of the cases where such discussions occurred (data not shown),

Table I.9 shows the percentage of projects that used each of a number of research methods, such as single or double-blind procedures, randomization, cross-over designs, or placeboes. Although each of these methods appears infrequently, one or another is used in the majority of projects.

II. Selection of Research Subjects (Tables II.1 to II.8)

Review committee emphasis on subject selection. Subject selection was not an area of major IRB involvement, according to investigators. IRB's by and large accepted investigators' plans for subject selection (Table II.1). Change was required in five percent of the projects, usually by limiting or restricting the sample in some way.

Characteristics of research subjects. In a large majority of projects, investigators reported that subjects were selected because of a specific condition or characteristic (Tables II.2, II.3). While investigators for eight percent of the projects at institutions for the mentally infirm reported that no condition or characteristic was used to select subjects, it is possible that this percentage is artifically high. Since the research had already been identified as taking place at an institution for the mentally infirm, the investigators may have meant by their response that subjects were not selected for any condition beyond their being mentally infirm.

The presence of a specific mental disorder was mentioned as a selection criterion in 74 percent of the projects reviewed by IRB'S in institutions for the mentally infirm and in 94 percent of the projects in other institutions (Tables II.4, II.5). In institutions for the mentally infirm, the presence of a psychosis was used most often to select subjects. In other institutions, the presence of a psychosis and the presence of a neurosis were used equally often to select subjects. Behavioral problems were the basis for subject selection in 12 percent of the projects in institutions for the mentally infirm. Usually, the problem was one of personal adjustment.

Demographic characteristics were used to select subjects in 20 percent of the projects at institutions for the mentally infirm and in six percent of the projects at other institutions. Age was the demographic characteristic

used most often for subject selection.

In 13 percent of the projects conducted at institutions for the mentally infirm, either no criteria or only demographic criteria were used for selecting subjects (data not shown). (As explained above, this percentage may be artificially high.) Two of these projects (18 percent) involved the administration of drugs and one project entailed primarily the clinical evaluation of bodily fluids. Other projects focused on educational innovation, psychological and educational testing, behavioral observation, and interviewing. In only two projects conducted in other institutions were subjects selected on the basis of only demographic criteria or no criteria. One of these projects involved the clinical evaluation of bodily fulids; the other involved survey procedures (Table II.6).

Subjects in most projects were. reported to be "from an institutional population to which the investigator has professional ties" (Tables II.7, II.8). Investigators used their own patients for about one-fourth of the projects. Referrals by other professionals were used about twice as often in other institutions as in institutions for the mentally infirm.

III. Risks and Benefits of Research (Tables III.1-III.17)

Research which, according to investigators, was designed primarily to benefit subjects directly, accounted for slightly more than one fourth of all projects involving the mentally infirm (Table III.1). Almost one third of the projects, while not primarily intended to benefit the subjects directly, were intended to benefit in the future persons with conditions similar to those of the subjects. An additional 29 percent of the projects were conducted primarily for other purposes--for example, to contribute to scientific knowledge. These studies designed for "other purposes" fall into two groups: First, those projects in which the subjects were selected specifically because of a particular condition, characteristic, or illness (26 percent) and, second, those in which the subjects were not selected for a particular condition (three percent).

This last group includes four projects. One of these projects was designed to gather data on normal and abnormal bodily functions and involved the drawing of venous blood. The second and third projects were behavioral--one was intended to change staff interaction with patients and the other involved some pschological testing. The principal procedure of the fourth project was to measure electrical activity of the body. None of these investigators mentioned any probability of benefit for the subject and only one mentioned any risk (a medium probability of minor psychological stress and a very low probability of embarrassment).

Much of the biomedical research involving mentally infirm subjects was designed primarily to benefit the subjects, according to investigators (44 percent; Tables III.2 and III.3). A smaller percentage (23 percent) was intended to benefit, in the future, other people with conditions similar to those of the subjects. In most cases, biomedical projects conducted for other purposes focused on subjects who were selected because of a particular condition or illness. Most behavioral

intervention studies were intended to benefit either the subjects (43 percent) or other persons with similar conditions (32 percent). The majority of the other (non-intervention) behavioral studies were not intended primarily to benefit subjects. Similarly, the projects involving secondary analyses were intended to benefit others similar to the subjects or to achieve other purposes.

Risks and benefits of research intended primarily to benefit subjects. Each investigatorwas asked about the probability of different types of risks and benefits to subjects "in terms of your understanding of the risks and benefits at the time the study began." Almost two-thirds of the investigators whose projects were intended primarily to benefit subjects estimated that their research would have a medium or high probability of psychological benefit (Table III.4). Slightly more than one fourth reported a medium or high probability of medical benefits to subjects. None of these investigators estimated as much as a medium or high probability of serious risk, though 64 percent of them reported some probability of minor psychological stress and 34 percent reported some probability of minor medical complications.

Risks and benefits of research intended primarily to benefit others like the subjects. Approximately two thirds of the investigators of these projects estimated some probability of psychological benefit and of minor psychological stress for subjects (Table III.5). Some probability of medical benefit was reported in 30 percent of the projects. Very low or low probability of minor and serious medical complications, serious psychological stress, fatal complications, and legal risk due to a breach of confidentiality were reported by small numbers of investigators. Thirty-eight percent of the projects involved a very low or low probability of embarrassment due to a breach of confidentiality. Overall a smaller percentage of investigators reported probabilities of benefits and risks in this type of research compared to research intended to benefit subjects.

Risks and benefits of research conducted for other purposes. These projects involved a lower probability of risks and benefits to subjects than did those projects which were intended to benefit the subjects or other people like the subjects. Forty percent of investigators estimated some probability of psychological benefit (Tables III.6 and III.7). According to the investigators, one third of these projects involved a low or very low probability of minor psychological stress and embarrassment due to a breach of confidentiality. Fourteen percent of the investigators reported a very low or low probability of serious psychological stress, but none of the projects involved any possibility of serious medical or fatal complications.

The distribution of benefits and risks by type of research (i.e., biomedical, behavioral intervention, other behavioral, and secondary analyses) appears in Tables III.8 to III.11.

Investigators' present assessments of risks and benefits. Most investigators reported that the risks and benefits actually experienced corresponded to their initial estimates (Tables III.12 and III.13). Almost all investigators reported that they were certain or fairly certain before the study began that they knew all of the risks that the project entailed (Table III.14). Very few investigators reported that the risks involved in their research outweighed the benefits to subjects. This was true for their assessments of the balance of risks and benefits both before and after subjects became actively involved (Tables III.15 and III.16).

Injuries or harm as a consequence of research and provisions for compensating injured subjects. Each investigator was asked if any subjects sustained injuries as a result of participating in the research, without regard to whether there was negligence. These questions referred to unexpected problems and not to the predictable effects that are an integral part of the therapy. An investigator

who had conducted a study that was designed to benefit the subjects reported such injuries. These injuries (sustained by two subjects) were classified as trivial.

Slightly more than half of the investigators in projects intended primarily to benefit subjects indicated having provisions for treating subjects should they suffer any harmful effects due to the research (Table III.17). Less than one third of the investigators conducting projects not primarily intended to benefit the subjects reported provisions for treating injured subjects. More than half of the investigators conducting such projects considered the question "inappropriate" presumably because they did not consider their research as entailing risk or harm. Provisions for financial compensation to subjects in case of harmful effects are found only in projects intended to benefit others.

Breach of confidentiality. Only one project reported the occurrence of a breach of confidentiality which had harmed or embarrassed *a* subject. Most investigators reported having some procedure to protect the confidentiality of. their subjects. The procedures most often mentioned were separation of names from data, limited access to data, mechanical means such as locking up the material, and not using names in publications.

IV. Informed Consent (Tables IV.1-IV.31)

Review committee action. Review committees required changes in the procedures for obtaining consent in about a fifth of the projects involving mentally infirm subjects. Changes were required less frequently (11 percent) in projects at institutions for the mentally infirm than at other institutions (27 percent). Most of the changes for both institution types pertained to the explanatory materials to be presented to subjects and proxies (Table IV.1). Protocols involving behavioral interventions were more likely to elicit a recommendation for change than were other types of protocols. The most frequent change in behavioral intervention projects was the requirement that written consent be obtained. Most of the changes required in biomedical and other behavioral projects centered around the simplification of or other alterations in materials to be presented to subjects (Table IV.2).

Written and oral consent. Oral and/or written consent was obtained from subjects in over 80 percent of the projects from both sets of institutions (Table IV.3). With respect to research types, oral and/or written consent was obtained from subjects in over 90 percent of biomedical, behavioral intervention, and other behavioral projects, and in 12 percent of secondary analysis projects* (Table IV.4). Reasons cited by principal investigators to explain why no consent was obtained include: (1) names of subjects were unavailable to the researcher; (2) consent was obtained elsewhere; (3) no risks to subjects were involved; and (4) the review committee did not require that consent be obtained. Consent was usually obtained in writing** (Table IV.3) and principal investigators of about two thirds of the projects said that they provided an oral explanation of the study to subjects or proxies (Tables IV.5 and IV.6).

*Only oral consent was obtained in these secondary analysis projects.

**In the case of both mentally retarded and mentally ill subjects, written consent was obtained for about 75 percent of the projects.

The consent process: who obtains consent? Investigators had either exclusive or shared responsibility for obtaining consent in the majority of the projects (Tables IV.7 and IV.8). The other persons who obtained consent were most frequently on the study staff, but on several projects a person not on the study staff obtained consent. Professional colleagues or research assistants of the principal investigator were the most frequent other persons to obtain consent. Less frequent were interns, nurses, and students (Table IV.9).

Aside from the person who obtained consent, the subject, and/or the proxy, other people were present in 40-50 percent of the projects when consent was sought. At institutions for the mentally infirm, this other person was most often a nurse, whereas in other institutions, it was more often a family member of the subject (Table IV.10). The persons most often present for biomedical and behavioral projects were nurses and research assistants (Table IV.11).

Gaining the participation of research subjects. We analyzed the relationship between aspects emphasized by investigators seeking consent and the purpose of the research. For those projects whose primary purpose was to benefit the subjects, that direct benefit was emphasized most in the majority of cases, although other purposes of the research were also mentioned frequently (Tables IV.12 and IV.13). When the primary purpose of the study was to benefit others, that fact was most frequently given the greatest emphasis, according to investigators, although in almost a third of these projects the investigators also emphasized a direct benefit to the subject.

Finally, for research with some other primary purpose, its potential benefit to others and its benefit to scientific knowledge were each emphasized in about half the cases; investigators reported emphasizing direct benefits to subjects for about a fifth of these projects. It is very likely, according to investigators in many biomedical studies, that benefits will accrue to subjects even though the project may not be designed primarily to benefit subjects

When obtaining consent, principal investigators generally reported that they presented the possibility of participation as a request. However, when the primary purpose of the research was to benefit the subjects, participation was most frequently described as both a recommendation and a request (Table IV.14).

Investigators of some projects did not reveal all information to subjects. Information was withheld most frequently in biomedical projects and at institutions for the mentally infirm. The information not divulged focused most often on the purpose or specific procedures of the study, the medication or treatment being used, and possible benefits to the subject (Tables IV.15 and IV.16). Most reasons for this withholding of information concerned biases that divulging could introduce in the data.

Investigators of several behavioral projects reported that subjects were told things that were not true. The aspects of false information centered around the purpose or specific procedures of the study (Tables IV.17 and IV.18), and the reasons again involved fear of biasing the data.

In the vast majority of projects, subjects were not paid for participation. In the remaining projects, payments were small, usually $1 to $25, and occurred only in those cases where the research was not designed to benefit the subject directly (Table IV.19).

Principal investigators felt that the decision to participate in the study was not difficult for subjects in the majority of projects (Table IV.20). Difficulties were experienced more often in projects designed to benefit the subject directly or others like the subject. Some subjects declined to participate in projects that were designed for each of the four different purposes. Prospective subjects declined to participate most often in projects designed to benefit others with conditions similar to those of the subjects (Table IV.21).

Proxy consent. Proxy consent was obtained in 35 percent of the projects from both institution types. (Table IV.22). It was obtained most frequently in behavioral intervention projects (59 percent) and never in secondary analysis projects (Table IV.23). While proxy consent was obtained in about 80 percent of the projects involving mentally retarded subjects, it was used in only about a third of the projects involving the mentally ill.

In the projects where proxy consent was used, consent was obtained only from proxies about twice as often as it was from subjects as well as proxies. The major criteria for determining whether proxy consent would be used were the subject's age* and degree of illness. The subject's intellect was a less frequent determinant of whether proxy consent would be obtained.**

Parents, relatives, or legal guardians of the subjects were the most frequently used proxies. Institutional representatives served as proxies in only one percent of the projects from institutions for the mentally infirm and in two percent of the biomedical projects. Courts were used as proxies more often in projects from institutions for the mentally infirm and in biomedical and behavioral intervention projects*** (Tables IV.26 and IV.27). Approval for participation was obtained from the subject's physician in a majority of cases when the subject was the patient of someone other than the principal investigator.

A majority of the investigators reported that subjects for whom proxy consent was obtained were rarely or never reluctant to participate. In four percent of the projects from institutions for the mentally. infirm investigators

*The age above which no proxy consent was obtained was reported most often as 18 years. The age below which consent was not obtained from subjects as well as proxies was about nine years.

**As can be expected, age and intellect served as criteria for obtaining proxy consent much more often for mentally retarded subjects than for mentally ill subjects. Degree of illness was the criterion used in obtaining proxy consent more frequently with mentally ill than mentally retarded subjects.

***Parents and legal guardians served as proxies more frequently far mentally retarded subjects than for mentally ill subjects.

reported that their subjects were sometimes or often reluctant to participate (Table IV.28).* Behavioral intervention projects were more likely than other types to have reluctant subjects, according to the reports of investigators (Table IV.29). Investigators indicated further that when such instances occurred, the most frequent outcome was that the subject did not participate.

Most investigators reported that proxy consent protected subjects "very well" or "fairly well." Twenty percent of the projects from institutions for the mentally infirm, and 16 percent from other institutions, however, indicated otherwise (Table IV.30). The main explanations given for the inadequacy of proxy consent were: (1) where only proxy consent is used, subjects may not be able to decide themselves whether or not they wish to participate in the research; (2) subjects are not given complete information about the research; (3) the proxy may not be able to understand the research; and (4) the proxy may not care about protecting the rights of the subject.

*A few of the investigators who had mentally retarded people as subjects reported that their subjects were occasionally reluctant to participate, but none of the investigators with mentally ill subjects reported such reluctance.

V. Consent Forms (Tables V.1-V.16)

As was shown in Table IV.3, written consent forms are used in more than 80 percent of research on the mentally infirm. Most consent forms were developed specifically for a particular study. Others were based on a standardized format provided by the institution (Table V.1). Ninety three percent of forms from institutions for the mentally infirm and 81 percent of forms from other institutions comprise less than 300 words; these are designated as "short" forms in our analyses (Table V.2).

In most projects, subjects/proxies are not given a copy of the form to keep (Table V.3).

Content of consent forms. Consent forms contain information about a wide variety of topics. To increase comparability of consent forms, an index of completeness was constructed. This index represents the extent to which a consent form covers each of the following: (1) the purpose of the research, (2) procedures involved, (3) the risks, (4) the benefits, (5) a statement that subjects are free to withdraw from the research, and (6) an invitation to subjects to ask questions about participation. (See Table V.4 and the accompanying explanation for more information about this index.)

The index of completeness shows only five percent of the forms from institutions for the mentally infirm and 21 percent of those from other institutions to be complete or nearly complete (Table V.4). Some elements receive more coverage than others (Table V.5). Purpose is mentioned in more than half of forms from institutions for the mentally infirm and in 70 percent of forms from other institutions. Procedures receive mention in more than three quarters of all forms, freedom to withdraw in more than two thirds of all forms, risks in 45 percent of all forms. Of those projects which make

no mention of risk in either their consent form or oral consent information statement, 60 percent were described by investigators in our interview as entailing at least some risk. Mention of benefits (or their absence) and an invitation to ask questions received less coverage. Of those elements not mentioned in consent forms, only purpose and procedures receivedsubstantial mention in the oral consent information statement (Table V.6).

It would be appropriate that alternative treatments be mentioned in consent forms for projects designed primarily to benefit subjects; however, this occurs only rarely (Table V.7). Similarly, consent forms from projects described by investigators as including an experimental element might be expected to mention this fact. Forty percent of consent forms from experimental projects in institutions for the mentally infirm and 61 percent of forms from such projects in other institutions identify the experimental nature of the project through the use of words such as experiment, research, or investigation (Table V.8).

The investigator's description of projects in the interview was compared to the consent forms and *to* the oral explanation given to subjects, as reported by investigators (Table V.9). In two thirds of the projects in which a possibility of a breach of confidentiality was indicated by investigators, this possibility was mentioned in either their consent forms or explanations to subjects/proxies. Investigators for about half of those projects that were expected to benefit subjects described benefits in their consent forms or explanations to subjects/proxies. Investigators for about the same percentage of projects that were not intended primarily to benefit subjects described benefits to subjects in their consent forms or explanations. Thirteen percent of the projects in which subjects were assigned to one of several treatments or procedures mentioned this fact in their consent forms Or explanations. Eleven percent of the projects in which some information would be

withheld from subjects mentioned this. The frequency with whichother topics of interest appear in consent forms is shown in Table V.10.

Readability of consent forms. We used the Flesch technique to assess readability of consent forms. The details of this technique are described in a note following Table V.10. Short consent forms were given an overall readability score while long forms were given a score for each of three content areas: purpose, procedures, and risks.

Tables V.11 to V.15 summarize our analyses, and show that consent forms tend to be difficult to read.

Complexity of sentence structure along with word length determine the readability score. Appearance of medical and technical terms is infrequent in consent forms. Most that do appear are in the more difficult forms. Such terms comprise well below five percent of all words in consent forms, and thus are too rare to explain the difficult reading level of most forms. Nonetheless, they are typically found at points critical to understanding the consent form and project. Furthermore, very few consent forms provide lay explanations of their medical and technical terms (Table V.16).

VI. The Attitudes and Suggestions of Investigators and of Some Subjects and Proxies (Tables VI.1-VI.4)

Attitudes of investigators toward the review process. Attitudes of researchers doing research on the mentally infirm were mixed. Most of the researchers from both institutional types felt that the procedure protected the rights of subjects and that the procedure ran with some degree of efficiency (Tables VI.1-VI.2). While a majority of respondents from both institutional types felt that the procedure improved the quality of research at least to some extent, 48 percent of those doing research in mental institutions and 39 percent of those doing research in other institutions indicated that the procedure had not improved the quality of research at all. Relatively few of the respondents doing research reviewed at mental hospitals found the procedure to be an unwarranted intrusion on the investigator's autonomy, but as many as 32 percent of those from other institutions indicated that this was a problem to some extent. A fair percentage of respondents from both institutional types felt that committees get into areas not appropriate to their functions, make judgments they are not qualified to make, and impede the progress of research, at least to some extent.

Investigators' comments and suggestions. Many researchers expressed satisfaction with, or acceptance of, the review procedures as they are presently operating. Nonetheless, over half of the respondents did make suggestions or express concern about problems with the review process as they experienced it.

Comments of investigators fall into five major categories (Table VI.3). The first concerns "bureaucratic problems" such as the complicated and time-consuming nature of the review process and the adverse effects of the process in slowing and preventing research. (Bureaucratic problems were mentioned by

23 percent of investigators doing research in institutions for the mentally infirm and by 22 percent of investigators from other institutions.) The time consuming nature of the process was a common complaint. Thus one respondent complained that, "now, it takes at least six weeks--if you politic, maybe three weeks" and another that, "I think we went through five committees--so it took about four months." Others explained that one "can't wait so long for approval" and that "with such a delay people are discouraged from carrying out projects." Another investigator elaborated a bit more on the consequences of delay stating, "if the Review Committee operates so slowly and the review is held up, the likelihood that the investigator will be honest is reduced." Others discussed the adverse consequences of these problems on the conduct of research stating, "changing regulations and laws regarding patient consent, etc., has made physicians and administrators uneasy about involvement in patient research and me too..." and "social-psych research has gone down the drain; it is based on deception."

The second set of concerns, related to the first, reflects the feeling that parts of the review process should be eliminated (mentioned by 18 percent of investigators at institutions for the mentally infirm and 15 percent of investigators from other institutions). Many of the investigators who made such suggestions focused on differentiating between high and low risk research, proposing that more care be exercised for high risk research and no review be required for innocuous research. Thus one investigator proposed that "there should be more distinction between no risk and limited risk research--especially with regard to the difference between wholly non-invasive techniques and invasive techniques," and another investigator proposed that studies should be "rated on a scale of high and low risk" and treated accordingly. Other researchers

proposed that written or informed consent be eliminated in certain circumstances and that review boards be more flexible in the application of rules and procedures.

A third set of comments concerns the structure or authority of the committee (mentioned by 12 percent of investigators at institutions for the mentally infirm and eight percent of investigators from other institutions). Some of these investigators proposed changing the composition of the committee and the way it is selected. Most individuals who emphasized the committee composition wanted a greater representation of experienced researchers, rather than non-professionals. One individual, however, did feel that the review committees. should be more representative of the population being studied stating,

> Most of the people on these committees tend to be white upper-class males and have little similarity with the subjects, and I wonder how thorough they can be in examining the possible risks. So I'd like to see more people from the target population and if it involves poor people, there should be some poor people on the committee.

Other investigators discussed the need for consultants and other help if the review committee is unable to understand or handle aspects of some proposals. One individual remarked, "on the Committee there should be consultants: experienced people such as past presidents of medical or biological and professional societies, presidents of congresses--national and international, and chairmen of symposiums."

A fourth set of suggestions concerns the need for more information and increased communication (mentioned by 19 percent of investigators at institutions for the mentally infirm and 13 percent of investigators from other institutions). Many of these investigators desired more definition and clarification of informed consent and what must be done to meet the "informed consent

requirement." Thus one respondent stated, "something has to be done with the concept of informed and voluntary consent--to be sure that it is informed and voluntary--we need guidelines for that," and another suggested, "I think there should be a standardized consent form. I went everywhere looking for a consent form that was acceptable." Other respondents desired an opportunity for interaction between the researcher and the committee, many of these having in mind an oral presentation of the protocol by the researcher to the committee.

A fifth category of suggestions concerns protecting human subjects to a greater extent than is presently done (mentioned by eight percent of investigators at institutions for the mentally infirm and eight percent of investigators from other institutions). A number of respondents desired more follow-up after review to see that proposed procedures were actually implemented. Others made general comments that committees do the job more carefully by having more strict review and by being "tougher."

Attitudes of Subjects and Proxies. Some of the principal investigators who were interviewed for this study agreed to contact their subjects or proxies on our behalf, Subjects and proxies were asked, by these investigators, to return a card to us if they wanted to participate in our study. This procedure enabled us to interview 33 subjects and 12 proxies. The data based on the interviews should be treated cautiously, since they have been provided by a very small number of respondents who do not represent, in any statistical sense, the larger population of mentally infirm subjects and their proxies.

Most of our respondents understood, before their participation began, that they were to be involved in "research" and remembered giving their consent for their (or the subject's) participation. Only one respondent did not recall giving either written or oral consent. Eleven precent, however, did not understand, before their participation began, that they were to be

involved in "research."

In general, our interviewees felt that they personally were provided with clear, sufficient, and accurate information about the research projects. (Almost half of the proxies, however, indicated that the researchers did not explain the research to the subject and that the subject did not have a very good understanding of what was going to be done.) Seventy-seven percent of the proxies and subjects reported that someone connected with the study talked with them and told them what was going to be done. More than eighty percent of our respondents felt that the information they were given was clear and accurate, but twenty-eight percent would have liked to receive more information. Most of these subjects and proxies (88 percent) saw the researchers as willing to answer their questions, and 61 percent did ask questions concerning the subject's participation. Many of these questions centered on the purpose of the research, the procedures to be followed, and the risks and possible side-effects of the procedures.

The proxies and subjects who were interviewed apparently had few problems deciding whether or not they (or the person for whom they gave consent) should participate in the research. Seventy-six percent of the respondents said that the decision to participate was "not at all" difficult and only four percent said that it was a very difficult decision. Consistent with this finding, proxies and subjects cited many reasons for participating and very few reasons for not participating. The expectation that participation would directly benefit the subject was the most important and most frequently-mentioned reason for participating. A small number of respondents cited better care, less expensive care, and other personal advantages; and a few subjects said they participated because they wanted to help science, the research,

or people with similar conditions. Ninety-one percent of the respondents cited no reasons for not participating. The few people who saw reasons for not participating mentioned the side-effects, unpleasant procedures, or inconvenience.

A series of interview items focusing on expected risks and benefits generated responses similar to those reported above. Eighty-two percent saw some possibility of benefit as a result of participating in the research. Direct psychological and educational benefit to the subject were mentioned most frequently. Thirty-eight percent of the respondents felt that participation in the project implied at least a very slight risk of harmful effects. Anticipated harmful effects included minor discomforts and the possible side-effects of drugs or procedures.

About one of every four respondents reported having experienced unexpected difficulties as a result of the study. These difficulities included side-effects, physical discomforts, or emotional problems. One respondent felt that the unexpected difficulties were very serious and seven people said they were somewhat serious. On the other hand, 69 percent of our interviewees said that the subject benefited as a result of participating in the research. Most of the subjects reported that the actual experience of participating in the research was better than expected or about the same as expected; only four subjects said the experience was worse than they had expected it to be. Seventy one percent of the subjects (or proxies) said that they would be very willing to participate in a similar study again. Those who might be less than willing mentioned such factors as the time and trouble involved, the lack of personal benefits, the fear of side-effects, or the inadequate explanations given to subjects.

Subjects' and proxies' comments and suggestions. Approximately one-half

of the subjects or their proxies offered suggestions. These suggestions fall into three categories (Table VI.14). One (27 percent) concerns requests for more and better information to subjects. In many of these statements, subjects expressed a desire to receive a description of the results of the research. Thus one subject remarked,

> Send them the results. What's the good in doing the experiment if you never find out about the results?

and another complained,

> I've never been told of the results--what the drug did for me, if anything.

Other statements in this category were remarks about the desire for more information. Thus one stated,

> I would like more information to subjects on particular aspects of the project. . . . The researcher should not wait for the subject to ask questions but should assume that the subject is curious about everything that is done and should explain everything fully.

Another wanted "more explanation of the research being done."

A second category of suggestions (22 percent) concerns the experimenters' conduct of the research. Some subjects wanted experimenters to be more kind and courteous in dealing with subjects. One subject remarked that she "felt lke a guinea pig" and another stated,

> Start thinking of them as human beings and not test subjects. Doctors have a tendency to diagnose a mental disorder and then feel they don't have to deal with patients, except to refill prescriptions. In this study, I resented being treated as a child, and the patronizing tone of the doctors. They could have provided better hours. Group therapy fell apart. Should answer direct questions instead of skirting the issue. They never asked me if I felt better.

Others were concerned that the experimental procedures themselves be performed more carefully and more humanely.

A third, and smaller, category (nine percent) concerns improving the risk/benefit ratio by increasing types of care and service benefits or by reducing risks through testing more thoroughly before the experiment. One subject simply stated that "research projects should not be harmful to subjects."

APPENDIX

Tables

Table I.1

Percent of Projects Involving
the Mentally Infirm

	Percent of Projects (N=1835)*
Projects Including the Mentally Infirm	11%
Projects not Including the Mentally Infirm	89
All Projects	100%

*Based on the assumption that 172 out of 1835 that are non-respondent cases distribute like the respondent cases.

Table I.2

Research Involving Mentally Infirm
Subjects: Type of Institution

Type of Institution	Percent of Projects (N=174)*
Universities**	7%
Medical schools***	26
Hospitals****	16
Institutions for the mentally infirm	50
Other institutions*****	1
Total	100%

* The N's reported in these tables regarding the mentally infirm include projects for which investigators were not interviewed.

** Including IRBs at universities only if the IRBs are separate from the medical school review board.

*** Including IRBs at universities that share an IRB with a medical school.

**** Including children's hospitals.

***** For example, biomedical research institutions.

NOTE: This table is one of several tables provided by the Survey Research Center on November 3, 1976 to substitute for tables in the original report of September 8, 1976. "The data in these tables will differ from that included in our earlier report on the mentally infirm. More cases have been added and new weighting procedures have been applied which compensate for research investigators who did not respond to our interviews." (Letter from Robert A. Cooke, November 3, 1976.)

Table I.3

Type of Research Involving the Mentally Infirm

	Percent of Projects (N=151)
Biomedical	34%
Behavioral intervention	15
Behavioral	44
Secondary analysis	7
Total	100%

Table I.4

The Primary Intervention or Procedure in Each Study

	Percent of Projects (N=151)
Biomedical	
Clinical evaluation of bodily tissues or fluids	15%
Administration of drug, chemical agent or blood product	19
Use of diagnostic and/or therapeutic devices	*
Behavioral Intervention	
Educational intervention	6
Modification of an organization or a service delivery system	3
Social or psychological therapy	2
Behavior modification or experimentation	4
Behavioral (other)	
Interviews-questionnaires	11
Psychological or educational testing	19
Behavioral observation	11
Interviews with patient (e.g., medical histories)	3
Secondary Analysis	
New analyses of existing data	4
Review of medical records	2
Third party study of tissue or fluids obtained for other purposes	1
Total	100%

*Less than 1 percent but more than zero.

Table I.5

Is this a Phase I, II, III, or IV test?

	Percent of Projects (N=151)
Phase I	0%
Phase II	4
Phase III	1
Phase IV	4
None of these	3
Don't know	4
No answer	3
Inappropriate*	81
Total	100%

*Includes other than drug administration research.

Table I.6

General Types of Research Involving the Mentally Infirm: Type of Institution (Percent of Projects)

	Biomedical (N=62)	Behavioral Intervention (N=24)	Behavioral Other (N=74)	Secondary Analysis (N=10)	All (N=170)
Universities	1%	21%	10%	9%	7%
Medical schools	40	12	19	13	26
Hospitals	16	0	17	37	16
Institutions for the mentally infirm	43	67	52	41	50
Other	0	0	2	0	1
Total	100%	100%	100%	100%	100%

NOTE: This table is one of several tables provided by the Survey Research Center on November 3, 1976 to substitute for tables in the original report on September 8, 1976. "The data in these tables will differ from that included in our earlier report on the mentally infirm. More cases have been added and new weighting procedures have been applied which compensate for research investigators who did not respond to our interviews." (Letter from Robert A. Cooke, November 3, 1976.)

Table I.7

Actions Formally Required of the Investigator by the Review Board: Types of Research (Percent of Projects)*

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
More information	25%	41%	27%	16%
Modification in consent procedures	14	29	16	0
Modification in scientific design	5	15	0	0
Modification in subject selection	12	5	0	0
Modification regarding risks, discomforts	10	13	2	0
Modification regarding confidentiality	0	5	8	0
Other modifications	12	5	5	0

*Percentages need not add to 100% since respondents might indicate fewer or more than one action required.

Table I.7a

Formal and Informal Review Board Actions on Projects Involving the Mentally Infirm: Type of Institution
(Percent of Projects)

	Type of Institution					
	Universities (N=24)	Medical Schools (N=54)	Hospitals (N=15)	Institutions for Mentally Infirm (N=80)	Other (N=1)	All (N=174)
Informal (prior to formal review)						
Investigator discussed project with board member	30%	27%	21%	43%	100%	35%
Investigator modified project as a result of informal discussions	21	16	8	22	0	18
Formal actions						
More information requested	39	35	32	28	0	31
Modification in consent form or procedures	16	18	18	12	100	16
Modification regarding risks, discomforts	0	3	8	8	0	6
Modification regarding confidentiality	12	2	0	6	0	4
Modification in scientific design	0	1	0	6	0	3
Modification in subject selection	0	2	15	4	0	5
Other modifications	0	8	8	9	0	8

NOTE: This table is one of several tables provided by the Survey Research Center on November 3, 1976 to substitute for tables in the original report of September 8, 1976. "The data in these tables will differ from that included in our earlier report on the mentally infirm. More cases have been added and new weighting procedures have been applied which compensate for research investigators who did not respond to our interviews." (Letter from Robert A, Cooke, November 3, 1976.)

Table I.8

Prior to the submission of your proposal for review by the committee, did you have any informal discussions with any committee members concerning the use of human subjects or obtaining consent?: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Yes	31%	63%	34%	53%
No	69	32	66	47
No information	0	5	0	0
Total	100%	100%	100%	100%

Table I.9

The following is a list of some methods which you may be using for your study--please check as many as apply.*
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=71)**	Other (N=63)**
Single-blind method (i.e., subject does not know which study technique is being used)	17%	11%
Double-blind method (i.e., neither subject nor experimenter knows which study technique is being used)	16	11
Different treatment or procedures assigned by random method	11	14
Cross-over design (treatment or procedures switched between groups during the study)	14	3
Placebo administration	19	9

*Totals need not add to 100% since respondents could indicate fewer or more than one method.
**Excludes respondents who did not answer the relevant questions.

Table II.1

Did the review committee require you to make modifications in the proposed selection of subjects for your study? If yes, what changes? (Percent of Projects)

	Type of Institution	
	Institutions for the Mentally Infirm (N=83)	Other (N=68)
Changes required	5%	5%
Change to fewer subjects	0	2
Other limitations/restrictions in sample	5	3
No changes required	93	95
Don't know	2	0
Total	100%	100%

Table II.2

Reasons for Selection of Subjects: Type of Institution
(Percent of Projects)

Are subjects selected because they have a specific disease, condition, problem, or characteristic?	Type of Institution: Institution for the Mentally Infirm (N=83)	Type of Institution: Other (N=68)
Yes	91%	95%
Some are, some not	1	1
No	8	4
Total	100%	100%

Table II.3

Reasons for Selection of Subjects: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Are subjects selected because they have a specific disease, condition, problem, or character-istic?				
Yes	93%	85%	93%	100%
Some are, some not	2	0	1	0
No	5	15	6	0
Total	100%	100%	100%	100%

Table II.4

Conditions Used as Basis for Subject Selection: Type of Institution
(Percent of Projects)*

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Disease or Medical Condition	7%	6%
Mental disorders	74	94
Psychoses	51	36
Neuroses, personality disorders	5	33
Mental retardation	13	13
Other (including psychosomatic illness)	5	12
Behavioral problem	12	3
Educational problem	3	0
Legal problem	1	0
Personal adjustment problem	7	0
Other behavioral problem	1	3
Demographic characteristic	20	6
Age	9	5
Sex	4	0
Race	0	0
Income	0	0
Social class	0	0
Genetic or kinship ties	2	0
Educational, vocational situation	3	1
Life/family situation	1	0
Personal characteristic	1	0
Other selection criterion	1	0
No selection criterion	8	4

*Percentages may add to more than 100% since respondents could mention more than one condition.

Table II.5

Conditions Used as Basis for Subject Selection: Type of Research
(Percent of Projects)*

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Disease or medical condition	1%	0%	2%	12%
Mental disorders	90	76	77	76
Psychoses	60	26	44	25
Neuroses, personality disorders	19	15	11	18
Mental retardation	6	25	17	0
Other (including psychosomatic illness)	5	10	5	33
Behavioral problem	0	15	13	16
Educational problem	0	0	4	0
Legal problem	0	0	2	0
Personal adjustment problem	0	15	5	0
Other behavioral problem	0	0	2	16
Demographic characteristic	11	20	17	12
Age	2	5	12	12
Sex	7	0	0	0
Race	0	0	0	0
Income	0	0	0	0
Social class	0	0	0	0
Genetic or kinship ties	2	5	0	0
Educational, vocational situation	0	5	3	0
Life/family situation	0	0	2	0
Personal characteristic	0	5	0	0
Other selection criterion	0	5	0	0
No selection criterion	5	15	6	0

*Percentages may add to more than 100% since respondents could mention more than one condition.

Table II.6

Types of Research Conducted for Those Projects Where No Selection Criteria or Where Demographic Selection Criteria Were Used: Type of Institution (Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=11)	Other (N=3)
Interviews and/or questionnaires (non-medical)	0%	36%
Psychological or educational testing	18	0
Behavioral observation	18	0
Research on educational innovation	18	0
Interviews with patient	9	0
Drug administration	18	0
Clinical evaluation of body parts or fluids	9	64
Social-psychological therapy	10	0
Total*	100%	100%

*The total here represents only those projects where no selection criteria or only demographic criteria were used for selecting subjects. These projects represent 13 percent of the research conducted in institutions for the mentally infirm and four percent of the research conducted in other institutions.

Table II.7

Which of the following sources are used to obtain subjects for this study?: Type of Institution (Percent of Projects)*

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
From among own patients	24%	27%
Referrals by other physicians, professionals	12	23
Referrals by other subjects	5	2
Information from records	11	19
Institutional population via professional access	63	58
Advertisement or notice	2	2
Other source	1	14
General population	0	1
Formal groups, organizations	0	13
Other sources	1	0

*Percentages may add to more than 100% since respondents could mention more than one subject source.

Table II.8

Which of the following sources are used to obtain subjects for this study?: Type of Research (Percent of Projects)*

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
From among own patients	33%	20%	18%	43%
Referrals by other physicians, professionals	26	19	9	0
Referrals by other subjects	7	5	2	0
Information from records	6	11	12	76
Institutional population via professional access	60	62	62	59
Advertisement or notice	2	3	2	0
Other-source	2	9	9	0
General population	0	0	1	0
Formal groups, organizations	2	9	6	0
Other sources	0	0	2	0

*Percentages may add to more than 100% since respondents could mention more than one subject source.

Table III.1

Distribution of Projects by Purpose of Research

	Percent of Projects (N=151)
Benefit subject	27%
Benefit others	31
Other purpose--subject selected by condition	26
Other purpose--subject not selected by condition	3
No information	13
Total	100%

Table III.2

Distribution of Projects: Type of Research*
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Benefit subjects	44%	43%	12%	0%
Benefit others	23	32	35	41
Other purpose--subject selected by condition	23	15	29	47
Other purpose--subject not selected by condition	4	5	2	0
No information	6	5	22	12
Total	100%	100%	100%	100%

*Based on data provided by the investigators.

Table III.3

Primary Intervention or Procedure of Study: Purpose of Research
(Percent of Projects)

	N*	Benefit Subjects	Benefit Others	Other Purpose (Subjects Selected by Condition)	Other Purpose (Subjects not Selected by Condition)	No Information	Total
Biomedical							
Clinical evaluation of bodily tissues or fluids	23	25%	26	38	5	6	100%
Administration of drug, chemical agent	28	62%	19	13	4	2	100%
Administration of vaccines, blood products	1	0%	0	0	0	O	100%
Behavioral Intervention							
Educational intervention	11	43%	18	13	13	13	100%
Modification of an organization or a service delivery system	4	0%	76	24	0	0	100%
Behavior modification or experimentation	6	62%	21	17	0	0	100%
Social psychological therapy	3	67%	33	0	0	0	100%
Behavioral (other)							
Interviews-questionnaires	17	8%	53	24	0	15	100%
Psychological or educational testing	27	8%	38	28	0	26	100%
Behavioral observation	16	24%	10	29	7	30	100%
Interviews with patient (e.g., medical histories)	6	0%	44	56	0	0	100%

Table 3 (continued)

Secondary Analysis	N*	Subjects	Benefit Others	Other Purpose (Subjects Selected by Condition)	Other Purpose (Subjects not Selected by Condition)	No Information	Total
Retrospective review of data	5	0%	45	55	0	0	100%
Retrospective review of data (medical)	2	0%	0	50	0	50	100%
Third party evaluation of bodily parts or fluids	1	0%	100	0	0	0	100%

*N's are unweighted; percentages are weighted,

Table III.4

Probability of Risks and Benefits to Mentally Infirm Subjects: Research Expected to Benefit Subjects*
(Percent of Projects)** (N=76)

	None***	Very Low	Low	Medium	High	Unknown	Total
Medical benefits	53%	6	3	19	14	3	100%
Psychological benefits	8%	2	1	33	50	6	100%
Other benefits	70%	1	8	11	10	0	100%
Minor psychological stress	32%	43	15	7	3	0	100%
Serious psychological stress	83%	14	2	0	0	1	100%
Minor medical complications	73%	14	7	5	0	1	100%
Serious medical complications	83%	15	2	0	0	0	100%
Fatal complications	92%	8	0	0	0	0	100%
Embarrassment (breach of confidentiality)	65%	31	4	0	0	0	100%
Legal risk (breach of confidentiality)	92%	8	0	0	0	0	100%
Other risks	96%	2	4	0	0	0	100%

* Based on data provided by investigators,

** Percentages exclude missing cases (no information).

*** The "none" category includes projects where the investigator saw the risk or benefit as "not applicable" to his/her research.

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Table III.5

Probability of Risks and Benefits to Mentally Infirm Subjects: Research Not Expected to Benefit Subjects*
(Percent of Projects)** (N=65)

	None***	Very Low	Low	Medium	High	Unknown	Total
Medical benefits	90%	7	3	0	0	0	100%
Psychological benefits	64%	16	17	0	0	3	100%
Other benefits	98%	1	0	0	1	0	100%
Minor psychological stress	60%	31	7	2	0	0	100%
Serious psychological stress	88%	9	3	0	0	0	100%
Minor medical complications	91%	8	1	0	0	0	100%
Serious medical complications	98%	1	1	0	0	0	100%
Fatal complications	98%	2	0	0	0	0	100%
Embarrassment (breach of confidentiality)	73%	16	11	0	0	0	100%
Legal risk (breach of confidentiality)	83%	9	8	0	0	0	100%
Other risks	99%	1	0	0	0	0	100%

* Based on data provided by investigators.

** Percentages exclude missing cases (no information).

*** The "none" category includes projects where the investigator saw the risk or benefit as "not applicable" to his/her research.

NOTE: This table is one of several tables provided by the Survey Research Center on November 3, 1976 to substitute for tables in the original report of September 8, 1976. "The data in these tables will differ from that included in our earlier report on the mentally infirm, More cases have been added and new weighting procedures have been applied which compensate for research investigators who did not respond to our interviews," (Letter from Robert A, Cooke, November 3, 1976.)

Table III.6

Probability of Risks and Benefits to Subjects: Research Conducted for Other Purpose*
(Subjects Selected by Condition) (Percent of Projects) (N=39)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	18%	3	4	2	3	0	70	100%
Psychological benefits	18%	10	10	13	7	6	36	100%
Other benefits	0%	3	3	0	5	0	89	100%

Minor psychological stress	51%	22	14	0	0	0	13	100%
Serious psychological stress	73%	11	3	0	0	0	13	100%
Minor medical complications	49%	9	0	2	0	0	40	100%
Serious medical complications	60%	0	0	0	0	0	40	100%
Fatal complications	63%	0	0	0	0	0	37	100%
Embarrassment (breach of confidentiality)	60%	19	13	0	0	0	8	100%
Legal risk (breach of confidentiality)	70%	12	7	0	0	0	11	100%
Other risks	0%	0	2	0	O	0	98	100%

*Based on data provided by the investigators.

Table III.7

Probability of Risks and Benefits to Subjects: Research Conducted for Other Purpose*
(Subjects Not Selected by Condition) (Percent of Projects) (N=4)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	25%	0	0	0	0	0	75	100%
Psychological benefits	0%	0	0	25	0	0	75	100%
Other benefits	0%	0	0	0	0	0	100	100%

Minor psychological stress	50%	25	0	25	0	0	0	100%
Serious psychological stress	100%	0	0	0	0	0	0	100%
Minor medical complications	50%	25	0	0	0	0	0	100%
Serious medical complications	75%	0	0	0	0	0	25	100%
Fatal complications	75%	0	0	0	0	0	25	100%
Embarrassment (breach of confidentiality)	75%	25	0	0	0	0	0	100%
Legal risk (breach of confidentiality)	75%	0	0	0	0	0	25	100%
Other risks								

* Based on data provided by the investigators.

Table III.8

Probability of Risks and Benefits to Subjects: Biomedical Research*
(Percent of Projects) (N=53)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	11%	9	2	21	12	4	41	100%
Psychological benefits	8%	3	4	20	19	5	41	100%
Other benefits	0%	4	0	2	7	2	85	100%
Minor psychological stress	29%	42	16	1	1	0	11	100%
Serious psychological stress	75%	11	0	0	0	2	12	100%
Minor medical complications	42%	33	10	2	0	2	11	100%
Serious medical complications	64%	22	3	0	0	0	11	100%
Fatal complications	68%	12	0	0	0	0	20	100%
Embarrassment (breach of confidentiality)	77%	14	0	0	0	0	9	100%
Legal risk (breach of confidentiality)	85%	6	0	0	0	0	9	100%
Other risks	0%	4	0	0	0	0	96	100%

*Based on data provided by the investigators.

Table III.9

Probability of Risks and Benefits to Subjects: Behavioral Intervention Research*
(Percent of Projects) (N=24)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	8%	5	0	10	5	1	71	100%
Psychological benefits	0%	3	14	19	40	5	19	100%
Other benefits	0%	0	2	15	14	12	57	100%
Minor psychological stress	25%	36	19	10	0	0	10	100%
Serious psychological stress	60%	20	5	0	0	0	15	100%
Minor medical complications	37%	5	0	0	0	0	58	100%
Serious medical complications	35%	5	0	0	0	0	60	100%
Fatal complications	45%	0	0	0	0	0	55	100%
Embarrassment (breach of confidentiality)	44%	30	10	0	0	0	16	100%
Legal risk (breach of confidentiality)	53%	19	0	0	0	0	28	100%
Other risks	0%	5	2	10	0	0	83	100%

*Based on data provided by the investigators.

Table III.10

Probability of Risks and Benefits to Subjects: Other Behavioral Research*
(Percent of Projects) (N=66)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	9%	5	5	0	0	0	81	100%
Psychological benefits	7%	17	6	11	14	6	39	100%
Other benefits	0%	0	0	1	3	6	90	100%
Minor psychological stress	38%	28	7	2	0	0	25	100%
Serious psychological stress	63%	6	4	0	0	0	27	100%
Minor medical complications	41%	3	0	0	0	0	56	100%
Serious medical complications	43%	0	0	0	0	0	57	100%
Fatal complications	43%	0	0	0	0	0	57	100%
Embarrassment (breach of confidentiality)	40%	26	6	0	0	0	28	100%
Legal risk (breach of confidentiality)	62%	6	2	0	0	0	30	100%
Other risks	0%	0	2	0	0	0	98	100%

* Based on data provided by the investigators.

Table III.11

Probability of Risks and Benefits to Subjects: Secondary Analysis Research*
(Percent of Projects) (N=8)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	12%	0	0	0	0	0	88	100%
Psychological benefits	12%	0	0	0	0	0	88	100%
Other benefits	0%	0	12	0	0	0	88	100%
Minor psychological stress	37%	0	0	0	0	0	63	100%
Serious psychological stress	53%	0	0	0	0	0	47	100%
Minor medical complications	53%	0	0	0	0	0	47	100%
Serious medical complications	53%	0	0	0	0	0	47	100%
Fatal complications	53%	0	0	0	0	0	47	100%
Embarrassment (breach of confidentiality)	57%	0	18	0	0	0	25	100%
Legal risk breach of confidentiality)	57%	0	18	0	0	0	25	100%
Other risks	0%	0	0	0	0	0	100	100%

* Based on data provided by the investigators.

Table III.12

From what you have learned, in this study, which of the following best describes your present assessment of benefits to subjects as compared to your expectations when the research began?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=39)	Other Purpose (Subjects not Selected by Condition) (N=4)
Much more benefit than expected	10%	1%	3%	0%
Somewhat more benefits than expected	4	10	8	0
Benefits as expected	56	61	44	25
Somewhat less benefit than expected	10	0	9	25
Much less benefit than expected	5	0	0	0
Assessment cannot be made	15	15	21	25
No information	0	13	15	25
Total	100%	100%	100%	100%

* Based on data provided by the investigators

Table III.13

From what you have learned in this study which of the following best describe your present assessment of risks to subjects as compared to your expectations when the research began?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition (N=39)	Other Purpose (Subjects not Selected by Condition (N=4)
Much more risk than expected	0%	0%	0%	0%
Somewhat more risk than expected	0	0	0	0
Risk as expected	71	80	80	75
Somewhat less risk than expected	13	0	3	0
Much less risk than expected	3	1	0	0
Unable to assess	11	12	9	0
No information	2	7	8	25
Total	100%	100%	100%	100%

*Based on data provided by the investigators.

Table III.14

Before involving subjects in this study,
how certain were you that you knew all of the risks to subjects?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition (N=39)	Other Purpose (Subjects not Selected by Condition (N=4)
Very certain	57%	62%	79%	75%
Fairly certain	40	31	21	25
Not very certain	3	0	0	0
Not at all certain	0	0	0	0
No information	0	7	0	0
Total	100%	100%	100%	100%

*Based on data provided by the investigators.

Table III.15

Before you began involving subjects in this study, which one of the following statements best describe your assessment of the balance of risk and benefits to the average subject?* (aside from any financial benefit) (Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition (N=39)	Other Purpose (Subjects not Selected by Condition (N=4)
Much more risk than benefit	0%	0%	0%	0%
Somewhat more risk than benefit	0	6	0	0
Equal risk and benefit	2	5	10	0
Somewhat more benefit than risk	0	11	6	0
Much more benefit than risk	85	34	27	25
No risk or benefit	4	35	53	75
Assessment cannot be made	6	4	0	0
No information	3	5	4	0
Total	100%	100%	100%	100%

*Based on data provided by the investigators.

Table III.16

How would you assess the balance of risks and benefits to subjects at the present time?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected-by Condition (N=39)	Other Purpose (Subjects not Selected by Condition (N=4)
Much more risk than benefit	0%	0%	0%	0%
Somewhat more risk than benefit	0	4	4	0
Equal risk and benefit	0	7	11	0
Somewhat more benefit than risk	5	8	6	0
Much more benefit than risk	77	37	23	50
No risk or benefit	9	35	49	50
Assessment cannot be made	6	4	0	0
No information	3	5	7	0
Total	100%	100%	100%	100%

*Based on data provided by the investigators.

Table III.17

Is there any provision for giving treatment to subjects if they suffer any harmful effect due to this research?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition (N=39)	Other Purpose (Subjects not Selected by Condition (N=4)
Yes	58%	28%	31%	25%
No	5	11	8	0
Don't know	3	5	6	0
Question inappropriate	34	56	55	75
Total	100%	100%	100%	100%

* Based on data provided by the investigators.

Table IV.1

Modifications by Review Committee Regarding Informed Consent: Type of Institution (Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Did, the review committee require that you make modifications in your study in regard to how consent would be obtained from subjects?		
Yes, change required*	11%	27%
Required written (rather than oral) consent	2	6
Required addition of material to be disclosed	0	2
Required simplification of material to be disclosed	1	5
Required other changes in material to be disclosed	5	12
Required change in setting in which consent obtained	0	0
Required change in timing of obtaining consent	0	0
Required change in who obtains consent	0	0
Required presence of witnesses when consent obtained	0	0
Required proxy consent	0	0
Required subject as well as proxy consent	0	0
Other changes	3	4
No, no change required	88	73
No information	1	0
Total	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.2

Modifications by Review Committee Regarding Informed Consent: Type of Research (Percent of Projects)

Did the review committee require that you make modifications in your study in regard to how consent would be obtained from subjects?	Type of Research: Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Yes, change required*	14%	29%	16%	0%
Required written (rather than oral) consent	1	10	4	0
Required addition of material to be disclosed	2	0	0	0
Required simplification of material to be disclosed	3	0	4	0
Required other changes in material to be disclosed	10	5	7	0
Required change in setting in which consent obtained	0	0	0	0
Required change in timing of obtaining consent	0	0	0	0
Required change in who obtains consent	0	0	0	0
Required presence of witnesses when consent obtained	0	0	0	0
Required proxy consent	0	0	0	0
Required subject as well as proxy consent	0	0	0	0
Other changes	0	14	2	0
No, no change required	84	71	84	100
No information	2	0	0	0
Total	100%	100%	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.3

Type of Consent Obtained in Projects Involving the Mentally Infirm: Type of Institution
(Percent of Projects)

	Universities (N=24)	Medical Schools (N=54)	Hospitals (N=15)	Institutions for Mentally Infirm (N=80)	Other (N=1)	All (N=174)
On this study, is either oral or written consent obtained from subjects or someone acting for subjects?						
Yes, oral	6%	5%	3%	4%	0%	4%
Yes, written	67	58	30	61	100	56
Yes, oral and written	18	33	48	23	0	29
No consent obtained or needed	9	4	19	12	0	11
Total	100%	100%	100%	100%	100%	100%

NOTE: This table is one of several tables provided by the Survey Research Center on November 3, 1976 to substitute for tables in the original report on September 8, 1976. "The data in these tables will differ from that included in our earlier report on the mentally infirm. More cases have been added and new weighting procedures have been applied which compensate for research investigators who did not respond to our interviews." (Letter from Robert A. Cooke, November 3, 1976.)

Table IV.4

Type of consent obtained: Type of Research
(Percent of Projects)

In this study, is either oral or written consent obtained from subjects or someone acting for subjects?	Type of Research: Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Yes, oral	1%	5%	4%	12%
Yes, written	57	76	55	0
Yes, both	32	16	32	0
No consent obtained/needed*	10	3	9	88
Return of questionnaire implies consent	0	0	0	0
Have sign-up sheet	0	0	0	0
Participation voluntary--no further specification	0	0	0	0
Anonymous/confidential research	0	0	0	12
Research involves necessary treatment/procedure	2	0	0	0
Subject's own physician determines participation	1	0	0	0
Research involves routine procedures	0	0	0	0
Only existing records used	0	0	0	63
Materials from previous research being used	2	0	0	12
Consent obtained elsewhere	0	0	0	12
Participation requested/ recommended by someone other than research staff	0	0	0	0
Not required by review committee	0	0	4	0
Investigator says "no risk/harm involved for subjects"	0	0	5	0
Other	5	3	2	0
No Information	0	0	0	0
Total	100%	100%	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "no" response was checked. More than one of the offset responses could be checked in any project.

Table IV.5

Oral Explanation of Study: Type of Institution
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Are subjects (or proxies) given an oral explanation of the study?		
Yes	64%	83%
No	9	4
Question inappropriate	16	12
No information	11	1
Total	100%	100%

Table IV.6

Oral Explanation of Study: Type of Research
(Percent of Projects)

Are subjects (or proxies). given an oral explanation, of the study?	Type of Research: Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Yes	68%	78%	79%	12%
No	7	19	6	0
Question inappropriate	12	3	9	88
No information	13	0	6	0
Total	100%	100%	100%	100%

Table IV.7

Who Obtains Consent: Type of Institution
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Who obtains consent?		
Investigator usually obtains consent	21%	27%
Investigator shares consent responsibility	30	40
Others usually obtain consent	35	21
Question inappropriate	14	12
No information	0	0
Total	100%	100%

Table IV.8

Who Obtains Consent: Type of Research
(Percent of Projects)

Who obtains consent?	Type of Research: Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Investigator usually obtains consent	15%	31%	29%	0%
Investigator shares consent responsibility	49	34	26	0
Others usually obtain consent	26	32	36	12
Question inappropriate	10	3	9	88
No information	0	0	0	0
Total	100%	100%	100%	100%

Table IV.9

Others Who Obtain Consent: Type of Institution
(Percent of Projects)*

Study Staff	Type of Institution: Institution for the Mentally Infirm (N=83)	Type of Institution: Other (N=68)
Professional colleague	28%	23%
Resident or research fellow in medicine	1	5
Intern/medical student/dental student	2	1
Graduate student	7	4
Nurse/physical therapist	4	1
Technician/dental assistant/physician's assistant	2	0
Research assistant/students	14	29
Interviewer	4	3
Other	4	3
Social worker/counselor	0	3
Secretary/receptionist	0	0
Elementary/secondary school staff	0	0
Other	4	0
Staff (not on study)		
Professional colleague	7	2
Resident or research fellow in medicine	1	1
Intern/medical student/dental student	0	0
Graduate student	2	0
Nurse/physical therapist	2	0
Technician/dental assistant/physician's assistant	1	0
Research assistant/students	0	0
Interviewer	0	3
Other	6	-
Social worker/counselor	5	-
Secretary/receptionist	0	0
Elementary/secondary school staff	0	0
Other	1	0
Question inappropriate	43	42
No information	3	0

* Percentages may add to more than 100% since more than one response could be checked.

Table IV.10

Who Else is Present When Consent Obtained: Type of Institution
(Percent of Projects)

Aside from yourself and the subject (and/or proxy), is anyone else usually present when consent is sought?	Type of Institution: Institution for the Mentally Infirm (N=83)	Type of Institution: Other (N=68)
Yes*	40%	50%
Family member	4	26
Physician or dentist	5	22
Nurse	14	19
Research assistant	7	22
Other**	18	19
NO	31	34
Question inappropriate	17	15
No information	12	1
Total	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

** The others who were present when consent was sought included institution staff, secretaries, ward assistants, or anyone who was available at the time.

Table IV.11

Who Else is Present When Consent Obtained: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Aside from yourself and the subject (and/or the proxy), is anyone else usually present when consent is sought?				
Yes*	43%	61%	43%	0%
Family member	8	22	12	0
Physician or dentist	14	22	6	0
Nurse	22	26	10	0
Research assistant	6	30	13	0
Other	10	33	23	0
No	26	29	42	12
Question inappropriate	15	10	9	88
No information	16	0	6	0
Total	100%	100%	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.12

Emphasis in Description of Study: Primary Purpose of Research
(Percent of Projects)*

	Primary Purpose of Research			
Are any of the following. emphasized when you described this study to a prospective subject or proxy?	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=39)	Other Purpose (Subjects not Selected by Condition) (N=4)
Direct benefit *to* subject	59%	37%	11%	25%
Benefit to other individuals' in the future	48	68	36	25
Benefit to scientific knowledge	51	44	41	50
Something else	9	11	17	0
No direct benefit to subject	0	3	3	0
Emphasized risks, hazards	8	0	6	0
Other (unspecified)	1	8	8	0
Question inappropriate	31	15	29	25
No information	0	9	10	0

* Percentages may add to more than 100% since more than one response could be checked.

Table IV.13

Major Emphasis in Description of Study: Primary Purpose of Research
(Percent of Projects)

	Primary Purpose of Research			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=31)	Other Purpose (Subjects not Selected by Condition) (N=4)
Where more than one issue is emphasized in describing this study, which one is emphasized most?				
Direct benefit to the subject	34%	11%	0%	0%
Benefit to other individuals in the future	6	31	19	0
Benefit to scientific knowledge	7	2	12	0
No direct benefit to subject	0	0	0	0
Something else	0	0	2	0
Question inappropriate	48	34	55	50
No information	5	22	12	50
Total	100%	100%	100%	100%

Table IV.14

Participation Request or Recommendation: Primary Purpose of Research
(Percent of Projects)

When you are obtaining consent, is participation in this study presented to subjects (or proxies) as your request, your recommendation, or both?	Primary Purpose of Research: Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=39)	Other Purpose (Subjects not Selected by Condition) (N=4)
Request	30%	62%	54%	50%
Recommendation	2	4	0	0
Both	32	10	8	0
Neither	5	2	0	25
Question inappropriate	31	14	29	25
No information	0	8	9	0
Total	100%	100%	100%	100%

Table IV.15

Information Not Divulged to Subjects: Type of Institution
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
In some research the design of the study requires that certain information not be divulged to subjects. Is that the case in this study?		
Yes, certain information not divulged*	23%	18%
Existence of study	2	1
Purpose of study	7	4
Purpose of specific procedures	10	8
Existence of confederate	0	1
Tape recording/filming/photographing	0	0
Possible benefits to subjects	2	4
Possible risks or discomforts to subjects	1	0
Medication or treatment being used	7	2
Other	7	8
No, not required by study design or all information divulged	76	81
No information	1	1
Total	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.16

Information Not Divulged to Subjects: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
In some research the design of the study requires that certain information not be divulged to subjects. Is that the case in this study?				
Yes, certain information not divulged*	26%	15%	22%	0%
Existence of study	4	0	2	0
Purpose of study	6	6	7	0
Purpose of specific procedures	6	11	13	0
Existence of confederate	0	3	0	0
Tape recording/filming/photographing	0	0	0	0
Possible benefits to subjects	2	0	5	0
Possible risks or discomforts to subjects	2	0	0	0
Medication or treatment being used	12	3	2	0
Other	10	5	8	0
No, not required by study design or all information divulged	72	83	78	100
No information	2	2	0	0
Total	100%	100%	100%	100%

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.17

Subjects Told Things Not True: Type of Institution
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
For purposes of your study is it necessary to tell some subjects some things which are not true?		
Yes, necessary to tell things not true*	2%	1%
Existence of study	0	0
Purpose of study	0	0
Purpose of specific procedures	0	1
Existence of confederate	0	0
Tape recording/filming/photographing	1	0
Possible benefits to subjects	0	0
Possible risks or discomforts to subjects	0	0
Medication or treatment being used	0	0
Other	1	0
No, not necessary	97	98
No information	1	1
Total	100%	100%

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.18

Subjects Told Things Not True: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
For purposes of your study is it necessary to tell some subjects some things which are not true?				
Yes, necessary to tell things not true	0%	5%	2%	0%
Existence of study	0	0	0	0
Purpose of study	0	0	0	0
Purpose of specific procedures	0	0	1	0
Existence of confederate	0	0	0	0
Tape recording/filming/photographing	0	5	0	0
Possible benefits tosubjects	0	0	0	0
Possible risks or discomforts to subjects	0	0	0	0
Medication or treatment being used	0	0	0	0
Other	0	0	2	0
No, not necessary	98	93	98	100
No information	2	2	0	0
Total	100%	100%	100%	100%

* Percentages in the offset columns represetn distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.19

Payment for Participation: Primary Purpose of Research
(Percent of Projects)

	Primary Purpose of Research			
Are subjects paid? If so, what is the average payment?	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=39)	Other Purpose (Subjects not Selected by Condition) (N=4)
All subjects paid	0%	5%	3%	0%
Some subjects paid	0	3	3	0
Average payment				
$1-5	0	2	0	0
$6-10	0	0	3	0
$11-15	0	0	0	0
$16-20	0	4	0	0
$21-25	0	2	3	0
$26-50	0	0	0	0
$51-75	0	0	0	0
$76-100	0	0	0	0
$101-150	0	0	0	0
$151-200	0	0	0	0
$201-300	0	0	0	0
More than $300	0	0	0	0
Other payment (e.g., dollars per hour)	0	0	0	0
No subjects paid	100	91	92	6
No information	0	1	2	94
Total	100%	100%	100%	100%

Table IV.20

Difficulty in Deciding to Participate: Primary Purpose of Research
(Percent of Projects)

	Primary Purpose of Research			
How difficult for prospective subjects is the decision to participate?	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=39)	Other Purpose (Subjects not Selected by Condition) (N=4)
Very difficult	1%	2%	0%	0%
Somewhat difficult	10	10	0	0
Not very difficult	25	36	19	9
Not at all difficult	30	31	42	61
Question inappropriate	14	9	25	12
No information	20	12	14	18
Total	100%	100%	100%	100%

Table IV.21

People Decline to Participate: Primary Purpose of Research
(Percent of Projects)

	Primary Purpose of Research.			
	Benefit Subjects (N=41)	Benefit Others (N=50)	Other Purpose (Subjects Selected by Condition) (N=39)	Other Purpose (Subjects not Selected by Condition) (N=4)
Have any people declined to participate in this study after having been given information about it?				
Yes, some declined	36%	57%	46%	18%
Percentage declining	9	20	23	11
No, none declined	27	21	17	52
Question inappropriate	14	9	25	12
No information	23	13	12	18
Total	100%	100%	100%	100%

Table IV.22

The Use of Proxy Consent in Projects Involving the Mentally Infirm: Type of Institution
(Percent of Projects)

	Type of Institution					
	Universities (N=24)	Medical Schools (N=54)	Hospitals (N=15)	Institutions for Mentally Infirm (N=80)	Other (N=1)	(N=174)
No consent obtained	9%	4%	19%	12%	0%	11%
Consent obtained from subjects only	28	76	47	39	100	49
Consent obtained from proxies only	15	4	4	8	0	7
Consent obtained from subjects and proxies	6	2	2	6	0	4
Consent obtained from subjects and/or proxies*	42	14	27	35	0	29
Total	100%	100%	100%	100%	100%	100%

* This is a residual category which includes projects where consent is not, in all cases, obtained from subjects and proxies, from proxies only, or from subjects only. The category thus contains projects where consent procedures vary from subject to subject. Additionally, this residual category includes projects which could not be placed within the other categories due to insufficient information,

NOTE: This table is one of several tables provided by the Survey Research Center on November 3, 1976 to substitute for tables in the original report of September 8, 1976. "The data in these tables will differ from that included in our earlier report on the mentally infirm. More cases have been added and new weighting procedures have been applied which compensate for research investigators who did not respond to our interviews." (Letter from Robert A, Cooke, November 3, 1976.)

Table IV.23

Instances of Proxy Consent: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Are there instances in this study in which proxy consent is involved?				
Yes	34%	59%	33%	0%
No	39	38	53	12
Question inappropriate	10	3	9	88
No information	17	0	5	0
Total	100%	100%	100%	100%

Table IV.24

Circumstances under Which Proxy Consent Used: Type of Institution
(Percent of Projects)*

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Under what circumstances has proxy consent been obtained?		
Age	14%	19%
Intellect	10	10
Degree of illness	17	5
Other	2	0
Question inappropriate	58	68
No information	11	4

* Percentages may add to more than 100% since more than one response could be checked.

Table IV.25

Circumstances under Which Proxy Consent Used: Type of Research
(Percent of Projects)

Under what circumstances has proxy consent been obtained?	Type of Research: Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Age	9%	19%	23%	0%
Intellect	12	8	10	0
Degree of illness	22	20	5	0
Other	0	10	0	0
Question inappropriate	59	50	62	100
No information	11	0	11	0

* Percentages may add to more than 100% since more than one response could be checked.

Table IV.26

Who Acts as Proxy: Type of Institution
(Percent of Projects)*

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Who is asked to give proxy consent for subjects in your study?		
Parent or other relatives	29%	32%
Legal guardian	14	14
Subjects own physician	1	0
Institutional representative	1	0
Courts	4	2
Someone else	0	1
Question inappropriate	58	68
No information	10	5

* Percentages may add to more than 100% since more than one response could be checked.

Table IV.27

Who Acts as Proxy: Type of Research
(Percent of Projects)*

Who is asked to give proxy consent for subjects in your study?	Type of Research: Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
Parent or other relatives	30%	40%	31%	0%
Legal guardian	7	35	15	0
Subjects own physician	0	5	0	0
Institutional representative	2	0	0	0
Courts	2	5	4	0
Someone else	0	2	0	0
Question inappropriate	59	48	62	100
No information	11	2	9	0

*Percentages may add to more than 100% since more than one response could be checked.

Table IV.28

Subjects Reluctant to Participate: Type of Institution
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other Other (N=68)
In this study, how often do instances arise in which subjects for whom proxy consent has been obtained are reluctant to participate?		
Often	2%	0%
Sometimes	2	2
Rarely	11	4
Never	15	21
Question inappropriate	58	68
No information	12	5
Total	100%	100%

Table IV.29

Subjects Reluctant to Participate: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=53)	Behavioral Intervention (N=24)	Behavioral (Other) (N=66)	Secondary Analysis (N=8)
In this study, how often do instances arise in which subjects for whom proxy consent has been obtained are reluctant to participate?				
Often	0%	10%	0%	0%
Sometimes	2	10	0	0
Rarely	16	2	6	0
Never	12	24	21	0
Question inappropriate	59	48	62	100
No information	11	6	11	0
Total	100%	100%	100%	100%

Table IV.30

Proxy Consent Protection for Subject: Type of Institution
(Percent of Projects)

	Institution for the Mentally Infirm (N=83)	Other (N=68)
Recognizing that it is necessary to use proxy consent in some circumstances, from your general experience, do you feel that proxy consent protects the interests of subjects very well, fairly well, not very well, or not at all?		
Very well	18%	18%
Fairly well	24	32
Not very well	16	6
Not at all	4	10
Question inappropriate	14	13
No information	24	21
Total	100%	100%

Table IV.31

Proxy Consent Inadequate Protection: Type of Institution
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
In what ways or in what situations may proxy consent not adequately protect subjects?		
Subjects do not know they are involved in research	0	1
Subjects are not given complete information	3	0
Subjects not told about risks/hazards	0	0
Subjects have no choice about participating	5	2
Subject's right to privacy is violated	1	0
Subjects are incapable of giving consent	0	0
When children are involved	0	0
Proxy not adequately informed about research	0	7
Proxy not adequately informed about risks/ hazards	1	4
Proxy may not care about/want to protect subject	9	14
When proxy incapable of understanding research	19	3
When proxy is a representative of the institution in which the research in done	0	0
When proxy feels under obligation to the institution	0	0
When proxy does not want to assume responsibility for subject	0	1
When proxy believes some good could come from subject's condition	0	0
When proxy has something to gain from subject's participation	1	0
Other conflicts of interest of proxy	1	0
When research dangerous/potentially harmful	2	0
Oppose proxy consent in general	0	5
Think consent, in general, no guarantee	1	0
Other	1	0
Question Inappropriate	45	51
No information	13	14

*Percentages may add to more than 100% since more than one response could be checked.

Table V.1

Types of Consent Forms Used: Type of Institution*
(Percent of Projects)

Type of Form	Type of Institution: Institution for the Mentally Infirm (N=56)	Type of Institution: Other (N=49)
Institutional standard form with no details included about the particular study	6%	14%
Institutional standard form which included details about the particular study	27	12
Original form	64	62
Not differentiable as to standard or original**	3	12
No information	0	0
Total	100%	100%

* Table based on those projects for which consent forms were available.

** These forms typically included details about the specific study, though in a form and format which suggested they may have been written on a standardized blank form.

Table V.2

Distribution of Long and Short Consent Forms: Type of Institution*
(Percent of Projects)

Length of Form	Type of Institutions: Institution for the Mentally Infirm (N=56)	Type of Institutions: Other (N=49)
Short (less than 300 words)	93%	81%
Long (more than 300 words)	7	19
No information	0	0
Total	100%	100%

* Table based on those projects for which consent forms were available.

Table V.3

Are subjects given a copy of the consent form to keep?:
Type of Institution*
(Percent of Projects)

	Type of Institution	
	Institution for the Mentally Infirm (N=56)	Other (N=49)
Yes	17%	10%
Upon request	3	20
No	68	68
No information	12	2
Total	100%	100%

* Table based on those projects for which consent forms were available.

Table V.4

Index of Consent Form Completeness: Type of Institution*
(Percent of Projects)

Degree of Completeness **	Type of Institution: Institution for the Mentally Infirm (N=56)	Type of Institution: Other (N=49)
1 Complete or nearly complete	5%	21%
2	14	9
3	31	21
4	22	22
5	14	15
6 Totally or nearly incomplete	7	10
No information	7	2
Total	100%	100%

*Table based on those projects for which consent forms were available.

**This index is based upon six items: description of (1) purpose of the research, (2) the procedures involved, (3) the risks, (4) the benefits, and the presence of statements indicating that (5) participation is voluntary or that subjects could withdraw without prejudice and that (6) subjects and proxies might ask questions about participation. A consent form in the most complete category, for example, would contain at least four detailed descriptions and two brief mentions of these six elements. A form in the least complete category could include no complete descriptions and no more than one brief mention of any of these elements. See the following page for more information about the coding schemes used in the index.

Table V.5

Components of Index of Consent Form Completeness: Type of Institution*
(Percent of Projects)

Component	Type of Institution: Institution for the Mentally Infirm (N=56)						Type of Institution: Other (N=49)					
	No Mention	Unspecific Certified Statement**	Brief Mention	Detailed Description	No information	Total	No Mention	Unspecific Certified Statement**	Brief Mention	Detailed Description	No information	Total
Purpose	39%	5	47	7	2	100%	24%	4	66	4	2	100%
Procedures	11%	0	66	21	2	100%	16%	6	54	22	2	100%
Benefits	52%	5	16	25	2	100%	53%	16	12	19	0	100%
Risks***	45%	5	13	32	5	100%	39%	14	17	28	2	100%
Withdrawal	16%		56	23	5	100%	29%		41	26	4	100%
Questions ****	71%			27	2	100%	43%			55	2	100%

*Table based on those projects for which consent forms were available.

**For example, "I certify that I have been informed about the purpose, procedures, and risks of this study."

***Of those projects which made no mention of risk in either the written consent form or the oral consent information statement, more than two thirds were characterized by investigators on our questionnaire as entailing at least a very low probability of minor harm to the subject.

****Coded dichotomously: either provided statement inviting questions or did not.

Table V.6

Oral Mention of Completeness Elements
Not Mentioned in the Written Form: Type of Institution
(Percent of Projects)

Element not mentioned in consent form	Type of Institution: Institution for the Mentally Infirm N	Mentioned	Not Mentioned	No Information*	Total	Other N	Mentioned	Not Mentioned	No Information*	Total
Purpose	(22)	36%	50	14%	100%	(14)	66%	26%	8%	100%
Procedures	(6)	83	17	0	100%	(7)	89	0	11	100%
Benefits	(29)	28	55	17	100%	(25)	23	74	3	100%
Risks	(25)	28	64	8	100%	(15)	25	64	11	100%
Withdrawal	(9)	11	56	33	100%	(12)	6	82	12	100%
Ask Questions	(40)	10	70	20	100%	(18)	20	74	6	100%

*This category includes projects in which there was no oral statement as well as those projects for which oral mention of the elements could not be ascertained.

Table V.7

Mention in Consent Form of Availability of Alternative Procedures:
Type of Institution
(Percent of Forms)*

Mention of Alternatives	Type of Institution: Institution for the Mentally Infirm (N=21)	Type of Institution: Other (N=21)
No Mention	100%	72%
Alternatives exist	0	18
Alternatives offered	0	5
No alternatives	0	0
No information	0	0
Total	100%	100%

*This table is based on 42 consent forms from projects described (by the investigator) as intending to benefit subjects. Seventy-four percent of these projects made no mention in their consent form or oral statement of alternative procedures or treatments available to subjects.

Table V.8

Mention in Consent Form of Experimental Nature of the Research:
Type of Institution
(Percent of Forms)*

Mention of Experimental Nature of Project	Type of Institution: Institution for the Mentally Infirm (N=10)	Type of Institution: Other (N=9)
No Mention	50%	39%
Brief Mention	40	61
Experimental elements identified	0	0
No information	10	0
Total	100%	100%

*This table is based on 19 consent forms from projects described as experimental in nature. Forty-three percent of these projects made no mention of the project's experimental nature in either their consent form or oral statement.

Table V.9

Mention of Project Characteristics
in Consent Form or in Oral Explanation
(Percent of Projects)

Investigator reported in interview that:	% Mentioned	% Not Mentioned	No Information	Total
Project entailed risk of breach of confidentiality (N=33)	69%	28%	3%	100%
Subjects were assigned to different treatments or procedures (N=85)	13	78	9	100%
Project involved the *use* of placeboes (N=18)	53	35	12	100%
Information about research was withheld from subject (N=20)	11	84	5	100%
Project should benefit subject (N=78)	47	46	7	100%
Project should not benefit subject (N=17) [This now shows the percentage of forms or explanations that indicate benefits]	54	33	13	100%

Table V.10

Mention of Elements Not Covered by Completeness Analyses
(Percent of Forms)
(N=105)

Element	% Mentioned	% Not Mentioned	No Information	Total
Expected duration of participation	28%	69	3	100%
Mention of review committee approval	5%	92	3	100%
Agreement of participation included	94%	6	0	100%
Discuss voluntary nature of participation	38%	61	1	100%
Mention injuries will be treated	0%	97	3	100%
Mention harm will be compensated	1%	96	3	100%
Investigator or institution released from responsibility' for harm incurred	0%	97	3	100%
Project contact information (phone number) included	12%	85	3	100%
Provision to contact subject for future research	2%	95	3	100%
Provision to allow future use of data	6%	91	3	100%
Results will be made available to subject	6%	91	3	100%

Table V.11
Readability of Short Consent Forms: Type of Institution and Overall
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects (N=91)	1%	0	3	6	22	56	10	2	100%
Institutions for the Mentally Infirm (N=52)	2%	0	2	4	25	56	7	4	100%
Other Institutions (N=39)	0%	0	4	10	16	57	13	0	100%

*Table based on those projects for which consent forms were available.

Table V.12
Readability of Long Consent Forms-Purpose Area: Type of, Institution and Overall
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects (N=14)	0%	0	0	0	3	40	48	9	100%
Institutions for the Mentally Infirm (N=4)	0%	0	0	0	0	25	50	25	100%
Other Institutions (N=10)	0%	0	0	0	5	48	47	0	100%

*Table based on those projects for which consent forms were available.

Table V.13

Readability of Long Consent Forms-Procedures Area: Type of Institution and Overall
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Infor-mation	Total
All Projects (N=14)	0%	0	0	0	37	34	29	0	100%
Institutions for the Mentally Infirm (N=4)	0%	0	0	0	100	0	0	0	100%
Other Institutions (N=10)	0%	0	0	0	0	54	46	0	100%

*Table based on those projects for which consent forms were available.

Table V.14

Readability of Long Consent Forms-Risks Area: Type of Institution and Overall
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects (N=14)	0%	0	0	19	5	45	0	31	100%
Institutions for the Mentally Ill	0%	0	0	0	0	25	0	75	100%
Other Institutions (N=10)	0%	0	0	30	9	56	0	5	100%

*Table based on those projects for which consent forms were available.

Table V.15

Average Readability of Long Consent Forms: All Projects
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects (N=14)	0%	0	0	0	23	45	23	9	100%

*Table based on those projects for which consent forms were available.

Table V.16

The Percentage of Medical and Technical Terms
Accompanied by Lay Explanations in Consent Forms
(Percent of Projects)
(N=105)*

	Percentage of terms accompanied by a lay explanation					
	0 - 10%	10.1-35%	35.1-60%	60.1-85%	No Information	Total
Medical terms	73%	0%	1%	0%	26%	100%
Technical terms	83	1	1	1	14	100%

*Table based on projects for which consent forms were available.

Table VI.1

Attitudes of Investigators Toward Review Procedure and Committees: Institutions for the Mentally Infirm (Percent of Projects)*

	To a Large Extent	To Some Extent	Not at All	Total
Procedure protected rights of subject (N=69)	86%	13	1	100%
Procedure improved quality of research (N=67)	16%	36	48	100%
Procedure an unwarranted intrusion on investigator's autonomy (N=70)	0%	17	83	100%
Procedure runs with reasonable efficiency (N=68)	56%	35	9	100%
Committee gets into areas not appropriate to its function (N=61)	5%	43	52	100%
Committee makes judgments it is not qualified to make (N=65)	11%	32	57	100%
Procedure impeded progress of research (N=63)	11%	41	48	100%

* Percentages do not include non-respondents.

Table VI.2

Attitudes of Investigators toward Review Procedure and Committees: Other Institutions (Percent of Projects)*

	To a Large Extent	To some Extent	Not at All	Total
Procedure protected rights of subject (N=62)	76%	24	0	100%
Procedure improved quality of research (N=60)	21%	40	39	100%
Procedure an unwarranted intrusion on investigator's autonomy (N=62)	1%	31	68	100%
Procedure runs with reasonable efficiency (N=61)	54%	39	7	100%
Committee gets into areas not' appropriate to its function (N=60)	5%	47	48	100%
Committee makes judgments it is not qualified to make (N=62)	2%	44	54	100%
Procedure impeded progress of research (N=60)	3%	39	58	100%

* Percentages do not include non-respondents.

Table VI.3

Suggestions for Improvement: Principal Investigators
(Percent of Projects)*

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
No suggestions	30%	39%
Comments regarding "bureaucratic problems" with review process and their negative consequences for research	23	22
Speed up the process; takes too long now	10	8
Simplify; too complicated; too much to do	4	8
Review procedures are having adverse effects on research; slow it; prevent it; etc.	8	5
Less emphasis on details; more on human subject protection	1	1
Rules should be consistent across boards; avoid multiple reviews by having a consistent procedure	2	2
Review committees are overly protective, extreme in concern for subjects	4	1
Timing and scheduling of review causes problems	0	1
Parts of review process should be abolished	18	15
Be less rigid/more lenient in application of rules and procedures	5	3
Review subject use only; don't review study design and purpose. Should not control research beyond human subject treatment; committee gets into areas and decisions not appropriate to its purpose	0	1
Eliminate reviews on previously approved studies; don't review renewals or continuations of projects	0	2
Differentiate; more caution when risk/intervention involved, less severe/rigid for more innocuous research, no review for innocuous research	10	11
Eliminate reviews on standard research practices	0	1
Be less rigid with research on patients with life threatening conditions and terminally ill patients	1	0
Eliminate written/informed consent in some circumstances (for example, participant observation and cases where results would be biased)	2	4

Table 3 (continued)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Change structure and/or authority of review process or review committee	12%	8%
Get help or consultants if the review committee is not able to understand or handle aspects of some Proposals	5	1
Change or improve the composition of the committee; get different kinds of people; use a different selection process	2	4
Give more authority to local boards	2	0
The committee is too political	1	3
Monitor the review committee for thoroughness, fairness, efficiency	1	0
Have outside authority to which to appeal review committee decision	0	1
Abolish the committee, certify investiagors, and let them decide	2	0
Give more information to researchers; improve communications between committees and researchers; define; clarify, and set guidelines	19	13
Need more guidelines in general	0	2
Define "informed consent;" tell investigators more clearly/specifically what needs to be done to meet "informed consent" requirement; provide sample consent forms	8	4
Decide/clarify when written consent must be obtained	1	0
Decide/define what research must be reviewed; define "human subject" for review purposes	1	0
Define/clarify risks and deception	1	0
Define/clarify proxy consent	2	0
Should be opportunity for interaction between the researcher and the committee	4	7
Need special guidelines on children, fetal research	1	0
Do more to protect human subjects--be stricter	8	8
Do job more carefully/be tougher; more strict review	0	4
Do more follow-up after review to see that proposed procedures are implemented	2	4

Table 3 (continued)

	Type of Institution	
	Institution for the Mentally Infirm (N=83)	Other (N=68)
Stress privacy and confidentiality for subjects	1%	0%
Simplify consent forms for subject	1	0
Insure that all or more research is reviewed	2	1
Physician/patient *treatpent* should be reviewed	2	0
Miscellaneous and other suggestions	5	2

* Percentages will add to more than 100% since investigators could make more than one mention.

Table VI.4

Suggestions for Improvement: Subjects and Proxies

	Percent of Subjects/Proxies* (N=45)
No suggestions	47%
Increase benefits and reduce risks; improve ratio	9
Increase benefits to subjects--care/services	2
Increase benefits to subjects--general	2
Reduce risks; test more thoroughly before human experimentation	4
More and better information to subjects	27
More, better, or simpler explanation of procedures	4
More, better, or simpler information given--general or other areas	13
Give information on results to subjects and/or proxies	13
Conduct of research	22
Perform procedures more carefully, more humanely	9
Perform procedures more efficiently; be better organized	4
Be more courteous and kind in dealing with subjects; take more time with subjects	11
Make it more convenient; more conveneint location and scheduling	2
Miscellaneous	9

* Percentages may add to more than 100% since respondents could make more than one suggestion.

ON THE RIGHT OF THE "INSTITUTIONALIZED MENTALLY INFIRM" TO CONSENT TO OR REFUSE TO PARTICIPATE AS SUBJECTS IN BIOMEDICAL AND BEHAVIORAL RESEARCH

Joseph Goldstein, Ph.D., LL.B.

ON THE RIGHT OF THE "INSTITUTIONALIZED MENTALLY INFIRM" TO CONSENT TO OR REFUSE TO PARTICIPATE AS SUBJECTS IN BIOMEDICAL AND BEHAVIORAL RESEARCH

Joseph Goldstein[+]

This essay has been requested by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research for the purpose of evaluating "the competence and freedom of the institutionalized mentally infirm . . . to make a choice for or against involvement in biomedical and behavioral research," The Commission's objective is to develop "appropriate requirements for informed consent" for such persons in such circumstances. In responding to this request, this essay presents first a brief summary of the current state of "relevant" law and commentary; second a brief comment on human dignity and constitutional considerations; third a restatement of the problem posed to accord with a recommended mode of analysis; fourth an effort to resolve the problem; and finally, a recapitulation summarizing the suggested resolution for the problem.

I. Review of Law and Commentary

In order to put in context the review of law and commentary and in order to alert the reader to the analytic stance and value orientation of the writer, this essay begins with the following general observations from his article entitled For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain, 84 Yale L.J. 683, 685-686 (1975):

+ I wish to acknowledge the very substantial research assistance of Donn Pickett and the critical substantive and editorial assistance of Mr. Pickett and Lon Babby, both 3rd year students at Yale Law School.

The rules for regulating the doctor-scientist's relationship with the patient who requires therapy or with the experimental subject who may or may not be a patient and who may or may not be subject to institutional restraints are rooted in a basic commitment of the legal system to respect human dignity by protecting the right of every adult to determine what he shall do and what may be done to him. [The rules] have been designed to assure that citizens . . . the patient or experimental subject . . . remain free to make their respective critical choices without coercion or deception by the authorities, doctor-scientist, hospital administration, guardians, review committees. Yet these rules often disserve their common purpose. They mistakenly direct [as the summary of law and commentary will disclose] the attention of supervising decisionmakers away from the conduct of the authorities and to the actual state of mind--the understanding, knowledge, intent and motivation--of the "consenting" citizen. To assign to supervising courts and executive agencies the function of determining whether, for example, an individual citizen's consent is informed or intelligently made is to attribute to such decisionmakers a capability they do not have. More importantly, in fulfilling that assignment, these agents of decision arrogate to themselves and to the authorities who are to be supervised that which deference to human-dignity dictates is to remain with the adult citizen. They act to undercut, rather than to reinforce, respect for the individual's competence and right to determine for himself what he needs to know (including that he does not want to know anything) in order to choose what he thinks is best for himself. ["To respect anyone is to protect his choosing function so long as its exercise does not seriously imperil the corresponding freedom of others." McDougal & Lasswell, The Identification and Appraisal of Diverse Systems of Public Order, 53 Am. J. Int'l. L.J. 24 (1959).]

The law must establish standards of conduct for the authorities, not for the citizens, in these transactions. The rules should force supervising agents to focus (primarily, if not exclusively) on the appropriateness of the authorities' conduct in communicating with the citizens concerned and in manipulating the settings in which decisions to consent are obtained. The priority of attention for inquiry would thereby be shifted from more subjective to more objective concerns, from the consenting citizen's state of knowledge and understanding to the conduct of the authorities in the process of informing the citizen for decision. Whether the citizen actually gave or denied consent would not be relevant to the inquiry. What would be critical to a finding that the state's commitment to human dignity was served or disserved would be the authority's conduct in light of the more objective standards set. (emphasis supplied)

The state's police power to require medical "treatment" of the mentally infirm, without regard to their wishes, has long been recognized. E.g. Buck v. Bell 274 U.S. 200, 203 (1927) (upholding a Virginia statute providing for the sterilization of the institutionalized insane); cf. Skinner v. Oklahoma, 316 U.S. 535 (1942) (invalidating an Oklahoma sterilization statute solely on equal protection grounds). In recent times, most reported cases concerning the institutionalized mentally infirm have dealt with a patient's right to treatment, e.g. Jackson v. Indiana, 406 U.S. 715 (1971).

However, the issue of "informed consent" (whatever that means) by institutionalized patients to proposed research has infrequently arisen and the judicial and scholarly response thus has been rather sparse. The courts have not dealt with the institutionalized mentally infirm's right to refuse treatment. Nor have the courts considered the important distinction between experimentation and treatment, nor between research with or without the potential for benefitting the subject. This remarkable lack of coherent precedent and analysis is characterized by an absence of discussion of the institutionalized mentally infirm in the leading legal text on "informed consent," J. Katz (with Capron and Glass). Experimentation with Human Beings (1972).

Several courts have sought to establish "informed consent" procedures. For example, in Knecht v. Gillman, 488 F.2d 1136 (8th Cir. 1973) a behavioral "therapy" administered without the patient's consent, was enjoined as cruel and unusual punishment in viola-

tion of the Eighth Amendment. Plaintiffs, institutionalized in the Iowa Security Medical Facility, complained that they had been injected with the drug apomorphine without their consent. The drug was injected as "aversive stimuli" for the inmate's violation of behavior protocol including talking, swearing, and lying. Id. at 1137. The drug induced vomiting within fifteen minutes and the vomiting lasted for another fifteen minutes to an hour. The court held that this Pavlovian form of "treatment" could only be "administered to a patient who knowingly and intelligently has consented to it." Id. at 1140 (emphasis supplied). In an effort to guarantee such consent the court required that

> 1. A written consent must be obtained from the inmate specifying the nature of the treatment, a written description of the purpose, risks and effects of treatment, and advising the inmate of his right to terminate the consent, at any time. This consent must Include a certification by a physician that the patient has read and understands all of the terms of the consent and that the inmate is mentally competent to understand fully all of the provisions thereof and give his consent thereto.
>
> 2. The consent may be revoked at any time after it is given and if an inmate orally expresses any intention to revoke it to any member of the staff, a revocation form shall be provided for his signature at once. Id.

Despite the court's detailed consent procedure, neither the institutionalized patient's freedom of choice nor the Iowa officials' conduct in the process of informing about the implications of "aversive stimuli" "treatment" were considered.

Similar guidelines for the informed consent of an institutionalized mental patient were developed in the leading case of Wyatt v.

Stickney, 344 F. Supp. 387, 395-407 (M.D. Ala. 1972) aff'd sub. nom. Wyatt v. Aderholt, 503 F.2d 1305 (5th Cir. 1974). In articulating minimal constitutional standards for adequate habilitation of the mentally retarded, the court stated that "/r/esidents shall have a right not to be subjected to experimental research /or any unusual or hazardous treatment procedures including, for example, "/b/ehavior modification programs involving the use of noxious or aversive stimuli..."/ without the express and informed consent of the resident, if the resident is able to give such consent, and of his guardian or next of kin, after opportunities for consultation with independent specialists and legal counsel." Id. at 401-02 (emphasis supplied). The research or treatment procedures were subject to review and approval by the institution's Human Rights Committee prior to the seeking of consent. "Express and informed consent" was defined by the court as "/t/he uncoerced decision of a resident who has comprehension and can signify assent or dissent."

The most significant case dealing with the consent of an institutionalized person to be a research subject is Kaimowitz v. Michigan Department of Mental Health, Civil No. 194-199 (Mich. Civ. Ct. July 10, 1973) (reproduced in substantial and relevant part in Goldstein, Dershowitz and Schwartz, Criminal Law Theory and Process at p. 76 et. seq. (Free Press 1974).) John Doe had been committed to the Ionia State Hospital, a maximum security mental institution, eighteen years earlier as a "criminal sexual psychopath." In November 1972, he was transferred

to the Lafayette Clinic to become one of twenty-four subjects in a study of uncontrollable aggression. "The experiment was to compare the effects of surgery on the anygdaloid portion of the lembic system of the brain with the effect of the drug cyproterone acetate on the male hormore flow." John Doe was selected as a candidate for the psycho-surgery, and he and his parents signed an "informed consent" form agreeing to the operation. The procedure was approved by a Community panel of three, comprised of a priest, a lawyer, and an accountant. These facts draw into question the procedure for informing an institution-alized mentally infirm person and obtaining his or her consent to bio-medical experimentation.

The court established three prerequisites to a legally recognized consent to an experimental procedure. The patient must be competent to consent; he must knowingly give his consent; and the consent must be voluntarily given. The court held that an involuntarily committed in-dividual could not be competent to render an informed consent:

> Although an involuntarily detained mental patient may have a sufficient I.Q. to intellectually comprehend his circumstances, the very nature of his incarceration disminishes the capacity to consent to psychosurgery. He is particularly vulnerable as a result of his mental condition, the deprivation stemming from involuntary confinement, and the effects of the phenomenon of 'institutionalization'.

Furthermore, the court reasoned that the consent was not knowingly made. "/T/he facts surrounding experimental brain surgery are profoundly uncertain, and the lack of knowledge on the subject makes a knowledge-able consent to psychosurgery literally impossible." Finally, the

court held that John Doe could not make a voluntary consent: "It is impossible for an involuntarily detained mental patient to be free of restraint or coercion when his very release from the institution may depend upon his cooperating with the institutional authorities and giving consent to experimental surgery." (emphasis supplied) In short, the court held that psychosurgical experimentation could not be performed because it was (a) impossible to obtain truly "informed consent" from an involuntarily committed individual and (b) the scientific foundation for proposed research was too weak to permit the experiments to be conducted on human subjects. The court supported this holding by asserting that the First Amendment and the right of privacy constitutionally protect "/t/he freedom to generate ideas" and the freedom from "intrusion into one's intellect."

The court did, however, close its opinion with a holding "that an involuntarily detained mental patient today can give adequate consent to accepted neurosurgical procedures." (emphasis supplied) According to the court, proper and adequate consent could be given by an institutionalized patient to psychosurgery only "/w/hen the state of medical knowledge develops to the extent that the type of psychosurgical intervention proposed here becomes an accepted neurosurgical procedure and is no longer experimental...." Thus, the court held that psychosurgical, if not other, research may not be conducted upon the institutionalized mentally infirm. By implication the court seems to be saying that if any such experiments are to be authorized, potential subjects

must first be drawn from the free, non-institutionalized, population. Otherwise what is experimental could never become "an accepted neurological procedure, In fact, the John Doe of Kaimowitz was released from the hospital on finding that Michigan's Sexual Psychopath Law under which he was being held was unconstitutional. Once part of the free community he became eligible, it would seem, to consent to be a subject of psychosurgical research. But he suspended his "consent" "to see how it felt as a free man...." (See an excellent article by one of the attorneys for John Doe, Professor Robert A. Burt, Why We Should Keep Prisoners From The Doctors, Hastings Center Report 25, 30 (Feb., 1975).

In summary, and without reviewing in detail the legal commentary which, except for the Burt article, is by and large peripheral to the Problem posed by the Commission, there appears to be a consensus that "informed consent" of the institutionalized mentally infirm person should be required prior to initiating experimental research. Indeed, Wyatt v. Stickney, supra, and Knecht v. Gillman, supra, suggest that consent may also be necessary for therapeutic treatment. Furthermore, with the exception of the Kaimowitz Court, there is agreement that the competence of an institutionalized patient: to give "informed consent" is not necessarily inadequate.

However, little, if any, attention has been focused directly on the process of informing for decision. Nor has the distinction between therapeutic treatment and experimental non-beneficial research been adequately made. Finally, the freedom of an institutionalized person to give consent is only erratically considered. For example, in

Knecht the problem is not discussed, while in Kaimowitz it is central to the court's holding. Despite the optimism of some commentators that the requirements detailed in Wyatt may rectify the effects of institutional coerciveness, those requirements do not confront the problem beyond the dictate that "informed" consent be an "uncoerced decision." (See e.g. Note, Advances in Mental Health: A Case for the Right to Refuse Treatment, 48 Temple L.Q. 354, 380-82 (1975). But courts, commentators or legislators do not seem to recognize the confusion, if not duplicity, that is introduced by the notion of proxy or substituted "consent" which is no more than a euphemistic disguise for coerced submission to treatment or experiment. (See e.g. Note, The Right Against Treatment: Behavior Modification and the Involuntarily Committed, 23 Cath. U. L. Rev. 774, 784-85 (1974) concluding that "informed consent" should be given by a patient if he is capable, otherwise by a "neutral decisionmaker;" and more to the point Pub. Law 93-348 directing the Commission "to determine the nature of the consent obtained from /the institutionalized mentally infirm/ or their legal representatives...")

Overall, it is apparent that the current state of the law and scholarly commentary concerning informed consent" by the institutionalized mentally infirm to be research subjects is unsettled and unsettling. Given this conclusion, a real opportunity to formulate effective policy is presented to the Commission,

II. Safeguarding Human Dignity and Constitutional Considerations.

In resolving the policy questions relating to the Problem posed, there is no need in this essay to address the constitutional issues which may exist under the First, Eighth, or Fourteenth Amendments. Constitutional parameters set certain minimum limitations on state intervention

within which policymaking develops, but they do not and ought not to determine policy. Full respect for human dignity does not require considering, then, how close the state can come to the limitations set by the Constitution without violating it. The Commission must design a process fully sensitive to the sancity of human beings, not one which just barely comports with the Constitution. Whether the policy to be served is stated in terms of dignity, respect or autonomy, these words must not obscure that the value at stake is no less than individual freedom and liberty and the freedom and liberty to be an individual.

III. The Problem Restated

The Commission's letter of understanding requested that this essay address the following Problem:

> "in establishing "appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research" and "in identifying appropriate requirements for informed consent" how "competent and free" are the "institutionalized mentally infirm to make a choice for or against involvement in biomedical and behavioral research?"

A. Who are the "institutionalized mentally infirm?"

The "institutionalized mentally infirm" 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." Pub. Law 93-348.

They are, for our purposes, "adult"* persons in mental institutions:

a. Who recognizing their own need for medical care sought on their own initiative admission for treatment. As voluntary patients in either public or private institutions, such persons, conceptually at least, though not always by statute, are presumed competent to determine for themselves what treatment, if any, they will accept;

or

b. Who are judged to be mentally ill and removed to a hospital authorized to detain them, without regard to their wishes, usually for an indeterminate period. As involuntary patients in either public or private institutions, such persons conceptually at least, are declared incompetent and without authority to decide what if any medical treatment they should undergo.** Such involuntary hospitalization often rests on a finding that the mentally ill person is either or both a danger to himself or to others. (See Brackel & Rock, The Mentally Disabled and the Law, 17-132 (Rev. Ed. 1971).

B. Two Questions.

The word competent in the Problem forces focus on the capacity of potential research subjects to decide, to make a choice, about participation in: research. The word free in the Problem forces focus more

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* A person who has reached the chronological age of majority is an adult. To be an adult in law then is not to be a child. A child is the responsibility of and is subject to the control of at least one adult called parent. It is thus presumed that parents of children are the appropriate decision-making adult for children who may be voluntarily institutionalized by their parents and who may be considered potential research subjects.

** Such institutionalized persons may include those declared incompetent to stand trial in a criminal proceeding, those acquitted of crime by reason of insanity; as well as those convicted of crime who are found mentally incompetent to serve the sentence imposed.

on the conduct of research and institutional authorities in relation to their placing limits on the right, (not on the competence), of the institutionalized mentally infirm to decide free of coercion or deception. It is the burden of this essay that the competence of the institutionalized mentally infirm to decide must be presumed and that their freedom to exercise their capacity to choose must be safeguarded from violation by those in authority -- the researcher, institutional personnel including research review committees and the state, including guardians appointed to act on their behalf. It is the conduct of those in position to exploit their relationships with potential research subjects that must be subject to scrutiny. These authorities must be held accountable for their activities in relation to potential subjects, rather than vice versa.

The function of resolving the Problem of concern is not to find a way of holding individual research subjects accountable for their "mistakes" in judgment, for being "uninformed" or "irrational" about participating or not participating in research. Rather a resolution requires establishing a process of accountability for those engaged in research who, with the power and prestige of position and training, may manipulate "institutionalized persons" by reducing their freedom of choice, (not their competence to choose) beyond that which comes with the mere fact of institutionalization.

The tension in focus is highlighted by separating the Problem into the two questions which it poses:

(1) "How competent is the institutionalized mentally infirm to make an "informed choice?"

"How free to make a choice is the institu-
ionalized mentally infirm from the coercive
deceptive pressure of research and in-
stitutional authorities?"

1. Competence and Informed Consent - An Inappropriate Consideration

To empower a group of self appointed (or politically appointed) wisemen to determine, in response to question (1), whether an adult individual has the competence to judge what is best for himself or herself is a total affront to his or her human dignity. To force upon potential subjects a determination of the "rationality" of their processes of decision in accord with some philosophical or psychological dogma about what and who is rational, is to deny autonomy to all such persons and to affront their dignity even if their choices are determined to be "rational" and "informed." To establish such a process would defeat its professed function of safeguarding each person's right to consent, to refuse to consent and even to refuse to negotiate in good faith, in the collective bargaining sense, with the researcher who seeks consent. Finally, it is beyond the competence of law which is; after all, a gross instrument for the regulation and control of interpersonal relationships, to provide guidelines for deciding whether a person's consent or refusal to consent "informed" or "rational" or more to the point, whether the person wishes to be restricted to "rational" decisions, if there be such, to participate as a subject of non-therapeutic or non-beneficial research experiments.

Question (1), in the tradition of the "informed consent" doctrine, obscures rather than facilitates clarification of the goal which the Commission was established to serve. The goal is not to protect a subject from himself but is to protect his or her person and autonomy from the exploitative potential of authority to coerce, cajole, entice or deceive anyone, but particularly disadvantaged persons into "consenting" to be and to remain research subjects without regard to their wishes. Pursuing a response to question (1) has led to the proposal and development of more detailed and complex rituals of negotiation and third party review which too easily obscure the extent to which the researchers' goal -- to conduct his or her experiments - actually determines the means of obtaining from a potential subject a signed "informed consent" form. It is just such routines for "assuring" that a potential research subjects' decision is "rational" that shifts the critical light of inquiry from the researchers and which too easily relieves them of both responsibility for making critical choices and accountability for their conduct and its consequences, (See Robert Levine's paper for Commission dated December 1, 1975).

Further, there is a momentum in the procedure for "informed consent" which builds up pressures for obtaining "consents" (not "refusals"). It is fed by a generally accepted picture of researchers motivated by the search for knowledge for society's benefit -- leaving unstated, if not denied, the perfectly appropriate but less benign personal and institutional motivations for fame and fortune. Not unlike the promiscuous way in which "national security" is used to rationalize violations

of human rights, so too the goal of "crossing the frontiers of medical knowledge" has come to justify experiments on people, particularly the exploitation of the specially vulnerable institutionalized poor and minority persons, by imposing upon them a "consent' obtained from their "guardians." (See N.Y. Times, Editorial, p. 30, Jan. 23, 1976).

In the name of respect for human dignity, the current concept has been subtly construed to deny it (a) by granting to the authorities (court, supervisory administrative agency or licensed professional) rather than to the individual (patient or subject) the final word in determining what is best for him, including what he *must* know -- i.e., how "well informed" he must be -- in order to make that decision; and

(b) by proceeding as if an authority's breach of obligation to disclose a known risk "is legally without consequence" if the risk did not materialize during the research. Canterbury v. Spence, 464 F.2d 772, 790 (D.C. Cir. 1972). The materialized risk requisite demonstrates the extent to which the concept has departed from its purpose. It does not recognize that a potential subject can be wronged without being "harmed", that his dignity as a human being, has been violated and that an assault has taken, place the moment the deceiving authority commences research, even if it turns out to be "beneficial."

Finally, "consent", as opposed to "decision", in the legal concept of informed consent introduces a bias for perceiving refusals as uninformed, especially in research which has a therapeutic potential. Refusals may then be used as a justification for challenging the capacity of potential subjects to decide for themselves. Findings

of incompetence and mental infirmity deprive individuals of authority to decide for themselves, thus constituting the ultimate disregard of their human dignity. "Consent by proxy," a dangerous legal fiction for the right to impose one's will on another, may then be obtained to accord not only with what a potential research subject in his or her "right mind" ought to want, but also with what he or she ought to want to know if he or she is to know what he or she wants. The researchers thus get their way without risking liability--and avoiding this risk seems to be the actual (primary) though unstated concern of those who design what are strangely called "informed consent forms" to be signed by the research subject.

Question (1) then is the wrong one for the Commission to address. Because that question can be answered by presuming the competence of potential subjects (infra p. 25-26), critical focus in the remainder of this essay can be primarily in response to Question (2) which forces focus where it belongs on the conduct of the persons who seek consent of potential research subjects among the institutionalized mentally infirm. Only then will there be some chance of accomplishing, not defeating, the intent of the Congressional assignment to the Commission.

2. Freedom to Choose - The Proper Inquiry.

While it is beyond the capacity of law to ascertain the competence of an adult individual the law can monitor and regulate the conduct of authorities who are in a position to exploit those in their custody and care. The legal process can establish some fundamentals though minimum, standards of conduct for research and institutional authorities

in seeking to negotiate and in negotiating with potential subjects of research. The law can determine prospectively, in guidelines, and retrospectively in fact finding, what constitutes coercion and deception on the part of the authorities and whether in seeking or obtaining consent the authorities refrained from using force (a) by manipulating or offering to manipulate the institutional setting, (b) by deceiving the potential subject about what he or she was being asked to do, or (c) by refusing to provide the potential subject, unless the potential subject objected, not only with all of the information which the researcher or regulatory body believed relevant to the exercise of choice, but also with all of the information the potential subject believed relevant to his or her decision.

In considering the Problem as posed primarily in Question (2) on whether the institutionalized mentally infirm person is free to make a decision it becomes important to consider whether a distinction should be made for such purposes between the voluntary and involuntary patient and between the patient who is committed as a danger to himself and the one who is committed as a danger to others. To the extent those distinctions have more than statutory meaning it seems appropriate to consider the voluntary patient like any other hospital patient who is ultimately (or ought to be) presumed both free and competent to decide As for the involuntarily institutionalized mentally infirm person committed as a danger to self or to others, it should first be noted that, like mental illness and infirmity, the "dangerousness" categories are suspect classifications and without adequate definition to justify the use of the coerceive force of the state to de-

prive a person of his or her liberty and freedom of choice, Goldstein and Katz, Dangerousness and Mental Illness etc., 70 Yale L.J, 225, 235 (1960). By and large this "civil" commitment process serves to circumvent the more stringent restraints on state power imposed by and on the criminal process. To be found "a danger to oneself" (a finding which ought to be beyond the reach of a secular legal system) would be to suggest that such person is "incompetent to make a choice for or against involvement in research," and is thus outside, or ought to be outside, the pool of potential research subjects. On the other hand a finding of only "dangerousness to others" would have no bearing on the question of competence to make a choice except to the extent of the added risk to others in research requiring such subjects to have contact with one another. In that event, research subjects would be entitled to know of that risk. Otherwise, such involuntary patients ought to be perceived, to the extent a distinction is to be made, as no different from voluntary patients who may be presumed to be free and competent to decide what is best for themselves. Of course to say that a person has been involuntarily committed to an institution is to say that he has been denied freedom to choose, amongst other things, where he will live. Such persons, however, have not by such a process been automatically denied the freedom to choose everything concerning what they will do or allow to be done to or for themselves. Even within such settings of restraint the question of freedom to choose has a meaning which question (2) appropriately forces into consideration. The freedom of concern is freedom from coercive, exploitative and deceptive conduct by those in authority within such settings.

It becomes critical then to make explicit the goals of requiring consent -- the goals of requiring that the decisions of potential subjects be uncoerced. Consent requirement cannot be justified because research persons and institutions must be protected from personal injury suits and criminal liability or because science should be promoted. Requiring consent by the subject or patient is a recognition that the decision to include an individual in a research project is made by the individual for himself and not by the state or surrogate panel of experts for that person. Consent is the means of protecting a person's individual, autonomy and of guaranteeing societal respect for his human dignity. It is not a means of assuring that he decide "rationally." Thus the State may require the manufacturer of dangerous products to label the product with an appropriate warning. However, it nay not force the purchaser of the product, for example the cigarette smoker, to read the warning nor may it justify declaring him dangerous to self, though possibly dangerous to others, because he does not abstain. The goal of respect for human dignity is advanced only by allowing the patient to agree to or refuse the proposed procedure. The standard procedure in practically all cases involving the voluntary as well as the involuntarily institutionalized must be to offer the patient a choice, follow his or her desires, and permit the decision to be made by that person,

IV. Resolving the Problem - Informing for Decision

In an effort to resolve the Problem posed by directly addressing question (2) on how free is, or should be, the institutionalized mentally

infirm to choose to participate as subjects of research it would be more productive to analyze the issues in terms then not of "informed consent" but "the process of informing for decision." Though a cumbersome phrase it directs attention to the real task of the Commission which is to think through standards of conduct for authorities who ask a citizen to waive his possible claims in tort or criminal law by granting permission for the proposed research intervention. It is, after all, a function of the law of torts and crimes to protect the integrity of each citizen from unwanted intrusions upon his person and property without due process. In these research transactions intervention may not be tolerated unless it is wanted--unless consent is given,

Minimally, deference for a potential research subject as a human being would require researchers and institutions who seek consent (a) to determine whether the potential subject is willing to discuss possible participation in a research project and only if a potential subject is willing to enter into such a negotiation,* (b) to offer to disclose the purpose, nature, and conceivable risks which the authority believes would be relevant to a reasonable person's exercise of choice as well as alternatives to the proposed research experiment, (c) to honor the wishes of the potential subject who does not want to be told of some or of any information the authority must offer to disclose, and to answer, (if necessary with an "I don't know,") any questions the potential subject asks, even if the researcher thought that it was not "relevant" to a reasonable person's rational decision or that it would not be "good" for the person

*Of course, if the potential subject does not wish to consider participation in the proposed research, further efforts to obtain consent would constitute coercion and be in violation of a person's freedom to choose.

to know the answer, (d) to offer to provide and to facilitate an opportunity for an independent consultation, (e) to honor the wish of a potential subject who says to the researcher, "I prefer to rely on your judgment, for you to inform me of whatever you think I should know, and for you to do whatever you think is best for me or even for others like me, or for society, or whatever," (f) to honor a potential subject's refusal to consent - without threatening to use or using the refusal as a basis for asserting incompetence, or of justifying the appointment of a guardian or the review of the decision by a special committee, and (g) to honor the subject's request to withdraw from the research experiment at any time.

These communications must, of course, be made by research and institutional authorities in a way which reflects a full commitment to respect the wishes of potential subjects and in a language and in words comprehensible to them, as individuals. True decisions by potential subjects in such transactions can only be protected to the extent that the authorities, without coercion or deception, facilitate and provide unrestricted access to as much or as little information as the potential subject is willing and wishes to have. This does not mean that potential subjects must negotiate in good faith with authorities, nor does it mean that if they consent to consider participation in the proposed research that they must ask for information before a research experimenter is required to offer to disclose. The burden is always on the authorities, both individual and institutional, to determine if the potential subject is willing to consider, discuss the proposal or offer to participate.

And if the potential subject is willing to negotiate, the authorities must offer to disclose (and to disclose and explain unless the potential subject objects) at least that which legislative, judicial, or Commission standards define as critical to a reasonable person's refusal or consent.

To circumscribe the process in this way is to set a standard of conduct not for the potential subject, but rather for the research and institutional authority. The potential subject may or may not take into account that which might be divulged. He or she may or may not take into account even information which he or she requests before making a decision, whether it is considered relevant or irrelevant to the "informed" consent or refusal of reasonable people. Thus, the usual court and commentator assertion that "the patient's right of self-decision . . . can be effectively exercised only if the patient possesses enough information to enable an intelligent choice" should be tilted slightly to read that "the patient's right of self-decision is effectively safeguarded if the authorities provide him with a real opportunity (not with an obligation) to possess what information he and a reasonable person might require in order to exercise a choice." To acknowledge that "the potential subject's right of self-decision shapes the boundaries of the duty to reveal" requires not that the choice be an intelligent, informed and unemotionally determined decision, but rather that it be the potential subject's choice and that the authorities--both institutional and individual--out of regard for him or her as a human being, honor that choice, even if it be for death.

To assert this view as a guide to state supervision of authority is neither to question nor to challenge the following statement by

Pope Pius XII: "/T/he patient (or experimental subject) is not absolute master of himself, of his body or of his soul. He cannot . . . freely dispose of himself as he pleases. . . . He has the right of use; limited by natural finality, of the faculties and powers of his human nature." Because he is a user and not a proprietor, he does not have unlimited power to destroy or mutilate his body and its functions. Furthermore, "the patient cannot confer rights he does not possess . . . /t/he decisive point is the moral licitness of the right a patient has to dispose of himself. Here is the moral limit to the doctor's action taken with the consent of the patient." Address by Pope Pius XII, His Holiness, to the First International Congress on the Histopathology of the Nervous System, Sept. 14, 1952, (reprinted in J. Goldstein, A. Dershowitz & R. Schwartz, CRIMINAL LAW THEORY AND PROCESS 91-92 (1974).) What is challenged here is the notion in current legal doctrine and commentary that the power of the state may be employed to impose that moral limit upon citizens who do not share it or that such power be used to push believing citizens beyond that moral boundary.*

A. Up to this point, the guides to the conduct of researcher and of institution in their efforts to negotiate a consent free of coercion, duress and deceit have neither sought to distinguish the voluntarily from the involuntarily institutionalized mentally infirm nor to make a distinction between those in public and private institutions.

*Though Congress falls into the informed consent error for the citizen in Title **, "Protection of Human Subjects of Biomedical and Behavioral Research," of the National Research Service Award Act of 1974 (§ 202(a)(1)(B)(iv), (A)(2), Pub. L. No. 93-348, 88 Stat. 342), it does defer to the human dignity of the researcher as citizen in his own right by providi: inter alia, that "[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity... if his performance...would be contrary to his religious beliefs or moral convictions," and that no institution receiving grants under the Act may "discriminate in the employment promotion or termination of employment" of such persons either because they participated or refused to participate in such activity. Id. 214.

It is primarily to these distinctions that attention is now directed. Biomedical and behavioral research too often seems, however, to have been limited (as it ought not to be) to the inherently coercive settings of the publicly funded involuntarily institutionalized mentally infirm -- settings not unlike those which provoked the Nuremberg declaration of principles for conducting medical experiments on human beings. Involuntary institutionalization of the mentally infirm person is in itself a deprivation, albeit with due process, of his human dignity -- of his freedom to choose for himself. Although nothing can fully remove this violation of personal dignity especially if institutionalization is "for one's own good", it remains appropriate in such circumstances to enforce, indeed with special vigilance, standards of conduct for research and institutional authorities in offering and providing information to the inmate in order to safeguard his or her personal right to be or not to be an experimental subject or even to enter or not to enter into negotiations to be a subject. While the coercive setting does not require altering the standards for a process of informing for decision, it does require recognition that the quality of volition in refusing or consenting to negotiate or to participate, no matter how fully informed, has been altered. By definition, part of the information implicitly or explicitly communicated consists of the coercive reality of the setting for negotiations which the researcher hopes will result in consent.

Similarly, the status of being institutionalized coupled with that of being mentally infirm further reinforces the importance of focusing the supervisory function of the law on the informer (research and institutional authorities) and on the spirit and atmosphere surrounding the process of informing and negotiating with potential research subjects. Again, the need to protect the potential

subject's integrity is every bit as strong, if not stronger, than for either the noninstitutionalized mentally infirm or for the nonmentally infirm, institutionalized or not. The law must be especially careful to design an informing process that will permit and facilitate compliance with the individual wishes and needs of potential subjects. The requirements for assuring responsible conduct on the part of research and institutional personnel do not change depending on the potential subject's mental health or institutional freedom. What researcher and institution must know and expect is that they will and should be held accountable in tort and criminal law for violations of the person of potential and actual research subjects. Like the small print on standard contract forms, the signed standard "informed consent" form, more accurately designated "release form", should not constitute an automatic defense. On the other hand, the common law rule which presumes the competence of all adults to decide for themselves should generally prevail so far as the researcher's claim that a subject or potential subject, even if from the population of institutionalized mentally infirm, had the capacity, though not necessarily the freedom, to choose. To presume otherwise would be to deprive the mentally infirm and/or the institutionalized person of his or her entitlement to respect as a human being. Thus to deny such persons the right to decide whether to participate in research because he or she is incompetent is to reduce that person's individual autonomy beyond that which can be justified by the designation or the incarceration.

In order to safeguard individual autonomy, rather than to "promote" it or "to encourage rational decisionmaking" as Katz and Capron

would assert are functions of "informed consent," a strong presumption of competence would require honoring the wish of any potential or actual subject so long as the requirements and conditions of the process of informing for decision (not consent) were met in fact and spirit. Katz & Capron, Catastrophic Diseases: Who Decides What? 82-90 (Russell Sage 1975).

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. Even if a patient is demonstrated to be dangerous to himself or to herself, a conclusion of incompetence should not necessarily follow. To find incompetence in any great number of persons would be to deny the purpose of requiring consent. Respect for human dignity should not lessen according to an individual's mental health. But practice does undercut that respect by making provision for "substituted consents" by a legal representative who may be forced upon them without their "informed consent." To accept such proxy consents is to authorize invasions of person and personality without regard to the wishes of the research subject -- that is to deny them the freedom to choose without saying so. Hopefully any proposal by the Commission should preclude this mode for deceiving the public and itself into believing that consent of the potential subject is a requisite of research in a system which accepts proxies. The critical question then in reviewing research proposals and in determining responsibility and accountability for the actual conduct of researcher and institution in each transaction will be on setting and meeting the requirements of the process of informing for decision free of any coercion, deceit, or duress which might be attributable to researcher or institution.

B. The question remains whether institutionalized persons, particularly those not free to leave the institution at will, can be sufficiently free of pressures which originate with or are within the control of the researcher or institution to justify an expectation of there being a real opportunity for choice -- particularly to choose not to negotiate or not to participate in the proferred research. When the alternative is nothing but indefinite continued incarceration an opportunity to become involved in research, no matter how dangerous, may be compelling if a possible consequence, no matter how slight, of the success of the research experiment were to be release from the institution. Yet this would be an exercise of choice that could be honored. However, were the condition of release to rest solely on participation in the experiment, not on its outcome, there would be coercion. Freedom of choice so far as it is within the control of the researcher and institution would have been denied to the potential subject. In such a case, a subject would in fact have been eligible to be deinstitutionalized even if there had been no research. His decision would thus have been coerced.

But the institutional setting alone or even when coupled with the status of mental infirmity is not sufficient to rule out the possibility of persons being free to choose. Such facts do demand, however, additional scrutiny of the conduct of the researcher and institution, as the aftermath of Kaimowitz case dramatically demonstrates. There, neither the review committee's approval nor the signed "informed consent form" of

John Doe and of his parents safeguarded his autonomy, his freedom to choose. His later release, because of the unconstitutionality of his institutionalization, in no way could be attributed to the possible outcome of the research in which he was forced to agree to participate, despite this and the "consent" form of others on his behalf. If Kaimowitz and its aftermath suggests anything, it is that any invitation to the institutionalized mentally infirm persons to participate in research should be restricted by limiting inducements for participation to those that could only possibly be related to the results of the research -- i.e. nothing should be offered a potential subject so far as his institutional setting is concerned which could be offered to him even if there were no research or no research results. Thus researchers might appeal to a potential subject's interest in furthering the state of knowledge, but could not offer better food or accommodations to the institutionalized, because such provisions for better living within the institution could and should be made available without regard to research. The freedom from institutionalization which could have been made available to John Doe without his participation was the blinding star with which research and institutional authorities coerced "consent." Coupled with the numbing effect of "institutionalization" outlined in Kaimowitz, the opportunity for freedom may force patients, as John Doe, to opt for the role of guinea pig in hazardous, untested experiments rather than face a seemingly limitless future in the institution. And for that, however meticulously the researcher and the institution pursued the ritual of "informed consent" and review, they should have been held accountable in tort and criminal

law for their violation of person. However, if there were a possibility of release only if the experiment caused a change in the person which would make him eligible for release, John Doe would have been confronted with a real choice which he should have been free to accept or reject.

While this tension between safeguarding autonomy and protecting, albeit paternalistically, from coercion is not easily resolved, a value preference for individual autonomy and respect for human dignity leads one to conclude that the choice, however limited, must still be presented to the patient for his or her decision. It must be recognized that society has previously decided to deny a part of the patient's personal autonomy by placing him or her in the institution. Unless the decision to deny full free choice by institutionalizing is determined to be incorrect and the patient is released, the partial denial of autonomy should not be enhanced and strengthened by refusing even the very limited decision between further incarceration and participation in research. Respect for human dignity should be advanced, not denied, even within the tight boundaries of the institutionalized patient's choice. Institutionalization is a terrible deprivation and because of that very fact the patient should not be denied an opportunity for freedom from that environment -- if that is an opportunity which he or she wants and which society cannot provide any other way.

C. It now becomes appropriate to ask whether the force of law should ever be employed to prohibit or to compel certain research on human subjects. Should certain specific research be banned for all researchers and potential subjects? Should certain research be ordered and enforced by drafting researchers and subjects? Burt, has suggested, as has E. Shills, that prohibition would be appropriate for research which might be intrinsically "sacrilege", - which might reveal man as more "dog-like than God-like." The argument has an emotional force as strong as the meanings of the operative phrases are vague. The legal system must ultimately reject prohibitions, other than those generally condemned by the criminal law, unless it can discover (what is beyond its capacity to do) critically precise guides for distinguishing such research. In any event such prohibitions should be rare -- last resort determinations -- made with full recognition that some societal value must be identified which is superior to individual personal freedom and respect for human dignity. Further there should be a presumption against special prohibition because law does not have the power to preclude violations -- only hopefully to reduce their frequency and to respond to them when they occur --. Indeed, the prohibition often invites or provokes violation by the "outlaw" who might better serve societal interests were his activities subject to prior review, regulation and a process of accountability. Partial prohibitions might be imposed not for specific research but for any research in certain institutional settings because, for example, if the specific institution does not comply with standards set by court, legislature or Constitution. Nevertheless, the state may determine that the coercive nature of some institutions is so great that research will be prohibited

to protect the system from becoming exploitative, despite the deprivation of a potential subject's freedom to choose. The State may justify such a prohibition because it consciously decides that the sacrifice of individual freedom to be a research subject is slight on the scale of freedoms to be protected when weighed against the value of safeguarding all institutionalized persons from an abuse of power.

No one, it seems, since Nuremberg has openly suggested that which would be even more visibly offensive to both the autonomy of researcher and the potential research subject -- that is that some research might be ordered, not prohibited, by the state against the wishes of researchers or potential subjects. Both might be compelled to participate to serve an overriding state interest. As already noted, researchers are protected from such pressures under the act which established the Commission. Title II §§ 202(a)1(13)(IV)(a)2 88 Stat. 342. Conceptually the "informed consent" requirement of the Act and case law is designed to protect potential subjects from being forced to violate their own conscience. Of course, as with prohibition, complusory research on humans may be openly determined to be compelled by the national interest. In that event, which hopefully will never arrive, both researchers and subjects should be drafted in order to avoid exacerbating the abusive discrimination of past research which has meant that the deprived, the minority, the poor, the institutionalized have been more likely than not subjected to the risks of research on "voluntary" human subjects.

V. The Problem Resolved - A Recapitulation With Questions and Answers.

1. ARE THE INSTITUTIONALLY MENTALLY INFIRM COMPETENT TO CHOOSE IN WHAT AND WHICH ACTIVITIES THEY WILL OR WILL NOT ENGAGE?

All adults (by chronological age) in this category ought, out of respect for their human dignity and their fundamental right to pursue

their life in accord with their own individual concepts of what the good or the bad is, be presumed to have the capacity to decide what they wish to do with and for themselves. To the extent those in this category are children (by chronological age) the ultimate authority to choose must be with their parents. Parents, of course, can honor the wishes of the child concerned, and in effect give recognition to an individual child's competence to decide.

Competence goes only to capacity, not to authority or freedom to choose. But to deny capacity would preclude authority or freedom to choose.

a. Should a distinction be made between the voluntarily and involuntarily institutionalized mentally infirm so far as competence is concerned?

No. The voluntarily institutionalized, in theory at least, have demonstrated their competence to choose the care and treatment they wish. If however all or most voluntarily institutionalized mentally infirm are, in fact, persons who would and knew they would be involuntarily incarcerated if they refused to consent to institutionalization the distinction between voluntary and involuntary would seem to be without a difference.

To the extent all are, in reality, involuntarily institutionalized mentally infirm persons they have been deprived in law of competence to determine whether to accept or reject care and treatment -- not necessarily of any other competences and clearly and more specifically not of competence to decide whether to participate as subjects in biomedical research.

Of course the "informed" requisite to consent, which this essay argues against imposing on any potential subject, is a way of denying competence to all whose dignity the inquiry is designed to protect by delegating, without consent, to some third party the competence and the authority to determine whether the consent or refusal was informed i.e. competently made.

b. Should a distinction be made, so far as competence is concerned, between biomedical and behavioral research?

No. Although not specifically addressed in this essay, the distinction would seem to have no bearing on competence of a potential subject to decide. However, specific research for compelling state or national interests, may be, though it is difficult to conceive of any such circumstance, prohibited or ordered, bypassing for purposes of this inquiry both the questions of competence and of freedom to choose.

c. Should a distinction, so far as competence is concerned be made between those who are institutionalized as dangerous to themselves as opposed to dangerous to others?

No. This response, however, must be qualified by acknowledging that the writer questions the legitimacy, at least in terms of human dignity and personal autonomy, of the authority of the state to declare any adult a danger to him or herself. For those who are willing to accept the appropriateness of such a status, the question of competence to decide for oneself whether to participate as a research subject, as opposed to a treatment-and-care subject may still be answered "yes." On some relative scale of respect for human dignity and freedom a declaration of incompetence

limited to care and treatment is less offensive than one which covers more or all spheres of individual decision making.

If the answer to the competence question for those dangerous to themselves is "no", then of course they should neither be asked nor forced to participate as research subjects, nor should anyone be authorized to "consent" for them. They might, of course; be eligible to be drafted, in the rare event of a nationally ordered research project, so long as they are not discriminated against either by making them the only potential subjects or by excluding them as subjects.

d. Should a distinction so far as competence is concerned be made between the publicly and privately institutionalized mentally infirm?

No. Like race, creed, or color the public or private character of institutional status has no bearing on competence.

2. ARE THE INSTITUTIONALLY MENTALLY INFIRM FREE TO MAKE A CHOICE FOR OR AGAINST INVOLVEMENT IN BIOMEDICAL AND BEHAVIORAL RESEARCH?

Yes -- so long as free does not mean free in the usual sense of being at liberty, but free under the circumstances. Here the question must be phrased to ask should (as opposed to are) such persons be free to choose -- free in the limited sense of being free from conduct by research and institutional authorities which is unduly coercive -- i.e. which is more coercive than it need be to carry out in good faith the custody and care goals of institutionalization. Any restraint greater than necessary to achieve these goals would constitute coercion and a deprivation of a potential subjects freedom first to decide whether to consider and discuss participation in research and second, if willing to discuss, to

decide whether to participate in the proposed research.

Since the question is not one of the competence of the institutionalized mentally infirm to decide each of these questions, it is the research and institutional authority who must be subject to regulation and review for accountability in order to assure that a potential subject is not denied an opportunity to make a choice by the use of coercions beyond these already inherent and essential to the institutional setting in which the potential subject is held. To this end the guidelines

set forth on page 20 &/ above should be observed in fact and in spirit.

a. <u>If release from institutionalization is offered as a reward for participation in the research, is a potential subject being denied freedom to choose by the researcher or institution?</u>

Yes. Whether it be assumed that most institutionalized persons would prefer release is not relevant. What is relevant is that the force of authority should not be used to restrict freedom of movement for research purposes. Only if the direct consequences of the research directly alter the person of the subject to make him or her, who was otherwise ineligible, eligible for release would raising the possibility, if it is real, of release be allowed to be introduced as an incentive to participate. Of course such an "incentive" may be rejected by the potential subject without the possibility of his competence to decide being questioned or his decision being reversed by proxy.

b. <u>If financial compensation is offered to those who agree to participate is the freedom to choose the institutionalized mentally infirm being violated by the researcher or institutional authority seeking consent?</u>

Not necessarily. Money compensation is the traditional mode of exchange for encouraging free persons to do work others may wish them to do. Of course perceiving participation in research as employment facilitates recognizing that researchers should be obliged to be equal opportunity employers and that there must be no discrimination, unless relevant to the research itself, because of race, creed, color, sex, or age. Whether money could be offered to such persons unless they were being fully compensated for their stay in the institution, an unlikely prospect, is questionable. Money offered to such a deprived population for participation would in all likelihood be unduly coercive. Yet to make such a determination is to reduce the possible area of opportunity and choice for the potential subject. The discriminations of the past which pressed the underprivileged minorities into such "jobs" as research subjects prompts suggesting the establishment of some form of affirmative (or negative) action program. The apparent absurdity of that idea that researchers must, so far as potential subjects are concerned, be an equal opportunity employer reinforces the free exercise of choice notion which must be maximized for all.

c. If consent by proxy, or by substitute, is permitted has a potential subject been denied by researcher or institution his or her freedom to choose?

Yes. Consent, when qualified by "substitute" or "proxy" is a misnomer, unless the proxy was freely chosen by the potential subject to make such decisions on his or her behalf. To be free to decide (to consent or refuse to consent) does not mean to be free of either internal pressures

or the external pressures of family, friends and of the general environment. It means only to be free of coercive and deceptive pressures that may be exerted by the researcher or institution through the manipulation or offer to manipulate the institutional setting. If such pressures are exerted a potential subject has been denied his or her freedom to choose to participate or not to participate.

In any challenge by a subject or a potential subject to the violation of his freedom to choose, the burden would be upon the researcher and institution to overcome the presumption of coercion which characterizes institutional settings.

3. MUST INFORMED CONSENT BE OBTAINED FROM A POTENTIAL SUBJECT BEFORE A RESEARCHER IS ENTITLED TO ENGAGE HIM OR HER IN THE RESEARCH PROPOSED?

No. Consent must be obtained, whether orally or written, in accord with the process of informing for decision which must be observed by researcher and institution, but that consent need not be "rational" or "informed" whatever those words may mean to the reasonable, or the wise. The decision to participate must only be an exercise of choice, not in the sense of being free of all internal or external pressures, but only in the sense of being free of coercion and deception by the researcher, the institution, the state, or any persons acting on their behalf.

4. SHOULD ANY SPECIAL CONDITIONS BE IMPOSED ON THOSE WHO WISH TO ENGAGE THE INSTITUTIONALIZED MENTALLY INFORM AS RESEARCH SUBJECTS?

Yes. Because of the coercive setting in which such potential subjects are held, because of a history of abuse, the following special conditions (in addition to those to be generally imposed on all research) should be imposed:

a. No research should be authorized to be conducted exclusively in such institutional settings unless the knowledge sought in the research could, in the scientific sense, be obtained only from persons who are categorized as institutionally mentally infirm. If the knowledge sought can be obtained, in the scientific sense, from persons free of institutional restraint or free of the designation mentally infirm, research subjects would first have to be drawn from the free community. In any event, though quotas on their face are offensive, it may be appropriate to limit the percentage of institutionalized mentally infirm subjects, (fairly divided between public and private institutions) and the percentage of subjects from the free community to the percentages each group represents in the total adult population. At least the institutionally mentally infirm should not constitute a greater percentage of subjects than they represent in the total community.

b. Research for knowledge which, in a scientific sense, could only be obtained from subjects who are institutionalized mentally infirm persons might be further restricted or even prohibited, at the expense of the freedom of choice of such persons, upon a finding that the setting is so coercive the opportunity to make a choice is, in fact, not real. Such a finding could also be made with regard to research for knowledge which might be obtained from subjects in the free community. However, with the special conditions imposed in (a) it is anticipated that undue pressure on the mentally infirm to participate would be greatly reduced.

5. TO WHAT STANDARD OF RESPONSIBILITY AND ACCOUNTABILITY SHOULD RESEARCH AND INSTITUTIONAL SUBJECTS BE HELD WITH REGARD TO CONDUCTING RESEARCH ON THE INSTITUTIONALIZED MENTALLY INFIRM?

Research and institutional authorities should be held to the highest standards. Violations of procedures established for informing potential subjects for decision will be strictly enforceable and enforced in both tort and criminal law. Serious consideration should be given to making the failures to abide by the proscribed standards of conduct a matter of strict liability in criminal law. The enforcement of responsibility and the standards of accountability should not be diluted or undercut either by attaching high social goals indiscrimately to all research, or by the notion that "informed" attached to "consent" on the release form automatically safeguards potential subjects from coercion and deception by persons in authority.

LAW OF INFORMED CONSENT IN HUMAN EXPERIMENTATION:

INSTITUTIONALIZED MENTALLY INFIRM

George J. Annas
Leonard H. Glantz
Barbara F. Katz
Center for Law and Health Sciences
Boston University School of Law

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INTRODUCTION

The area of informed consent by institutionalized mental patients to experimentation combines the issues found in regard to prisoners and children. The problem is two-tiered, concerning both the legal capacity of the individual to consent and the issue of institutionalization. The major questions may be highlighted by reference to one of the principles of the Nuremberg Code.[1] Does an institutionalized mental patient, in general, have the legal capacity to consent? Is a particular mental patient competent so as to enable an "understanding and enlightened decision?" Is proxy consent ever valid, and, if so, under what circumstances? Does the fact of institutionalization create a situation which effectively removes the individual's ability "to exercise free power of choice?"

Institutionalized mental patients are perhaps the most isolated and underpriviliged members of our society. The human and legal rights of mentally ill and retarded persons[2] have been grossly violated for centuries. The result is that they are often victims of numerous social injustices, including horrible facilities, poor or non-existent treatment and education, indiscriminate sterilization, and deprivation of basic legal protections, including the performance of unethical and/or illegal human experimentation.

Large institutions, although outdated and often inefficient, have historically carried the responsibility for caring for the mentally

deficient individual who either cannot function in the community or whose family has decided not to have him remain at home.[3] This involves a substantial number of people. There are approximately 200,000 residents in 190 public institutions for the retarded in the United States.[4] Many have spent most of their lives in institutions. In addition, one out of every ten Americans will at some time be hospitalized for mental illness.[5] There is an abundance of literature critical of mental hospitals.[6] For many individuals, institutionalization results in a worsening of their mental condition.[7] Long-term residents actually sufferdeterioration and abuse.[8] Indeed, it has been estimated that the effects of institutionalization are so severe that, if a patient is not released within two years of his admission, the chances are good that he will die in the hospital.[9] Dehumanization has been amply demonstrated in such residential facilities.[10]

Institutionalized mental patients have traditionally been subjects of experiments, and not necessarily because the research has special applicability to this group.[11] Research frequently requires that a convenient, stable subject population be followed over a period of time. Thus, the institutionalized are particularly attractive to investigators because they constitute a "controlled" or "captive" community, with a relatively uniform diet, schedule of sleeping hours, and daily routine, and since they are often wards of the state, they form an inexpensive pool of experimental subjects.[12] In addition, people in institutions are often easily manipulated, either due to their own mental deficiencies or the lack of interest in their welfare

demonstrated by their legal guardians and/or facility administration and staff.

For example, it has been reported that eighty mentally defective patients of the District of Columbia Training School in Laurel, Maryland were the subjects of an experiment designed to measure the blood flow in people suffering from dementia. A long needle was inserted in the femoral artery in the thigh of each individual. Then the juglar vein in the neck was treated similarly, with another needle going in just below the jaw and extending to the bulb in the vein. Finally, the patients were forced to inhale radioactive gas through a tight-fitting mask, and their blood flow was checked.[13] In another case, a meningitis vaccine was injected into mentally retarded children at the Hamburg State Home and Hospital Institution in Pennsylvania without the consent of either subject or parent, since the investigator thought that the administrator of the hospital was the legal guardian of the involved minors.[14]

An especially illustrative example of experimentation on institutionalized mental patients involves the drug Depo-Provera, a derivative of progesterone that was approved by the FDA in 1960 for treatment of a gynecologic condition known as endometriosis, and in 1972 for treatment of carcinomia of the lining of the uterus. The drug has been investigated for contraceptive use in human clinical and animal studies under an Investigational New Drug Application (IND) since 1963. In 1970, studies in dogs revealed that Depo-Provera produced mammary tumors, and new information received in 1972 indicated that some

of these nodules were malignant.[15] Contraceptive studies with Depo-Provera under the IND were severely limited and the subjects under study were required to sign the following detailed written informed consent form.

REVISED DEPO-PROVERA WRITTEN INFORMED CONSENT FORM
FOR CONTRACEPTIVE STUDIES

IMPORTANT NOTE: This is NOT the same informed consent form that you signed before. It has been changed to bring to your attention that breast cancers have developed in some beagle dogs undergoing long-term tests with injections of Depo-Provera. Please read it carefully.

This is to certify that I,_____hereby agree and consent to receive an experimental drug called Depo-Provera every three months under the care and supervision of Dr._____. I understand that this injection will ge given to me in an attempt to keep me from becoming pregnant. I have been told that tests in dogs injected with this drug showed that some of them developed tumors in their breasts. Some of these tumors were cancer and spread to other organs. It is not known whether or not similar tumors or cancers will grow in my breasts after receiving the drug.

It has been explained to me that there are avilable other non-experimental methods of preventing pregnancy such as pills, vaginal creams, jellies, foams, diaphragms, various devices which are inserted into my womb and use of a rubber (condom) by my husband. The effectiveness of these various methods of contraception, as well as the advantages and disadvantages of each method, has been explained to me. Surgical sterilization of myself or my husband (along with its risks, advantages and disadvantages) has been explained to me as a nonreversible method of contraception. I have also been told of the effectiveness of Depo-Provera.

I have read and understand the pamphlet prepared by the American Medical Association, American College of Obstetricians and Gynecologists and the Food and Drug Administration informing users of the pill about the possible problems which a woman may encounter during its use. I understand also that Depo-Provera is similar to the pill in that I may have some of the same problems occurring that are mentioned in the pamphlet such as blood clots, tender

breasts, nausea, vomiting, weight gain, weight loss, spotty darkening of the skin of the face, mental depression, elevated levels of sugar and fatty substances in the blood, dizziness, loss of hair, increase in body hair and increased or decreased sex drive.

It has been explained to me that it is quite likely that I will have unexpected vaginal bleeding, completely irregular menstrual cycles or no menstrual bleeding at all as a result of the Depo-Provera injections. I also understand that the injections may have some effect on the amount of estrogenic and adrenal hormones produced in my body and that the importances of these changes is still being investigated.

I understand, also, that after a woman stops taking Depo-Provera there may be an unpredictable and prolonged delay before she is able to become pregnant or may be unable to become pregnant at all. Because of the possibility of an occasional case of permanent sterility, Depo-Provera should not be used by women who may wish to have another baby in the future.

I have tried all other kinds of birth control methods and cannot use them or I refuse to use all other kinds of birth control methods. Therefore, I hereby volunteer of my own free will to receive injections of the experimental birth control drug, Depo-Provera, with the full knowledge and understanding that it produced breast tumors and cancer in some dogs and it is not known whether similar tumors or cancers will develop in my breasts.

I understand that I may withdraw from this investigational study of the use of Depo-Provera for contraception at any time.[16]

Although Depo-Provera is an experimental drug for the purpose of birth control, it was considered by the authorities of the Arlington Hospital and School, a facility for the mentally retarded in Tennessee, as a viable and valuable contraceptive method since it is highly effective, temporarily halts the patient's menstrual cycle, and need only be administered through an injection once every three months. Beginning in 1970, almost 200 female child-bearing age residents of the institution were receiving Depo-Provera.[17] However, in contrast

to the elaborate consent form presented to the "normal" subjects using Depo-Provera, the following form was employed to obtain the consent of the parents or guardian of the institutionalized individuals to the administration of the drug:

PERMIT FOR DEPO PROVERA PROGRAM

I,_____, (father, mother or legal guardian) of _____, now a resident of Arlington Hospital and School, give my permission to enter her into the program designed at Arlington Hospital and School to use depo provera.

This drug is to be injected every three months for the purposes of preventing menstruation, thereby making resident more comfortable and to lessen nursing care. A second purpose is that of preventing pregnancy in the event of exposure.[18]

Indeed, based on the statements by Dr. James S. Brown, superintendent of the facility, before Senator Kennedy's 1973 Hearings on Human Experimentation, the institutional authorities were either unaware of or had little concern for the experimental nature of the drug.

Dr. Brown: I would like to clarify a couple things, at least in terminology, as I listened to the hearings this morning. We keep referring to Depo-Provera as an experimental drug. It has never been our understanding that it is an experimental drug, and our use of Depo-Provera has not been within the context or the framework of the way we would go about doing an experimental study if we did one.

Senator Kennedy: Just to clarify our terms. Dr. Edwards (Commissioner of Food and Drugs, Department of Health, Education, and Welfare) indicates Depo-Provera is an experimental drug for the purpose of birth control.

Dr. Brown: What is an experimental drug? If you have a drug such as Depo-Provera that is licensed for human

use at a certain dose, and for certain indications, is it experimental?

This is the question in my mind. Is it experimental again for another indication that you are using it for in human beings?

Senator Kennedy: Dr. Brown, Dr. Edwards just said this morning it is not to be used for birth control purposes.

Dr. Brown: He said the FDA has not licensed it for birth control purposes.

Senator Kennedy: That is right.

Dr. Brown: Senator, I am not an expert on Depo-Provera. As a pediatrician and as an administrator I would like to tell you about our problem and what we did and how we went about it.[19]

Dr. Brown went on to indicate that the major reason for administration of the drug was to provide an effective means of preventing pregnancy and menstruation, two conditions which present problems to the efficient functioning of an institution. Indeed, the testimony continued as follows:

Dr. Brown: Senator, I do not think that anyone has given you any information on the unsafety of the drug for human use. We do not have it either. If we could get it, we would stop the drug today.

Senator Kennedy: The Food and Drug Administration, which is the present regulatory agency, which has the resources - financial and research resources - to make these judgments, has indicated that it has not approved this for this purpose.

Your consultants have reached other conclusions. What we must determine is whether we are going to have individual doctors using these various drugs, or State agencies in effect substituting their judgment for the judgment of the Food and Drug Administration.

Should that be permitted?

. . . .

Dr. Brown: Well, certainly, if there is any question about its safety and the FDA had not told me what it is, my consultants would certainly find out and advise us, and we would take our people off the drug. I think we still have note quite established this, Senator Kennedy.

Senator Kennedy: You what?

Dr. Brown: I am not sure we have established what this is, at least so far as communicating is concerned.

Senator Kennedy: Do you think physicians should independently be able to decide whether or not a drug is safe?

Dr. Brown: No, I do not. I certainly do not.

Senator Kennedy: Is this not really what has happened here?

Dr. Brown: Well, I do not think the FDA has said it was unsafe.

Senator Kennedy: Unresolved questions of safety? You say there is a significant doubt, a serious doubt.

Dr. Brown: That is correct.

Senator Kennedy: That doubt on the part of the Food and Drug Administration is in no way reflected in your consent form, is it?

20

Dr. Brown: No, it is not.

It seems clear that the administrator of an institution for the mentally retarded failed to understand the significance of the fact that the method chosen by the facility to achieve a particular purpose was experimental, and that accordingly different factors enter into the determination as to its use and the parameters of the informed consent required before its employment.

CAPACITY TO CONSENT

In general, "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[21] Thus, the competent adult has the right to choose the course of his care and to be apprised of the facts necessary to make that choice.[22] This is true even though the reason for a particular medical decision may seem irrational when viewed objectively. For example, in Palm Springs General Hospital v. Martinez,[23] the court determined that a conscious adult patient who was mentally competent had the right to refuse medical treatment involving surgery and blood transfusions, although medical opinion deemed the procedures necessary to save her life.[24]

Institutionalization in a facility for the mentally deficient and legal incompetence are not necessarily synonymous.[25] Thus, the institutionalized individual is often deemed to have the same legal ability to exercise his rights as a free-living person.[26]

This principle has been recognized by court action in a number of states.[27] In the recent case of Horacek v. Exon,[28] it was determined that all mentally retarded persons in Nebraska, including those institutionalized, have the same rights as all other persons in that state. The court in McAuliffe v. Carlson[29] ruled that the Connecticut statute which provided for the appointment of the state Commissioner of Finance as conservator for the funds of residents of mental institutions was unconstitutional because the conservator was appointed

without any hearing to determine that the resident was incompetent to manage his own affairs. A somewhat similar process for state management of patient finances was struck down in Vecchione v. Wohlgemuth,[30] based on the court's determination that the fact of institutionalization does not in and of itself create a status of incompetency.

This principle is applicable to the ability of an institutionalized patient to give or withhold consent to medical treatment. In the case of In re Yetter,[31] a sixty-year-old involuntarily committed mental patient declined to consent to a recommended surgical breast biopsy. Her fears were based on the death of an aunt following such surgery (although the court was presented evidence indicating that the aunt had died fifteen years following the surgery from unrelated causes), as well as the concern that the operation would interfere with her genital system, affecting her ability to have babies, and would prohibit a movie career. Although her reasoning was becoming somewhat delusional, the court found that at the time the patient made her initial decision not to have the surgery, she was lucid, rational, and had the ability to understand the recommended procedure and the possible consequences of her refusal, including the risk of death. Even though it indicated that the patient's decision in this situation might be "irrational and foolish," the court nevertheless determined that Ms. Yetter was competent to reach this conclusion, and therefore declined to appoint a guardian for her for the purpose of consenting to the surgery. The court stated that the mere commitment of an individual to a state facility does not destroy the person's competency

nor require the appointment of a guardian.

Several states, such as California,[32] Minnesota,[33] Michigan,[34] Massachusetts,[35] New York,[36] Oklahoma,[37] South Carolina,[38] South Dakota,[39] and Tennessee,[40] have statutes which specify that institutionalization is not automatically equivalent to incompetency. Other state statutes deal with the question on an issue-by-issue basis, determining whether institutionalization renders an individual incompetent for a particular purpose. Thus, for example, mental patients are specifically given the right to vote in South Carolina,[41] South Dakota,[42] New Mexico,[43] Louisiana,[44] Kentucky,[45] Alaska,[46] Georgia,[47] Maryland,[48] and New York,[49] the right to contract in South Carolina,[50] Louisiana,[51] Kentucky,[52] and Alaska,[53] the right to marry in South Carolina,[54] and the right to make a will in South Carolina[55] and Georgia.[56]

However, the laws in a number of states still envision the mental patient as one who is and will continue to be devoid of ail ability to comprehend or exercise any rights.[57] A number of states have blanket restrictions on the right to marry, vote, contract, drive, or conduct one's affairs, giving little regard to the particular individual's capacities to exercise those rights.[58] For example, a West Virginia law provides that "[t]he entry of an order ordering hospitalization for an indeterminate period shall relieve the patient of legal capcity."[59] while a Wisconsin law provides that "[h]ospitalization under this chapter, whether by voluntary admission or commitment . . . raises a rebuttable or disputable presumption of incompetency while the patient

is under the jurisdiction of hospital authorities."[60] The rights to vote, make a will, contract, or marry are restricted in Alabama,[61] Arkansas,[62] Maine,[63] and New Jersey.[64]

Overall, the state of the law in this area may be summarized as follows:

> 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 a presumptive incapacity; and in still others, there is a complete separation of hospitalization and incompetency. . . . In many states the effect of a hospitalization order on competency cannot be determined from the written law, [but] the trend in legislation during the last 15 years has been toward a complete separation of hospitalization and incompetency.[65]

It may reasonably be concluded that mental patients are not presumptively incompetent in most jurisdictions.

In general, therefore, as concerns a therapeutic[66] biomedical or behavioral procedure, informed consent is needed prior to its performance. This consent is to be obtained from the patient, unless he is a minor or has been judicially declared an incompetent, in which case the requisite consent is obtained from his parent or legal guardian, respectively. This substitute consent is valid since, by definition, a therapeutic procedure is for the benefit of the individual.[67] Thus, if an incompetent mental patient needed an appendectomy,[68] the substitute consent of his guardian would be sufficient. In regard to non-therapeutic procedures, while informed consent is still a prerequisite, this consent may only be secured from a competent patient himself. Since the procedure is not for the patient's benefit,

proxy consent is not sufficient.

A. Effects of "Institutionalization"

The problem of whether an institutionalized individual is competent to consent is complicated by various factors. In the first place, the very fact that the individual is institutionalized may have a practical effect on the issue of competency. This is due to the results of a process termed "institutionalization." People who are cordoned off from the outside world are often effectvely stripped of their concept of "self," a perception which is vital in order to satisfy the demands of informed consent. Erving Goffman, in his book Asylums,[69] discusses the effects of "total institutions."

> In total institutions there is a basic split between a large managed group, conveniently called inmates, and a small supervisory staff. Inmates typically live in the institution and have restricted contact with the world outside the walls; staff often operate on an eight-hour day and are socially integrated into the outside world. Each grouping tends to conceive of the other in terms of narrow hostile stereotypes, staff often seeing inmates as bitter, secretive, and untrustworthy, while inmates often see staff as condescening, high-handed, and mean. Staff tends to feel superior and righteous; inmates tend, in some ways at least, to feel inferior, weak, blameworthy, and guilty.[70]

This may result not only in lowered self-esteem, but in a diminution of decision-making power as well.[71] The total effects of this can be devastating. For example, a report by the Michigan Auditor General on the Caro Residential Center for the Mentally Retarded found at least five people in that facility who were not retarded

but had been institutionalized for so long that the Center felt that they would not be capable of living in the outside world.[72]

Further complicating this situation is the element of duress present within the institution whenever an attempt is made to obtain consent. Physicians are often able to "engineer" consent from their patients/subjects by manipulation of their "fiduciary" relationship. In addition, a patient will often be swayed by hopes of influence with institutional authorities or release from an indeterminate commitment - even if these things were never promised nor even mentioned by the physicians in his discussions with the individual. The supreme inducment to consent is the hope of obtaining freedom. This is revealed in the words of a former mental patient, "I played the game of patient to wits end, as the only means of escape."[73] The institutional setting makes it difficult for one not to feel some sort of coercion or encouragement to consent merely in being approached for the particular procedure. This is particularly true for those individuals who see little or no hope of their eventual release, but who are assured that this particular treatment may make this possible.

This was the situation under consideration in Kaimowitz v. Department of Mental Health.[74] The controversy arose with a proposal for a research project designed to compare the effectiveness of psychosurgery and drug therapy for stopping uncontrollable aggression in chronically violent wards of the state. The chemical method involved the administration of cyproterone acetate, a drug which renders the patient impotent as well as docile. The surgical procedure was to

have consisted of measuring waves on an electroencephalogram to determine whether the patient's brain manifested a disturbance that could be charted. If so, electrodes would have been inserted into his brain to determine if the condition was generalized or localized. If generalized, no further action would have been taken; if localized, the amygdala would have been removed by electrocoagulation, a sophisticated form of surgery involving the burning out rather than the cutting out of the alleged affected parts.[75]

The original program outline was to include twenty-four patients. The subjects were all to be non-psychotic brain damaged males who had not responded to traditional treatment and who were deemed to be capable of understanding and deciding whether they wanted to undergo the treatment. The first subject chosen was thirty-six-year-old Louis Smith, a criminal sexual psychopath who had been in state institutions for the criminally insane for seventeen years after confessing to murder and rape. Both Smith and his parents signed the following detailed consent form.

> Since conventional treatment efforts over a period of several years have not enabled me to control my outbursts of rage and anti-social behavior, I submit an application' to be a subject in a research project which may offer me a form of effective therapy. This therapy is based upon the idea that episodes of anti-social rage and sexuality might be triggered by a disturbance in certain portions of my brain. I understand that in order to be certain that a significant brain distrubance exists, which might relate to my anti-social behavior, an initial operation will have to be performed. This procedure consists of placing fine wires into my brain, which will record the electrical activity from those structures which play a part in anger and sexuality. These electrical waves can then be studied to determine the presence of an abnormality.

> In addition electrical stimulation with weak currents passed through these wires will be done in order to find out if one or several points in the brain can trigger my episodes of violence or unlawful sexuality. In other words this stimulation may cause me to want to commit an aggressive or sexual act, but every effort will be made to have a sufficient number of people present to control me. If the brain disturbance is limited to a small area, I understand that the investigators will destroy this part of my brain with an electrical current. If the abnormality comes from a larger part of my brain, I agree that it should be surgically removed, if the doctors determine that it can be done so, without risk of side effects. Should the electrical activity from the parts of my brain into which the wires have been placed reveal that there is no significant abnormality the wires will simply be withdrawn.
>
> I realize that any operation on the brain carries a number of risks which may be slight, but could be potentially serious. These risks include infection, bleeding, temporary or permanent weakness or paralysis of one or more of my legs or arms, difficulties with speech and thinking, as well as the ability to feel, touch, pain and temperature. Under extraordinary circumstances, it is also possible that I might not survive the operation.
>
> Fully aware of the risks detailed in the paragraphs above, I authorize the physicians of Lafayette Clinic and Providence Hospital to perform the procedures as outlined above.[76]

Conventional therapies had been considered to be ineffective for treatment of Smith's condition. Therefore, although he was later released from the institution on the basis of the court's conclusion that he could be safely returned to society,[77] the psychosurgery appeared at the time to be the only possible hope for securing his freedom.

The court adopted the Nuremberg Code as a guide in its determinations.[78] Therefore, it concluded that, in order for the informed consent of an individual to be valid, the three necessary components - competency, voluntariness, and knowledge - must be present.[79]

In its consideration of competence, the court did not maintain that a mental patient is automatically legally incompetent. Instead, the court found that the process of institutionalization and the dependency which often accompanies residence in a mental hospital lead to an atrophying of a patient's decision-making powers, rendering him incapable of making decisions as serious and complex as whether to undergo experimental psychosurgery. As concerns voluntariness, the court considered the issue in relation to the institutional setting. It perceived that a captive person unavoidably views any cooperation with his keepers as a potential key to release.[80] Even in the absence of direct pressure from institutional authorities, the realities of confinement and total institutional control over every minute detail of a patient's life[81] create an inherently coercive environment. In this setting, the potential subject is not "able to exercise free power of choice, without the intervention of force . . . or other ulterior form of constraint or coercion."[82] The fact that Smith, upon his release from the institution, revoked his consent to the psychosurgery, adds credence to the court's point of view.[83] With respect to the knowledge factor, the court considered expert testimony about the complexity of the brain, and evidenced concernabout the lack of extensive animal and human experimentation in determining and studying brain function. It viewed the risks and benefits of psychosurgery as profoundly uncertain, and held that "lack of knowledge on the subject makes a knowledgeable consnet to psychosurgery literally impossible."[84]

There are various problems with the court's reasoning. To begin with, if institutionalization leads to the deterioration of decision-making abilities, thereby rendering a patient incompetent to consent to experimental psychosurgery, it would seem that this same condition would render the person incompetent to make other important and complex decisions. Yet any extension of this concept beyond the specific facts of the case would be unacceptable because it would practically resurrect the notion that mental patient status per se establishes legal incompetence (at least as to those patients who have been institutionalized for a long period of time) - a notion that is rapidly losing credence in the law.

Similarly, the court's conception of coercion has disturbing possible ramifications. If the chance for release is the coercive element behind consent to psychosurgery, then it may also be viewed as such in relation to other, more generally accepted forms of therapy. Involuntary commitment could therefore be considered to coerce all decisions to engage in therapy, thereby making all such decisions invalid.

In its discussion of knowledge, the court, as noted earlier, found that the lack of knowledge about experimental brain surgery makes knowledgeable consent to experimental psychosurgery impossible to obtain. However, the consent form signed by the patient was extremely detailed, listing numerous serious risks, including the possibility of death. It may be argued that such a complete form adequately notifies the patient of the potential risks involved in psychosurgery,

since it is practically impossible to inform a subject of hazards which are unknown to the medical profession generally when a proposed treatment involves innovative procedures. This interpretation of the knowledge element of informed consent is unprecedented, and has yet to be followed by another court.

Furthermore, the court concluded that, when psychosurgery is no longer considered experimental but becomes an accepted neurosurgical practice, an involuntarily commited mental patient can give legally binding informed consent to its performance. However, this seems to weaken the court's earlier discussion of the effect of institutionalization on the elements of competence and voluntariness. The presence of added knowledge concerning psychosurgery and its possible risks and benefits should have no effect on whether the patient can give voluntary and competent consent to the procedure.[85]

Ultimately, the decision of the court may be seen as a condemnation of choices, the consequences of which it deems unacceptable. Thus, choices considered beneficial typically are sustained despite the presence of many of those same elements which negated the effectiveness of the patient's consent in the present case. If the conditions of the entire situation are regarded as reasonable, the consent will not usually be legally condemned. Thus, psychosurgery, because it is experimental, drastic, and irreversible, with no known lasting benefits and many possible unknown side effects, is at present considered by this court to be an inappropriate and impermissible treatment or research choice for involuntarily confined patients. It is reasonable

for patients to submit to generally accepted therapy, but it is unreasonable for them to submit to no-benefit or low-benefit, high-risk experimentation.

B. Ability to "Comprehend"

Another troubling factor influencing the issue of competency is the fact that there are numerous levels of mental retardation and mental illness, ranging from rather mild to severe, found within each facility. It is estimated, for example, that eighteen percent of the mentally retarded residents of institutions are either mildly or borderline retarded, while another twenty-two percent are moderately retarded.[86] These individuals are capable of a relatively independent life, as opposed to the severely and profoundly retarded, who range from those who may function under sheltered conditions to those who are completely helpless. The same holds true for the difference in the level of functions of the various groups of mentally ill. The severely mentally ill constitute only about one percent of the total hospital population.[87] Many forms of mental illness have a highly specific impact, leaving the decision-making capacity and reasoning of the involved individuals largely unimpaired.[88] In addition, while the condition of the mentally retarded, which is often due to deficiencies from infancy, can usually be improved with programs of care and rehabilitation, it is a relatively stable and constant condition, not subject to the same possibility for rapid, frequent, and complete

change in mental capacity as is the case with mental illness. A mentally ill patient may be competent to consent one day and yet become incompetent the next. An acute onslaught of particular forms of mental illness are often possible, so that a patient's condition can change dramatically in a very short period of time.

Finally, it is not always easy to distinguish competency from incompetency. Although a particular patient may not have been judicially determined to be incompetent, from a practical view-point it may be impossible to gain adequate consent from him. For example, how does one obtain consent from a severely ill catatonic schizophrenic who sits and stares at a blank wall all day, refusing to speak to anyone? Certainly if a patient is psychotic or hallucinating and cannot assimilate information about a proposed procedure, he does not have the capacity to reach a decision about the matter in question. Some mental patients are incapable of evaluating information in what most people would call a rational manner. A treatment decision might ordinarily be based on considerations of perceived personal objectives, or long-term versus short-term risks and benefits. But there are patients whose acceptance or rejection of a treatment is not made in relation to any "factual" information. To add to this dilemma, while a mental patient may refuse to give his consent to a procedure, his refusal may only be a manifestation of his illness, having little resemblance to his actual desires.

PROXY CONSENT

Individuals who are legally incompetent are precluded from making legally binding determinations concerning medical care. The fact that the person has not reached the age of majority is usually taken to mean that he does not have the intelligence and capability to comprehend fully the nature and purpose of a procedure or to engage in the weighing of risks and benefits which is involved in the decision-making process. The same holds true for someone who, as the result of a judicial hearing, has been declared legally incompetent to manage his own affairs, and has therefore had a guardian appointed for him. Thus is created a situation in which other parties the parents for the child and the court-appointed guardian for the adjudicated mentally incompetent adult, assume this function for him. The purpose of this is the protection of the incompetent individual from harm that might result from either his own lack of knowledge or from coercive methods used to obtain his consent. However, under the common law, guardian consent on behalf of an incompetent may only be granted or withheld on the sole basis of the incompetent's welfare. Indeed, the judgment of the guardian regarding the incompetent's best interests is not always conclusive, and the courts will intervene to protect the welfare of the incompetent.[89] Therefore, the state, exercising its ultimate responsibility for the welfare of the mentally deficient under the doctrine of parens patriae, which provides that the state has the duty to care for those individuals who are not able to do so themselves, will

intervene when the question arises as to whether the guardian has acted in the best interest of his ward.[90] A more detailed discussion of proxy consent may be found in the earlier section of this Report dealing with children.[91] The general conclusions in that analysis are applicable to the area of mental patients as well.

However, the proxy consent scheme runs into a number of serious problems when one considers it in relation to institutionalized mentally ill and mentally retarded persons. For example, there is the question as to whether the parent/guardian has both the motivation and capability to represent the best interests of the institutionalized incompetent. Implicit in the guardianship status is the belief that there is an identity or, at least, compatibility of interest between the guardian and incompetent. In addition, it is assumed that there is a capability on the part of the guardian to care for and deal with the incompetent and represent him in his dealings with society in general and the institution in particular.[92]

There may be a conflict of interest between the guardian and ward so as to preclude adequate representation of the institutionalized person's interests. Thus, the parent/guardian may have been the individual who originally "voluntarily" placed a minor/incompetent in the facility. There are many societal pressures that operate to induce this, including mental and physical frustration, economic stress, hostility toward the individual stemming from added pressures, and perceived stigma of mental deficiency.[93] Often, the individual is institutionalized less for his own benefit than for the comfort of others. Similarly, the guardian may have been the initiator of

involuntary commitment proceedings against the incompetent. In general, the fact of institutionalization affords the guardian the opportunity to "distance" himself from his ward and to deal with the situation in an abstract manner, thereby absolving himself from responsibility because the incompetent is entrusted to an institution.

Additionally, the particular guardian may be unable to deal effectively with the public and private institutional providers of service due to the disparity in leverage and sophistication that normally exists between guardian and institution. The guardian may be hesitant to counter the requests of the institution because the person in the facility is constantly subject to the threat of subtle, or not so subtle, retaliation. Moreover, the guardian may worry that if he disturbs the institutional authorities, the incompetent may, under certain circumstances, be released and perhaps thereby become a direct burden on the guardian.

Accordingly, in making provisions for the application of proxy consent on behalf of an institutionalized mental patient, one should always be aware of these-potential conflicts. Particularly as regards consent to experimentation, consent by proxy should be viewed with suspicion, and should not be accepted as valid and legally adequate until it has been critically reviewed to assure that it serves its original purpose, i.e., the protection of the interests of the individual subject.

THERAPEUTIC EXPERIMENTATION

A. Biomedical Procedures

There is little statutory or case law dealing specifically with experimentation on institutionalized mental patients. Therefore, it is necessary to analogize to the factors involved in the non-experimental situation. While this is probably worthwhile, it is also potentially dangerous. One must always keep in mind that, in the non-experimental situation, the patient's well-being is, theoretically at least, the physician's only concern. With an experiment, not only are there usually more uncertainties and greater risks, but the physician who contemplates the procedure is motivated in part or entirely by a search for medical information. The physician-patient relationship is altered by the broadened objectives of the physician-researchers, who may no longer be sufficiently disinterested to be an objective participant. Thus, it is likely that, with informed consent, the law will be stricter and more protective of the subject's rights in its analysis of the experimental situation. The main codes of ethics which guide researchers in their work with human subjects - the Nuremberg Code (1948), the American Medical Association Code (1946 and 1966), and the Declaration of Helsinki (1964)[94] - all base their protections ultimately on the adequacy of informed consent.[95]

As stated earlier,[96] in general, informed consent is necessary before the performance of a therapeutic medical procedure. This consent may take the form of an assent by a competent patient or

an assent by a guardian for an incompetent patient.

A number of states have passed statutes which specifically limit the performance of certain medical procedures, usually surgery, without the consent of the patient.[97] However, several statutes also provide for proxy consent to such medical procedures, seemingly regardless of whether the patient is deemed to be legally incompetent. For example, Tennessee provides that surgery may be performed if the consent of either the patient, parent, guardian, or next-of-kin is obtained.[98] Several states allow substitute consent when the patient is incompetent or of "unsound mind" to give consent, but most do not go on to define incompetent so as to indicate whether it is confined to those situations in which the patient has been adjudicated incompetent.[99] In Alaska, the head of the hospital makes the competency determination, and on this basis may substitute the consent of a parent, spouse, or guardian for that of the patient.[100] As can be seen, not only is proxy consent permitted under these questionable circumstances, but the person given this authority is expanding beyond the confines of a legal guardian to include parents of children who have reached majority, spouses, and even just the next-of-kin. Indeed, in New Jersey, the head of the institution can consent to physician-prescribed medical, surgical and dental treatment for the inmates of the facility.[101]

However, there is evidence that certain therapeutic procedures may be given separate and different consideration by the law. For example, let us consider the case of sterilization.

It is possible that the sterilization of an incompetent individual may be deemed to be "therapeutic," or in his best interests. For those incompetents who do not have the requisite mental capacity to adequately

use alternative forms of birth control, sterilization may be the only viable option for preventing pregnancy. There may be medical reasons preventing the adoption of other birth control options, as well as social and psychological information which contra-indicate these methods.

Regardless of this, the court in Relf v. Weinberger[102] decided that the consent of a representative of a mentally incompetent individual cannot impute voluntariness to a person actually undergoing irreversible sterilization.[103] This finding was based on the determination that, at least when important human rights are at stake, there is a requirement that "the individual have at his disposal the information necessary to make his decision and the mental competence to appreciate the significance of that information."[104] Therefore, since the federal statute under consideration only permitted federally-assisted family planning sterilizations on a voluntary basis, the court held that they cannot be performed on any person incompetent to personally consent to the procedure. Thus, proxy consent to sterilization was found not to be voluntary consent, seemingly regardless of whether the particular sterilization was considered therapeutic or not. In a further development in this case, the court in Relf v. Mathews[105] rejected proposed modifications of its previous judgment. The court noted that it intended to implement its decision that federal funds be available for sterilizations only for persons having the necessary capacity to decide voluntarily and free of coercion, and that the modifications were designed to substitute a universal federal standard of voluntariness which would permit sterilization of persons eighteen years of age and older even where such persons were otherwise incompetent in fact because of age or mental condition under state standards.

Similarly, the sterilization guidelines of the New York Health and Hospitals Corporation absolutely prohibit sterilization of women who are legally incompetent.[106]

In Wyatt v. Aderholt,[107] a three-judge federal court declared that the Alabama involuntary sterilization statute is unconstitutional. In addition, it promulgated guidelines for the voluntary sterilization of institutionalized mental patients. Initially, the court determined that, not only must the sterilization be in the "best interest" of the resident, but it also may not be performed without the consent of the person to be sterilized if he is competent to consent. If the individual is incompetent, the court does not allow guardian/proxy consent, even though the procedure must be, according to the guidelines, in the best interest of the ward, and therefore traditionally within the scope of authority of a guardian. Instead, the court provides that sterilization may not be performed under these circumstances unless it is approved by the director of the institution, a review committee, and a court of competent jurisdiction.[108]

This principle of protecting the incompetent's interests by requiring court review was followed by the court in In re Anderson.[109] In this case, the father and guardian of a mentally retarded woman petitioned the court for an order authorizing him to consent to her sterilization. In denying the petition, the court stated that sterilization may only be performed when it is in the person's best interest, and that, regardless of this, the authorization to sterilize may not come from the guardian but only from a court after a full evidentiary

hearing.

Thus, there is authority for the performance of serious therapeutic medical procedures upon a mental patient without his consent. However, there is also authority for the proposition that certain medical procedures are by their very nature so important and intrusive that either proxy consent will not be found valid at all, or it will only be allowed in the context of stringent procedural safeguards. While this has been found to be the case with irreversible sterilization, it is unclear exactly which other procedures would be included in this category. However, it seems clear that, the more drastic the procedure and its possible effect upon the patient and the exercise of his rights, the more likely that the stricter standards will apply.

B. Behavior Modification

The problem of consent becomes even more complex when one considers behavior modification procedures. The term behavior modification at one time had a precise and narrowly defined meaning.[110] Its underlying principle was that behavior is primarily influenced by its consequences, so that in order to change behavior, it is necessary to alter the consequences of that behavior. However, in recent years it has come to mean all of the ways in which human behavior is modified, changed, or influenced, and that is the definition which will be used for purposes of this report. Therefore, behavior modification may include milieu therapy, psychotherapy, positive reinforcement, token

economy programs, aversive conditioning, as well as electroconvulsive therapy, injection of psychoactive drugs, and psychosurgery.[111] In this sense, behavior modification is used to refer only to the end product of the process - a change in behavior.

Initially, one may begin with the assumption that the analysis made earlier is valid here, [112] i.e., a mental patient has the power to consent or withhold consent to behavior modification, unless he is legally incompetent, in which case a guardian can consent to those procedures which are for his benefit.

Thus, in Winters v. Miller, [113] an involuntarily commited mental patient alleged that her rights had been violated due to the imposition of forced medication, mostly in the form of tranquilizers. Although the court based its decision on First Amendment grounds, in that the patient was a Christian Scientist who was refusing to consent to the treatment on religious grounds, the court nevertheless emphasized the fact that, although Winters was involuntarily committee, she had never been legally determined to be incompetent, and therefore retained the ability to make her own choice concerning consent to treatment. Similarly, the court in Belger v. Arnot [114] found that the consent of the husband to the care and treatment of his wife's mental condition was not valid and did not bar an assault and battery action against the treating physician. Since the woman had never been declared legally incompetent, it was her consent which was essential.

However, the situation is complicated by consideration of the purpose behind institutionalization of mental patients. [115] The majority of hospitalized mental patients in the United States are

involuntarily confined.[116] The statutory standards governing involuntary commitment vary greatly from state to state.[117] About thirty-five states provide for commitment of those people found to be "in need of care and treatment." This *parens patriae* theory has traditionally been held a proper state purpose.[118] Since 1845,[119] both courts and legislatures have generally assumed that the *parens patriae* power justifies the involuntary commitment of the mentally deficient for care and treatment and protection from harm.[120] Thus, under this rationale, an individual may be committed when he lacks the capacity to make a rational decision concerning hospitalization, and the treatment available would be sufficiently beneficial to outweigh the deprivations which commitment would impose. There is legal authority for the proposition that inherent in this exercise of the state's *parens patriae* power is the decision that the patient can be forced to accept treatments found to be in his best interest. Thus, under these circumstances, the concept of consent by the institutionalized individual becomes meaningless.

> It is widely assumed that the commitment of a person to a mental hospital . . . confers on the hospital administrators the authority to "treat" him in whatever manner they deem appropriate.[121]

The case of *Whitree v. State*[122] seems to support this view. The court held that a state hospital must provide treatment to a mental patient even if the patient will not consent to treatment. In its decision, the court stated:

> We find that he [Whitree] was not treated with any of the modern tranquilizing drugs or any of their less effective antecedents during his entire stay in the hospital. We find that the reason for not using such

> drugs was that Whitree refused them. We consider such reason to be illogical, unprofessional and not consonant with prevailing medical standards.[123]

If the above principle is accepted, the question follows whether this is applicable to all treatment offered under the parens patriae authority of the state, i.e., in an attempt to treat the patient's mental condition, or whether it only applies to those procedures generally recognized and accepted as treatment modalities. The problem here is that the arts of rehabilitation and treatment are in a fairly primitive state.[124] For example, even trained personnel cannot accurately determine the most effective treatment in each instance.[125] Indeed, there is a growing skepticism of the mental health profession's ability to diagnose, treat, or even define various forms of mental illness.[126] There is also the predicament of the patient with a condition which is found not to be responsive to any of the traditional techniques. Thus, the range of available treatment will often be presented in the context of what may be considered experimental treatment and rehabilitation techniques.

However, some states allow involuntary commitment only if the individual is dangerous to himself or to others. The trend seems to be in the direction of requiring this standard as the prerequisite to involuntary commitment.[127] It would seem that such patients would maintain the ability to make treatment decisions.[128]

Moreover, what is the situation of the voluntary mental patient? It may be argued that such a patient has the legal right to make his own decisions concerning treatment. If he refuses to consent to recommended therapy, the facility may simply expel him unless the

legal standards for an involuntary commitment proceeding can be met. The practical application of this principle may be difficult, since for many institutionalized mental patients the option of release is not a valid alternative, so they may often be "forced" to give their consent to a procedure as an involuntary patient. Nevertheless, this does not change the premise that the ability to give or withhold consent is theirs.

Another view of this situation holds that, when a person is voluntarily committed, he cedes to his custodians all decisions concerning treatment during that confinement.[129] There are numerous difficulties with this. Again, the question arises as to whether this only is meant to include treatment within the bounds of generally accepted procedures, or whether experimental therapies are also encompassed. Next is the problem of withdrawal of consent. Does not the right to consent always imply the right to revoke? Although the patient may have impliedly consented to treatment upon commitment, can he not reverse his decision when later confronted with a particular therapy? However, permitting this may result in no effective treatment at all, thereby frustrating the purpose of voluntary commitment. Finally, most voluntary commitments are voluntary only in that a parent or guardian (usually in these cases a state agency) volunteers his child or ward to be institutionalized. Therefore, the actual patient has not chosen to be placed in the facility, and cannot be said to have personally consented to treatment. However, this situation appears to be changing, as several cases have held that minors may not be "voluntarily" committed to an institution without due process guidelines

being observed.[130]

Indeed, the entire distinction between voluntary and involuntary hospitalization is often murky. The majority of voluntary admittees enter "voluntarily" only under the threat of involuntary commitment, so that the situation actually involves substantial elements of coercion.[131] For example, in Massachusetts, most voluntary patients in institutions for the mentally ill are admitted as "conditional voluntary" patients.[132] This means that the patient must give three days notice to the superintendent of his intention to withdraw from the facility. However, if, during this time, the superintendent petitions the court to order the patient's involuntary commitment, the patient will remain institutionalized until a hearing on the matter is held.[133]

Yet there are indications that, for the more severe and intrusive behavior modification techniques, more protective consent mechanisms are legally required, regardless of whether the institution views the procedure as therapeutic and beneficial for the patient. The more the procedure is drastic and violative of self-determination, controversial and experimental, and seems akin to punishment, the more likely it is that these special requirements will arise.

In Kaimowitz,[134] the court held that the performance of psychosurgery on an involuntarily committed mental patient would violate his constitutional rights. The court noted that psychosurgery is "irreversible and intrusive, often leads to the blunting of emotions . . . and limits the ability to generate new ideas." In addition, the court noted that the surgery was experimental, posed unknown risks, and was not even known to be beneficial. Under these circumstances,

although the surgery was recommended as the only available alternative which could possibly control the patient's hostility and aggressiveness; thereby giving him what was considered his only possibility of release from the facility, it was found that the procedure could not be performed in that the patient's consent was a necessary prerequisite.

In Mackey v. Procunier,[135] the plaintiff, a prisoner, alleged that he consented to electroshock therapy as a behavior modification technique. Instead of receiving this therapy, he was given succinylcholine, a drug generally used as an adjunct to electroshock and given while the patient is unconscious. Succinycholine is a terrifying drug that stops the patient's breathing and produces feelings of imminent death. The administration of the drug was part of an experimental design to test aversive therapy. The court held that proof of the administration of this particular experimental process without the patient's consent could "raise serious constitutional questions respecting cruel and unusual punishment or impermissible tinkering with the mental processes."[136]

Knecht v. Gillman[137] deals with the administration of the drug apomorphine to two prisoner-residents of the Iowa Security Medical Facility. The vomit-inducing drug was used on unconsenting patients as part of an aversive conditioning program for individuals with minor behavioral problems. Administration of apomorphine without informed consent was found to violate the patients' constitutional rights, and its administration was enjoined except with the written consent from the participant which could be withdrawn at any time.

The court in the recent case of Scott v. Plante[138] found that there are numerous constitutional deprivations which may accompany the administration, without his consent and against his will, of psychotherapeutic substances to a patient confined in a state mental institution. First, the involuntary administration of drugs which affect the mental processes could amount, under an appropriate set of facts, to an interference with the patient's rights under the First Amendment. Furthermore, although the patient under consideration may have been properly commitable, he had never been adjudicated an incompetent who would be incapable of giving informed consent to medical treatment. Therefore, due process would require, in the absence of an emergency, that some form of notice and opportunity, to be heard be given to the patient or to someone standing in loco parentis to him before he could be subjected to such treatment. In addition, under certain conditions, such a claim could raise an Eighth Amendment issue respecting cruel and unusual punishment. Finally, a fourth possible constitutional deprivation might be an invasion of the patient's right to bodily privacy. Accordingly, the court held that the forced administration of drugs states a valid cause of action.

Similarly, the case of New York Health and Hospitals Corporation v. Stein[139] concerned an involuntarily committed mental patient's refusal to consent to electroshock therapy. The New York City Health and Hospitals Corporation and the director of the institution applied to the court for permission to administer the therapy without the

patient's consent. Although the court took note of the possibility that, without this treatment, the patient's condition might become irreversible, the court seemed even more concerned with the fact that electroshock therapy is "the subject of great controversy within the psychiatric profession, both as to its efficacy, and as to its dangers."[140] The court concluded that, while the patient was sufficiently mentally ill to require further retention, she still had the requisite ability to consent or withhold consent to electroshock therapy, regardless of whether the court or others viewing the situation objectively would agree with her decision. Therefore, the application was denied.

The requirement of patient consent prior to the provision of shock therapy has also been found by courts in Mitchell v. Robinson,[141] Wilson v. Lehman,[142] and Aiken v. Clary.[143]

Recently, a number of states have decided to deal with this situation by passing applicable statutes which require consent before the administration of particularly intrusive procedures. The most frequently regulated procedures are psychosurgery and electroconvulsive therapy.[144] Some states require informed consent prior to the administration of experimental drugs and other experimental procedures.[145]

However, many of those states which specifically require consent to these procedures also make allowances for the application of proxy consent by relatives, a guardian, or a court,[146] while others even allow these consent requirements to be overridden by the director of the mental institution. For example, Massachusetts requires the patient's consent to electroconvulsive therapy unless the superintendent

determines that there is "good cause" for the therapy and the patient's guardian or nearest relative consents.[147] There are a few cases which permit this as well.

Thus, in Farber v. Olkon,[148] the court found that the consent of the parent of an institutionalized adult child to shock therapy was legally sufficient..[149] Again, in Anonymous v. State, the consent of the father to shock therapy on his institutionalized child was upheld, even though the patient was thirty-four years old and had never been adjudged incompetent. Even the consent to shock treatment of one spouse for another who had not been declared legally incompetent had been found to be valid.[150]

The recent decision in Price v. Sheppard[151] takes a more complex view of the issue of consent than that exhibited in the previous cases. In this case, a minor was involuntarily committed to a mental institution, where his condition was diagnosed as simple schizophrenia. He was treated with tranquilizing and antidepressant medications, but apparently failed to respond and was instead aggressive and assaultive to the staff and other patients. His physician at the facility prescribed electroshock therapy, and sought the consent of the patient's mother to the procedure. Although the mother refused to give her consent, a series of twenty electroshock treatments was administered to the patient. An action was filed claiming, that the administration of shock therapy to an involuntarily committed minor patient without the consent of the minor's guardian violated his right to be free from cruel and unusual punishment and his right of privacy. The court

quickly dismissed the Eighth Amendment ground, stating that the electro-shock therapy served the legitimate purpose of treatment, rather than being used as a deterrent or to reprimand the individual, so that the cruel and unusual punishment clause was inapplicable.

However, the court had more trouble with the issue of the right of privacy. Defining the concept as the right to conduct one's life free from governmental intrusion, it nevertheless stated that this was not an absolute right, and must therefore give way to certain legitimate and important state interests. The balancing process involved here was seen as turning on "the impact of the decision on the life of the individual. As the impact increases, so must the importance of the state's interest."[152] In addition, the means utilized in serving this interest must, in light of the alternatives, be the least intrusive.[153] In applying this principle to the situation under consideration, the court determined that the impact of the decision as *to* whether the patient will undergo psychiatric treatment is enormous, since the result may be the alteration of the patient's personality. The state's interest involved in assuming the decision is in the performance of its parens patriae function, or the fulfilling of its duty to protect the well-being of its citizens "who are incapable of so acting for themselves."[154] The court concluded that, if this state interest is sufficiently important to allow it to deprive an individual of his physical liberty, it followed that it would be important enough for the state to assume the treatment decision, as long as the means chosen was necessary and reasonable under the circumstances of a particular

patient's case.

Yet while the court upheld the right of the state to administer treatment to an involuntarily committed mental patient without the consent of the patient or his guardian, it nevertheless declined to leave this decision solely within the discretion of institutional personnel when it involved the imposition of the more intrusive forms of treatment. Therefore, the court mandated that, in future cases, if the patient is incompetent to give consent or refuses consent or his guardian refuses to consent, before more intrusive forms of treatment may be utilized, the medical director of the institution must petition the court for an order authorizing treatment. A guardian ad litem is to be appointed to represent the interests of the patient, and during an adversary proceeding, the court is to determine the necessity and resonableness of the prescribed treatment. In making this determination, the decision stated that the patient's need for treatment should be balanced against the intrusiveness of the procedure, and included a list of six factors to be considered in this determination:

> (1) The extent and duration of changes in behavior patterns and mental activity effected by the treatment.
>
> (2) The risks of adverse side effects.
>
> (3) The experimental nature of the treatment.
>
> (4) Its acceptance by the medical community of this state.
>
> (5) The extent of intrusion into the patient's body and the pain connected with the treatment.
>
> (6) The patient's ability to competently determine for himself whether the treatment is desirable.[155]

The court did not clearly establish how one would determine which forms of treatment are so intrusive as to require this procedural hearing. It did, however, state that the use of mild tranquilizers or those therapies requiring the cooperation of the patient would certainly not fall within this category, while psychosurgery and electroshock therapy would definitely be included.

Therefore, even though the court in Price permits the administration of electroshock therapy without the patient's consent, it nevertheless requires a detailed and elaborate system of review, and authorizes the use of this procedure only with the proxy consent of a court. Significantly, in making its authorization decision, one of the elements to be considered by a court is the experimental nature of the procedure. Accordingly, it seems that the more experimental the proposed treatment, the more likely it is that the individual's privacy right will outweigh the state's interest in providing treatment, so that the state, or court, would not have the authority to authorize its administration.

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The court in Wyatt v. Stickney attempted to resolve the dilemma in this area. This important case dealt with a class action on behalf of patients involuntarily confined in institutions for the mentally ill and mentally retarded. The court found that these individuals have a constitutional right to treatment, and furthermore that conditions in the respective institutions were such as to deprive the patients of this right. Accordingly, the court issued sets of

minimum constitutional standards for the adequate treatment of both the mentally ill and mentally retarded.

Included in these standards were provisions which state that patients of institutions for the mentally ill have "a right not to be subjected to treatment procedures such as lobotomy, electroconvulsive treatment, adversive reinforcement conditioning 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."[157] In addition, patients 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."[158] It is also necessary for the proposed research *to* have first been reviewed and approved by the institution's Human Rights Committee. It is unclear from the court's opinion whether this provision refers to therapeutic as well as non-therapeutic experimentation.

In regard to the institutionalized mentally retarded, the court formulated slightly different standards. Behavior modification programs involving the use of noxious or aversive stimuli are to be reviewed and approved by the institution's Human Rights Committee and are to be conducted only with the express and informed consent of the resident, if he is able to give such consent, and of his guardian or next-of-kin, after opportunities for consultation with independent specialists and legal counsel. The same procedure must be followed for unusual

or hazardous treatment procedures. Electric shack treatment is considered a research technique and is allowed only "in extraordinary circumstances to prevent self-mutilation . . . and only after alternative techniques have failed."[159] The provision regarding experimental research is the same as for the mentally ill.

Thus, the court in Wyatt recognized that certain behavior modification procedures may be deemed so offensive, frightening, or risky that their use should be restricted by requiring the patient's informed consent.[160] Although there are some provisions for proxy consent, the court nevertheless took steps to provide added layers of protection by requiring the opportunity for outside, independent consultation, as well as the involvement of a Human Rights Committee.

It seems that the cost of some therapies is considered too great, while others are considered acceptable. The problem comes in determining the boundaries of the two.[161] In deciding whether a particular procedure is so intrusive or coercive as to require these added protections, one commentator has suggested the following guidelines:

1) The extent and duration of changes in behavior patterns and mental activity effected by the therapy - the degree of change in personality.

2) The side effects associated with the therapy.

3) The extent to which the therapy requires physical intrusion into the inmate's body.

4) The degree of pain, if any, associated with the therapy.

5) The extent to which an uncooperative inmate can avoid the effects of the therapy.[162]

Thus, informed consent is not a unitary concept. It will vary depending on the nature of the procedure for which it is requested. The more potentially harmful, intrusive, or experimental the procedure, the stricter and more numerous must be the safeguards to protect the individual. Thus, there is precedent for the scrutiny of potentially hazardous or intrusive "treatments" and for an attempt to delimit the conditions under which informed consent is obtained. Since each state has differing statutes and case law concerning the use of behavioral techniques, it is impossible to generalize as to the limitations which may be imposed. However, it is clear that there is a trend toward increased regulation and imposition of protection in this area.

NON-THERAPEUTIC EXPERIMENTATION

The earlier analysis of capacity to consent provides the basis for a discussion of non-therapeutic experimentation.[163] To briefly summarize, since non-therapeutic experimentation is, by definition, not for the benefit of the subject, no proxy consent is theoretically permissible. Therefore, unless the particular patient is legally competent to give informed consent, it would seem that there could be no non-therapeutic experimentation on institutionalized mental patients.

Thus, in Frazier v. Levi,[164] a mother, acting as guardian, sought a sterilization for her adult pregnant daughter, who had a mental age of six years, was sexually permissive, and had two retarded illegitimate children. Although the mother maintained that she was no longer financially and emotionally able to support any more of her daughter's children and that the operation would therefore be to everyone's benefit, she admitted that the operation was not medically necessary. The court refused to authorize the procedure and held that the daughter lacked the mental capacity to consent to the operation and that, without consent, she could not be deprived of her legal rights.[165]

Similarly, in In re Richardson,[166] an action was brought by the parents of a minor retarded child to permit the donation of one of the child's kidneys for transplantation into the child's older sister. The mother, father, and older sister all consented to the procedure, but the mentally retarded child, having a mental age of a three- or

four-year old, was not capable of giving legal consent. The court defined its duties to be the protection and promotion of the ultimate best interest of the child. In particular, it determined that the minor had a right to be free from bodily intrusion to the extent of the loss of an organ unless it was specifically found that the removal of the kidney was in the child's best interest. Rejecting a claim that the child would benefit by a successful operation because, when his mother and father die, his older sister would be able to take care of him, the majority found that the operation would clearly be against the child's best interest, and that therefore neither his parents nor the courts could authorize the surgery.[167]

However, there are circumstances under which non-therapeutic procedures are performed on incompetents. These situations also involve the transplantation of organs and sterilization.

In Strunk v. Strunk,[168] the mother of an incompetent ward of the state petitioned the court of equity to permit the removal of one of his kidneys for transplantation into his twenty-eight-year-old brother. The potential donor was twenty-seven years of age, but had a mental age of approximately six years and had been previously committed to a state institution for the feeble-minded. All other members of the family and the Department of Mental Health had consented to the operation, but the donor was considered incompetent to give legally valid consent. A guardian ad litem had been appointed to contest the state's authority to allow the operation at every stage of the proceeding.

The court placed controlling emphasis on the psychiatric testimony. A psychiatrist who examined the incompent determined that, in his

opinion, the death of the brother would have "an extremely traumatic effect" on the potential donor. It was also argued that, while mental incompetents have difficulty establishing a sense of identity with other people, they nevertheless have a need for close intimacy, so that the donor's identification with his brother, who was his family tie, made it vital to the incompetent's improvement that his brother survive.

Even though the transplant, from the donor's point of view, was physically non-beneficial, the Kentucky Court of Appeals implicitly and summarily equated benefit in the constitutional sense with a vague showing that possible psychological detriment might be avoided. The court concluded that, while a parent did not have the authority to consent to such an operation, except when the life of the incompetent himself was in danger, the court did have the ability to do so by exercising its equitable powers under the doctrine of parens patriae.[169]

Another case following this mold is Howard v. Fulton-DeKalb Hospital Authority.[170] In this case, a mother was suffering from chronic renal disease and the only person medically suitable for transplant purposes was her fifteen-year-old "moderately retarded" daughter. Both mother and daughter consented to the operation. However, the court found that, due to her minority and mental retardation, the daughter's consent was not legally valid. It also recognized the duty of the court, through its function as parens patriae, to independently review the circumstances of the case to assure that the best interests of the child were being protected, regardless of the existence of the mother's consent. However, this court also paid

special attention to the psychiatric testimony, and decided that the kidney transplant should be allowed to proceed so as to protect the daughter from "the physical deprivation and emotional shock" which would result from the loss of her mother.

However, the factors involved in this type of situation, including the fact that a specific life will be saved in exchange for the imposition of a minimal risk on the incompetent donor, as well as the concept of family unity in making determinations of this type, make this line of cases somewhat inapplicable to other instances of non-therapeutic procedures on incompetents.[171]

Analogy can also be made to the compulsory sterilization of incompetents for non-therapeutic purposes. At present, twenty-three states have laws providing for some form of sterilization of persons suffering from mental disorders.[172] All of these laws provide for sterilization of persons in state institutions. The statutes vary in their provisions. Most permit the superintendent of the institution in which the individual is confined to begin the proceeding. Some also permit relatives, guardians, physicians, state welfare boards or others to initiate the proceeding. Most of the statutes provide for notice to the person who is to be sterilized and usually to his relatives, as well as for a hearing before an administrative agency or a court. Some states (Montana, Connecticut, Maine, Minnesota, North Carolina, and West Virginia) have "modernized" their compulsory sterilization laws by introducing new procedural safeguards. Some of these states have added a requirement that the candidate for

sterilization, or his relatives or guardian, consent in writing to the procedure; others guarantee that the person to be sterilized have a hearing, with the right to counsel at all stages of the proceedings.[173] None of the new laws, however, provide for a review committee.

The validity of such statutes was upheld by the Supreme Court in Buck v. Bell.[174] The issue was the constitutionality of a Virginia statute authorizing the sterilization of patients in state institutions who were afflicted with hereditary forms of mental illness and mental retardation. The statute was premised on the assumption that the state was supporting in institutions "many defective persons who if . . . discharged would become a menance but if incapable of procreating might be discharged with safety and become self-supporting with benefit to themselves and to society."[175] The Court accepted the trial court's finding that "Carrie Buck 'is the probable potential parent of socially inadequate offspring.'"[176] Analogizing sterilization to compulsory vaccination, the Court held that the means chosen were reasonably related to a permissible state purpose, preventing society from being "swamped with incompetence."[177] In the closing words of Justice Holmes: "Three generations of imbeciles are enough."[178] The Buck case has never been specifically overturned, so that it is still the law today. However, recent developments in both law, concerning the right to privacy, particularly as it involves marriage and procreation, and genetics, which opens to question the scientific base of the decision, make it unlikely that the same controversy would be decided in a similar manner at the present time.[179]

In the only other sterilization case heard by the Supreme Court since Buck, Skinner v. Oklahoma,[180] procreation was determined to be a fundamental interest. Therefore, in order to justify the sterilization statutes, a state interest of sufficient importance to subordinate the individual's interest must be found. Two legitimate state interests are generally considered to be furthered by such legislation. The first is eugenic, or the interest of the state in avoiding another generation of mentally deficient people and, more generally, in improving the gene pool of the population,[181] although, as mentioned above, this justification is becoming viewed with suspicion among the scientific community. The second is the state's interest in providing children with fit and capable parents.[182]

In the case of Cook v. Oregon,[183] the plaintiff appealed from a sterilization order by the State Board of Social Protection. The court determined that the seventeen-year-old girl in question, who was both mentally ill and mentally retarded, would not be able to provide the parental guidance and judgment which a child requires. Inability of an individual to provide a proper environment for a child was considered to be an adequate reason for the state to require sterilization. Therefore, on that basis, the court affirmed the sterilization order.[184]

Thus, there may be situations in which a procedure that is admittedly non-therapeutic may be carried out, without the consent of a competent institutionalized individual and regardless of the common law inability to obtain valid consent on behalf of an incompetent. However, this exception is limited to those circumstances in which a

valid state interest sufficiently outweighs the rights of the individual so as to justify use of the police power in this manner. Thus, its application is admittedly narrow.-

The most notorious case of non-therapeutic experimentation on institutionalized individuals took place in New York's Willowbrook State School.[185] The crowding and unsanitary conditions of the facility, coupled with poor personal hygiene, caused an epidemic of fecally-borne infectious hepatitis. Hepatitis is frequently protracted and debilitating and sometimes fatal to the victim. Nearly everyone at the school was infected, so that new arrivals would probably have contracted the virus within six months.

Physicians at the institution worked at finding a vaccine for this particular strain of infectious hepatitis. They isolated strains of the virus, then with parental consent, infected several retarded children newly admitted to the school. Many of the children became quite ill. All of them risked serious illness. However, as a result of these efforts, a vaccine for the Willowbrook virus was developed. Ironically, an expert in the field of mental retardation, Dr. Richard Koch, has noted that the immunization work is "probably the only good thing that's ever come out of the institution."[186]

This experiment was one of the factors which, combined with the general horrible conditions of the facility, led to the filing of the suit in New York State Association for Retarded Children v. Carey.[187] The court found that voluntarily institutionalized mentally retarded individuals have a constitutional right to protection from harm. This is similar to the right to treatment found by the court in Wyatt v.

Stickney.[188] Appropriately, the court approved a detailed consent decree which set up standards and procedures, similar to those in Wyatt, which would serve to ensure the recognition of the residents' right to protection from harm. This was felt to be necessary because "harm can result not only from neglect but from conditions which cause regression or which prevent development of an individual's capabilities."[189] Significantly, the decree absolutely forbids medical experimentation.. In addition, it creates three boards with important functions. The Review Panel will oversee the implementation of standards and procedures mandated in the consent decree, the Consumer Advisory Board will evaluate alleged dehumanizing practices and violations of individual and legal rights, and a Professional Advisory Board will give advice on professional programs and plans, budget requests, and objectives, as well as investigate alleged violations.

Presently pending in Michigan is a case which may decide many of the issues in this area. Jobes v. Michigan Department of Mental Health[190] involves a suit brought to prevent a study which hypothesizes zinc deficiency as a cause of behavior and intellectual problems. This experiment was to be carried out on minor residents of a state mental institution. Plaintiffs allege that parental or court consent is valid only if there is a direct therapeutic benefit to the child-subject, which is absent in the study under consideration. Thus, the case is concerned with, under what circumstances and from whom, one may obtain legally binding informed consent to non-therapeutic experimentation on an incompetent mental patient.

In August 1975, the Michigan Department of Mental Health promulgated administrative rules that deal with many of the points raised in the case. Specifically the regulations require that any experiment which places subjects at physical, psychological or social risk must be reviewed and approved by a committee. They allow participation in an experiment which places a subject at risk only if the participant is eighteen years of age or over and competent. In addition, the subject must give his express and informed consent, and this is in turn reviewed by a consent committee. Based on these regulations, plaintiffs have moved for a summary judgment in the case on the issue of research and experimentation.

CONCLUSIONS AND RECOMMENDATIONS

1) In acknowledgement of the problems pertaining specifically to institutionalized mental patients, the law has scrutinized consent with special care, but in general has permitted either resident or substitute consent to procedures after ascertaining that reasonable efforts have been undertaken to ensure capacity and voluntariness.

2) Consent is even more carefully analyzed and protected when the procedure to be employed is particularly hazardous and/or intrusive. Yet sound public policy dictates that standards for consent be formulated which balance the threats to the obtaining of informed consent against the equally serious threat of paternalism.

3) There seems to be no legal reason for precluding institutionalized mental patients from participating in therapeutic experimentation.[191] A competent patient could consent for his own treatment, while proxy consent by a guardian would be appropriate for an incompetent individual.

4) Unless the illness is serious and any conventional and/or less intrusive or less hazardous treatments have either already been exhausted or are not likely to help, the risks should not be great.

5) A problem arises concerning patients who are incompetent in the practical, as opposed to legal, sense of the term, as discussed earlier.[192] A possible solution to this dilemma has been offered by one commentator, who suggested that persons incapable of giving consent should be treated with the least intrusive therapies until they learn "to appreciate the value of treatment and those who offer it."[193] Another possibility would be to bring all people falling

within this category to court for a competency hearing. If found incompetent, a guardian could then be appointed. Problems with this approach include the fact that the procedure would be burdensome and time-consuming. In addition, it may be an instance of "overkill." Does one really want to subject the patient to the stigma of the incompetency label, as well as the removal of many of his rights, under these circumstances? Beyond that, many of these individuals would probably not meet the standards necessary for declaring someone legally incompetent. Persons who are mentally handicapped may have impaired functioning in some areas but be perfectly functional and competent in others.

Another way of approaching the predicament would be to, on a procedure-by-procedure basis, classify legally competent patients who are potential subjects into two groups: those having the capacity to give consent and those not having that capacity either because of an inability to communicate or because of their illness. Those in the second group would be subjects in the experiment if a neutral decision-maker decided it was in their best interest.

In determining which patients are members of which category, one could define the requisite competency in a number of ways. For example, one could require the reviewer to determine whether the patient's decision was one which a reasonably competent person would have made.[194] Competency could be defined as the capacity to understand the nature of the procedure, to weigh the risks and benefits, and to reach a decision for rational reasons.[195] The reviewer could be

obliged to honor the patient's decision so long as he had a sufficient understanding of the nature of the procedure, its risks and benefits, and the possible alternatives.[196] Alternatively, competency could simply be defined as the ability to understand and knowingly act upon the information provided.[197]

The goal in choosing a standard of competency is to enhance self-autonomy and guard against paternalism, while simultaneously providing for added protection. in determining the best interest of the patient when necessary. Any determination of what personalities and traits are considered worthy of protection is highly subjective. Unfortunately, too little attention has been focused on this problem to date.

6) It is difficult at this time to make a hard and fast rule about non-therapeutic experimentation based on the law. In general, competent patients may consent to participation.

7) When the need for the information is great, and the risk to the individual participant absolutely minimal, this type of research should probably be permitted with incompetent patients as well, assuming that proxy consent has been obtained. Examples of procedures included in this category are the taking of blood and the collection of urine specimens. However, the refusal of an incompetent person to involvement in the experiment should be binding, regardless of either his reasons for the decision or the wishes of the patient’s guardian.

8) Non-therapeutic research is justified only when the condition under investigation is related to mental diability and cannot be obtained from non-institutionalized subjects.

9) Institutions often seem to impute constraints on the rights of patients which are simply not found in the law. Thus, in that the institutional setting always carries a serious potential for abuse of the rights of residents, a system of review should be developed to make sure that the above guidelines are being followed.

Initially, there should be a review of the experimental procedure. In addition, there should be a review of the consent itself. This would ensure the competent and voluntary character of the consent. The closer that the institution came to meeting the constitutional minimum standard of Wyatt v. Stickney, the more likely it would be that, as concerns the effect of institutionalization on a patient's competence and voluntariness, the consent would be found to be valid. For adjudicatively-found incompetent patient, this would review the best interest determination made by his guardian in his proxy consent decision. For the practially-incompetent patient, this would consist, not of a review of a consent decision by the patient or guardian, but of an original determination of the best interest of the patient. The categorizing of the patient as a member of this group could be made either at this level or, as an added means of protection, by an earlier determination by a separate review mechanism.

10) These review mechanisms may take several different forms. The director or superintendent of the facility could perform this function. However, there may be a possible conflict of interest problem here.

> A problem may also be presented by the possibility of role conflict arising from the entrusting of the notice and explanation of right function to the same agency which undertakes to perform the therapeutic function.[198]

Instead, a committee structure could be used, either totally independent of the institution or one composed partly of institutional administration and staff and partly of independent people. The committee could be patterned after the Human Rights Committee provided for in Wyatt. Alternatively, this review could be done by an agency specially created to protect mental patients' rights. Finally, there could be court review of the adequacy of these procedures. However, this last procedure might prove very costly and cumbersome, so that it might be best to reserve it for those cases in which particularly coercive or intrusive experiments are being considered.

REFERENCES

1. See, section II, supra at 89.

2. This section is concerned with the problem of informed consent to experimentation by those institutionalized individuals considered mentally infirm, including the mentally ill, the mentally retarded the emotionally disturbed, the psychotic, and the senile. However, the important issues are common to all of these categories, and since the majority of the law in this area deals specifically with the mentally ill and/or the mentally retarded, we will throughout the section refer to these particular groups.

3. See, Silent Minority, President's Committee on Mental Retardation, DHEW Pub. No. (OHD) 74-21002, at 10.

4. Mental Retardation Source Book, Department of Health, Education and Welfare, 15, 19 (1973).

5. Ennis and Siegel, The Rights of Mental Patients, 11 (1973).

6. See, e.g., Dybwad, Challenges in Mental Retardation, 21 (1964); Herr, Civil Rights, Uncivil Asylums and the Retarded, 43 Cinn. L. Rev. 679 (1974).

7. See, Comment, Civil Restraint, Mental Illness, and the Right to Treatment, 77 Yale L.J. 87, 88 (1967).

8. See, e.g., Harter, Mental Age, IQ and Motivational Factors in the Discrimination Learning Set Performance of Normal and Retarded Children, 5 J. Experimental Child Psych. 123 (1967); Iscoe and McCann, The Perception of an Emotional Continuum by Older and Younger Mental Retardates, 1 J. Personality & Social Psych. 383 (1965); Lyle, The

Effect of an Institutional Environment upon the Verbal Development of Imbecile Children, 3 J. Mental Deficiency Research 122 (1959).

9. Bloomberg, A Proposal for A Community Based Hospital as a Branch of a State Hospital, 116 Am. J. Psych. 814 (1960).

10. E.g., Blatt and Kaplan, Christmas in Purgatory: A Photographic Essay on Mental Retardation (1966).

11. Comment, Behavior Modification and Other Legal Imbroglios of Human Experimentation, 52 J. Urban L. 155, 157 (1974).

12. See, Ritts, A Physician's View of Informed Consent in Human Experimentation, 36 Fordham L. Rev. 631 (1968).

13. Experimentation, The Real Paper, Aug. 7, 1974, at 6.

14. Wecht, Medical, Legal, and Moral Considerations in Human Experiments Involving Minors and Incompetent Adults, J. Legal Med., Feb. 1976, at 27, 30.

15. Hearings on Quality of Health Care - Human Experimentation Before the Subcomm. on Health of the Senate Comm. on Labor & Public Welfare, 93d Cong., 1st Sess., pt. 1, at 42-44 (1973).

16. Id. at 111-113.

17. Id. at 66, 94-98.

18. Id. at 109.

19. Id. at 94.

20. Id. at 99-100.

21. Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 105 N.E. 92, 93 (1914). See, Prosser, Law of Torts 34 (4th ed. 1971).

22. E.g., Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960);

Bang v. Charles T. Miller Hosp., 251 Minn. 427, 88 N.W.2d 186 (1958).

23. Dade Co., 11th Circuit Ct., Fla., No. 71-12687 (July 2, 1971).

24. Accord Erickson v. Dilgard, 44 Misc. 2d 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962). See, Cantor, A Patient's Decision to Decline Life-Saving Medical Treatment: Bodily Integrity versus the Preservation of Life, 26 Rutgers L. Rev. 228 (1973); Note, Compulsory Medical Treatment: The State's Interest Re-evaluated, 51 Minn. L. Rev. 293 (1966); Note, Informed Consent and the Dying Patient, 83 Yale L.J. 1632 (1974).

25. Shapiro, Legislating the Control of Behavior Control: Autonomy and the Coercive Use of Organic Therapies, 47 So. Calif. L. Rev. 237, 308-309 (1974).

26. Schoenfeld, Human Rights for the Mentally Retarded: Their Recognition by the Providers of Service, 4 Human Rights 31 (1974), in which he discusses the 1971 United Nations Declaration of General and Special Rights of the Mentally Retarded, in which the international community recognized the principle that the mentally retarded have the same rights as other citizens of the same country and age.

27. See, Wyatt v. Stickney, 344 F. Supp. 373, 387, 399 (M.D. Ala. 1972), aff'd sub nom. Wyatt v. Aderholt, 503 F.2d 1305 (5th Cir. 1974): "No person shall be presumed mentally incompetent solely by reason of his admission or commitment to the institution." See, also Davis v. Watkins, 384 F. Supp. 1196, 1206 (N.D. Ohio 1974).

28. Dist. Ct. Neb., Civil No. 72-L-299 (Aug. 6, 1975), consent order approved by court (Oct. 3, 1975).

29. 377 F. Supp. 896 (D. Conn. 1974), supplemental decision, 386

F. Supp. 1245 (D. Conn. 1975).

30. 377 F. Supp. 1361 (E.D. Pa. 1974).

31. 62 Penn. Dist. & Cty. Rpts. 2d 619 (1972).

32. Cal. Welfare and Inst. Code § 5331 (West Supp. 1974).

33. Minn. Stat. Ann. § 253A.18.1 (1971).

34. Mich. Stat. Ann. § 14-800 (702) (1974).

35. Mass. Gen. Laws Ann. ch. 123 § 25 (Supp. 1972).

36. N.Y. Mental Hygiene Law § 29.03 (McKinney Supp. 1973).

37. Okla. Stats. Ann. ch. 43A § 64.

38. S.C. Code art. 5 § 32-997.

39. S.D. Stats. ch. 27-12-15.

40. Tenn. Code Ann. § 33-306(e) (Cum. Supp. 1975).

41. S.C. Code art. 5 § 32-997.

42. S.D. Stats. ch. 27-4-22.1.

43. N.M. Stats. Ann. art. VI § 3-6-3.

44. La. Rev. Stat. 28:171.

45. Kent. Stat. ch. 202.272.

46. Alaska Stat. § 47.30.150 (Cum. Supp. 1970).

47. Ga. Code Ann. § 88-502.7 (1971).

48. Ann. Code Md. art. 59 §§ 50-51 (1972).

49. N.Y. Mental Hygiene Law § 15.01 (McKinney Supp. 1973).

50. S.C. Code art. 5 § 32-997.

51. La. Rev. Stat. 28:171.

52. Kent. Stat. ch. 202.272.

53. Alaska Stat. § 47.30.150 (Cum. Supp. 1970).

54. S.C. Code art. 5 § 32-997.

55. Id.

56. Ga. Code Ann. § 113-201, 202 (1971).

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

58. See, generally Allen, Ferster and Weihoffen, Mental Impairment and Legal Incompetency (1968).

59. W. Va. Code § 27-5-4 (Supp. 1973).

60. Wis. Stat. § 5l.005(2) (1957).

61. Ala. Code tit. 17 § 15; tit. 1 § 1-2; tit. 9 § 43.

62. Ark. Stat. tit. 3 § 101.

63. Maine Rev. Stat. Ann. tit. 19 § 32 (1965).

64. N.J. Stats. Ann. ch. 19 § 4-1; ch. 3A § 3-1.

65. Allen, et al., supra note 58, at 46-49.

66. It should be emphasized that, throughout this section, the term "therapeutic" experimentation is used according to the manner in which it was defined in section I, supra at 3. Therefore, although it designates procedures that may be of direct benefit to the subject, the intent of the investigator is not always controlling. Where the risks to the subject are very great, the procedure is considered non-therapeutic regardless of the motivation of the researcher and the subject.

67. See, discussion of proxy consent, text accompanying notes 89-93 infra.

68. Id.

69. Goffman, Asylums, Essays on the Social Situation of Mental

Patients and Other Inmates (1962).

70: Id. at 7. See, Kramer, The Subtle Subversion of Patients' Rights by Hospital Staff Members, 25 Hosp. & Community Psychiat. 475 (1974).

71. Fletcher, Human Experimentation - Ethics in the Consent Situation, in Medical Progress and the Law 75-76 (C. Havighurst ed. 1969).

72. Kaimowitz, Patient or Victim, 11 Trial, Nov./Dec. 1975, at 14, 15.

73. A Report on Involuntary Commitment, Citizens Commission on Human Rights 2 (1975).

74. Civ. No. 73-19434-AW (Cir. Ct. Wayne County, Mich., July 10, 1973).

75. Amended Petition and Complaint for the Petitioners - Plaintiffs, Kaimowitz v. Department of Mental Health at 7 (1973).

76. Kaimowitz v. Department of Mental Health, at 4 n.5.

77. Id. at 6.

78. Id. at 23. For a discussion of the Nuremberg Code and its legal standing, see, section I, supra at 9. For the entire text of the Nuremberg Code, see, Appendix I, infra.

79. There are two unreported cases on psychosurgery which have also considered the issue of informed consent. Medical News, 225 J.A.M.A. 1035, 1036, 1044 (1973). In Virginia, the parents of a patient who engaged in acts of self-mutilation consented to the use of psychosurgery. However, upon learning of the proposed procedure, the Virginia Attorney General's office intervened on behalf of the patient. The court stayed the surgery on the ground of the patient's inability to give consent. The second case was settled before trial. The plaintiff, who had been blinded as a result of a psychosurgical procedure,

recovered a settlement on the ground that she was inadequately informed of the risk in the procedure.

80. Kaimowitz v. Department of Mental Health at 27.

81. Id. at 27-29.

82. Id. at 27.

83. Id. at 29.

84. Id. at 27.

85. Annas and Glantz, Psychosurgery: The Law's Response, 54 B.U.L. Rev. 249, 263 (1974).

86. Changing Patterns in Residential Services for the Mentally Retarded 20 (Kugel and Wolfensberger eds. 1969).

87. Bomstein, The Forcible Administration of Drugs to Prisoners and Mental Patients, Clearinghouse Rev., Oct. 1975, at 379, 380.

88. See, e.g., Dershowitz, Psychiatry in the Legal Process: A Knife That Cuts Both Ways, 4 Trial, Feb./March, 1968, at 2932; Siegel, The Justifications for Medical Commitment - Real or Illusory, 6 Wake Forest Intra. L. Rev. 21, 31-33 (1969).

89. From Roman law comes the idea that in some circumstances the state should relate to the citizen as the parent to his child. Known as the doctrine of parens patriae, this concept is firmly recognized in Anglo-American law. It gives the sovereign both the right and the duty to protect the persons and property of those who are unable to care for themselves because of minority or mental illness.

Ross, Commitment of the Mentally Ill: Problems of Law and Policy, 57 Mich. L. Rev. 945, 956-957 (1959).

90. See, Hawaii v. Standard Oil Co., 405 U.S. 251, 257 (1972) quoting W. Blackstone, Commentaries 47.

91. See, section II, supra at 107.

92. See, Allen, Legal Rights of the Disabled and Disadvantaged 23 (1969).

93. Allen, The Retarded Citizen: Victim of Legal and Mental Deficiency, 2 U. Md. L.F. 4 (1971). Cf., Lewis, McCollum, Schwartz and Grunt, Informed Consent in Pediatric Research, 16 Children 143, 144-145 (1969).

94. For the text of each of these codes, see, Appendix I (Nuremberg), Appendix II (Helsinki), and Appendix III (A.M.A.), infra.

95. See, Comment, Behavior Modification and Other Legal Imbroglios of Human Experimentation, supra note 11, at 167.

96. See, text accompanying notes 21-68 supra.

97. See, Alaska Stat. § 47.30.130 (Cum. Supp. 1970) (consent required for surgery and psychiatric therapies); Conn. Gen. Stat. Ann. § 17-206d (Cum. Supp. 1975) (no medical or surgical procedures, including electro-shock therapy, may be performed without consent); Mich. Stat. Ann. § 14.800(716) (1974) (consent required for non-emergency surgery and electroshock therapy); N.Y. Mental Hygiene Law § 15.03(b)(4) (McKinney Supp. 1974-1975) (consent required for surgery and shock treatment); N.C. Gen. Stat. 2 122-55.6 (1974) (informed consent required for non-emergency surgery and electroshock treatment); Vt. Stat. Ann. tit. 18 § 7708 (1968) (consent required for surgery); Wash. Rev. Code Ann. § 71.05.370(7) (Supp. 1974) (involuntarily detained patient has right to refuse shock treatment and non-emergency surgery).

98. Tenn. Code Ann. 3 33-307 (Cum. Supp. 1974).

99. E.g., Ark. Stat. tit. 82 § 363; Conn. Gen. Stat. Ann. § 17-206d

(Cum. Supp. 1975); Fla. Stats. Ann. ch. 394.459.

100. Alaska Stat. § 47.30.130 (Cum. Supp. 1970).

101. N.J. Stats. Ann. ch. 30 § 4-7 (Supp. 1974).

102. 372 F. Supp. 1196 (D.D.C. 1974).

103. Id. at 1202.

104. Id.

105. 403 F. Supp. 1235 (D.D.C. 1975).

106. Kaiser, Against Sterilization Policy Here, N.Y. Times, Jan. 12, 1976, at 29, col. 2.

107. 368 F. Supp. 1382 (M.D. Ala. 1973).

108. Id. at 1384.

109. Dane Cty. Ct., Branch I, Wis. (Nov. 1974). Cf., Wade v. Bethesda Hosp., 337 F. Supp. 671 (S.D. Ohio 1971); In re M.K.R., 515 S.W.2d 467 (Mo. 1974); In re Kemp, 118 Cal. Rep. 64 (Ct. App. 1974); Holmes v. Powers, 439 S.W.2d 579 (Ky. 1969).

110. See, Krasner and Ullmann, Case Studies in Behavior Modification 1-2 (1965).

111. See, Ayllon, Behavior Modification in Institutional Settings, 17 Ariz. L. Rev. 3 (1975); Kassirer, Behavior Modification for Patients and Prisoners: Constitutional Ramifications of Enforced Therapy, 2 J. Psychiatry & L. 245 (1974).

112. See, text accompanying notes 21-68 supra.

113. 306 F. Supp. 1158 (E.D.N.Y. 1969), rev'd on other grounds, 446 F.2d 65 (2d Cir. 1971), cert. denied, 404 U.S. 985 (1971).

114. 344 Mass. 679, 183 N.E.2d 866 (1962) (dicta).

115. Many of the issues presented in this section are currently being considered in an action pending in Massachusetts. Rogers v. Macht, Civil Action No. 75-1610T.

116. Bomstein, supra note 87, at 383.

117. See, Schwartz, In the Name of Treatment: Autonomy, Civil Commitment, and the Right to Refuse Treatment, 50 Notre Dame Lawyer 808, 817 (1975).

118. Jackson v. Indiana, 406 U.S. 715, 737 (1972).

119. In re Oakes, 8 Law Rep. 122 (Mass. 1845).

120. See, Comment, Wyatt v. Stickney and The Right of Civilly Committed Mental Patients to Adequate Treatment, 86 Harv. L. Rev. 1282, 1289 (1973); Note, The Nascent Right to Treatment, 53 Va. L. Rev. 1134 (1967).

121. Brooks, Law, Psychiatry and the Mental Health System, 877 (1974).

122. 56 Misc. 2d 693, 290 N.Y.S.2d 486 (Ct. Cl. 1968).

123. Id. at 699, 290 N.Y.S.2d at 501.

124. See, Schwitzgebel, The Right to Effective Mental Treatment, 62 Calif. L. Rev. 936 (1974).

125. Crinker, Emerging Concepts of Mental Illness and Models of Treatment: The Medical Point of View, 125 Am. J. Psychiatry 865, 866 (1969).

126. See, e.g., Rosenham, On Being Sane in Insane Places, 179 Science 250 (1973), reprinted in 13 Santa Clara Lawyer 379 (1973).

127. E.g., Suzuki v. Quisenberry, 44 U.S.L.W. 2422 (D. Haw. Feb. 24, 1976); Cal. Welfare & Inst. Code §§ 5008(h), 5300-6, 5350-68 (West 1972); Mass. Gen. Laws Ann. ch. 123 §§ 1-37 (Supp. 1974); N.C. Gen. Stat. §§ 122-58.1-.8 (1974).

128. Developments in the Law - Civil Commitment of the Mentally Ill, 87 Harv. L. Rev. 1190, 1351 (1974).

129. Cf., O'Donoghue v. Riggs, 73 Wash. 2d 814, 820 n.2, 440 P.2d 823, 828 n.2 (1968): "One who enters a hospital as a mentally ill person . . . impliedly consents to the use of such force as may be reasonably necessary to the proper care of the patient."

130. Bartley v. Kremens, Civil No. 72-2272 (E.D. Penn, July 24, 1975); J.L. v. Parham, 44 U.S.L.W. 2421 (M.D. Ga. Feb. 26, 1976).

131. Gilboy and Schmidt, "Voluntary Hospitalization of the Mentally Ill, 66 NW. U.L. Rev. 429 (1971).

132. Materials for Civil Rights Officers, Proposed Draft, Mass. Dept. of Mental Health 7.

133. Mass. Gen. Laws Ann. ch. 123 §§ 10-11 (Supp. 1972).

134. Kaimowitz v. Department of Mental Health, Wayne Co.; Civil NO. 73-19434-AW (July 10, 1973).

135. 477 F.2d 877 (9th Cir. 1973).

136. Id.

137. 488 F.2d 1136 (8th Cir. 1973).

138. Scott v. Plante, 44 U.S.L.W. 2480 (3d Civ. March 29, 1976).

139. 70 Misc. 2d 944, 335 N.Y.S.2d 461 (1972).

140. Id. at 464.

141. 334 S.W.2d 11 (Mo. 1960).

142. 379 S.W.2d 478 (Ct. App. Ky. 1964).

143. 396 S.W.2d 668 (Mo. 1965).

144. See, e.g., statutes included in note 97 supra. See, also Cal.

Welfare & Inst. Code § 5326 (West Supp. 1974).

145. See, Ga. Code Ann. § 88-502.3(a) (1971) (unless consent is given, no treatment which is not recognized as standard psychiatric treatment shall be given); N.Y. Mental Hygiene Law § 15.03(b)(4) (McKinney Supp. 1974-1975) (consent required for experimental drugs or procedures); N.C. Gen. Stat. § 122.55.6 (1974) (treatment involving experimental drugs or procedures shall not be given without informed consent).

146. See, e.g., Ga. Code Ann. § 88-502.3(a) (1971); N.J. Stat. Ann. §§ 30:4-7.1-7.2 (Supp. 1974); N.C. Gen. Stat. § 122-55.6 (1974).

147. Mass. Gen. Laws Ann. ch. 123 § 23 (Supp. 1972). See, ch. 173 § 24 (1973), Idaho Code 379.

148. 40 Cal. 2d 546, 254 P.2d 520 (1953).

149. 17 A.D.2d 495, 236 N.Y.S.2d 88 (1963).

150. Maben v. Rankin, 358 P.2d 681 (Calif. 1961) (husband consenting for wife); Lester v. Aetna Casualty & Surety Co., 240 F.2d 676 (5th Cir. 1957) (wife consenting for husband).

151. 239 N.W.2d 905 (Minn. 1976).

152. Id. at 910.

153. Id.

154. Id. at 911.

155. Id. at 913.

156. 344 F. Supp. 373 and 387 (M.D. Ala. 1972), aff'd sub nom. Wyatt v. Aderholt, 563 F.2d 1305 (5th Cir. 1974).

157. Id. at 380.

158. Id.

159. Id. at 387, 401.

160. See, generally, Wexler, Token and Taboo: Behavior Modification, Token Economies, and the Law, 61 Calif. L. Rev. 81 (1973).

161. Friedman, Legal Regulation of Applied Behavior Analysis in Mental Institutions and Prisons, 17 Ariz. L. Rev. 39, 90 (1975).

162. Note, Conditioning and Other Technologies Used to "Treat?" "Rehabilitate?" "Demolish?" Prisoners and Mental Patients, 45 So. Calif. L. Rev. 616, 659 (1972). See, Note, Advances in Mental Health: A Case for the Right to Refuse Treatment, 48 Temple L.Q. 354, 363 (1975).

163. See, text accompanying notes 21-68 supra.

164. 440 S.W.2d 393 (Tex. Ct. Civ. App. 1969).

165. Accord In re M.K.R., 515 S.W.2d 467 (Mo. 1974). Cf., Wade v. Bethesda Hosp., 337 F. Supp. 671 (S.D. Ohio 1971).

166. 284 So. 2d 185 (La. App. 1973).

167. Accord In re Pescinski, 67 Wis. 2d 4, 226 N.W.2d 180 (1975).

168. 445 S.W.2d 145 (Ky. 1969).

169. See, Baron, Botsford and Cole, Live Organ and Tissue Transplants from Minor Donors in Massachusetts, 55 B.U.L. Rev. 159, 170 (1975); Comment, Spare Parts From Incompetents: A Problem of Consent, 9 J. Family L. 309 (1969).

170. 42 U.S.L.W. 2322 (Ga. Sup. Ct., Fulton Cty. NOV. 29, 1975).

171. For further discussion of this point, see, section II, supra at 95.

172. Arizona, Arkansas, California, Connecticut, Delaware, Georgia, Idaho, Iowa, Maine, Michigan, Minnesota, Mississippi, Montana, New

Hampshire, North Carolina, Oklahoma, Oregon; South Carolina, Utah, Vermont, Virginia, West Virginia, and Wisconsin. See, Pate and Plant, Sterilization of Mental Defectives, 3 Cumberland-Samford L. Rev. 458 (1972).

173. Paul, The Sterilization of Mentally Retarded Persons: The Issues and Conflicts, 3 Family Planning/Population Rep. 96, 97 (1974).

174. 274 U.S. 200 (1927).

175. Id. at 205-206.

176. Id. at 207.

177. Id.

178. Id.

179. Baron, Voluntary Sterilization of the Mentally Retarded, in Genetics and the Law, 267 (Milunsky and Annas eds. 1976).

180. 316 U.S. 535 (1942).

181. See, Silent Minority, supra note 3, at 33; Kittris, The Right to Be Different: Deviance and Enforced Therapy, 298 (1971).

182. See, Murdock, Sterilization of the Retarded: A Problem or a Solution?, 62 Calif. L. Rev. 917, 924-932 (1974).

183. 9 Ore. App. 224, 495 P.2d 768 (1972).

184. See, In re Moore, 44 U.S.L.W. 2385 (N.C. Sup. Ct. Jan. 29, 1976). In re Cavitt, 182 Neb. 712, 157 N.W.2d 171; 183 Neb. 243, 159 N.W.2d 566 (1968).

185. Krugman, Ward, Giles and Jacobs, Infectious Hepatitis: Studies on the Effect of Gamma Globulin and on the Incidence of Inapparent Infection, 174 J.A.M.A. 823 (1960). For some description of conditions

at Willowbrook, see, Rivera, Willowbrook: A Report on How It Is and Why It Doesn't Have to Be That Way (1972); Ramsey, The Patient As Person 47-58 (1970); N.Y.U. Medical Center, Proceedings of the Symposium on Ethical Issues in Human Experimentation: The Case of Willowbrook State Hospital Research (Urban Health Affairs Program, N.Y.U. Medical Center, May 4, 1972).

186. Bedlam in 1972 - Retarded Care at Willowbrook, Med. World News, Jan. 28, 1972, at 15, 17. See, Ingelfinger, Ethics of Experiments on Children, 288 N. Eng. J. Med. 791 (1973); Ratnoff, Who Shall Decide When Doctors Disagree? A Review of the Legal Development of Informed Consent and the Implications of Proposed Lay Review of Human Experimentation, 25 Case Western Res. L. Rev. 472, 489-491 (1975).

187. 393 F. Supp. 715 (E.D.N.Y. 1975).

188. See, text accompanying notes 156-160 supra.

189. 393 F. Supp. at 718.

190. Civil No. 74-004-130 DC (Cir. Ct., Wayne Cty., Mich.) (filed Feb. 19, 1974).

191. See, note 66 supra.

192. See, text accompanying notes 86-88.

193. Katz, The Right to Treatment - An Enchanting Legal Fiction, 36 U. Chi. L. Rev. 755, 773 (1969).

194. Note, Civil Commitment of the Mentally Ill: Theories and Procedures, 79 Harv. L. Rev. 1288 (1966).

195. See, e.g., Postel, Civil Commitment: A Functional Analysis, 38 Brooklyn L. Rev. 1 (1971).

196. See, Note, Informed Consent and the Dying Patient, 83 Yale L.J.

1632 (1974).

197. Friedman, Legal Regulation of Applied Behavior Analysis in Mental Institutions and Prisons, 17 Arizona L. Rev. 39, 99 (1975).

198. Thorn v. Superior Court, 1 Cal. 3d 666, 675, 464 P.2d 56, 62, 83 Cal. Rptr. 600, 606 (1970).

II

PAPERS PREPARED FOR THE NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION

4

THE RISE OF DRUGS IN BEHAVIORAL MODIFICATION PROGRAMS

Rudy Lombard, Ph.D.

The National Minority Conference on Human Experimentation
January 6-8, 1976

The Rise of Drugs in Behavior Modification Programs

Rudy Lombard, Ph.D.

Is there now or was there ever a conspiracy to use drugs in order to modify the behavior or personality of black political activists? This question goes directly to the important implications of our topic for discussion. We are familiar with references to the narcotization of so-called hyperactive children, emotionally disturbed adults, felons, anxiety-ridden housewives and persons dependent on illicit drugs. We are less familiar with specific cases in which drugs have been used to discredit or control key members of groups within the non-white communities. However, because of recent revelations in the news media and congressional hearings concerning FBI and CIA efforts to discredit Dr. Martin Luther King and others, the conspiracy theory does not now presently seem so far-fetched.

I can recall a black student-activist at Texas Southern University in the late 60's receiving a 25 year jail sentence for alleged possession of a small amount of marijuana. I also remember the story of Lewis Tackwood, a Los Angeles police informer who used drugs to befriend members of the Black Panthers and other groups. Who could forget the tribulations of singer Billie Holiday, a lady who after kicking the habit was framed by federal narc agents. Black slaves in the U. S. were encouraged to indulge themselves in alcohol on official national holidays. The opium abuses and wars in China is a legacy of colonial powers. Today black musicians, entertainers and athletes, the favorite images of the black community, openly use and condone a wide variety of illicit narcotics.

In my opinion, we are free enough to decide that the net effect of all of this and the best historical perspective for understanding it is indeed conspiracy. If we assume the conspiracy theory as I do, we must acknowledge that it is not only real but also successful. If black behavior was at one time in the 1960's a serious threat to the status quo it is, in my opinion, no longer so in the 70's. Our behavior has been effectively modified, and what is perhaps more unfortunate, the modifications tend to be for the most part self-imposed. Yes, I think narcotics have been used to blunt political activism. It is therefore, important for us to understand the nature of our volnerability. In the health field as in any other, black vulnerability through exploitation is due in large measure to a lack of perspective and common sense. I define common sense as the ability to reach intelligent conclusions based upon experience which requires no specific training sophistication or specialized knowledge, and includes the ability to analyze information and to act in one's best interests. It is what some of us call having good understanding.

In the main we lack a body of integrated assertions, theories, and aims which constitute a socio-political program. We lack also a firm institutional source of well-organized information and communication, as well as the power to make and enforce decisions. I Will attempt to cite a few issues and examples to clarify the above contention, and let me pick a subject which I am sure is the favorite at this conference and has been discussed before.

The controversy over psychotechnology has led to the emergence of numerous issues around which blacks are languishing in unresolved conflict. Proponents of psychotechnology, which includes psychosurgery, electro convulsion therapy, conditioning behavior, etc., argue that it is useful and necessary for the altering of thoughts, social behavior patterns, personality traits, and emotional reactions which are not solely neuropathological in nature. Opponents of psychotechnology believe that in the alleged attempts to suppress violence and other anti-social behavior the largest social pressures are ignored in favor of focusing on individual abnormalities. Let us refer to a couple of statements to highlight the above argument,

Dr. Jesse Barber, in an article to Urban Health in October of 1975, has made the following statement: "Psychosurgery offers the best hope we have at the present time for patients who are treatment failures in other modes of therapy. The newer modes of psychosurgery are safe, reasonably successful and, despite their great potential for abuse as a tool to control political, civil and social dissent, they have an equally great potential for treatment of patients." Barber defines psychosurgery as the removal, destruction or stimulation of brain tissue by surgical or radiothermal techniques in the absence of known organic brain diseases at the site with the primary intent of altering behavior, thought or mood of the patient.

The counter argument is well-stated by Stephen Korova, and I quote "I think that the most important task before us is to develop alternate ways of perceiving social problems. We must learn to see such things as violence and hyperactivity as something other than individual infirmity. We must shift the emphasis in our thinking from a preoccupation with controlling individuals deviant to the problem of understanding the various systems, social, political and family, of which both deviance and its control are interrelated."

Dr. Barber's definition of psychosurgery indicates use in the absence of known organic brain disease. Yet another psychosurgery proponent, Dr. Vernon Marks, who co-authored the book Violence and the brain, a professor at Harvard University, defined psychosurgery as brain surgery to correct mental and behavioral disorders and states that in his opinion such treatment "should be used only if some recognized disease is the primary cause of a patient's unwarranted and abnormal behavior." The Barber and Marks definitions are in conflict, and it is not surprising that blacks can be found supporting both sides of the controversy. My opinion, the definition, terminology, and underlying theoretical framework of the psychotechnology controversy is shrouded in confusion.

What are the appropriate criteria for such terms of conflict as abnormal behavior, disease, emotional disorder, unwarranted behavior, primary cause? What is anxiety, depression, and aggression? Are they behavioral traits associated with brain disfunction or environmental pressure? Who is to decide? Is science and medicine ever purely objective and value free? Is the medical model scientific? Is there not a history of science having been used to justify oppression? Dr. Marks feels that "The medical model upon which psychosurgery rests is more scientific, more cautious, and ultimately more humane than the socio-political alternative. It demands an accurate and thorough diagnosis of each patient for treatment." Marks views socio-political criticism as an attack on psychiatry and the rights of patients treatment.

Dr. Korova, on the other hand, has argued that when we begin to investigate a social or behavioral problem, how we decide what the cause and best solutions are, in other words, how we make a diagnosis depends upon what aspect of the situation we choose to study. When we decide to study a problem in a certain way we are making a decision that has political import. If we start with a predisposition to identify and deal only with symptoms of disorders of the individual as many behavioral scientists do, we adopt an arbitrary and essentially non-scientific perspective. We inevitably tend to ignore other possible approaches. Once we focus our attention on the behavior of the individual, it becomes highly unlikely that we will be disposed to deal with the larger social concept in which behavior occurs.

Now self-destruction of brain tissue is irreversible. It is important to know whether specific benefice for patients flow from brain lesions, or if we are giving same to a medical procedure which is experimental in nature with consequences that are not only unpredictable but possibly repressive. The issues confronting blacks are no less confused by their would-be allies. For instance, Dr. Korova, while he is critical of psychotechnology advocates the legalization of illicit drugs. It is hard for me to imagine how any narcotic could improve the skills of certain stances of black people. I do not know, at least to my knowledge, any drug which one could take that would make him politically astute and effective.

My general point is simple. Blacks have no sophisticated or common-sense way of constructively dealing with the confusion and contradictions of issues confronting them in the fields of health, education and welfare. So long as this is so, our vulnerability will continue adnauseam. What is the true signif-icance of concepts such as informed consent or right to patients among the people who are without the inherent power and resources to enforce them? There is not much sense in denying that the absence of financial wealth and economic opportunity make the securing of rights for minorities especially difficult. Conferences, peer group review, legal and legislative action cannot be depended on to resolve the confusion. They are necessary but not totally sufficient solutions. Moreover, although they believe otherwise, the mentality of many scientists and physicians is not conducive to a proper sense of social responsibility or accountability.

Dr. Marks for instance, has categorically stated, "There has never been a society or culture without mental illness." Only persons who are ethnocentric, chauvinistic or possessive of a colossal sense of their own omnipotence could make such a statement.

If is a reflection of a mentality with which the powerful or specially afflicted, it is they who tend to believe that their history and their culture and their values are supreme. The signs of our times are ominous. The latest manifestation of black self-imposed behavior modifications is the change in the nation of Islam from separatist to integrationist. There is a civil war in Angola, west Africa being fought on neocolonial terms. Many outstanding black leaders have been assassinated. Civil rights groups are now defunct, financially impoverished, or meek. Black nationalists have retreated into the tired rhetoric of Marx and Lenin. There is not much black behavior left which is worth modifying. It is only necessary to maintain what is.

We do not have a development plan for unifying cultural aesthetics to make us conscious of what constitutes a functional and constructive existence. We have been oppressed far too long perhaps to understand the full nature of our dilemna. However, there is no excuse for inaction.

In closing, I would take the liberty to say that I feel a kind of anxiety in our people. It is as if we expect something biblical to happen. Something is gravely wrong and we sense that solutions are life-threatening in nature. It may well be that the ultimate solution to our problem is a kind of political pill which apparently we are all too reluctant to swallow.

INFORMED CONSENT:

ETHICAL ISSUES IN BEHAVIORAL RESEARCH

Jackquelyne Jackson, Ph.D.

INFORMED CONSENT: ETHICAL ISSUES IN BEHAVIORAL RESEARCH*

JACQUELYNE JOHNSON JACKSON, PH. D.**

A few years ago, I prohibited my daughter, now eleven years old, from subject participation in any research conducted on her school's premises by outsiders without my specific permission. I also informed the appropriate school officials of this proscription, and requested their cooperation. The triggering event was her use as an uninformed consent subject in a federally funded research study, whose principal investigator was a psychologist at a neighboring institution. I learned about her participation from her after the fact. My concern increased as she described the tasks she completed. Subsequent investigation confirmed my suspicion that another study focused upon racial differences in learning was underway. I also critiqued several published articles by that psychologist, and was dismayed by his inappropriate methodology for isolating racial differences, as well as by his prejudicial interpretation of racially comparative results.

My proscription to my daughter was based upon my belief that informed parental consent is sine qua non for a black child's assumption of the subject role in any research, including educational, psychological, sociologi-

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**Associate Professor of Medical Sociology, Department of Psychiatry, and Senior Fellow, Center for the Study of Aging and Human Development, Duke University, Durham, North Carolina.

cal, and similar research using race as a variable, as may be true in research about school desegregation or mental health. Black parents should invoke this proscription by forbidding their minor children from becoming subjects in any research in the absence of a priori voluntary and informed parental consent. Black adults should also generally refrain from subject. participation in behavioral research unless that participation is voluntary and is preceded by their informed consent.

Individuals making such decisions for themselves or others may well be confronted by ethical and pragmatic difficulties in determining their specific rights in becoming or refusing to become subjects in human experimentation in behavioral research, as well as their specific rights in seeking to induce others to become or refrain from becoming such subjects. Obviously, different individuals will reach different decisions, depending upon a variety of factors, including their assessments of the need for research, qualifications of researchers, use of research outcomes, and the relationship which ought prevail between the individual and the society. Extremely few individuals will oppose human experimentation with a reasonable probability of expansion of the knowledge parameters critical to the promotion of individual and societal welfare. But few will also voluntarily subject themselves to risky experimentation even when the probability of personal benefit may be high. Most individuals prefer the selection of other individuals as subjects in risky experimentation, and most individuals deplore the deceptive use of other individuals in high-risk experimentation.

Nevertheless, some unethical researchers have deliberately abused the rights of unsuspecting subjects for unworthy purposes, as in the Tuskegee syphilis study. Others, for example, have deceptively injected live cancer cells into elderly patients at the Jewish Chronic Disease Hospital in Brooklyn, or hepatitis virus into mentally defective children at the Willow Brook State School on Staten Island. Many other examples, no doubt, lay buried, but they all fall within the genre of the continued physical and psychological abuse and harm of unsuspecting subjects by unethical researchers, or by researchers who place significantly higher value upon the good of the society than the good of the individual.

Inasmuch as the unprecedented growth in unethical researchers over the past few decades can be attributed directly to the unprecedented and vast public funding made available for the initiation and execution of behavioral research, and inasmuch as public pressures have forced the government to reconsider carefully its proper regulatory role in the conduct of human experimentation, it is fitting that the government move toward more stringent and direct control of the conditions mandatory for human experimentation within behavioral research. It is also necessary, simultaneously, for individuals qua individuals to become more sophisticated about research, so that they, themselves, will be able to determine for themselves the extent to which they may wish to become guinea pigs.

Consequently, one of the major issues surrounding human experimentation in behavioral research is that of informed consent. It is good that the National Commission for the Protection of Human Subjects of Biomedical and

Behavioral Research has been charged with the responsibility of considering the nature and definition of informed consent in various research settings, and of identifying the requirements for informed consent for participation by children, prisoners, and the institutionalized mentally infirm under Title II of Public Law 93-348 (12 July 1974). The Commission has a major responsibility in protecting both the rights of subjects and the rights of researchers, and, no doubt, on occasion, the Commission has been pressured by representatives of the latter group much more intensely than by representatives of the former group, and especially by members of the former group who are disproportionately overrepresented among the impoverished least likely to be able to provide their informed consent in the event that they participate as subjects in human experimentation.

Thus, in the time remaining, I wish to review briefly some aspects which have led us from a state of "no consent" to "informed consent," and to offer for your consideration some general recommendations about the nature and definition of and requirements for informed consent from a minority perspective.

From No Consent to Informed Consent

The most influential evolution of written codes of ethical principles governing the use of human subjects in behavioral research has occurred within the medical sphere. However, following the exposure of the gruesome Nazi abuses in human experimentation, it was not until the year 1946 that the American Medical Association made any specific mention of the problems of human experimentation, when, according to Romano (1974:129), it stated

that:

> "(1) It is essential to obtain voluntary consent of the person on whom a new study (involving new drugs or procedures) is to be carried out; (2) The danger of each procedure must be previously investigated by animal experiments; (3) The clinical research must be performed under proper medical protection and management."

Over the next two decades, and with almost no law as a guide, the American Medical Association studied codes of behavior regarding the protection of human subjects which existed in various research institutes, as well as principles enunciated in the 1947 Nuremberg Code and the 1964 Declaration of Helsinki. In 1966, the American Medical Association's House of Delegates endorsed the Declaration of Helsinki, and its Judicial Council, again according to Romano (1974:129-130), issued the following "Ethical Guidelines for Clinical Investigation:"

> Consent of the subject must be obtained.
> Research should be conducted only by qualified persons under adequate supervision.
> Importance of the objective must be in proportion to the inherent risk to the subject; all possible risks must be carefully assessed, in comparison to foreseeable benefits to the subjects and others.
> Nature, purpose, and risk of the research must be explained to the subject by the doctor.
> At any time during the course of research the subject should be free to withdraw permission for work to continue.
> Researchers should discontinue their work if continuation would prove harmful to the subject.
> Investigators must demonstrate concern for the welfare, safety, and comfort of the subject, and safeguards must be provided.

A comparison of the 1946 and 1966 statements by the American Medical Association shows that the consent scope was widened, including the subject's entitlement to an explanation of the nature, purpose, and risk of the research. The risks/benefits ratio was introduced. The burden of responsibility for

protection of the welfare of the subject by the researcher was increased dramatically.

Romano (1974:131) believes that such variables as the establishment of the National Institutes of Health, substantial increases in public funds for research initiation and execution, the immense development of new drugs, and various technological advancements led to new complex problems, including the need for precise definitions of death, as well as problems caused by the growing number of behavioral researchers who were not physicians and who "did not carry with them traditional medical ethics, namely, biologists, social scientists, and psychologists." In addition, threats to individual privacy, caused by technological advances in computer processing and storage data banks led to the appointment by the President's Office of Science and Technology of a panel to study the relationships between the right to privacy and behavioral research.

The 1967 report of that panel indicated that attention should be given to the protection of the privacy of research subjects, that the scientific obligation included the protection of privacy of individual subjects and subject protection from permanent physical or psychological harm. It re-affirmed individual investigators as the guardians of ethical practices in research, and merely suggested that Government agencies should satisfy themselves that the institutions employing federally funded research had effectively accepted their responsibilities to require ethical standards. The report clearly repudiated the need for any legislation to assure appro-riate rights of human subjects, due largely to its inflexible characteris-

tics, but reaffirmed the right of the professions to develop and enforce their own ethical codes. The panel also called for voluntary subject participation, and informed consent insofar as it was consistent with the research objectives, but consent could also be based solely upon trust in the qualified investigator and the integrity of the supporting institution.

The five specific recommendations (Romano, 1974:132) placed the burden of ethical policing of the rights of human subjects upon individual institutions, and, with respect to informed consent, recommended specifically

> That investigators and institutions be notified of the importance of consent and confidentiality as ethical requirements in research design, and that when either requirement cannot be met, the reasons must be explained in the application for funds.

This 1967 report can be viewed positively in the evolution of federal concerns about human abuses in behavioral research, but its conclusions and recommendations smack heavily of vested interests. That is, more explicit and implicit protection was given to the researchers than to those to be researched.

For example, the panel recommended the acquisition of informed consent from subjects, as previously noted, only if such an acquisition was not contrary to the research objectives. The specification that subject consent could be based upon trust in a qualified investigator and institutional integrity presupposes conditions frequently absent in the impersonal research world, a world where increasingly the principal researchers are surrounded

by a battery of assistants generally untrained in ethical principles of research, and in research itself. The determination of invasion of privacy of the subject was left up to the investigator and his peers, whose judgments about the risks/benefits ratio may not parallel that of the subjects, or subject subsets. The panel's anti-legislational stance was designed to reduce to the bare minimum any governmental intervention. No recommendations were set forth for identifying, apprehending, and punishing those investigators who violated individual subject rights, nor was there any conclusion or recommendation about a grievance and compensation procedure for human subjects whose rights might be abused or violated under behavioral research conditions. Finally, no recommendation focused upon the important factor of dissemination information about the rights of human rights to the general public. This educational responsibility is critical if individuals must give their informed consent to become research participants.

The December, 1971 U. S. Department of Health, Education, and Welfare's The Institutional Guide to DHEW Policy on Protection of Human Subjects (DHEW Publication No. NIH 72-102) stressed a flexible approach to ground rules and regulations. Developed without the assistance of lay persons, the responsibility for safeguarding the rights and welfare of human subjects was placed directly upon the institutions receiving DHEW research grants, with the proviso that such institutions establish internal review committees.

The operational definitions and guidelines for the concept of informed consent are important within the present context. The Guide was quite clear

in stating that "No subject can be expected to understand the issues of and benefits as fully as the [institutional review] committee. Its agreement that consent can reasonably be sought for subject participation in a project or activity is of paramount practical importance" (p. 7).

The verbatim rendition of the sections pertaining to informed consent is as follows:

> The informed consent of subjects will be obtained by methods that are adequate and appropriate.
>
> Note.--In the United States, adherence to the regulations of the Food and Drug Administration (21 CFR 130) governing consent in projects involving investigational new drugs (IND) is required by law.
>
> Informed consent is the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.
>
> The basic elements of informed consent are:
>
> 1. A fair explanation of the procedures to be followed, including an identification of those which are experimental;
> 2. A description of the attendant discomforts and risks;
> 3. A description of the benefits to be expected;
> 4. A disclosure of appropriate alternative procedures that would be advantageous for the subject;
> 5. An offer to answer any inquiries concerning the procedures;
> 6. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.
>
> In addition, the agreement, written or oral, entered into by the subject, should include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence.
>
> Informed consent must be documented....Consent should be obtained, whenever practicable, from the subjects themselves. When the subject group will include individuals who are not legally or physically capable of giving informed consent, because of age, mental incapacity, or inability to communicate, the review committee should consider

the validity of consent by next of kin, legal guardians, or by other qualified third parties representative of the subjects' interests. In such instances, careful consideration should be given by the committee not only to whether these third parties can be presumed to have the necessary depth of interest and concern with the subjects' rights and welfare, but also to whether these third parties will be legally authorized to expose the subjects to the risks involved.

The review committee will determine if the consent required, whether to be secured before the fact, in writing or orally, or after the fact following debriefing, or whether implicit in voluntary participation in an adequately advertised activity, is appropriate in the light of the risks to the subject, and the circumstances of the project.

The review committee will also determine if the information to be given to the subject, or to qualified third parties, in writing or orally, is a fair explanation of the project or activity, of its possible benefits, and of its attendant hazards.

Where an activity involves therapy, diagnosis, or management, and a professional/patient relationship exists, it is necessary "to recognize that each patient's mental and emotional condition is important...and that in discussing the element of risk, a certain amount of discretion must be employed consistent with full disclosure of fact necessary to any informed consent."

Where an activity does not involve therapy, diagnois, or management, and a professional/subject rather than a professional/patient relationship exists, "the subject is entitled to a full and frank disclosure of all the facts, probabilities, and opinions which a reasonable man might be expected to consider before giving his consent."

When debriefing procedures are considered as a necessary part of the plan, the committee should ascertain that these will be complete and prompt....

2. Informed consent. An institution proposing, to place any individual at risk is obligated to obtain and document his informed consent....The actual procedure in obtaining informed consent and the basis for committee determinations that the procedures are adequate and appropriate are to be fully documented. The documentation will follow one of the following three forms:

a. Provision of a written consent document embodying all of the basic elements of informed consent. This form is to he signed by the subject or his authorized representative. A sample of the form as approved by the committee is to be retained in its records. Completed forms are to be handled in accordance with institutional practice.

b. Provision of a "short" form written consent document indicating that the basic elements of informed consent have been presented orally to the subject. Written summaries of what is to be said to the patient are to be approved by the committee. The "short" form is to be signed by the subject or his authorized representative and an auditor-witness to the oral presen-

tation and to the subject's or his authorized representative's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons obtaining the consent on behalf of the institution and by the auditor-witness. Sample copies of the consent form and of the summaries as approved by the committee are to be retained in its records. Completed forms are to be handled in accordance with institutional practice.

c. Modification of either of the above two primary procedures, All such modifications must be approved by the committee in the minutes signed by the committee chairman. Granting of permission to use modified procedures imposes additional responsibility upon the review committee and the institution to establish that the risk to any subject is minimum, that use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and that any reasonable alternative means for attaining these objectives would be less advantageous to the subject.

As is apparent from a careful examination of the above, legal requirements govern the consent of human subjects using investigational new drugs, while local institutions or other DHEW grant recipients are permitted a significant amount of flexibility in operationalizing and approving informed consent. Further, the required signature of the consenting subject provides greater protection for the investigator and the institution than it does for the subject. Further, inasmuch as subjectivity undoubtedly influences professional judgments about the validity of given research objectives and methodologies, the omission of external reviewers is significant. In this respect, it should be noted that the minimal review which may be done by the specific granting agency is insufficient to override this objection.

Quite significant, as well, is the glaring provision permitting informed consent after the fact. In all professional/subject research, I believe that a priori informed consent is essential. For example, I wonder if the

subjects in Gentry's (1971) the "Effect of White Instigated Attack on Black Anger, Aggression, and Vascular Arousal" might have cooperated if they had been aware in advance of the research objectives. There, a white psychologist used 28 black students enrolled in psychology courses at a black college to determine the effects of interpersonal attack upon aggression and related behaviors in an interracial situation by deliberately deceiving them about the research intent. The experimental conditions included subjecting one-half of the subjects to verbal abuse by a white of the same sex. The attacked subjects experienced a significant increase in diastolic blood pressure under the experimental conditions.

Gentry (1971) concluded that anger, verbal aggression, and a rise in diastolic blood pressure were all higher in the treatment than in the control group. His findings contradicted other findings which showed the relative absence of anger and aggression in blacks following white frustration or attack. He attributed the differences in findings to such factors as design differences and the rapidly changing black social position. He also determined that hostility was significantly higher among the attacked females than among the attacked males, a sex difference which became difficult to explain. Possible explanations offered by him were greater societal tolerance of aggressivity in black females than black males; the fact that the male models available to black males as they grow up are weak, powerless, inferior, and totally dependent on whites who frustrate them, and the existence of the black matriarchy; and the possibility that sex differences may relate to the particular type of aggression under study.

We cannot dispose of Gentry's (1971) research in which informed consent of the subjects was not obtained in advance without asking if the research objectives were sufficiently worthwhile to subject some blacks to elevated diastolic blood pressures? Did any psychological harm occur as a result of the experienced abuse when some black subjects were chastised for their immature behavior, ineffective cooperation, and poor attitude throughout the experiment? We should also be concerned about the extent to which the subjects were really willing volunteers. Each, incidentally, received one dollar for participation.

The Nature and Definition of Informed Consent

While I know that the Commission shall have deliberated carefully about the nature and definition of informed consent in behavioral research in various settings, including that involving blacks or other minority populations overrepresented among those groups most likely to be subjected to high risk human experimentation without their informed consent, or most likely overrepresented among those groups least likely to exercise full and freely conceived consent, it is probable that the Commission may, once again, be more heavily influenced by their ethical commitments to research or to the greater societal good.

Thus, I would recommend that the Commission, if it has not already done so, should consider at least the following recommendations.

1. The operational nature and definition of informed consent in behavioral research should be legislated. It is true that research purposes and designs vary considerably in their complexities, but it is also true

that sufficient expertise exists to typologize along a continuum the various categories of informed consent required for various types of behavioral research.

2. Such legislation should spell out explicitly the conditions under which a priori informed consent is to be waivered, and no such consent should be waivered in any professional/subject investigation, without an independent judgment determined by an outside panel composed of five persons, one of whom must be a peer of the proposed subject class.

3. Prior to signing an informed consent form, every potential subject, or the authorized representative, must be presented with a research prospectus, including the purpose and nature of the study, the research design, the significance of the study, and a clear explanation of the probable risks directly to the individual, or to the demographic or socioeconomic groups represented by the individual. In addition, minority subjects must be advised if racial breakouts are to be used in the analysis and reporting of the data.

4. Under conditions when subjects participate blindly, and informed consent is obtained after the fact, should the subjects object to the use of the data, such data must be destroyed immediately by the investigator to the satisfaction of the subjects.

5. In professional/patient situations where informed consent of the patient cannot be received in advance, the determination to use the patient as a research subject cannot be made solely by one physician, but must be made by a panel of three physicians, one of whom must be of the same race and sex as the patient, and at least one of whom is not involved

in any way in the care of the patient or the proposed research, and such decision to involve the patient as a subject must be concurred with by the next-of-kin or legal guardian.

6. The informed consent statement signed by subjects willing to participate in human experimentation must include a proviso that, in the event the subjects experience physical or psychological harm as a result of participation in the experiment, appropriate compensation, including monetary compensation, will be received. The determination of physical and psychological harm will be made by parties independent of the given institution or research site, with such a group containing professionals and laymen, at least one third of whom must be socioeconomic peers of the subject claiming injury or harm.

Requirements for Informed Consent for Special Groups

I reaffirm my earlier conviction that the use of children as subjects in professional/patient and professional/subject relationships should be based upon informed parental consent, or the appropriate representatives, provided that loyalty to the children supercedes that to the researchers.

I believe that prisoners sound in body and mind should be permitted to make their own decisions about subject participation in human experimentation, provided that their consent is voluntary and informed. I am aware of various objections which might meet this idea, since many believe that voluntarism is impossible within the prison walls. However, I believe the federal government should make certain that no harmful research will be conducted on prisoners, or, to the extent that such research may be

harmful, then well-informed prisoners who wish to consent to participate may do so. When the research is likely to benefit society, those prisoners who are harmed by the investigation should receive compensation, which can be appropriately meted out through reduced sentences, monies, or in other ways. Beyond this, requirements for informed consent for prisoners would be similar for the normal, noninstitutionalized population.

Informed consent for the mentally infirmed should require a determination by a panel composed of one physician, one psychiatrist, one biomedical scientist, and one attorney that the individuals may be feasibly subjected to research without violating their rights, or, to the extent that such rights are violated, the potential benefit to the subject or to the subject class must outweigh the harm. Concurrence from the next-of-kin or the appropriate legal guardian would be mandatory. In addition, institutionalized individuals who maintain some contact with reality would be required to provide their own informed consent.

Some Special Concerns

The establishing of regulatory legislation to protect the rights of human rights in behavioral research, and to require the informed consent of such subjects as a condition of participation, will by no means guarantee that the rights of blacks functioning as human subjects will be protected. Sufficient evidence about the enforcement of the Civil Rights Act of 1964 is already available to indicate the need for effective implementation and enforcement of legislation designed to halt the abuse of blacks under

unethical research conditions. Even when legislation has been effected, administrative officials responsible for implementing that legislation frequently abuse the rights of blacks, a condition which, in my judgment, is inappropriately explained by the concept of institutional racism. As a case in point, NIH requires training grant recipients seeking renewals to provide information about the status of minorities within its programs, and the perceived barriers to minority participation. In some specific cases, I know that such information has been falsified, and, nevertheless, accepted as valid by the receiving agent. This is an instance of the government abdicating its policing responsibility by entrusting itself to the trust of the project director and the integrity of the institution. It seems to me that it would have been very reasonable for the Office of Civil Rights to have required some form of informed consent from the minorities within the applicable institutions, or, at the very least, to have engaged in a random examination of the abuses which have typically occurred in the so-called affirmative action efforts to recruit black faculty and students. For this reason especially, then, I am opposed to the responsibility for determining and policing informed consent remaining within the hands of the institutions in the absence of legislation.

Blacks should also be well aware of the fact that the presence of a black face in any given agency or institution, or even when a black requests one's services as a subject, is no guarantee that the subject will be protected.

Finally, blacks should help promote good biomedical and behavioral re-

research which has a good probability of reducing critical knowledge gaps, including those related to etiological and epidemiological factors in cardiovascular disorders and malignant neoplasms.

Above all, blacks must increase their sophistication about research, so as to to increase the possibility of rational decisions which may be made in giving informed consent as participants in human experimentation within behavioral research.

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ETHICAL ISSUES ON MENTAL HEALTH RESEARCH FROM A MINORITY PERSPECTIVE

Mary S. Harper, Ph.D.

THE NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION

Ethical Issues on Mental Health Research from a Minority Perspective

BY

Mary S. Harper, Ph.D., R.N.

Reliable statistics describing the incident and prevalence of mental and emotional disorders do not exist. Nevertheless, overall estimates, even if erring on the high side by a generous margin indicate that no less than 10% of the United States population, or roughly 20 million people suffer from some form of mental illness. About one-seventh of those afflicted actually receive phychiatric care of some sort.

Based on these figures, and taking into account such factors as the mentally ill individuals' loss of earnings and cost of care both in and out of institutions, the annual cost of mental illness in this country is estimated to be about $21 billion, or almost one quarter of the national defense budget. Included in the above is economic cost of alcoholism alone at $15 billion annually and annual cost of drug abuse at $10 billion. It is impossible to quantify the cost of individual, family, friends, and societal suffering and emotional trauma.

In 1971, the admission to all psychiatric inpatient and outpatient services were at the rate of 1239.6 per 100,000. (1) Non white admission accounted for 757.9 per 100,000, which is 60% of the annual admissions. The admission rate for non white schizophrenia is about three times that for white, (2). It is estimated that over half of the resident population of public mental hospitals is non white, whose length of stay in the hospital is longer and length of stay in the community is shorter than that for whites.

Non whites constitutes 70 to 80% of the prison population in the big city jails in the U.S. (3).

In 1970, the Census found 2.1 million persons were inmates of prison mental hospitals, juvenile facilities and similar institutions to a large extent, unfortunately the Civil-legal-needs, and ethical issues are not addressed and unassessed. Almost, uniformly, the institutionalized population is poor and non white (4).

With the large proportion of all institutionalized populations in public institutions being non white, it is appropriate that we now discuss the ethical issues in mental health research

In this presentation, I shall refer to American Indians, Asian Americans, Blacks, Spanish as racial and ethnic minorities. The problem of access to

good quality of mental health services and lack of protection in human experimentation are also experienced to some extent by the poor lower socio-economics, illiterate, new immigrants, children, youths, and captive populace (i.e. prisoners, juveniles, mental patients, etc). Webster's Dictionary defines a minority as "a racial, religious ethnic or political group smaller than and differing from the larger, controlling group in a community, nation, etc."

The groups mentioned above are generally the target populations of human experimentation throughout history. Franz J. Gall (1758-1827), an anatomist, carried his childhood notions of phrenology (study of the relationship between mental characteristics and the shape of the head) into his professional research. The first subjects of his investigation were the lower class of society who were in jails and asylums (5).

After establishing a mind set that minorities are frequently a target group for human experimentation, I will now establish a conceptual framework for ethnical issues.

Ethics in its strict sense is the science of moral duty (6). The principles of morality, including both the science of the good and the nature of the right. Ethics, properly speaking, deals with the rightness or wrongness of the professional, provider's action in light of principles

which rise out of the nature of man as a person. It establishes perspective guides which govern specific situations in such a way that the rights of the patient are always preserved. On the other hand professional etiquette, deals with duties arising out of a relationship staff with each other and out of the dignity of the calling. Etiquette implies a formal requirement governing behavior in polite society. The etiquette of the profession may be altered materially if such change allowed for better service to the patient/client. The truly ethical care of the codes of ethics derives from the dignity and rights of the patient as a person. This is the criterion against which, new staff arrangements must be measured, (7) (8).

When one considers some of the risk taking and lack of protection of the person in human experimentation, it is obvious that the research assistant/associate or co-investigators have confused etiquette (relationship/respect for the other professional with their commitment to maintain/respect the rights and dignity of the patient. If we could keep our ethical commitment to the patient, we may not have ever had a "Tuskegee situation."

The nations of ethas, ethical, code, ethics and morality must be clearly distinguished in spite of their inter relatedness. The ethas comprises those distinctive attitudes which characterize the culture of a professional group insofar as this occupational subculture foster adherance to certain

values and the acceptance of a specific hierarchy of values. Ethas implies membership in a vocational group rendering an irreplaceable service to the community and dedicated to the values other than those of financial gain.

Ethas is to be distinguished from the ethical code, which consists of a studied effort to foster and guarantee the ethas but is meant to go beyond it by assuring to the patient and to the public a professional standard of human services/relationships. Ethical code services more as a guide than control.

The morality of the professional lies in his subjective personal realization of the proper approach to his profession, his living the fullness of his ethas.

In such a time when the country is facing economic, political, moral, social and integrity crises, it is imperative that we clarify our vocabulary and notions about ethas, ethics, and morality. Again, with some of the risks and exploitations which have occurred to minority groups in human experimentation, it is obvious the processes, words nor procedures were understood.

There are six basic principles which I have abstracted from the codes of ethics from the professions of nursing, sociology, psychology, medicine, and social work, namely:

1. Every human being has a right to life in the fullest sense.

2. Every human being has a right to truth. The right to truth means that every man has a right to know those things which in justice or charity he should be told, and in no case should he be deceived by a lie.

3. Justice is due to every human being. He possesses a right to those things that properly belong to him by nature, by birth, by gift, by contract or in virtue of any other circumstance by which rights are established. Hence, too, a patient has a right to the competent and conscientious care of the professional/provider who has accepted him as a patient.

4. The facilities and power of man must be used according to the purpose for which they were evidently intended by the nature and in the manner evidently intended by nature.

5. If an act is ethically wrong, one is not only obliged to refrain from it himself, but he is also obliged to refrain from formal cooperation with another in the performance of the act,

6. Evil nay never be done that good may result from it. One (individual or government, or organization) is obliged in such a way that the fundamental values of freedom justice, and security are respected.(9)

When the ethical principles and codes of ethics are violated, a professional should expose without fear or favor, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession.

Unethical or incompetent practices should be reported either to the administration/management/supervisor of the place of employment, to the professional organization's ethical committee or to the licensing/certification board. It is a duty to report unethical/incompetent practices/behavior regardless of the position of the person.

Nearly everyone agrees that ethical violations do occur. The practical question is how often one hundred (100) consecutive human studies published in 1964 in an excellent journal were examined; twelve of these seemed unethical. In England, Pappworth has collected more than 500 papers based upon unethical experimentation (330). It is evident from such observations that unethical or questionably ethical procedures are not uncommon (11).

I don't want to profile the mental health professionals/researchers as all bad, there has been a few in the past who have temporarily lost their sense of goodness in unethical/incompetent behavior as have been the case in other disciplines.

It seems as if the public is holding the researcher and mental health/behavioral scientist increasingly responsible and accountable for their behavior, conduct, and quality of performance provided. This observation is evident through the amount of legislation monitoring and "controlling" our performance; PSRO, Protection of Human Subject regulations and the Privacy Act.

In addition to the regulations on the Protection of Human Subjects in mental health research, the ethical codes/oaths, we have licensing, certification and accreditation which help to assure quality of performance by professionals/providers.

Accreditation is the process by which an agency or organization evaluates and recognizes an institution or program of study as meeting certain predetermined criteria or standards.

Licensure is the process by which an agency of government grants permission to persons to engage in a given profession or occupation by certifying that these licensed have attained the minimal degree of competency necessary to ensure that the public health, safety and welfare will be reasonably well protected.

Certification or registration is the process by which a governmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Such qualifications may include:

(a) graduation from an accredited or approved program;

(b) acceptable performance on a qualifying examination or a series of examinations; and/or

(c) completion of a goven amount of work experience (12) (13).

Accreditation of educational programs licensure by a government agency and certification of personnel by the professional have developed independently of one another to meet pragmatic functional and social needs. Based on this historic pattern of evaluation, the structure of these evaluative systems today interlock with each other. So here are three other regulatory groups/ activities designed to assure a safe and good quality of service. (14) (15)

Although minority groups have been involved in mental health research, much of it has been of a "pathological" and deficit model, describing how the minority contrast/ and is unlike the majority (16).(17)

Mental health as an adjustment of human beings to the world and to each other with a maximum of effectiveness and happiness, mental health is a condition and level of social functioning which is socially acceptable and personally satisfying (18). I consider health, not as a condition associated with an absence of disease, but a state in which the mind, the body and spirit function in an optimal manner.

Six approaches to a concept of mental health are:

1. Attitudes of an individual to his own self.
2. Integration/synthesizing one and two above.
3. Autonomy - singles out the individual's degree of independence from social influences as most revealing of the state of his mental health.

4. Individual's style and degree of growth, development, or self-actualization.

5. Manifestation of one's mental health through his adequacy of perception of reality.

6. Environmental mastery (ability to love, adequacy in love, work, and play, adequacy of interpersonal relations, efficiency in meeting situational requirements, capacity for adaptation and adjustment and efficiency in problem solving (18).

These indicators, concepts and definitions of mental health are very important in mental health research for minority groups. Frequently, research findings in mental health of minority groups have identified as pathological what was really normative behavior. One speculates that much of what is identified as mental illness is minority groups is responsive behavior to a racist oppressed society. Much of the behavior may be the most economical use of the resources (mental, social, and cultural and physical) which are available at that time.

Although there has been many advances in mental health research, there has been little impact on the increase of discharge rates and enhancing the quality of life. This outcome may be because minority groups have not had equal access to quality treatment, the predominant treatment, modality for minority patients is chemotherapy and custodial care. In research, one may

purdue ethnomedicine, the study of how members of different cultures think about disease and organize themselves toward medical treatment and the social organization of treatment itself, has been viewed as one of the various "domain" of culture (19). This treatment model includes the resources of the family, culture and community. We must remember one of the principle ethical issues, health is the responsibility of the family, individual and the community. These groups usually determine admission to a treatment program and they determine his re-entry to the community and family. Such an approach might minimize or lower the high readmission or recidivison rate to institutions, the family and individual should always be involved in the family and individuals in its counseling/socialization program regardless to whether it relates to a program or precaution of school violence, divorce counseling or clinical care.

Most of the research on social problems have had serious deficits.

1. Too little emphasis on underlying conditions -- on the interplay of social, psychological, biological and on the processes of social change and behavior modification.
2. Lack of attention to the probability that social problems have causal factors in common.
3. Too little concern with evaluating ameliorative programs.
4. Too little attention to the institutional constraints on the utilization of research findings. Many social problems are interrelated (i.e. alcohol, drug dependency, depression, suicide, homocide and schizophrenia, delinquency.

Very much needed:

1. Better measure of social problems

2. Models for comprehensive and treatment and rehabilitation program which include the individual and his family.

3. Research on the organization of remedial programs.

4. Social experimentation

5. Cross cultural research.

6. Analysis of interaction of social, psychological and biological conditions.

Better quality of research in alcoholism is needed. Dr. Harper surveyed 16,000 alcohol related studies reported in scientific journals over the past 30 years. Of this number, only 77 reflected findings related to black alcoholism, with only 11 of these dealing exclusively with blacks. Most of the studies involved black adult males with research on youth, college students, and women being practically non-existent. Dr. Harper found that the majority (7) centered on drinking patterns and behavior, or treatment. Data on alcohol and safety, health and physiological effects, crime, and alcohol related offenses, and alcohol education and prevention were uncommon (20).

The delivery of mental health services and mental health research have not taken into considerations the findings of research in planning and projecting its programs and budget. For example,

A. Sue and McKinney (21) found that Blacks were more likely to be seen by paraprofessions than whites;

B. Rosenthal and Frank (22) showed that more whites than Blacks were selected for insight-oriented therapy;

C. Yamamoto, James and Palley (23) provided evidence that minority groups received "qualitatively inferior" or less preferred forms of treatment;

D. Lowe and Hodges (24) found that in terms of alcoholism, whites are channeled toward treatment, whereas blacks are disproportionately committed to prison;

E. Hendrie and Hanson suggested that differential treatment is related to staff attitudes regarding the potential benefits of different types of treatment for different types of clients. Subject attitudes are, of course, subject to stereotypes and other types of perceptual distortions and racism in mental health.(44)

F. Evaluation studies of long term followup and to treatment are, of course rare, and outcome criteria often reflect process or intermediate outcome variables, For example, treatment attendance is often assessed as an indirect measure of satisfact/with treatment. Due, et al (21) found that blacks and asians attended fewer sessions than whites. The same findings have been confirmed by Rosenthal and Frank (22), Yamamoto and Goen (25), and Krebs (23). The same studies (21) (22) (23) found higher treatment dropout rates for blacks than whites. In particular, Sue and McKinney (21)

found that 52.1% of blacks dropped out after the first session as opposed to only 29.8% of whites. Jackson (26) indicated that once accepted for treatment, black children were seen for shorter periods of time than white children.

On public hospital settings the treatment program for all minoritites are generally less well planned and length of stay is inappropriately short or longer.

Each of the aforementioned studies suggests less positive treatment outcomes for minority groups. There are a number of hypotheses to account for such differences: e.g. racism in mental health, stereotyped attitudes about minorities, more severe symptomology, differential treatment, culturally alien therapists, staff, teachers, lack of faith in mental health staff attitudes, etc. In any event, what appears most important, is as Warheit (26) Padilla (27), Sue (21) Willie (28) and Short (29) Bergmann and Townsley (30) concluded from a review of the literature and personal/professional experiences that minority groups are usually found to have poorer recovery rates and poorer quality of treatment programs whether in the hospital, outpatient, in a correctional program, or in most of the inner city schools. Basically, the poor quality of programs exist for minorities regardless of ethnic/racial identities, education, sex, age or geographic location.

Of course, the same is true for a person less informed. I had a personal friend who recently went into the hospital for a gall bladder operation. Upon her first visit to the physician, she was informed that one of her ribs was removed. There was no consent from her nor her family. Another startling experience was a non-minority surgical patient shared a room with a medical patient who was assigned to that room until they could rule out hepatitis. Two days later the patient was isolated for hepatitis. I guess I was startled because that hospital had been singled out to me as one of the best in town. Although I've been in the health profession for about 35 years, I'm still startled at unethical, incompetent and inconsiderate actions. I am sorry none of my friends have called me about any outstanding experiences of good quality of programs in hospitals, prisons and schools for minorities. I guess I'll have to agree with J. Segal (1) who said "when patients come from minority groups or lower socio-economic classes, the difficulty of determining the appropriateness and efficacy of treatment is particularly great." I agree but I think that this nation and the behavioral scientist, chemists, genetists, biochemists, social scientists, and health providers have broken the backbone of lethagy in mental health before and I think they can do it now if they commit themselves to the task and competent/sensitive and committed and ethical leadership in and out of the minority communities. History and experience have enabled me to know what the care of mentally ill persons without the phenothiazines, without the

shock therapies and without elaborate buildings but with committed/ ethical providers of care (both the professional and non-professional/ allied health practitioner. Those were the days when we had one psychiatrist to 40-1,000 patients. The ratio of health providers to patient load is much better. I'd like to ask what's the difference in "quality"? I know we have a lot more of gadgetary and a lot "different" staff, Beyond my cynacism, I still think we can meet the task of a better quality of care.

Please pardon my mental excursion and my "show" of commitment and concern. I have been encouraged by a new perspective presented by J. Zubin (31) entitled "Vulnerability - A New View of Schizophrenia," N. Garmezy, entitled "In praise of Invulnerables and Fabrega (19) entitled, The Need for an Ethnomedical Science.

Unlike the businessman who aims to market a product, compete end make a profit, the professional's first commitment is to perform a service -- to patients, to students, to families, etc. Therefore, society gives the professional certain privileges. But lately, society has been monitoring the "store" / professional with greater vigilence, and in some areas we're kinder on "probation." For if we don't hurry and demonstrate our accountability and responsibilities, I'm afraid that we will lose some of our privileges and opportunities to self-regulate our profession - professional

practices. The professionals regulate the functions of their colleagues through professional associations. And I should add that Congress had wed with the professionals in regulating its functions (see "Behavior Modification Under Fire" (32), and the PSRO HMO Protection of Human Subject, Privacy Act and PL-93-641, Health Planning and Resources Development Act of 1974, PL-93-380, the Education Amendment of 1974 - the Safe School Study).

From a minority perspective, I see ethical issues arising out of five areas--

1. The delivery of mental health services and quality and relevance of mental health research;
2. ethical problems in the collecting and storing of large amounts of personal data and the violation of privacy and confidentiality;
3. new methods of treatment - many of which have not been grounded in theory, a rational nor well thought out;
4. ethical considerations in the manipulation and control of behavior through new behavioral technology;
5. ethical issues in community research;
6. ethical factors involved in advocacy as a professional activity;
7. safety and lack of exploitation in human experimentation;
8. less arbitrary use of minority groups in human experimentation because they're "captive" populace in most public institutions;
9. a program which takes into consideration the culture, folklores, life style and the psycho-social-cultural context in which minority groups live in a capitalistic - political and racist society. We need more indepth studies of the underpinnings, dynamics, and impact of generations Of exposure to oppression and racism in mental health in order how/to program for minority groups.

The health bill of the nation in 1972 was 75 billion dollars or 7.4% of the gross national product (G.N.P). As the private outlay increased 9%, the government expenditures for health rose 14%. Nearly two-fifths of the rise in government spending was due to the 25% increase in Medicaid outlays (33). So I am not qualming with the fact that a government and the private sector are not heavily endowing many of the programs which serve minorities. I do qualm with the fact that the quality of service, the administration of the services and the attitudes of too many of the providers and staff are so poor and in some cases unbearable. In some public clinics, the waiting time ranges from 2 to 12 hours. The waiting time and poor quality of services to minorities seem to exist in many institutions administered by minorities as well as non-minorities. Is it the ethics, attitudes, racism or classism? Whatever it is, it is an urgent ethical issue that ALL persons in leadership should address themselves to because it is wasteful of the taxpayers money.

Minority groups need the Medicaid/Medicare coverage because most of them cannot afford or do not value insurance which have mental health coverage. Far instance, the Social Security Administration made a survey on 1969 and found that only 80% of the American public had limited mental health coverage under insurance plans.
In this country, $1 1/2 billion are paid to private psychiatrists and psychologists annually (34).

In the planning of comprehensive programs for minority groups, we must respect their perceptions, values, customs and life style and culture. It is good ethics and etiquette that we respect the American Indians' preference for a medicine man instead of a western trained psychiatrist. It has been found that many American Indians continue to see the medicine men, the Puerto Rican continues to see the spiritualist, the Asian continues to see the herbsman, and the Mexican American continues to visit the Cuanderas in addition to the western trained psychiatrist, It is important that we try to identify where the program of each healer complement, supplement, and conflict with each other.

From a minority perspective, it is imperative that we "do some indepth assessment and evaluation of the use as well as damages of intelligence testing and labelling" for our minority youths. In so many instances the "score" alone is used to "shakle" that minority child to "failure" and despair for the rest of his life. As an old educator, I don't believe the benefits outway the damages. Unfortunately, most minorities are not college bound and they terminate their education or it is terminated for them at an early age. Most minorities would benefit more from an assessment of their abilities/capacities to make decisions, solve problems, plan to use their money, work behavior, rearing children, and how to cope with racism and oppression -- these are realities which would enhance the quality of their life.

To me, some of the basic problems and observations are unanswered in areas of intelligence testing are:

1. the significance of the I.Q. score as a tool for enhancing the quality of life;

2. is the score used by the school, parent, et al in planning and assessing programs or is it used primarily for "labelling" status and categorizing people?

3. what kind of cognitive processes constitute the essence of intelligence?

4. could one distinguish between intelligence and creativity? To what extent do they overlap?

5. what is in terms of basic cognitive factors the structure of intelligence?

6. how are individuals differences accounted for by tenetic and environmental factors?

The debate on the real "nature" of intelligence has for a long time been inspired by the fact that psychologists at an early stage were relatively successful in assessing with remarkable accuracy a socially important personality trait and in predicting behavior determined in part by that trait. Even if intelligence test scores did not account for more than 50% of the variation in scholastic attainments (and the intelligence tests were mainly used to measure scholastic aptitude), the instruments used to measure non-cognitive traits explained at most 10-15% of the variance. But in a highly industrialized society as ours, the controversy takes on another

note where cognitive competence has become conducive or perceived as being conducive, to upward mobility. From a minority perspective, it is here that the "labeling" of the "haves" and have not" serves a purpose not in favor of most minorities - other persons of lower socio-economic status.

Another pertinent ethical issue is the contingency that certain minority children have to be on tranquilizers or some similar drug because they are "labelled" as hyperkinetic, minimum brain damage (MBD). Many parents are alarmed about their children being on these drugs because they were not consulted and they were not aware of their child had been examined by a physician for any such condition. Some of the parents have learned that the teacher established the diagnosis because the child was restless, disruptive in the classroom and had a short attention span. On occasion, I personally looked into the allegation and on other occasions, I suggested that the parents call the local mental health association. In any case, I question the ethics of baths the teacher and the physician, who prescribed the medications (35) (36) (37).

From a minority perspective, I am concerned about the ethical issues of privacy, confidentiality and consent. I would like to make some comments about the latter because I've seen it abused so badly. Last year, I received a personal call one night from a group of nurses who were asking advice on a predicament they faced. They worked in a clinical setting in a correctional institution and were concerned by the practice that they were

asked to get the inmate to sign him to consent to surgery (43) form after his 10-20 day recuperation and just prior to his return to the building where his cell was located. Their concern was that it was unethical, illegal, and they were really unaware of the nature of the operation and so was the inmate. Yet, these tenure nurses, head of household could not question the administration or their superior, because they had seen what had happened to other staff who question practices, policies and administration!

What is informed consent to a person who doesn't speak english, illiterate, disturbed by the existence and uncertainty of illness, frightened by a sick role and distrustful of health facilities. It is an ignored/unacknowledged fact that the physician does not have the time and sometimes the patience to explain and implement all the items in the regulation about informed consent. The function of obtaining the consent should be established as policy or law. The physician doesn't have the time, the nurse, physician assistant or anesthesiologist think that the physician has done so. So the patient is generally uninformed, unless the aide or housekeeper comes along to tell you what is about to happen. This is a sad affair, it is a fairly generalized practice, it is unethical and immoral and unkind -- never mind about telling me what's in the regulation; I'm talking about what's in the "operations."

Another area of concern is the application of the consent concept to non-medical treatment/programs in laboratories, schools, correctional programs,

rehabilitation programs (38) (39) as well as to consent of involuntarily detained persons. Inasmuch as consent is required prior to experimentations what about the ethical issues and accountability of the professional for the actions during and after the treatment experimentation. I am an advocate of a contractural model for the protection of the Rights of Institutionalized Mental patients (40). Dr. Henry K. Beecher has said, "the informed consent of the subject, while often is a legal necessity, is a goal toward which we must strive but hardly ever achieved except in the simplest cases" (41)

My observations and experiences have indicated that most of the committees on Protection of Human Subjects/Human Experimentation do not have competent minority membership. One minority professional at a large university medical center has been on the Human Subjects/Human Experimentation Committee for 2 years and has never been called for a meeting. I do know in some instances the committee does not have a formal meeting, the chairman of the committee reviews or delegates another member to review and take action on the proposal. One committee at a large university recently approved a proposal as protection of human subject as adequate. The project was a study of American Indian elementary school children. There was no consent form. The investigators rationale was that a consent was not necessary because the children were already participants in another project which was unlike the one he was about to start.

So from a minority perspective, I think that the ethics, practices and functions of the committed should be monitored. The membership on the committees should include representation of the people they serve.

There are many ethical issues in the areas of risk, some of them include the active participation of the patient, family and staff in defining, determining and/or assessing risk.

Some of the variables/criteria in assessing risk should include:

A. Risk to the subject

1. physical
2. psychological
3. economic
4. social (effects on the job, in the marriage, status with peers, etc
5. legal
6. personally (effects on image, identity, willingness and eagerness to get well, the challenge of being/expectation of being a "well"/healthy person).

B. Risk to society

1. physical
2. social
3. legal
4. psychological
5. economic
6. maintenance of social role and life style

C. Risk of not doing the research

1. benefits

2. issues of scientific design and methodology

3. benefits to the person, tribe/race, society, ethnic groups, the family and culture

4. psycho-social benefits

5. religious/spiritual benefits

6. economic benefits

7. other derived benefits

8. is competent staff available on a continuing basis for the conduct and supervision of the research?

9. authority and limitation

D. Assessment and Evaluation of Risks

1. family

2. researchers and other consumers

3. other disciplines

4. roles of initial review board and the subject and family.

In summary, I am convinced that far too many of the practices and mental health research pertaining to minority groups are not so ethical, relevant nor of a satisfactory quality. I am not going to waste too much of my time outlining what I think should be done, because the "brains" know what needs to be done; we simply need to commit ourselves to it and put an end to the other "jazz" and "ongoing". In this country, we can do just about what we want to with great urgency when we value the people enough. We can program, teach ethics, supervise and enforce ethical practices when we're committed and value the people.

The public has lost faith in health and educational and correctional institutions. Traditional acceptance of health and other institutional programs on the basis of their past performance and apparent but unsubstantiated worth is no longer the rule. The public is demanding that schools, health, facilities and manpower are utilized well and "properly" that hospitals are not used to "warehouse" patient (see the Mental Health Law Project Summary of Activities, September 1975 (41).
But this has meant far more than mere financial accounting to ensure that funds have not been illegally spent or embezzled. What is demanded instead is that schools, health and other public facilities demonstrate that the outcome they are producing are worth the dollar investment provided by communities. In short, what the public has called for is a system of accountability and ethical consideration. Minorities tried their

"call" in the 60's and many minorities of the 55 million minorities are asking was it "worth" in contrast to the amount of suffering and the amount of ~~classism~~ racism which still exist out of classism as well as in the minority communities. But educational and health accountability are very much like other abstract virtues such as patritism and truthfulness which are universally acknowledged but not amenable to facile description.

Smith (42) has suggested 3 kinds of accountability.

A. Program accountability -- concerned with the quality of work carried out and whether or not it met the goal set for it and is it relevant and sensitive to needs of its minority group.

B. Process accountability -- ask whether the procedures used to perform the research were adequate in terms of the time and efforts spent on the work.

C. Fiscal accountability -- has to do with whether the items purchased were relevant and used for the project.

D. Outcome accountability -- produce of "care" research findings in keeping with the purpose and goal of the project and for the quality of the outcomes as stipulated in contract.

E. Goal and objective accountabilities -- shared between the staff, administration, board of trustees, management and the public. Goals and objectives must be assessed/evaluated periodically.

Therefore, I believe that the mental health researcher and service providers must be ethical and that they must be held accountable at every level.

Accountability is the product of a process; at its basic level, it means that an agent, public or private, entering into a contractual agreement to perform a service will be answerable for performing according to agreed upon terms within an established time period and with a stipulated use of resources and performance standards.

As a result of the above, delimena, I feel a great deal will be gained by holding persons accountable
(programmatically, fiscally, ethnically and the quality of outcome).

So I surmise that better ethical practices, accountability, licensure, accreditation, certification and the Good Lord a better quality of mental health research will occur and we'll have less "Tuskegee - Syphilis" incidents".

ome of the ethical issues raised in this paper from a minority perspective I would recommend the following:

1. membership in the IRB or any research committee pertaining to human experimentation include qualified minority members;
2. some system be established to monitor the activities, processes; outcomes and proceedings of the IRB on committees.
3. Establish an accountability system in which governmental staff will be held responsible and accountable for the safety and protection of the humans in an experiment. It is difficult to accept a potential repeat of the Tuskegee Syphillis Study which lasted for about 40 years (1932:1972) in which 400 Black males were denied treatment for syphilis which had been

diagnosed because of the constitutional violations and the apparent racist nature of the experiment. The study/project was ongoing in five other counties in addition to Tuskegee. The study sample did not include white persons.

4. An indepth study, analysis and evaluation should be made of the policies, procedures, practices, etc of acquiring informed consent and establishing levels or degrees of risk involved in mental health research.

Contingent upon the findings of this study and those of other studies, definite models for obtaining informed consent for persons who are illiterate, non-English speaking, emotionally ill, not familiar with medical jargon, lower-socio-economic groups, new immigrants, etc.

The responsibility and accountability for getting informed consent should be established.

5. Pilot the use of an ombudsman in about 10 clinical and non-clinical settings where mental health research is carried out to assist the members of minority groups in more effective understandings and participation in mental health research. The ombudsman might be an indigenous clinical or behavioral scientist who can prepare the person for participation in the research, obtain informed consent, insure privacy and confidentiality in the human experimentation.

6. Establish some kind of consumer program in which persons involved in research (voluntarily and involuntarily) can report unethical cases or incompetent practices and not be fired or disciplined. Such a consumer

program should not be established in a professional organization. Local mental health associations might provide such a service. The commission might recommend that such a program be funded and piloted for 3 to 5 years. The staff of the program should include qualified, ethical and committed persons.

7. To really ensure protection of human subject, I would recommend that 4 or 5 programs be established in clinical, correctional and social programs to assess the effectiveness of the contractual model for the protection of rights of institutionalized minority mental patients or inmates.

I must conclude with the level of distrust; economic, political and integrity crises, I do think that the public should "up" its monitoring, policing, supervision and questioning of educational, health, correctional, rehabilitation and research facilities and program and hold the professionals accountable and responsible.

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RESOLUTION AND RECOMMENDATIONS OF THE WORKSHOP ON THE INSTITUTIONALIZED MENTALLY INFIRM

Workshops 5 & 6

Resolution and Recommendations of the Workshop on the Institutionalized and Mentally Infirmed

National Minority Conference
on
Human Experimentation
January 8, 1976

RECOMMENDATIONS

GUIDELINES FOR THE SELECTION OF HUMAN SUBJECTS

1. Biomedical or behavioral experimental procedures or research should not be conducted on the institutionalized mentally infirm unless all the following criteria are met:

   A. the individual has a medical, clinical, or psychological condition demanding investigation and treatment, and

   B. the proposed experiment offers a reasonable likelihood for yielding results leading to the control or cure of the condition in question, and

   C. alternative medically established and accepted procedures to treat that condition do not exist or are inadequate, and

   D. the research cannot be accomplished outside of the institutional setting.

2. Very strict safeguards should be enforced against the disproportionate use of certain powerless groups; i.e., racial, ethnic, and low income groups as subjects of research.

3. Prior to the commencement of experimentation the appropriateness of the subject's institutionalization should be re-evaluated by at least two clinical professionals not affiliated with research team.

INFORMED CONSENT

1. No one should be a participant in an experiment against their will, regardless of mental competency or incompetency.

2. Within reasonable limits the prospective participant may secure outside opinions, at no cost to the participant.

3. Evidence that the guidelines for informed consent procedures were appropriately followed must be available to the public for inspection.

4. The confidentiality of research participants must be protected.

5. Patients should be given full information regarding an experiment including the results of previous studies and the possibility of being part of a research control group.

6. The informed consent procedure should insure that the subject is voluntarily giving consent and be witnessed by at least two people not connected with the institution, nor with the research project.

7. Any professional explanation provided to a prospective participant must be presented and written in the primary language on the educational level of the prospective participant and one other spokesman. The explanation should be fluent enough so that the prospective participant and the spokesman are fully informed.

8. The consent form should specify financial responsibility or liability in the event of untoward results occurring from the experiment which would require extensive or prolonged care. Liability should be born by the Federal government in Federally-sponsored research.

9. Subjects shall have the right to withdraw from the experiment at any time without the loss of any privilege or right and with assurance of continued treatment by the best available alternative procedures. This right shall be included in the consent form.

10. The consent form should allow for the signature of prospective participants who are minors but are seven years of age or older.

11. The participant should be given a conformed copy of the consent form.

THE INSTITUTIONAL REVIEW COMMITTEE

The committee's composition should:

(1) be composed of a majority of community representatives;

(2) reflect the racial, ethnic, economic, lingual and other sociological characteristics of the subject populations;

(3) rotate periodically; and

(4) include some representation of previous subject populations and/or present consumers of institutional health. services.

The institutional Review Committee's functions should:

(1) review every grant application in light of the benefit and risks to the subject;

(2) be reviewed in light of criteria for acceptable experimental procedures or research on the institutionalized mentally infirmed;

(3) periodically review the experiment and all information related to the experiment;

(4) periodically re-evaluate the appropriateness of the subject's institutionalization and research participation;

(5) monitor the "consent process" to insure that all criteria for consent are adhered to and that it is truly voluntary and informed;

(6) carefully scrutinize the inducements used to attract the subject group; and

(7) insure regular feedback to the subject, as to the experiment progress.

GENERAL

(1) It is recommended that there be established a permanent Minority Commission to give ongoing input for the protection of human subjects in experiments.

(2) Mechanisms should be developed to monitor and regulate biomedical and behavioral research conducted by all Federal agencies. In the absence of such mechanisms, all research should be prevented.

(3) Research findings both positive and negative should be reported to participants.

(4) Initial studies in humans should be conducted with adults rather than children, where possible.

(5) Research funds should be discontinued if periodic monitoring reveals violation of guidelines which are not corrected within a reasonable period of time.

(6) That the National Commission for the Protection of Human Subjects commend Geraldine Brooks for bringing together, for the first time, a group (of this type) to discuss human experimentation.

III

SUPPLEMENTAL RESOURCE INFORMATION

Excerpt from:

ETHICAL PRINCIPLES IN THE CONDUCT OF RESEARCH WITH HUMAN PARTICIPANTS

American Psychological Association, Inc., 1973

Excerpt from: Ethical Principles in the Conduct of Research with Human Participants, American Psychological Association, Inc., 1973.

C. *The Problem of Informed Consent from Those Not Competent to Give It*

Legally as well as ethically. some potential participants in psychological research do not have the competence to give their informed consent. The problem arises with children and legal minors, with the mentally retarded, and with psychotics. Sound practice from a legal standpoint requires that the informed consent of the legal guardian be obtained for such an individual's research participation; the corresponding ethical consideration holds that free and informed consent should be obtained from a person whose primary interest is in the participant's welfare. The information needed for a decision in the participant's interest should be supplied.

But even in the case of legally incompetent persons, consent on the part of a parent or guardian does not obviate the need to provide information understandable to the potential participant whose wishes are to be respected. When a child, a mentally retarded person, or a disturbed patient is capable of making some reasonable judgment concerning the nature of the research and of participation in it, permission should be obtained from the participant as well as from the responsible adult or guardian.

Excerpts from:

ACCREDITATION MANUAL FOR PSYCHIATRIC FACILITIES, 1972

and

STANDARDS FOR RESIDENTIAL FACILITIES FOR THE MENTALLY RETARDED, 1971

Joint Commission on Accreditation of Hospitals

ACCREDITATION MANUAL FOR PSYCHIATRIC FACILITIES 1972

(EXCERPT)

Joint Commission on Accreditation of Hospitals
875 North Michigan Avenue Chicago, Illinois 60611

RESEARCH

STANDARD I

Psychiatric facilities shall have a research program when consistent with their goals and resources.

INTERPRETATION

In psychiatric facilities whose goals include research, a research program organizationally comparable to other services shall be established. There shall be a research committee appointed to study and authorize all proposed investigative studies. The research committee shall be interdisciplinary, and should consider both the soundness of the theory supporting the proposed research and the validity of the research design.

Opportunities for submission of research proposals shall be made available to all professional staff. Contacts with colleges, universities and other appropriate institutions should be explored and developed to plan cooperative research programs.

In psychiatric facilities that do not. have research programs, research-oriented projects should be encouraged.

STANDARD II

A psychiatric facility with an organized research program shall have scientifically qualified and capable leadership with trained staff.

INTERPRETATION

Sufficient numbers of qualified technicians and clerical personnel shall be available to support research activities. Contacts should be made with appropriate educational institutions to recruit talented workers.

STANDARD III

There shall be a written statement of policies and procedures to guide a program of research.

INTERPRETATION

Policies and procedures should provide for at least the following:

- Whenever patients are involved in research, informed written consent shall be obtained from the patient involved, or from his personal representative. If the consent of the patient himself is obtained, care should be taken to ensure that he is capable of giving informed consent. There shall be no coercion, nor undue suffering or pain, either physical or psychological.
- Research in which human subjects are used should be conducted only if permitted by law and only by scientifically qualified individuals, in adequately equipped settings and with appropriate liaison with, or supervision by, a suitably qualified clinician. Where body integrity may be violated, or when otherwise appropriate, there should be medical liaison or supervision.
- Clinical research projects shall not be carried out unless the importance of the objective, to the subject as well as generally, is proportionate to the risk to the subject. Research projects should be evaluated, prior to work with subjects, with careful assessment of the relationship of the inherent risks to subjects or others to the benefits of the project to individuals or society. Such assessment shall be reflected in the research design.

STANDARD IV

When a research project is conducted, there shall be adequate provision for physical space, equipment and safety.

STANDARD V

Full and complete records and reports of all research activities, whether published or unpublished, shall be maintained.

INTERPRETATION

Reports of all research activities shall reflect utilization of manpower, time and funds, as well as the specific objectives of the research activity and the findings.

The patient's right to confidentiality shall not be violated by the research study or its utilization, unless authorization is granted by the patient involved.

STANDARD VI

There shall be educational resources available to support research studies.

INTERPRETATION

If the psychiatric facility does not have a reference library, professional and scientific journals, books and research reports shall be available from a resource close enough to be frequently utilized.

Attendance at scientific meetings with particular relevance to research in progress should be encouraged and supported.

Joint Commission on Accreditation of Hospitals

ACCREDITATION COUNCIL FOR FACILITIES FOR THE MENTALLY RETARDED

STANDARDS FOR RESIDENTIAL FACILITIES FOR THE MENTALLY RETARDED

(EXCERPT)

Adopted May 5, 1971

The development of these Standards was supported, in part, by
Grant Number 12-P-55178/5 from the Social and Rehabilitation Service,
and Grant Number 33121 from the Public Health Service,
U. S. Department of Health, Education, and Welfare.

SECTION 5. RESEARCH

5.1 Encouragement of Research

5.1.1 Recognizing that the understanding, prevention, and amelioration of mental retardation ultimately depends upon knowledge gained through research, the administration and staff of the facility (and, in the case of public facilities, the appropriate governmental agency) *shall* encourage research activity.

5.1.1.1 Opportunities and resources should be made available to members of the staff who are equipped by interest and training to conduct applied and/or basic research.

5.1.1.1.1 Research resources and/or necessary research assistance should be made available to all staff members who have identified researchable problems related to the programs for which they are responsible.

5.1.1.2 Research by qualified investigators who are not staff members of the facility *shall* be encouraged.

5.1.1.2.1 There *shall* be a written policy concerning the conduct of research in the facility by investigators who are not staff members.

5.1.1.2.2 Outside researchers *shall* fulfill the same obligations relative to staff information and feedback as do facility staff members.

5.1.1.2.3 Consideration should be given to the assignment of a facility staff member to each research project conducted by outside investigators.

5.1.1.3 Where feasible, there *shall* be ongoing, cooperative programs of research and research training with colleges, universities, and research agencies.

5.1.2 The administration of the facility *shall* make provision for the design and conduct, or the supervision, of research that will objectively evaluate the effectiveness of program. components and contribute to informed decision making in the facility.

5.2 Review of Research Proposals

5.2.1 An interdisciplinary research committee *shall* review all proposed studies to ensure:

5.2.1.1 Adequacy of research design;
5.2.1.2 Implementation of ethical standards in the design.

5.2.2 Facility staff members *shall* be consulted regarding the planning of research and the utilization of research findings in their areas of competence and interest.

5.3 Conduct of Research

5.3.1 The facility *shall* follow, and comply with, the appended Statement on the Use of Human Subjects for Research of the American Association on Mental Deficiency, and with the statement of assurance on research involving human subjects required by the U.S. Department of Health, Education, and Welfare for projects supported by that agency.

5.3.1.1 For the purposes of these Standards, the requirements stated in paragraphs 2, 3, 4, and 7 of the appended AAMD Statement *shall* be understood to be mandatory, and wherever it occurs in these paragraphs, the word "should" *shall* be interpreted to mean *"shall."*

5.3.2 Investigators and others directly involved in the research *shall:*

5.3.2.1 Adhere to the ethical standards of their professions concerning the conduct of research;

5.3.2.2 Have access to the record of informed consent.

5.4 Reporting Research Results

5.4.1 The principal investigator of each research project *shall* be responsible for communicating to the staff of the facility the purpose, nature, outcome, and possible practical or theoretical implications of the research.

5.4.1.1 Copies of the reports resulting from research projects *shall* be maintained in the facility.

5.4.2 Where research findings are made public, care shall be taken to assure the anonymity of individual residents and parents.

5.4.3 Clearly defined mechanisms *shall* exist for informing staff members of new research findings that have applicability to the programs and administration of the facility.

5.4.3.1 There *shall* be evidence that currently applicable research results are being implemented in the facility's programs.

American Association on Mental Deficiency
Statement on the Use of Human Subjects for Research

PRINCIPLES

1. Research in mental retardation must conform to the scientific, legal, and moral principles which justify all research, and should emerge out of sound theoretical bases or follow previously accepted research design.

2. Research in mental retardation in which human subjects are used should be conducted only by scientifically qualified individuals in adequately equipped settings and with the appropriate liaison or supervision in which a suitably qualified clinician is used. Where body integrity may be violated or when otherwise appropriate, medical liaison or supervision should be included.

3. Clinical research projects cannot be carried out legitimately unless the importance of the objective is proportionate to the risk to the subject. Such potential risks should be evaluated prior to work with subjects with careful assessment of the inherent risks to subjects or others as compared with the benefits to individuals or society that will accrue from the research, and must be reflected in the research design.

4. Caution in exercise of research should not be limited to physical harm but should include unwarranted psychological impairment to the individual subject or his family.

5. Coercion of subjects or of families must be prohibited.

6. Compensation should be provided for the expense or unusual inconvenience caused by the research involvement of the subject and/or his family.

7. Ethical aspects of experimentation in mental retardation should be clearly stated in the research design at all stages in its development.

8. Consent of the subject or of the subject's legal guardian should be obtained for any research.

9. Experimentation should be planned in such a way as to avoid pain, suffering, or inconvenience to the research subject and his family or guardian.

10. The researcher must assume responsibility for preparing an appropriate report of his work and for making this report available to colleagues or others in the scientific community.

10

Excerpt from:

NATIONAL STANDARDS FOR COMMUNITY MENTAL HEALTH CENTERS, 1977

Department of Health, Education, and Welfare

NATIONAL STANDARDS FOR COMMUNITY MENTAL HEALTH CENTERS

A Report to Congress

by

The Secretary of Health, Education, and Welfare

pursuant to

Section 304(b), Title III, of the Community Mental Health Centers Amendments of 1975, PL 94-63.

prepared by

National Institute of Mental Health, Alcohol, Drug Abuse, and Mental Health Administration, U.S. Public Health Service, Department of Health, Education, and Welfare,

Rockville, Maryland, January 1977

Excerpt from: National Standards for Community Mental Health Centers, A Report to Congress by the Secretary, Department of Health, Education, and Welfare, January 1977.

II. Clients' Rights

Standard #1

The Center shall establish written policies which shall be clearly posted and available to all those receiving services. These shall describe clients' legal rights relating to services rendered and all the rules and regulations governing their conduct while clients of the Center.

Criteria

A. Clients shall be informed of:

1. All their rights, and all rules and regulations governing their conduct while clients of the Center.

2. The treatments planned, the benefits expected, the risks entailed, and their right to refuse any treatment

3. The use of any experimental or non-standard forms of treatment

4. The confidential treatment given all information pertaining to them and their right to approve the release of identifiable data.

5. Their right to be treated with full recognition of their personal dignity and individuality and need for privacy, respect, and consideration

Source: Policy and Procedures Manual, staff and client interviews, surveyor observation

B. These policies shall be written in readily understandable language.

Source: Policy and Procedures Manual

C. These policies shall be written in the major language(s) spoken in the catchment area

Source: Policy and Procedures Manual

Standard #2

There shall be procedures to assure that the rights of clients and their welfare are protected and that appropriately executed written, informed consent is obtained whenever appropriate.

Criteria

A. Written, informed consent shall be obtained for:

1. All experimental treatments and procedures

2. All non-standard treatments and procedures

3. All procedures with an acknowledged inherent risk such as ECT and psychosurgery

4. Participation in provider education demonstration programs such as those involving audiovisual equipment and one-way mirrors.

Source: Policy and Procedures Manual

B. The Center shall have a Protection of Client Rights and Welfare Committee, made up of clinicians and appropriate others, which shall periodically review research and treatment given at the Center, and designate which are to be considered under categories A.1,2,3, above.

Source: Policy and Procedures Manual

1. The Committee shall maintain minutes which include meeting times, Committee members present, and matters discussed.

Source: Client Rights and Welfare Committee minutes

Excerpt from:

CONSENT HANDBOOK, 1977

American Association on Mental Deficiency

(EXCERPT)

Consent Handbook

H. Rutherford Turnbull, III
Editor

Douglas P. Biklen
Elizabeth M. Boggs
James W. Ellis
Charles V. Keeran, Jr.
Greig R. Siedor

Task Force of the AAMD Legislative and Social Issues Committee, 1975-76

American Association on Mental Deficiency, Inc.
Special Publication No. 3

G. Human Experimentation

Experimentation involves the application of unvalidated procedures and may or may not be research, depending on whether or not the scientific method is applied. Since these procedures require the direct exposure of selected individuals to specified events or agents whose effects are not always clearly known, they should be subjected to systematic analysis utilizing acceptable research design.

However, even with this type of safeguard the use of mentally retarded people as research subjects is a controversial ethical and professional issue. This is so in part because there was a tendency toward "exploitation," i.e., the relatively uncontrolled use of mentally retarded people as research subjects, particularly those who were institutionalized. In part, the institutionalized retarded were seen as an "available" and therefore convenient population. Exploitation, however, also reflected a devaluation of both the life and rights of retarded individuals.

It is also so in part, because, the Nürenberg trials revealed shocking information on the uses of human beings as "research" subjects. The trials led to the enunciation of minimum standards by which to protect human research subjects.[1] One requirement was the individual's informed, uncoerced consent.

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[1]AAMD Policy Statements on "Human Rights Review and Protection Boards" and "Use of Physical, Psychological and Psycho-pharmacological Procedures to Affect Behaviors of Mentally Retarded Persons," and the work of the National Commission on Experimentation on Human Subjects reflect similar concerns for protecting human subjects.

As standards were developed, refined and applied, questions arose regarding the ability of individuals with impaired capacity to understand the conditions and consequences of participation—the requirements, risks, and potential benefits of a research activity. Unless this understanding were achieved, could consent to participate as a research subject be truly "informed"? Moreover, participation by people confined in institutions was likely to result in rewards or special privileges for participating, or in express or implied threats for refusing to participate. How could a distinction be drawn among benefits, privileges, bribery, and implied coercion? Could consent from anyone in an institution be truly "voluntary"?

Proposals recently have been made to exclude from research projects at least institutionalized mentally retarded persons. But this development is alarming. It threatens an abrupt decline in research: the major hope for new knowledge that could benefit mentally retarded people.

By now, it is apparent that principles of normalization require that retarded persons not be excluded automatically from participation in research projects. However, their own inherent mental limitations and, at times, the potentially coercive elements of the environments in which they find themselves or in which the research will be conducted must be recognized and reflected in consent procedures.

Minimum Requirements of All Research Proposals. A retarded person should not be asked to participate in a proposed project if the research objectives can be met, within reason. by the use of nonretarded subjects. Further, the study must have a significant potential for directly benefiting a given participant or for contributing new knowledge that might benefit other retarded individuals or their families or prevent mental retardation. (Note that the "direct benefit rule" is only one criterion for participation in research; there is another criterion.)

If the proposed project meets these conditions, then it must be reviewed and endorsed as scientifically sound. Moreover, the plans and procedures for securing consent also must be reviewed and endorsed as adequate. Two types of review, then, are required: one as to scientific methodology, and another as to the adequacy of consent. Although these two functions may be performed by one review body, they also may be performed by two separate and distinct bodies. At least one body is necessary, or else neither review function will be performed. A significant problem with having one body perform both reviews is that this group may be overloaded with members prejudiced in favor of research or less inclined, because of their scientific training, to inquire closely into the

issue of whether effective consent has been obtained. The AAMD Policy Statement on "Use of Physical, Psychological and Psychopharmacological Procedures to Affect Behaviors of Mentally Retarded Persons" sets forth the Association's preference that two separate and distinct bodies perform the two separate and distinct functions of review.

Mentally retarded people must not be exploited as research subjects. They should not be used merely for the investigator's convenience. To put it another way, non-retarded people should not be used when the research objectives can be met equally by them. This is so because they are more likely to comprehend explanations regarding conditions of participation, risk, intrusiveness, and reversibility. Yet, under some circumstances, it is wholly appropriate for retarded people to be included in a project. This may occur, for example, when institutionalized mentally retarded people furnish the only subjects for research, such as research on the effects on the retarded of institutionalization or deinstitutionalization. It may also occur in other circumstances. The following example will clarify this point.

It is difficult to see why, except for convenience, the developer of a new cold remedy would want to test it first upon a group of institutionalized mentally retarded people. Could not equal or better results be obtained from tests on a "normal" population? However, at some point in the development of this potentially valuable remedy, the research design may call for a random sample of subjects. Failure to include retarded people who were naturally selected by the random process might modify the results. Furthermore, out-of-hand exclusion denies the retarded person equal opportunity to exercise a choice regarding participation or non-participation. Finally, because of the potential benefits of such a product to people living in close proximity, it may be possible to justify a study in which only institutionalized mentally retarded people would be utilized. This decision would be reached by evaluating the quality of the study, including a clear review of previous or related studies, the potential benefits, and usual considerations for risk, intrusiveness, and reversibility.

We acknowledge that research on institutionalized retarded persons has been conducted for reasons that are not wholly or even partially acceptable—for example, the convenience of the investigator. We also recognize that research on such people in some instances has been abusive. We do not, however, adopt the position that some people adopt, that research on institutionalized mentally retarded persons should never, under any circumstances, be performed. We approach research on such

persons in a different way, believing that procedural safeguards of the sort described throughout this handbook, coupled with professional ethics and the sanctions of the law, will be powerful assurances against the unwise and unpardonable practices of the past. (As noted in Chapter IV we do not subscribe to the theory that "voluntary" consent never can be given in an institutional environment.)

Who may determine when a retarded person's participation as a human subject in a research project is appropriate? The burden of responsibility for the adequacy of the research and the consent procedures rests with the investigator. Because of the potential for exploitation, a second review should occur. An independent group of individuals with relevant scientific expertise and adequate credentials as advocates should review and approve the proposal. Such a review group is called for by guidelines established by the Department of Health, Education, and Welfare. These guidelines must be followed if the study is supported by federal funds and they should be followed in all cases involving the use of human subjects. Moreover, as we stated above, a separate review of consent procedures should be carried out by another review body. These three reviews—by the investigator and the two review boards—constitute the minimum requirements for participation.

The Consent Procedure. Assuming the project meets the minimum requirements, the usual factors of risk, intrusiveness (including pain and discomfort), and reversibility will govern the formality of the consent procedures. For example, a project that calls only for measuring a client's weight and height would require far less consent formality than one that calls for the ingestion of a pharmaceutical or some other procedure having a high risk-benefit expectation.

There should always be compliance with HEW consent requirements, as follows:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonable to be expected;

(3) A description of any benefits reasonable to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the "subject;"

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the "subject."

In addition, there should be an explanation of the requirements to be made of the person as a participant in the project (i.e., what he will be asked to do) and an explanation of the disposition of the data about the participation.[1] As indicated, these explanations must be given in such a fashion as to help the potential subject understand them. The mechanism for testing this comprehension should be described in the proposal (see Chapter IV).

Certain situations deserve special consideration. One arises if the individual lives in an institution: in his case, it is particularly important to assure the absence of coercion or promised rewards. Also in his case it is common to doubt his ability to fully understand the ramifications of consent. Here, answers to two questions often suggest the appropriate decision:

1. Would another person with greater comprehension be equally suitable for the project?
2. How great are the potential benefits to the proposed subject himself?

If another person would be equally suitable and if the potential benefits to the proposed subject himself are questionable. another person should be sought. The decision becomes more difficult when the benefits and risks are high and a suitable alternative person is hard to locate. Under these circumstances, concurrent consent from an immediate family member or other qualified advocate should be obtained. (To repeat, we reject the "direct benefit" rule, see Chapter III.)

Occasionally, there will be high potential benefit and significant risks for a person with limited ability to consent. Then, not even concurrent consent is satisfactory. Investigators should secure an appropriately authorized substitute consent. As indicated in Chapter III, substitute consent can be provided by the parent or legal guardian.

In summary, an element of judgment enters all consent decisions. For example, when can one be reasonably sure the person understands?

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[1]Old data or previously collected specimens sometimes are useful in subsequent investigations. Can they be re-used? Again, the factors of risk, intrusiveness, and reversibility must be considered. Since it is old data or previously collected specimens, the consequences of risk and reversibility have been met. Therefore, the major consideration is intrusiveness. That element of intrusiveness most likely to require review is confidentiality and privacy. In this context, risk-benefit takes on a different hue. What type of individual would have access to the information? Is direct identification of the person possible? Are the recipients or data users accountable for complying with similar ethical considerations of confidentiality? What are the potential benefits to the individual or to other mentally retarded people or to their families? The answers to these questions will indicate the degree of formality of the consent procedure.

When can additional clarification be interpreted as coercion? When would rewards be considered bribery? We know of no substitute for sound professional judgment in arriving at these decisions.

In the final analysis, of course, the burden of responsibility for the adequacy of the consent rests with the investigator. When in doubt, he should take a conservative approach and exclude the proposed subject from participation until that doubt has been removed. In short, the professional should err on the side of a high degree of scrutiny and highly formal consent mechanisms.

H. Behavioral and Social Research

Research involving interviewing, testing, observing, behavior treatment (see Section E), and sociology is behavioral and social research. For the purpose of this section, we are concerned with sociological, psychological, and educational research (types of behavioral and social research) that involve participation by human subjects.

The courts have not yet addressed behavioral and social research to the same extent that they have addressed issues in human experimentation. Nevertheless analogous law and good ethical and professional practice suggest the considerations involved regarding consent of subjects in behavioral and social research.

No Consent Required. Some kinds of research will require no consent by the subject. For example, researchers need not obtain consent to study the daily, professional behavior of public officials, unless, of course, the research poses some physical risk or is so intrusive as to abridge even the particularly limited privacy rights of public officials. Similarly, researchers are relatively free without seeking consent, to observe people in public settings, including schools, institutions, and bureaucracies. In many states, it is also permissible to photograph (as part of research) people in public settings, without their consent. Also, researchers who use only aggregate data (e.g.. census statistics) would not concern themselves with the isssue of consent.

Implied Consent. In other kinds of research, consent is implied by virtue of the subject's participation; express consent is not expected. Most interviewing, including polling, is done in this fashion. A person's willingness to respond to the interviewer's questions implies consent. Obviously, some interviewing research is considerably intrusive and may have a significant impact on the subject. In such instances more formal procedures for obtaining consent would be required.

When Express Consent is Required. When research involves risk or

intrusiveness, and when its impact on the individual may be irreversible, the researcher must seek express consent. Researchers may be better able to decide whether to seek consent if they have asked the following questions: Is there some stigma associated with participation? Does the research involve a potentially harmful denial of treatment? Is the environment in which consent has been sought at all coercive? For example, is one's admission to an habilitative program contingent upon consent to participate in a research project? Is the research designed to benefit the individual directly, significantly, marginally, or not at all? Could the research be completed with the involvement of non-retarded persons?

In a non-coercive atmosphere, the researcher should fully describe the nature of a person's involvement, usually the research purpose (this may not be essential in all instances), the duration of involvement, all potential risks, the degree to which the research will intrude on the participant's fife, the possible benefits to him, and whether the research conforms to norms of research in the particular field (e.g., education or psychology.) Researchers must also pay close attention to the matter of whether the proposed subject can understand a description of the research. While the foregoing information may be given verbally, sound professional, ethical and legal judgment suggest that the researcher secure written consent.

As we have stated in Section G, "a retarded person should not be asked to participate in a proposed project if the research can be met, within reason, by the use of nonretarded subjects." If the risks are minimal and the results potentially valuable, a retarded person may participate as a member of a random sample. However, research usually should involve a mentally retarded person only when it will directly benefit him, when it may have important results not directly beneficial to him that can be accomplished only with his involvement, or when it has a significant potential for contributing new knowledge that might be beneficial to other retarded individuals or their families or lead to the prevention of mental retardation.

Members of control groups must also be regarded as research subjects. Whenever the control subject's participation involves risk or intrusiveness, his consent should be obtained.

Review Boards. In addition to the following formal consent procedures when there are elements of risk, intrusion, or irreversibility, researchers would be wise to review their consent procedures with human subjects review boards (see Section G). When behavioral or social research is conducted, the board reviewing methodology should be comprised of at least one behaviorist or social scientist, as appropriate.

Several examples may help to clarify the degree of scrutiny of consent to be applied by investigators and review boards. (A) Researchers who are observing the clothing styles of all people (some of whom may be retarded) who pass through a particular public setting would require no consent at all. (B) Research in which the investigator interviews retarded persons, anonymously, about their opinions on public issues would require no more than implied consent. (C) Research that involves psychological testing of retarded persons whose ability to understand the proposed procedure is questionable requires formal consent and, possibly, concurrent consent or formal review by an independent board. (D) At a more extreme end of the continuum, research that involves placing persons in a mental retardation program would require formal consent from that person and, possibly, depending on his capacity to understand the proposed procedure, substitute consent as well; review by an independent board also is appropriate.

Research that involves deception sometimes is necessary. The problem is that when the investigator deceives the retarded person, the relationship between them is impaired, the retarded individual's views of other investigators is adversely affected, public attitude toward research becomes jaundiced, the scientific community itself, together with its research efforts, are prejudiced and the possibility of exploitation is increased. Instead of avoiding all research that involves deception, the investigator might find ways of conducting his research without informing the participant in advance, of what hypotheses he intends to explore. He should offer to explain the hypotheses after he conducts his research, and he should, of course, offer the regular information about risk, intrusiveness, and irreversibility. It is one thing—a deplorable action—to play games with retarded people by deceiving them; it is another to conduct research in which the hypothesis is not stated in advance and in which other facts are given in order to satisfy the element of "informed" consent.

12

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