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THE CAPACITY OF HSOPITALIZED SCHIZOPHRENICS
TO GIVE INFORMED CONSENT

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THE CAPACITY OF HOSPITALIZED SCHIZOPHRENICS TO GIVE INFORMED CONSENT

By

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ABSTRACT

THE CAPACITY OF HOSPITALIZED SCHIZOPHRENICS TO GIVE INFORMED CONSENT

By

Genice Lovetta Rhodes-Reed

This study examined the ability of 102 legally competent hospitalized schizophrenics to make an informed decision to participate in research and the factors thought to be predictive of that ability. The performance of schizophrenics was compared to that of 92 nonschizophrenics on an instrument designed to measure the level of understanding of information provided to secure informed consent. The information contained in the instrument was developed according to federal guidelines and made comprehensible for the lowest educational level of subjects in the sample using the Flesch Readability Scale.

Schizophrenics performed significantly poorer than nonschizophrenics on the various elements of informed consent as well as on the individual items which comprised those elements. The group membership of 82 percent of the sample was retrospective identified based on four of the six elements of informed consent considered in this study. Purpose, research sponsorship, voluntariness, and benefit were found to better differentiate schizophrenics and nonschizophrenics than risk and procedure. Group membership (i.e., whether a subject was schizophrenic or nonschizophrenic accounted for the

greatest variance in informed consent scores. Although study groups differed significantly on years of education completed, education was found to minimally account for the variance in group performance. The effects of education were believed to have been mediated by the application of the Flesch Readability Scale.

Effort was also made to identify the characteristics of schizophrenics who performed well from those who did not. Schizophrenics who performed at or above the nonschizophrenic mean had a good prognosis, more education, were judged to have a better understanding of the questions posed to assess the level of comprehension, had been hospitalized for a shorter time, and required less time to complete the consent procedure than those who did not.

The least and most stringent standards proposed for determining whether subjects were informed suggest that between 37 and 95 percent of the schizophrenics might be considered uninformed participants. Considering that more debilitated subjects were not likely to complete the consent procedure or to have been included in the subject pool, these estimates are believed to be downwardly biased.

This study confirmed the findings of previous investigations, raising serious question about the ability of hospitalized schizophrenics to give informed consent to participate in research. These results were discussed in relation to unresolved theoretical, instrumentation, and sampling issues. Suggestions for future research were also offered.

In the sense in which a man can ever be said
to be at home in the world he is at home not
through dominating, or explaining, or appreciating,
but through caring and being cared for . . . .

Milton Meyeroff
On Caring

To my husband, James

for believing in me, loving me,

and sharing my dream

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My family and friends cajoled, exalted, and exhorted me to quicken my pace and to regard periods of low motivation as reflective of the need for brief respite on a long journey. Their love and encouragement sustained me during the most difficult portions of my venture. I am sure they share my joy that this quest has come to an end.

Chief among those who helped me to travel the last mile, which for many reasons was the most difficult, was my husband, James. His enthusiastic encouragement and acceptance of the demands that this journey placed on me provided the steadying influence that facilitated the final achievement of my goal.

And now, it is time to begin again . . . "for I have miles to go before I sleep, and miles to go before I sleep."

TABLE OF CONTENTS

	Page
LIST OF TABLES	vi
LIST OF FIGURES	vii
LIST OF APPENDICES	viii
INTRODUCTION	1
REVIEW OF RELATED LITERATURE	4
The Regulation of Research with the Mentally Disabled	4
Ethical Principles Underlying Research with Human Subjects: Implications for the Mentally Disabled	7
Respect for Persons	7
Beneficence	8
Justice	8
Elements of Informed Consent	9
Functions of the Informed Consent Process	10
The Responsibilities of IRBs	13
Informed Consent: A Goal Imperfectly Realized	14
Competence to Consent	15
Voluntariness	18
Comprehension	20
Literacy	21
Readability	22
Schizophrenia	23
Psychiatric Hospitalization	28
Empirical Assessments of the Competence of Psychiatric Patients	29
Consent to Voluntary Hospitalization	30
Knowledge of Patient Rights	31
Consent to Treatment	31
Subject Selection Bias	35
Summary	36
STATEMENT OF THE PROBLEM AND HYPOTHESES	39
METHOD AND PROCEDURE	41
Sample	41

Page

Study Group 42
Comparison Group. 45
Differences in Selected Sample Characteristics. . . . 46
Instruments. 47
Informed Consent Statement. 47
Readability of the Informed Consent Statement. . 48
Informed Consent Questionnaire. 50
Informed Consent Facets. 50
Construction of the Informed Consent Statement and Questionnaire. 54
Measurement of the Concept of Informed Consent . 56
Consent Form. 58
Rights Complaint Survey 58
Assessment of Satisfaction with the Rights Complaint Process as the Research Procedure. . . 59
Construction of the Survey Instrument. 60
Scoring the Survey Instrument. 62
Interviewer Observations Form 62
Patient Background Information Form 63
Staff Background Information Form 63
Procedure. 65
Requests for Hospital Participation and Appointment of Liaisons 65
Training of Interviewers. 65
The Interview Procedure 66

RESULTS 70

Hypotheses 70
Hypothesis I. 70
Hypothesis II 70
Hypothesis III. 71
Hypothesis IVa. 73
Hypothesis IVb. 73
Hypothesis V. 73
Hypothesis VI 73
The Effect of Differences in Group Demographics. 74
Additional Findings. 75
Comparison of Group Performance on Informed Consent Questionnaire Items 75
Group Classification by a Stepwise Discriminant Function of Informed Consent Scale Scores and Individual Items. 78
Alternative Definitions of Informed Consent 82
Percent Above Chance Predictions 82
Within Group Comparisons as the Standard 84
A Normative Definition Based on Differential Weighting. 84
Differentiation of High and Low Performance Schizophrenics. 86

Page

DISCUSSION 88

The Results and Their Implications. 88
Schizophrenic and Nonschizophrenic Differences in Informed Consent. 88
Explanations for Variations in Informed Consent. . . 91
Between Group Comparisons 91
Demographic Characteristics. 92
Group Membership 92
Participation Rates. 93
Length of the Consent Procedure. 94
Response Patterns. 95
Within Group Comparisons. 95
Other Explanations for Variations in Informed Consent. 96
Choosing the Standard: Informed versus Uninformed Consent. 97
Unresolved Issues in the Examination of Informed Consent 100
Elements of a Legally Valid Consent. 100
Competency. 101
Understanding 103
Voluntariness 105
Instrumentation 105
Subject Sampling. 107
Suggestions for Further Research. 108

SUMMARY AND CONCLUSIONS. 112

APPENDICES 120

A-1. Patient Informed Consent Statement. 120
A-2. Patient Informed Consent Questionnaire. 122
A-3. Patient Consent Form. 124
A-4. Rights Complaint Survey (same for both groups). . . 125
A-5. Patient Interviewer Observations Form 135
A-6. Patient Background Information Form 137
B-1. Staff Informed Consent Statement. 139
B-2. Staff Informed Consent Questionnaire. 141
B-3. Staff Consent Form. 143
B-4. Staff Interviewer Observations Form 144
B-5. Staff Background Information Form 145

REFERENCES 147

LIST OF TABLES

Table		Page
1.	RESPONSE RATES OF SCHIZOPHRENIC SAMPLE	43
2.	SELECTED SAMPLE CHARACTERISTICS	44
3.	GROUP DIFFERENCES OF SELECTED DEMOGRAPHIC CHARACTERISTICS	46
4.	INFORMED CONSENT INDICES	57
5.	ANALYSIS OF VARIANCE OF INFORMED CONSENT SCALE SCORES OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS	71
6.	STEPWISE MULTIPLE REGRESSION OF GLOBAL INFORMED CONSENT ON GROUP MEMBERSHIP, ATTITUDE, EDUCATION, AND INTEREST	72
7.	SELECTED DEMOGRAPHIC CHARACTERISTICS AND INFORMED CONSENT	75
8.	ANALYSIS OF VARIANCE OF INFORMED CONSENT QUESTIONS OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS	77
9.	CLASSIFICATION OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS BY A STEPWISE DISCRIMINANT FUNCTION USING INFORMED CONSENT SCALE SCORES	79
10.	CLASSIFICATION OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS BY A STEPWISE DISCRIMINANT FUNCTION USING INFORMED CONSENT QUESTIONNAIRE ITEMS	80
11.	STANDARDIZED DISCRIMINANT COEFFICIENTS OF SIGNIFICANT INFORMED CONSENT QUESTIONNAIRE ITEMS	81
12.	PERCENT ABOVE CHANCE PREDICTIONS OF GLOBAL INFORMED CONSENT SCORES OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS	83
13.	PERFORMANCE OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS MEETING NORMATIVE CRITERIA FOR INFORMED CONSENT	85
14.	CLASSIFICATION OF HIGH AND LOW PERFORMANCE SCHIZOPHRENICS BY A STEPWISE DISCRIMINANT FUNCTION	86

LIST OF FIGURES

Figure Page

1. PERCENT CORRECT RESPONSES BY ITEM OF SCHIZOPHRENICS AND NONSCHIZOPHRENICS 76

LIST OF APPENDICES

Appendix		Page
A-1.	PATIENT INFORMED CONSENT STATEMENT	119
A-2.	PATIENT INFORMED CONSENT QUESTIONNAIRE	121
A-3.	PATIENT CONSENT FORM	123
A-4.	RIGHTS COMPLAINT SURVEY (same for patients and staff)	124
A-5.	PATIENT INTERVIEWER OBSERVATIONS FORM	134
A-6.	PATIENT BACKGROUND INFORMATION FORM	136
B-1.	STAFF INFORMED CONSENT STATEMENT	138
B-2.	STAFF INFORMED CONSENT QUESTIONNAIRE	140
B-3.	STAFF CONSENT FORM	142
B-4.	STAFF INTERVIEWER OBSERVATIONS FORM	143
B-5.	STAFF BACKGROUND INFORMATION FORM	144

INTRODUCTION

Research is essential to the development and validation of methods for the diagnosis, treatment, and prevention of mental illness. Since much of this research has involved, and will likely continue to involve, those hospitalized as mentally disabled, serious ethical questions regarding their participation have arisen. The ability of the mentally disabled to understand the purpose and procedures of proposed research, to weigh the risks and benefits, and to make a decision for or against participation in light of that information, in short to give informed consent, has been challenged.

Informed consent has gained general acceptance as an ethical and legal requirement for conducting research with humans. A fundamental goal of the informed consent process is to ensure that the individual retains the status of an autonomous being, capable of assimilating information and making decisions on that basis. In addition to respecting the autonomy of the individual, informed consent procedures have been invoked to prevent abuse by protecting subjects from unwilling and/or potentially harmful involvement in research. These goals would seem imperfectly realized with the hospitalized mentally disabled--one of the groups considered most vulnerable to exploitation by researchers.

Those suffering from mental disability who require hospitalization, specifically those diagnosed as schizophrenic, present

a particularly perplexing problem and have been selected as the subject of this investigation. It is not clear, for example, to what extent these patients, given their diminished cognitive capacity and dependency status, are able to understand proposed research procedures and the attending risks and benefits, even when considered legally competent. To varying degrees, hospitalized schizophrenics would seem, by virtue of the nature of their illness, incapable of fully appreciating the information provided to secure informed consent. Consequently, their ability to make a rational decision for or against participation based on such information may be considered questionable.

The issue of the capacity of the mentally disabled to give informed consent has been heatedly debated by clinicians, ethicists, lawyers, philosophers, hospital administrators, researchers, patient advocates, and patients for the past twenty-five years (Annas, Glantz, and Katz, 1978; Feldman, 1978; Gert and Culver, 1980; Goldstein, 1978; Levine, 1981; Lidz, 1983; Lidz, Meisel, and Zerubavel, 1983; Lidz, et al., 1984; Meisel, Roth, and Lidz, 1977; Park, Covi, and Uhlenhuth, 1967; Redlich and Mollica, 1976; Stone, 1979). As a result, a voluminous literature has emerged. This discussion has been based more on theoretical analyses then empirical investigation. The purpose of the present investigation was to assess the extent to which a subgroup of the mentally disabled, specifically those receiving a primary diagnosis of schizophrenia and considered legally competent, were able to make an informed judgment to participate in a research study.

This study also attempted to identify the factors that were predictive of the ability to give informed consent and whether schizophrenics were better able to understand certain aspects required to be informed than others.

REVIEW OF RELATED LITERATURE

The Regulation of Research with the Mentally Disabled

Research with the mentally disabled is regulated not only by common law developments (Stone, 1979), but also by ethical guidelines (Frenkel, 1977), professional codes (American Psychological Association, 1983), requirements of regulatory agencies (Department of Health and Human Services, 1981), scientific peer review and, perhaps most significantly, by the ongoing activities of local interdisciplinary groups known as institutional review boards (IRBs) which review and monitor research with human subjects (Greenwald, Ryan, and Mulvihill, 1982; Levine, 1981). Because regulatory requirements and guidelines issued by the United States Department of Health and Human Services (DHHS), the major agency sponsoring biomedical and behavioral research, have the greatest influence on the conduct of research with the mentally disabled, this review will focus largely on these requirements. Despite considerable debate, medical and nonmedical research with the mentally disabled, as that involving other human subjects, is currently regulated by DHHS with local IRBs having major responsibility for overseeing the ethical propriety of such research.

In 1974, as a result of both scientific and lay concern about a multitude of abuses which were alleged to have occurred during the conduct of research, Congress passed legislation creating the National

Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereafter referred to as the National Commission). The mandate of the National Commission was "to review the problems and practices associated with protecting the rights and welfare of human subjects involved in the various forms of biomedical and behavioral research sponsored by the federal government" (Brady and Jonsen, 1982, p. 6). Particular attention was focussed on the use of certain "vulnerable" subgroups, which included fetuses, children, prisoners, and the "institutionalized mentally infirm."

The term, "mentally infirm," was used during Congressional hearings to denote a broad range of different clinical entities, ranging from relatively mild psychological disturbance to permanent and severe mental retardation. Because the kind of mental disability, i.e., mild versus severe, transient versus permanent, cognitive versus moral has a bearing on the degree of competence of the institutionalized mentally infirm, the heterogeneity of this group seemed clear. The term "mentally infirm" was subsequently changed in regulations proposed by the predecessor of DHHS, the Department of Health, Education, and Welfare (DHEW), to "mentally disabled" (1978a).

The National Commission noted that "in no other area subject to its scrutiny has the need for research been so clearly manifest" as that relating to mental infirmity (DHEW, 1978b, p. 11328). At the same time, however, the National Commission was cognizant of past and potentially future exploitation of the mentally disabled

as research subjects. This problem was considered two-tiered. The mentally disabled were viewed as being of questionable competence because of impaired comprehension resulting from psychiatric disability. Further, institutionalization was considered to compromise the ability of the mentally disabled to act voluntarily (Annas, Glantz, and Katz, 1978). In a summary of relevant case law prepared for the National Commission, Annas and his colleagues noted:

> Institutionalized mental patients are perhaps the most isolated and underprivileged members of our society. The human and legal rights of mentally ill and retarded persons have been grossly violated for centuries. The result is that they are often victims of numerous social injustices, including horrible facilities, poor or nonexistent treatment and education, indiscriminate sterilization, and deprivation of basic legal protections, including the performance of unethical and/or illegal human experimentation (1978, p. 1).

Data on the extent to which the mentally disabled are used as research subjects are sparse, but there is information which tends to indicate the magnitude of their usage. A national survey of IRBs revealed that 11 percent of the research projects reviewed between July, 1974 and June, 1975 involved the mentally disabled as subjects. Although the distinction between biomedical and behavioral research with the mentally disabled tends to overlap, about one-third of these projects might be considered biomedical; the remainder being primarily behavioral research (Tannenbaum and Cooke, 1978). In fiscal year 1975, 100 of 500 projects supported by the National Institute of Mental Health in the areas of clinical research, applied research, psychopharmacology, epidemiology, and services development research involved mentally disabled populations (DHEW, 1978b).

Ethical Principles Underlying Research with Human Subjects: Implications for the Mentally Disabled

The National Commission (1978) identified three basic values as relevant to the ethics of all of research involving human subjects: respect for persons, beneficence, and justice. These principles were not meant to be applied so as to resolve beyond dispute particular ethical problems. They were intended, rather, to provide an analytical framework within which the ethical problems arising from research with human subjects might be resolved. The National Commission stressed the need to consider these as competing values in constructing a policy of informed consent. The significance of these values in a policy on informed consent among mentally disabled research subjects is all the more important in the absence of satisfactory definitional guidelines in current law Barber (1980).

> Serious ethical dilemmas are created by the conflicts between and among these three values. Most of the controversial ethical issues involving those institutionalized as mentally infirm could be structured in the form of such dilemmas. The resolution of those dilemmas requires striking a balance among competing ethical obligations (DHEW, 1978b, p. 64).

Such balances were said to consist of a mixture in which respect for persons was given greater weight. These principles are discussed below in terms of their application.

Respect for Persons

The ethical principle of respect for persons requires that the permission of autonomous individuals be obtained prior to involving them in research and that their choices be honored.

It is this principle that is difficult, indeed impossible according to some, to uphold when the mentally disabled are involved in research. The mentally disabled are viewed as having diminished autonomy and an incapacity (or limited capacity) to give valid consent. This problem has led some researchers to take the position that the mentally disabled should not be included in research (National Commission, 1978).

Beneficence

Beneficence requires the provision of benefit and the avoidance of harm. This principle has been used to justify the conduct of research involving the mentally disabled. Such research, for example, may promote the health of the mentally disabled as a class thereby reducing the possibility of harm by improving methods of treatment or by evaluating the safety of procedures accepted as standard practice. Of course, the mentally disabled participant may also receive individual benefit from their involvement which may be medical, psychological, or moral. The principle of beneficence requires that the participants of research be protected from harm by limiting the risks to which they are exposed (National Commission, 1978). The objectives of minimizing risks to subjects and achieving an acceptable balance of risks and benefits are considered of basic importance in ethical discussions of research with the mentally disabled (Barber, 1980; Diener and Crandall, 1978).

Justice

The moral principle of justice requires an equitable distribution of the burdens and benefits of research to all groups.

This principle has major implications for research involving the mentally disabled as research participants. First, research studies are to be designed so as not to utilize the mentally disabled, or any group for that matter, simply because of their availability, compromised position, or potential manipulability. Secondly, because research studies were not to involve persons unlikely to be the beneficiaries of subsequent applications of the research, the mentally disabled were not to be selected as subjects unless they were the only appropriate group on whom the research should be conducted (National Commission, 1978).

Elements of Informed Consent

The 1981 DHHS regulations require that subjects or their legally authorized representative give legally effective informed consent to participate in research. Significantly, although subjects' assent, as opposed to consent, was considered permissible in previous regulations (DHEW, 1978a; 1978b), assent was ruled unacceptable in the new regulations. Research was defined by the regulations as a "systematic investigation designed to develop or contribute to generalizeable knowledge," whether or not such activities occurred in the context of treatment (DHHS, 1981).

The regulations require that consent, except in circumstances deemed to consist of minimal risk, be obtained in writing. The core of the disclosure requirements for obtaining the informed consent of subjects to participate in research includes the following elements: 1) a statement that the study involves research; 2) a description of any reasonably foreseeable risks; 3) a description

of any benefits to the subject or to others that might reasonably be expected to derive from the research; 4) a disclosure of appropriate alternative procedures; 5) a statement describing the extent to which confidentiality will be maintained; 6) an explanation as to whether compensation is available should injury occur as a result of the research; 7) a statement indicating who should be contacted to answer pertinent questions about the research; and, 8) a statement that participation is voluntary and that refusal to participate will not involve a penalty or the loss of benefits to which the subject might otherwise be entitled (DHHS, 1981). Other optional provisions are also given.

Significantly, federal regulations do not provide a basis for making judgments about how detailed specific disclosure requirements should be or identify the circumstances under which optional, or as yet unspecified, elements should be disclosed. Further, the regulations do not provide information about who might constitute a "legally authorized representative" of subjects who are believed to lack the capacity to give informed consent or how the competency of such subjects is to be determined.

Functions of the Informed Consent Process

The National Commission (1978) reasoned that the major intent of the informed consent process was not to provide protection from harm. Prior IRB and peer review were thought to provide the best means for accomplishing that, particularly given the often complex, technical nature of studies. Informed consent was regarded, rather, as a means of safeguarding the autonomy of subjects: "Respect for

persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them" (p. 10).

Indeed, there seem to be three interrelated functions of the informed consent process. The primary function of this process, as previously mentioned, is the formal recognition of the autonomy of the human subject. The procedures in biomedical and behavioral research, as well as in patient care, serve as a reminder that the client-professional relationship is a contractual one based on the right of the client to be informed of alternatives and to make a choice based on the information provided that is in one's own best interest.

The second function of the consent process is to actually obtain informed consent. Some would argue (Chayet, 1976; Feldman, 1978; Fellner and Marshall, 1970; Laforet, 1976; Lowenstein and Jackson, 1978; Priluck, Robertson, and Buettner, 1979; Schultz and Pardee, 1975), of course, about whether the process does (or even can) result in fully informed consent. Makarushka (1976) points out that there are limits to the investigator's ability to foresee all possibly relevant consequences of the research for the subject and to effectively communicate the often complex issues involved. Moreover, subjects' anxiety reaction to authority figures or trust in the investigator may result in his/her not perceiving a real choice. Beecher (1966b) described a minimum expectation:

> Imperfect as our attempt to get informed consent may be, an important reality nevertheless invariably emerges from such effort: The patient involved then knows he is to be the subject of an experiment--too often not otherwise the

> case--and knowing, can reject the opportunity if he chooses to do so (p. 1136).

The reality, however, seems to be that even under apparently ideal conditions, little information is often conveyed, and those who are informed may not feel free to refuse consent. This point will be discussed further later.

The third function of the consent process is to protect the investigator and the sponsoring institution or funding agency from legal culpability and negative public opinion if subjects are injured or their rights are abused. While this legal dimension of the consent process may appear complementary to the ethical dimension of the recognition of subject autonomy, it may also lead to a greater concern with form rather than substance (Gray, 1978).

There is no inherent incompatibility between the ethical and legal bases for informed consent requirements. The methods by which informed consent is sought, however, may be affected in important ways by whether one is attempting to achieve a high standard of ethical conduct or to avoid legal liability. For many researchers, the goal seems merely to obtain a signed Consent Form as documentation that information has been disclosed (Gray, 1978). Gray (1978) points out that the process has, in fact, resulted in a great deal of documentation of apparent informed consent and relatively little actual informed consent. Because the federal regulations leave so many questions to the discretion or interpretation of individual researchers, he concludes that the federal government implicitly emphasizes the process rather than the purpose of informed consent.

The Responsibilities of IRBs

In order to protect subjects from research risks, federal guidelines mandate that IRBs provide careful review of the appropriateness and safety of proposed research procedures, the competence of the researcher, the adequacy of procedures to protect subject privacy, and a clearly demonstrated need to involve the proposed population in the research (DHHS, 1981).

Further, IRBs were mandated to insure that appropriate safeguards are included in studies to protect the rights and welfare of subjects where some or all of the subjects are likely to be vulnerable to coercion or undue influence. Persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged were mentioned specifically. While the regulations addressed the similarity of consent problems of the mentally ill to those experienced by other physically ill or disadvantaged persons, no further guidance was provided to IRBs about how to determine the "vulnerability" of subjects (DHHS, 1981).

The DHHS commentary, published with the 1981 regulations, also contains points of special interest concerning research participation by mentally disabled persons. The preamble notes that the final regulations permit the alteration or waiver of the elements of informed consent and, therefore, provide a basis for tailoring the amount and complexity of information provided in the consent process where subjects are likely to have "somewhat impaired or limited capacity to understand." Institutional

review boards were given responsibility for insuring that procedures were developed to seek consent from subjects at a time when they were able to make a reasonable judgment and to determine that each subject had sufficient capacity to give consent. Significantly, IRBs were allowed to alter federal requirements for informed consent only for persons considered "functionally and legally incompetent to give consent," e.g., "persons with chronic or acute mental disabilities," "persons being treated with drugs which impair mental functioning," " aged persons with diminished capacity," or "persons of limited intelligence" (DHHS, 1981).

The 1981 DHHS regulations also permitted IRBs to monitor the consent process so as to afford protections for vulnerable subjects; namely, that IRBs "shall have authority to observe or have a third party observe the consent process and the research" (DHHS, 1981). The use of consent auditors were, thus, viewed as one option that IRBs might employ to provide safeguards for "vulnerable" subjects. Other safeguards which have been proposed include the routine use of a two-part consent form, testing of subject comprehension, pre-consent education of subjects, mandatory waiting periods, follow-up efforts to educate uninformed subjects, improved readability of consent forms, and more careful review by IRBs to insure adherence to federal guidelines and to identify unapproved research activities (Grundner, 1981; Heath, 1979; Meisel, Roth, and Lidz, 1977; Miller and Willner, 1974; Roth, Meisel, and Lidz, 1977; Schwarz, 1978, 1980).

Informed Consent: A Goal Imperfectly Realized

While obtaining informed consent would appear to be a relatively simple, straight-forward task, numerous authors have pointed to

serious difficulties in its fulfillment with 'normal' subjects (Cassileth, et al., 1980; Ingelfinger, 1972). Investigators have demonstrated that adequate knowledge of critical issues cannot be guaranteed despite thorough presentations and explanations. In these studies, adult subjects of all ages answered critical questions about the information that had been provided incorrectly (Cassileth, et al., 1980; Epstein and Lasagna, 1969; Lowenstein and Jackson, 1978; Schultz, Pardee, and Ensinck, 1975) and, in addition, denied or distorted important segments of information (Priluck, Robertson, and Buettner, 1979; Robinson and Merav, 1976). These problems occurred despite the fact that explanations were designed to conform to approved guidelines and subjects had signed informed consent documents which indicated that they understood the relevant information.

Competence to Consent

The problems encountered in obtaining informed consent from 'normal' subjects are likely to be compounded with those suffering from psychiatric disability. Of basic question is whether such persons are competent to give informed consent. The concept of competence, in this instance, is based on the assumption that subjects are able to appreciate the nature and consequences of their participation in a research study. Competence requires that subjects be able to evaluate information in order to make a reasoned decision for or against participation.

Owens (1977) emphasized the need for psychiatric patients to have a "minimum of intact cognitive functions...including perception,

comprehension, reality-testing, and a sense of reality of the self and the world." He also noted that the loosening of associations and intense ambivalence characteristic of psychiatric disturbance could interfere with a patient's ability to make a competent decision. Schwarz (1980) cited impaired cognitive (e.g., deficits in attention, comprehension, judgment, memory, and reality-testing) and affective states (e.g., passivity, dependency, anxiety) as being antithetical to obtaining informed consent with psychiatric patients.

Competency to give a valid consent has been the least researched area in the informed consent literature (Stanley and Stanley, 1981). A major difficulty in conducting research on competency lies in the fact that there is no standard definition of competence (Meisel, Roth, and Lidz, 1977; Roth, Meisel, and Lidz, 1977), no accepted test of competency (Appelbaum, Mirkin, and Bateman, 1981; Appelbaum and Bateman, 1981; Dabrowski, et al., 1978), and no clear agreement on the division between competency and incompetency. What one investigator regards as competency (Woodward, 1979), another may regard as incompetence (Bergler, et al., 1980).

The fact that the mentally ill have been considered as a homogeneous group in the few empirical investigations bearing on the subject of competency has also proved problematic. Samples of mentally ill subjects have included those with such varying diagnoses as personality disorder, schizophrenia, psychotic depression, mental retardation, and organic brain syndrome. In addition to including psychiatric patients with disparate diagnoses, both voluntary and involuntary patients have frequently been included

in the same sample where the results have not been reviewed independently. In order to appropriately evaluate competency, the setting in which consent is obtained must be considered as well as the background thereto. A hospitalized patient would seem to possess different characteristics from a patient in office practice and a patient who has been hospitalized involuntarily would seem to possess different characteristics from one who is in the hospital of his/her own accord. While all of those who are considered mentally ill may require special protection in certain research studies, empirical studies have not been undertaken to ascertain the extent to which this may be differentially warranted based on diagnostic subgroup or legal status.

Yet another problem with studies undertaken to demonstrate the competency, or lack thereof, of psychiatric patients is that often these studies have not included a comparison group or specified the normative standard against which patients were judged. Certain investigators (Stanley and Stanley, 1981) have advocated the use of medical patients as the ideal controls for psychiatric patients when attempting to determine the extent to which special precautions are required. These researchers failed to consider, however, that those suffering from certain kinds of physical illnesses may very well experience an impaired ability, albeit transitory, to comprehend the information provided to secure informed consent for treatment.

Given that the National Commission (1978) considered persons suffering from serious physical ills as "vulnerable," it seems reasonable to assume that certain medical patients may be as

hampered in their ability to be informed as certain psychiatric patients. It should be noted, however, that follow-up efforts to educate the uninformed mentally ill have almost invariably proven unsuccessful. Such efforts have proven to be more fruitful with nonpsychiatric patients suffering from medical illnesses. It seems clear that more must be understood about the rationale underlying decisions for or against treatment or consent to participate in research of both these groups.

Questions related to subjects' competency must necessarily be viewed in terms of, first, whether they are able to understand the information provided to secure informed consent and, secondly, whether they deem themselves as having been presented with the choice to participate in a research project or not. In the former instance, in addition to being mediated by cognitive and affective states, the literacy skills of the individual and the complexity of the information presented must be considered.

Voluntariness

Psychiatric patients should understand that they may refuse an invitation to participate in a study and that they will still be eligible for alternative services. They should also understand that should they consent to participate, they will be free to withdraw their participation at any time without penalty. Yet, the very nature of many psychiatric disorders makes difficult the ability to act voluntarily. Owens (1977) pointed out that cognitive disorganization limits a person's capacity to act voluntarily, because such action requires a significant degree of attention and comprehension.

Further, the compliance of a psychotic person who fails to understand his own actions may be construed by clinicians as voluntary behavior. In the case of depression, the volitional quality of an agreement is not easy to determine in the face of certain common features of the disorder, such as dependency, anxiety, apathy, and overcompliance (Imber, et al., 1986).

Kelman (1972) noted that the experimental situation itself creates an inherent power advantage for the researcher over the subject. He cautioned that subjects who occupy low-status or dependent positions in society are less likely to see themselves as having the option to refuse to participate. Similar reasoning led Reynolds (1979) to conclude that research subjects should be selected only from higher socioeconomic groups.

There is convincing evidence, in fact, that schizophrenics historically may not have experienced themselves as autonomous beings whose choices will be respected. Several researchers have reported the family pressure, indeed "striking manipulation," of family members in an effort to encourage patient participation in research despite patients' wishes (Ackerman, 1966; Alanen, 1968; Fellner and Marshall, 1970; Ketai, et al., 1981; Lidz, 1969, 1978; Lidz, Fleck, and Cornelison, 1965).

The most significant judicial decision on informed consent with a psychiatric patient relates to the issue of voluntariness (Stone, 1979). The patient, an institutionalized, aggressive sex offender, chose to submit to psychosurgery rather than antiandrogen therapy. In rejecting the propriety of this experiment, the court ruled that informed consent for such a procedure must be knowing,

competent, and voluntary (Kaimowitz vs. Department of Mental Health for the State of Michigan, 1976). The court questioned whether the above requirements for informed consent could be met, given the patient's long period of institutionalization. Their analysis of the voluntary aspect emphasized the coercive context of the patient's voluntary confinement. In so ruling, the court implied that the voluntariness of any consent would be dubious under the coercive conditions of institutionalization.

Some philosophers (Branson, 1976, 1977; Cook, 1976) have placed the value of voluntariness higher than that of the transmission of information. As one wrote,

> The crucial emphasis...lies with the voluntary nature of consent, not with the informational aspect. Notice that when we speak of informed consent, it always makes sense to ask whether it has been freely given; but if we speak of voluntary consent, we can neither ask whether it has been freely given nor whether it is informed (Cook, 1976, p. 13).

In this sense, information is not considered an end in itself but, rather, as a means of achieving a greater degree of voluntariness. These philosophers are in agreement that where voluntariness does not exist, as they believe it cannot in cloistered populations over which a variety of necessary controls are exercised such as in the case of the institutionalized mentally ill, other virtues are not compelling.

Comprehension

Comprehension is yet another aspect of informed consent subject to varying interpretation. In order for subjects to be informed, it is, of course, basic that they comprehend the information that has

been provided. Of issue is that what subjects comprehend is dependent, in part, on what, how, and by whom information is communicated. To this end, it is important that information be provided at a level that those in the proposed subject population will be able to understand. That is, the readability of consent materials should be tailored to the literacy skills of proposed subjects. In addition to poor literacy skills, subjects may conceivably possess other characteristics, such as cognitive and affective disorder, which may limit their ability to comprehend the information provided to secure informed consent.

Literacy. An issue that is basic to the ability of psychiatric patients to comprehend material provided to secure informed consent is that of literacy. In many instances, the literacy demands placed on psychiatric patients far exceed their literacy skills (Berg and Hammitt, 1980; Coles, Roth, and Pollack, 1978). Berg and Hammitt (1980) found that a tenth grade, and in some cases a college-level, education was required to understand various hospital documents presented to psychiatric patients. These patients, however, were often found to be functioning at a lower level than the highest year of schooling completed would indicate. The patients were able to recognize and pronounce words, but not to comprehend their meaning. Certain patients, e.g., those suffering from organic brain syndrome and mental retardation, were not able to pronounce the words, let alone comprehend their meaning. The reading comprehension scores of psychiatric patients were generally found to be at the fifth grade level, that is, they were functionally illiterate. In addition,

many of these patients had gross deficiencies in the body of practical knowledge that is ordinarily possessed by the population at large (Berg and Hammitt, 1980; Coles, Roth, and Pollack, 1978). Notably, poor literacy skills have been considered causally related to psychiatric disturbance (Coles, Roth, and Pollack, 1978; Lewine, et al., 1980; Phillips, 1968; Zigler and Phillips, 1962).

Readability. The level at which certain material is written may facilitate communication or make it impossible. Recent federal guidelines require that information provided to subjects to insure informed consent be presented in language that is understandable to the subject or, should the subject be incompetent, the subject's representative (DHHS, 1981). Yet, the readability of documents provided to psychiatric patients, such as admission forms, consent to treatment forms, brochures detailing the rights of patients, and information provided to secure informed consent to research were generally found to be too complex for the average patient to understand (Cooke, Tannenbaum, and Gray, 1977; Schultz, Pardee, and Ensinck, 1975).

Cooke and his associates (1977) used the Flesch Readability Scale (Flesch, 1948) to evaluate the readability of consent forms submitted to IRBs to enlist the participation of psychiatric patients in biomedical and behavioral research. These forms were generally found to be incomplete or too difficult to read. Few forms provided lay explanations of medical and technical terms. The major defect, however, was the complex sentence structure and the excessive length of words used. All of these, nonetheless, were believed to serve

as a hindrance to effective communication with research subjects. These defects in communication occurred despite the fact that all research protocols were approved by IRBs whose most common actions had to do with informed consent provisions (Cooke, Tannenbaum, and Gray, 1977). Significantly, the same has also been said of various hospital documents presented to medical patients who were not suffering from mental disability (Grundner, 1980; Meisel and Roth, 1983; Morrow, 1980).

Certainly, the level of complexity of informed consent materials is one reason that such materials may not be understood. It is important that information be presented at a level that is appropriate for proposed subjects. Suggestions for improving readability have been offered by several (Bellows, 1961; Flesch, 1948; Grundner, 1978, 1980, 1981). Short, varied sentences; the use of simple concepts and words that may be pictured or related to the intended reader's personal experience; the use of active verbs; and, a conversational tone have been cited as being facilitative of the comprehensibility of information.

Schizophrenia. Psychiatric disturbance is yet another reason that a subject may not be able to understand information when it has been presented in its most simplified form. Specifically, the characteristics of schizophrenic disorder, the discussion of which will follow, would seem to make it difficult for those diagnosed as such to give informed consent. It would seem that the ability to understand the information provided and to act autonomously, i.e., to weigh alternatives and make a reasoned choice in one's

best interest, would be greatly compromised because of the nature of the illness. As a matter of fact, even in what are believed to be the relatively few instances where these subjects are able to understand the material provided to secure informed consent, there would seem to be question about the voluntariness of the decision given the controlled situation in which they find themselves.

In early formulations, Bleuler (1911/1950) singled out the disruption of thinking as a cardinal feature of schizophrenia. Disturbances in association were pinpointed as the mechanism underlying all schizophrenic symptomatology. Since that time, numerous others (e.g., Arieti, 1974; Goldstein, 1944; Harrow and Quinlan, 1977; Spitzer, Andreasen, and Endicott, 1978a; Storms and Broen, 1969) have affirmed the key role of disordered thinking during the acute and chronic phases of the illness. While it has been demonstrated that disordered thinking is not unique to schizophrenics, it has been shown to be more severe in them, even when receiving neuroleptic medication, than in other psychiatric patients (Harrow and Quinlan, 1977).

More recently, the American Psychiatric Association (1980) operationalized diagnostic criteria for schizophrenia based on a systematic analysis of actual cases. These included a minimum duration and a characteristic symptom picture. Despite the fact that no single feature was considered to be invariably present or uniquely typical of those with schizophrenia, characteristic symptoms were reported to involve disturbances in both the "...content and

form of thought, perception, affect, sense of self, volition, relation to the external world, and psychomotor behavior" (p. 182). Furthermore, the illness involves a deteriorating course, where a complete return to the premorbid level of functioning is unusual (American Psychiatric Association, 1980; Spitzer, Andreasen, and Endicott, 1978a). The aforementioned clinical features are described below. This discussion should serve to highlight the difficulty involved in attempting to facilitate understanding of the material provided to secure informed consent in schizophrenics as well as the difficulty encountered by researchers in attempting to evaluate their level of understanding.

Disorder of the Content of Thought. The major disturbance in the content of thought involves delusions, i.e., idiosyncratic and autistic thinking which has no basis in fact. It is not uncommon, for example, for patients to feel that their feelings, thoughts, or actions are imposed by an external force, i.e., delusions of being controlled. "Overvalued ideas may occur...or marked illogical thinking (e.g., thinking that contains clear internal contradictions or in which conclusions are reached that are clearly erroneous, given the initial premises)" (American Psychiatric Association, 1980, p. 182).

Disorder of the Form of Thought. Disorders in the form or process of thought have been referred to as "formal thought disorder." It is characterized by the loosening of associations. Patients in whom the loosening of associations is severe may become incoherent. "There may also be poverty of content of speech, in which speech is inadequate in amount and conveys little information because it is vague, overly abstract or overly concrete, repetitive, or stereotyped" (American Psychiatric Association, 1980, p. 182).

The fact that schizophrenics have invariably been found to perform more poorly than normals on conceptual tasks has led certain researchers (Goldstein and Scheerer, 1941; Hanfmann and Kasanin, 1942) to conclude that they are deficient in abstracting ability. Goldstein and Scheerer (1941) interpreted the tendency of schizophrenics to sort objects by massive communalities (i.e., communalities shared by the whole object) to mean that they had lost the "abstract attitude" and, as a consequence, found it necessary to rely on the less adequate "concrete attitude."

A more tenable view, and one that has attracted considerable research attention, is that the poor performance of schizophrenics on conceptual tasks is a function of a distraction or interference phenomenon, i.e., the result of an intrusion of associations which normals would be likely to consider as peripheral to the stimulus situation (Broen and Storms, 1966; Buss and Lang, 1965; Cameron, 1938, 1939; Chapman, 1956, 1958, 1961; Lang and Buss, 1965; Rattan and Chapman, 1973; Shakow, 1962; Shimkunas, 1970; Storms and Broen, 1969, 1972). Shimkunas (1970) theorizes that competing responses are more likely to intrude in abstract conceptual processes than the developmentally more primitive concrete thinking because the latter is acquired earlier in life, is more stable, and less complex. He speculates that the schizophrenic may be better able to prevent interference with concrete expressions because they are easily assessible, while abstractions require more active and complex conceptualizations.

Disturbance of Perception. Disturbances in perception are manifested in the form of hallucinations. These occur in all

modalities, although auditory hallucinations are the most common. "Voices speaking directly to the individual commenting on his or her ongoing behavior are particularly characteristic. Command hallucinations may be obeyed, at times creating danger for the individual or others" (American Psychiatric Association, 1980, p. 183).

Disturbance of Affect. Disturbances of affect may involve blunting, flattening, or expression that is "discordant with the content of the individual's speech or ideation" (American Psychiatric Association, 1980). These symptoms have been found to consistently predict poorer outcome in schizophrenics (Knight, et al., 1979). Notably, the effects of psychotropic medication used to treat the illness may produce symptoms similar to those of affective blunting and flattening (American Psychiatric Association, 1980).

Disturbances of the Sense of Self. The sense of autonomy that usually gives the normal person a feeling of uniqueness and self-direction is frequently disturbed in those diagnosed as suffering from schizophrenic disorder. This disturbed sense of self may be manifested by a lack of a sense of identity, i.e., a loss of ego boundaries or delusional thinking which involves control by an external force (American Psychiatric Association, 1980).

Disturbances of Volition. Schizophrenics invariably tend to experience a disturbance in self-initiated or goal-directed activity. This may, of course, grossly impair work or other role performance. It may take the form of an inability to sustain an interest or drive in pursuing a course of action to its logical conclusion. The pronounced ambivalence involved in evaluating alternative courses of action may lead to a near cessation of goal-directed activity

(American Psychiatric Association, 1980). Antipsychotic medication may produce akinesia which often appears identical to a disturbance in volition. Such medication may also produce sedation which can result in a disturbance in volition (Spitzer, Andreasen, and Endicott, 1978b).

Disturbance in Relationship to the External World. Social withdrawal or emotional detachment is still another characteristic of schizophrenia. The preoccupation with "egocentric and illogical ideas and fantasies in which objective facts are obscured, distorted, or excluded" may become all-encompassing (American Psychiatric Association, 1980).

Psychiatric Hospitalization. There is considerable evidence that schizophrenics differ in the degree of debilitation experienced and the consequent need for hospitalization (DeWolfe, 1971, 1974; Higgins, 1969; Phillips, 1968; Sengel and Lovallo, 1980; Strauss, et al., 1977; Zigler and Phillips, 1962). Some schizophrenics have been shown to exhibit a life long pattern of poor social and academic adjustment, a marked inability to cope with the stresses of everyday life and, consequently, seem to require long-term hospitalization (Phillips, 1968).

Significantly, Zubin and Spring (1977) point out that what is often viewed as chronicity of psychiatric illness may well reflect "the iatrogenic influence of long-term incarceration" as much as, if not more than, an unremitting disease course. The specific relationship between the course of schizophrenic illness and the length of hospitalization is unclear. It has been noted, however, that patients hospitalized for long periods of time tend to exhibit chronically inappropriate behavior (Storms and Broen, 1969) and greater idiosyncracy of associations (DeWolfe, 1974). Storms and

Broen (1969) contend that habitual limiting or narrowing of attention results from long term hospitalization. The performance of schizophrenics on perceptual and cognitive measures tends to support this view (Broen, 1968). Chronic schizophrenics were found to use fewer cues and focus attention more narrowly than schizophrenics experiencing an acute illness reaction.

In a comparative study of chronic schizophrenics requiring hospitalization with those who did not, Siegel, et al. (1976) found that hospitalized schizophrenics showed greater overall deviant verbalizations including paucity of speech, perseveration, and repetition--variables thought to be indicative of impoverished thinking. These researchers acknowledge that these differences may have been due to greater severity of illness of the hospitalized schizophrenics.

A recent study aimed at evaluating the effects of differing lengths of psychiatric hospitalization found that self-neglect, disorganization of thought processes, and impulsivity had the highest correlation with hospitalization. Additionally, longer lengths of stay were not found to decrease the need for subsequent hospitalization, to significantly improve the social adjustment of patients, or diminish their psychopathology (Mezzich, et al., 1984).

Empirical Assessments of the Competence of Psychiatric Patients

Unfortunately, little effort has been directed toward the assessment of whether psychiatric patients in general or schizophrenics, in particular, are competent to give informed consent to participate in research. Those studies which tend to bear on this issue have most often been concerned with competency to consent to standard treatments (which often involve potential risks) rather than research. The

results of these studies are summarized below. It should be noted that the lack of conceptual clarity of what constitutes competency and the lack of information about or variations in populations and the methods used make only gross comparisons possible.

Those works which bear on the competency of the mentally ill may be grouped into three areas: 1) the ability to consent to voluntary hospitalization; 2) the ability to understand their rights as patients; and, 3) the ability to understand various treatment procedures (e.g., psychotropic medication, electroconvulsive therapy, psychosurgery, social skills training, etc.). Studies designed to assess the two former areas have involved the limited likelihood of risk, as well as limited direct benefit. The majority of the studies having to do with treatment procedures, on the other hand, may cause considerable risk, but also have a greater likelihood of directly benefiting research participants. The assessment of competency was not the major goal of some of these studies. They are considered here because the results and their implications bear on the issue of competency.

Consent to Voluntary Hospitalization

Studies which relate to the ability of psychiatric patients to understand the reasons for voluntary hospitalization have cast substantial doubt about whether more than a small percentage of voluntary admissions represent truly informed decisions (Appelbaum, Mirkin, and Bateman, 1981; Gilboy and Schmidt, 1971; Palmer and Wohl, 1972; Olin and Olin, 1975). Foremost among the suggestions for the protection of the rights of voluntary patients is the legal concept that voluntary admission be construed as a contractual agreement (Appelbaum and Bateman, 1981). This legal status requires that the patient be competent and

capable of giving an informed consent in order to establish the validity of the contract. Significantly, follow-up efforts to educate uninformed patients about their voluntary status were limitedly successful (Appelbaum, Mirkin, and Bateman, 1981; Olin and Olin, 1975; Palmer and Wohl, 1972).

Knowledge of Patient Rights

Relatively few studies have been concerned with psychiatric patients' general knowledge about the rights they have as patients (Mill, et al., 1983; Rhodes, 1980). These studies indicated that the ability to understand information materials concerned with patient rights was negatively related to the degree of patient disability. This is to say that those patients with the greatest disability were least likely to understand their rights as patients.

Consent to Treatment

Not surprisingly, most of the research attempting to evaluate efforts to educate psychiatric patients about various treatment procedures concerned the use of psychotropic medication (Beck and Staffin, 1986; Deveaugh-Geiss, 1969; Geller, 1982; Grossman and Summers, 1980; Linden and Chaskel, 1981; Mason, Backus, and Volberding, 1978; Marder, et al., 1983; Pryce, 1978). Although the general effectiveness of such drugs in both controlling florid symptoms and in preventing the onset of further episodes of acute illness has been empirically demonstrated (Donaldson, Gelenberg, and Baldessarini, 1981; Freeman, 1981; Hartmann, et al., 1980), the fact that patients may be predisposed to serious side effects has also been well documented (Cardon, Dommel, and Trumble, 1976; Richardson, Graupner, and Richardson, 1966; Soskis, 1978). The results of studies concerned with the ability of psychiatric patients to make informed

treatment decisions parellel those concerned with voluntary hospitalization and knowledge of rights. In general, chronically mentally ill persons were found to lack sufficient insight into their condition to make sound judgments about treatment. Even those who improved with medication did not improve in their insight into the need for treatment (McEvoy, et al., 1984). In addition, the overwhelming majority of psychiatric patients were found to be unable to appreciate the risks and benefits of antipsychotic medication. It was not uncommon, in fact, to find that these patients denied having been involved in discussions concerning the risks and benefits of their medication (Beck and Staffin, 1986; Mills, et al., 1983).

Also of interest is the finding of Beck and Staffin (1986) that significantly more of those who were voluntarily taking psychotropic medication and considered knowledgeable about its use, in comparison to those voluntarily taking psychotropic medication who were found to be unknowledgeable, felt coerced. Patients considered knowledgeable were those who knew the names of their medication and were able to cite one therapeutic benefit and one side effect. Even though considered to possess a minimal understanding of their medication, these patients might not be considered informed consumers in that they seemed not to understand that they had the right to refuse the medication. It is noteworthy that efforts to educate uninformed patients about treatment have rarely been successful (Appelbaum, Mirkin, and Bateman, 1981; Beck and Staffin, 1986).

Geller (1982) found that 92 percent of 261 psychiatric patients were without a full understanding of the medication they took. Guardians, however, had been appointed for only eight percent of these patients. If the absence of knowledge is due to incompetency, he points out, a form of substitute consent is needed. Unfortunately, he notes, the

question of competency is usually raised only in cases of drug refusal. If a patient takes his/her medication, but is uninformed, i.e., incompetent consent, his/her competency is not questioned.

In a study which examined the willingness of psychiatric and non-psychiatric patients confined to a medical unit to participate in a series of hypothetical studies, no differences were found between the two groups (Stanley, et al., 1981). The proposed studies ranged from minimal risk/high benefit to high risk/low benefit. A "relatively large number" of patients in both groups agreed to participate in the high risk/low benefit study although the study was not directly related to their condition. The investigators speculate that patients may have given a "socially desirable" response of agreeing to participate because the study was hypothetical and argue that this effect may have been diminished by the prospect of having to tolerate real risks. Interestingly, they conclude that, because the mentally ill made decisions no different than other hospitalized persons who did not suffer from mental disability, special safeguards for their protection seem unwarranted.

Studies concerned with the ability of psychiatric patients to give informed consent to electroconvulsive therapy (Culver, Ferrell, and Green, 1980; Gilbert, 1981; Kaufmann and Roth, 1981; Salzman, 1977) and experimental treatments such as hemodialysis (Ketai, et al., 1981) further affirm the questionable competence of these persons. Patients generally lacked a meaningful understanding of proposed procedures. Of issue is that they consented to involvement despite this lack of understanding.

Psychiatric patients have been shown to fail to understand fundamental aspects of research methods, aspects which may be considered to be of vital importance in giving an informed consent. A lack of

understanding of such aspects of research as randomized assignment, the use of placebos, the presence of control groups, and the use of double-blind procedures serves to critically handicap their ability to engage in an accurate assessment of the risks and benefits involved (Appelbaum, Roth, and Lidz, 1982; Imber, et al., 1986).

Although relatively little attention has been devoted to the appropriateness of disclosing scientific methodology in general, commentators have discussed various components of this subject. Of these, randomized assignment has received the most attention. The arguments made in connection with it, however, are generally applicable to other methodologic details. Fried (1974), who prepared a comprehensive and carefully reasoned discussion of the issue, noted that randomization results in the needs of the subject being subjugated for the good of the experiment. In so doing, the "care" provided to subjects is chosen with regard to the success of the experimental design rather than out of concern for the individual well-being of subjects (Gray, 1975). Of concern is that even when otherwise informed research subjects tend to assume that decisions about their care are being made solely with their benefit in mind. This mind set has been termed "the therapeutic misconception" (Appelbaum, Roth, and Lidz, 1982).

Appelbaum, Roth, and Lidz (1982) were able to distinguish two types of cases in which the therapeutic misconception influenced decision-making. In the first type, subjects had an entirely therapeutic mind set toward the study and interpreted nearly every aspect of research methods as related to their individual needs.

The reason that these subjects joined the study was to achieve additional help. They seemed unable to understand that certain aspects of the design might interfere with that goal. Their underlying "trust" that the investigator would act in their best interest hampered their ability to effectively pursue a decision that was in their best interest.

The second type of subject demonstrated a more subtle influence of the therapeutic misconception on decision-making. In this instance, subjects' deficits in understanding methodology were more focal. These patients possessed a good overall understanding of the research procedures. Their generalized trust of caretakers and medical care facilities, however, led them to believe that the study would be highly beneficial to them (Appelbaum, Roth, and Lidz, 1982).

Similar findings have been confirmed by others (Imber, et al., 1986; Lidz, et al., 1984; Park, Covi, and Uhlenhuth, 1967; Reicken and Ravich, 1982). In these studies, patients were generally found to be unaware that they were participating in research and lacked knowledge about the research dimensions of their care. They tended to view their participation in research as another aspect of their treatment. In fact, these researchers attribute the willingness of psychiatric patients to participate in research to their trust in the investigator-clinician rather than an actual understanding of research procedures and the attending risks and benefits.

Subject Selection Bias

Although the reasons that psychiatric patients agree or refuse to participate in research have not been systematically investigated,

there is mounting evidence to suggest that those who are more likely to consent to research or various programs of treatment are those who are more likely to understand the information provided to secure participation (Appelbaum, Mirkin, and Bateman, 1981; Grossman and Summers, 1980; Pryce, 1978; Rhodes, 1980). There is the suggestion, however, that these patients are also more likely to feel coerced, thus making questionable the voluntariness of their decision to participate (Beck and Staffin, 1986; Linden and Chaskel, 1981).

Those who refused or were not accepted for participation in research studies are often those who show a greater overall degree of incapacity, e.g., they tended to be mute, to ramble aimlessly, were incoherent, or suffered from great physical disability (Appelbaum and Gutheil, 1980; Marder, et al., 1983; Rhodes, 1980). In one of the few studies designed to investigate the reasons for consent and refusal, Marder and his associates (1983) compared subjects who consented to the use of psychotropic medication with matched subjects who refused. The refusers were found to exhibit greater clinical psychopathology and more negative attitudes toward treatment. Significantly greater conceptual disorganization, emotional withdrawal, and unusual thought content were also found to characterize the refusers as well as more hostile, uncooperative, and mistrustful attitudes toward the treatment team. In addition, they were more likely to believe that they were not ill.

Summary

The paradox should now be clear. The law requires that informed consent, i.e., consent freely given with a reasonable

understanding of the nature and consequences of what is proposed, be obtained from mentally disabled persons who participate in research. The law has given, even to the hospitalized mental patient, the rights and privileges of the "free living" individual. Mere admission to a psychiatric hospital, however, constitutes a symbolic statement that the individual involved is functioning at a less than adequate level--that he/she is a diminished person "emerging into, or regressed from autonomy and responsibility" (Harris, 1966). The hospitalized mental patient may be considered incapable, in certain respects, of acting for him/herself or for others. Moreover, it may be argued that treatment with "organic therapies" which act on the brain (the use of which is almost universal among hospitalized mental patients), undermines the autonomy and dignity of the individual (Lidz, 1983).

By requiring informed consent of the mentally disabled, the law accords them the very roles that were once denied them in order to delineate the boundaries of the category. In short, the category of "individual" is treated as an undifferentiated monolith (Lidz, 1983). As Lidz (1983) has so aptly stated, the question is:

> Whether modern psychiatry can steer a course between the Scylla of losing legitimacy by failing to respond to the value demands that their patients be treated as dignified and autonomous individuals, and the Charybdis of failing to define the boundaries of the cult of the individual by including everyone...(p. 27).

Research using schizophrenics, a subgroup of the mentally ill, is of particular importance because of the large gaps in the scientific base of knowledge related to this population.

The enormous volume and variety of research devoted to the study of schizophrenia attest to the enigmatic and controversial nature of the illness. Because of the refractoriness of the illness to treatment, research undertaken to understand and treat it has at times involved drastic and invasive procedures. Inasmuch as the final decision about whether to participate in a research study rests with the patient, the need for assessing the extent to which schizophrenics who require hospitalization are able to make an informed choice for or against involvement is of fundamental significance. It is this problem which serves as the subject of this population.

STATEMENT OF THE PROBLEM AND HYPOTHESES

Although the need for specific safeguards to protect the psychiatrically disabled from research risks has been demonstrated, little has been done to empirically assess the extent to which those requiring psychiatric hospitalization are able to make an informed judgment about participation in research. Inasmuch as the final decision about whether to participate in research rests with the patient, the need for assessing the extent to which legally competent psychiatric inpatients are able to make an informed choice for or against involvement is of fundamental importance.

The major purpose of this investigation was to determine by means of a specially designed instrument (i.e., the Informed Consent Questionnaire), whether those hospitalized as schizophrenic were able to make an informed decision to participate in a research study. This study was also aimed at providing information concerning the factors which were predictive of the ability to give informed consent. The study in which subjects were asked to participate essentially involved no risk and the limited likelihood of direct benefit. Accordingly, the following hypotheses were tested:

I. The mean global informed consent scores of schizophrenics are lower than those of nonschizophrenics.

II. The mean informed consent subscale scores (e.g., purpose, procedure, voluntariness, risk, benefit, research sponsorship) of schizophrenics are lower than those of nonschizophrenics.

III. Group membership accounts for a greater portion of the variance in global informed consent scores than education, interest in or attitude toward the research procedure.

IVa. The global informed consent scores of schizophrenics are negatively correlated with the duration of the present hospitalization.

IVb. The global informed consent scores of schizophrenics are negatively correlated with the total duration of psychiatric hospitalizations.

V. The global informed consent scores of schizophrenics are positively correlated with prognosis.

VI. There is no difference in the proportion of schizophrenics and nonschizophrenics who refuse to participate in the study.

METHOD AND PROCEDURE

Sample

The population for this study consisted of patients and staff of six public psychiatric hospitals whose complaints alleging violations of patient rights were resolved. Satisfaction with the rights complaint process was selected as the vehicle through which it was possible to implement this study. The investigator was concerned that the research procedure to test study hypotheses not involve risk or arouse undue anxiety in participants. Given the familiarity of prospective subjects with the rights complaint process and the possibility that their responses could result in substantive changes in the system, the assessment of user satisfaction with the system seemed an appropriate research procedure.

All patients and staff who had rights complaints resolved within a six month period up to two weeks prior to the start of data collection constituted the subject pool. This pool was believed to be larger than needed, but deemed necessary in anticipation of heavy patient and staff turnover. It was also expected that the patient sample would be further reduced because of study inclusion criteria and their willingness or inability to participate in the study. In consideration of these constraints, it was conservatively estimated that interviews with 60 subjects in each group could be completed. It was possible, however, to complete the interview procedure with 102 patients and 92 staff. This research is based on the performance of these subjects.

The names of prospective subjects were selected from the records of the Michigan Department of Mental Health, Central Office of Recipient Rights. The Central Office of Recipient Rights is the agency responsible for monitoring the level of rights protection in public psychiatric hospitals in Michigan. Copies of formal complaints and reports of the resolution status of these are kept on file in that office.

The psychiatric hospitals enlisted to participate in this study were selected on the basis of their location in central Michigan and the desire to obtain an adequate sample of patients hospitalized as schizophrenic. The hospitals selected were: Clinton Valley Center, Detroit Psychiatric Institute, Michigan Institute for Mental Health, and Kalamazoo, Northville and Ypsilanti Regional Psychiatric Hospitals.

Study Group

Central Office of Recipient Rights' records were reviewed to obtain the names of all patients whose complaints were resolved within the six months preceding the time of data collection. Only those patients who had been hospitalized for a minimum period of six months and received an Axis I diagnosis of schizophrenic disorder, in accord with classifications of the Third Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III), were included as possible subjects. Patients who received an Axis II diagnosis of organicity or developmental disability were excluded from the study. Patients suffering from a major physical illness were also excluded to avoid the potentially confounding effect of these variables.

The initial patient pool consisted of 363 potential subjects. This pool was reduced to 233 by the time of actual data collection because of patient illness, transfer, discharge, leave of absence,

and death. An additional 39 patients were excluded because they did not meet the study inclusion criteria. Of the remaining 194 patients, 21 percent refused to participate in the study. Twenty-six percent were unable or unwilling to complete the interview procedure. Table 1 summarizes the response rates of this group.

Table 1

Response Rates of Schizophrenic Sample

Response rate	=	$\frac{\text{Completed interviews}}{\text{Total number of attempts}}$	=	$\frac{102}{194}$	=	52.5%
Failure rate	=	$\frac{\text{Incomplete interviews*}}{\text{Total number of attempts}}$	=	$\frac{51}{194}$	=	26.3%
Refusal rate	=	$\frac{\text{Refusals}}{\text{Total number of attempts}}$	=	$\frac{41}{194}$	=	21.1%

*Includes unwilling (n=38) and unable (n=13)

Of the 102 patients who met the study inclusion criteria and completed the interview procedure, males comprised 57 and females comprised 43 percent of the study group. The patient sample ranged in age from 18 to 75 years. The mean age was 34.9 years. Three percent had been hospitalized for the minimum period of six months at the time of participation in the study. The mean period of the present hospitalization was 25.3 months. Ninety-seven percent had been previously psychiatrically hospitalized; 56 percent had been hospitalized for five years or more. Ninety-nine percent were receiving psychotropic medication at the time of the study. The characteristics of study and comparison groups are summarized in Table 2.

Table 2

Selected Sample Characteristics

Variable	Schizophrenics	Nonschizophrenics
Age		
Range	18-75 yrs	23-69 yrs
Mean	34.9 yrs	37.1 yrs
Sex		
Male	56.9%	51.1%
Female	43.1%	47.8%
Race		
White	68.6%	82.6%
Nonwhite	31.4%	16.3%
Marital Status		
Ever married	38.2%	76.1%
Never married	60.8%	20.7%
Education		
Range	6-16 yrs	8-18 yrs
Mean	10.6 yrs	15.1 yrs
Prognosis		-
Good	12.7%	
Fair	34.3%	
Poor	52.0%	
Present Hospitalization		-
Range	6-203 mos	
Mean	25.3 mos	
Number of Previous Hospitalizations		-
Mean	4.2%	
Total Previous Hospitalizations		-
6 months	3.0%	
6 months, < 1 year	3.9%	
1 year, < 3 years	13.7%	
3 years, < 5 years	23.5%	
5 years or more	55.9%	

Table 2 (cont'd)

Variable	Schizophrenics	Nonschizophrenics
Medication		-
Phenothiazines	53.9%	
Other neuroleptics	45.1%	
Neither phenothiazine nor neuroleptic	1.0%	

Note. Percentages which do not equal 100 are due to missing information.

Comparison Group

In order to assess the relative performance deficits of schizophrenics, a comparison groups of those presumed not to suffer from schizophrenic illness was selected. This group consisted of staff of the same public psychiatric hospitals from which the study group was chosen. As the study group, a requisite condition for selection was that subjects have filed a formal allegation of a rights violation on behalf of a patient or group of patients and received a final report.

The pool of 131 staff was reduced to 94 by the time of actual data collection because of illness, vacation, transfer, or termination. Two of the 94 staff refused interviews. Interviews were completed for the remaining 92. This group consisted of 51 percent males and 48 percent females. Staff ranged in age from 23 to 69 years, with an average age of 37.1. Staff occupations consisted primarily of direct-care workers, such as nursing staff and attendants.

Differences in Sample Characteristics

Chi-square was used to determine the similarity of study and comparison groups on age, race, sex, marital status, and education variables. Sex, race, and marital status were treated as dichotomous variables. For these analyses, age was grouped into three categories: 18-35; 36-49; and, age 50 and older. Education was also grouped into three categories: grades 6 through 11; grade 12; and, schooling beyond high school. These analyses revealed that the groups differed significantly in terms of race, $X^2(1, N = 193) = 5.01$, $p < .05$, marital status, $X^2(1, N = 190) = 29.39$, $p < .0001$, and education, $X^2(2, N = 191) = 105.41$, $p < .0001$. The results of these analyses, based on selected data shown in Table 2, are presented in Table 3.

Table 3

Group Differences of Selected Demographic Characteristics

Variables	df	Chi-square
Age	2	2.37
Sex	1	.34
Race	1	5.01*
Marital status	1	29.39**
Education	2	105.41**

*$p < .05$. **$p < .0001$.

Instruments

Informed Consent Statement

The Informed Consent Statement was designed by the present author to provide prospective subjects with adequate information at a potentially understandable level so that they might make an informed choice for or against participation in the study. The statement follows the guidelines proposed by the Department of Health, Education and Welfare (1978b) regarding the protection of "mentally infirm" subjects in research studies. It was used to insure that potential subjects were adequately informed about the purpose, procedure, risks, benefits, voluntariness and other important aspects of the study. Brief descriptions of the various aspects of informed consent which served as the focus of this research and how they specifically apply in this study are discussed later in this chapter.

Patient and staff forms of the Informed Consent Statement were constructed. The forms were identical, with minor exceptions. Patients were asked to give the interviewer permission to review their hospital records. This request was inapplicable to non-patients. Patients were offered assurance that refusal to participate in the study would not affect the services received from the hospital. Assurance was offered to staff that refusal to participate in the study would not affect their jobs or the services provided to the patient or patients on whose behalf a complaint was filed. The Informed Consent Statement may be considered long (consisting of 507 words for patients and 474 words for staff), but was thought

to be inclusive of information necessary to encourage informed participation. [See Appendix A-1 (patient) and B-1 (staff) for a copy of the Informed Consent Statement.]

Readability of the Informed Consent Statement. In order to insure that the information provided to prospective subjects was written in language that was potentially understandable by a majority of the sample who might choose to participate in this study, the Flesch Readability Yardstick (1948) was used to assess the level of readability, i.e., comprehension difficulty of the Informed Consent Statement.

The Flesch scale has been generally acknowledged as the most widely used method for analyzing readability or comprehensibility (Blumenfeld and Justice, 1975; Grundner, 1978; Klare, 1952). Although the Flesch, like other readability measures, was developed primarily to evaluate curricular materials in the field of education, it has frequently been used to assess the readability of psychology textbooks and other scientific materials (Gillen, 1973; Ogden, 1954). More recently, the Flesch scale has been used to determine the readability of information provided to medical patients to obtain informed consent (Grundner, 1980) and of consent forms of behavioral and biomedical research studies submitted to Institutional Review Boards for approval (Cooke, Tannenbaum and Gray, 1977). The scale has also been applied to discussions of specific aspects of consent forms (e.g., purpose, risks) and found to be sufficiently sensitive to evaluate their relative difficulty (Cooke, et al., 1977).

The Flesch Yardstick consists of specified formulae which provide independent predictions of the reading ease (RE) and human interest (HI) of reading samples. Reading ease and human interest scores may range from zero (minimum readability) to 100 (maximum readability). The reading ease score is based on the average sentence length (sl) in words and the average word length in syllables (wl) of 100-word samples (i.e., RE = 206.835 - .846wl - 1.015sl). The reading ease formula essentially provides a measure of the complexity of the sentences and the level of abstraction of the words used. The human interest score is based on the average percentage of personal words (pw) and personal sentences (ps) of 100-word samples (i.e., HI = 3.635pw - .314ps). The human interest score is thought to contribute only indirectly to the measurement of readability. Human interest is reported to increase the reader's attention and motivation for continued reading, consequently making a given text more understandable (Flesch, 1948).

Reading ease and human interest scores were computed for entire patient and staff forms of the Informed Consent Statement constructed for this study. Reading ease for both forms fell into the "fairly easy" range, with scores of 71.42 and 72.45, respectively. The human interest scores of the patient and staff Informed Consent Statements were 47.51 and 48.24, respectively, falling into the "highly interesting" range. These scores were considered to be acceptable for the purposes of the study. The readability of the material provided to subjects in this study to encourage informed participation may be considered superior to that generally provided to subjects to secure participation in a research study (Cooke, et al., 1977; DHEW, 1978b; Grundner, 1980).

Informed Consent Questionnaire

The Informed Consent Questionnaire was designed by the present researcher to assess the extent to which agreement to participate in this study was informed. The questions posed concerned various aspects of the information provided in the Informed Consent Statement given and read to each of the potential subjects. Subjects were asked to indicate verbally, after each question was asked, whether the correct answer was right or wrong based on the previously communicated material. After completion of the Informed Consent Questionnaire, questions were clarified which had been answered incorrectly. It was hoped that with feedback, subjects would move toward the correct response(s).

Patient and staff forms differed only in the number of items included. The patient form consisted of 19 rather than 18 items. The additional item on the patient form concerned a request to review their hospital record. Staff and patient comparisons were based only on the 18 common items. (See Appendix A-2 for the patient and B-2 for the staff forms of the Informed Consent Questionnaire.)

Informed Consent Facets. Six facets of informed consent served as the focus of this study: purpose, procedure, risk, benefit, voluntariness and research sponsorship. In the explanation which follows, each facet is defined in general and how this translates with reference to this study. The actual questions which were designed to assess the various facets are also presented. The questions are numbered as they appeared on the Informed Consent Questionnaire. A random number table was used to order items.

Parenthetically noted "W" and "R" indicate whether the question was right or wrong based on the information provided in the Informed Consent Statement.

Purpose: An explanation of what the research expects to accomplish as a result of the subject's participation. The goal of this research was twofold: (1) to assess complainant satisfaction with the rights complaint process and (2) to learn how well the study had been explained.

Questions designed to tap subject understanding of what the study was intended to accomplish included:

1. The purpose of this project is to solve rights complaints. (W)
5. The purpose of this project is to find out how well rights complaints are handled. (R)
7. The questions I will be asking are part of a research project. (R)
8. The purpose of this project is to learn how to file a rights complaint. (W)
18. One part of this project is to find out how well I've communicated what the project is about. (R)

Procedure: Explanation of what is expected of subjects in terms of participation in the research. In this instance, participation involved answering questions concerning satisfaction with the rights complaint process, asking questions about any aspect of the research and, in the case of patients, to allow review of their hospital record to collect background information for the study. Because of the structure of this study, the invitation to ask questions was incorporated as a part of the procedure dimension. The entire interview procedure was expected to average 30 minutes.

Questions designed to tap subject understanding of what participation in this study involved included:

3. You may interrupt me to ask questions about this project at any time if you want to. (R)

12. You must ask questions about this project. (W)

15. Your participation on this project will involve being interviewed about your experiences with the rights complaint process. (R)

*19. I will be asking to see your hospital record if you agree to participate in this study. (R)

Risk: An explanation of the possible harm that might befall the subject as a result of participation in the research and safeguards invoked to protect subjects against or to minimize this harm. This study did not involve legal or physical risks for the subjects and, given the confidentiality safeguards, the likelihood of psychological and/or social risks was considered minimal for patients and staff. With the exception of the signed Consent Form (which was detached from other questionnaire materials when the interview was completed), no questionnaire, record or data file bore the names of subjects. Data logged on the computer for analysis were identified by a unique number used only for the purposes of this study. Consent Forms bearing the names of subjects were kept in a locked file separate from that of the questionnaires. These materials were to be destroyed at the conclusion of the study. All data are reported in summary form so as to protect the anonymity of respondents.

Questions designed to tap subject understanding of the possible risk involved by participating in the study included:

11. This study will probably not involve any risk for you. (R)

*Included only on the patient form

13. Only the people working on this project will see the answers that you may provide. (R)

17. Your responses to this interview will be shown to the staff on your ward. (W)

Benefit: An explanation of the advantage or good to be accrued to individual subjects as well as in general as a result of what might be learned from the study. It was explained to subjects that they might not benefit directly from this research but, that depending on the responses of those who participated, it was possible that patients and staff at state hospitals might benefit in the long run from what was learned.

Questions aimed at tapping subjects' understanding of the benefit likely to results from the study included:

9. This study will definitely benefit you. (W)

16. All of the patients and staff at this hospital will receive direct benefits from this study. (W)

Voluntariness: An explanation that the decision to participate in the study was by personal preference or choice of the subject. This was communicated directly and indirectly in that no effort was made to coerce, deceive, or offer assurances of privileges to enlist participation. Subjects were also told that they were free to withdraw consent and to discontinue participation in the research at any time without prejudice.

Questions aimed at tapping subjects's understanding of the voluntary nature of participation in the study included:

4. Everyone who is asked must participate in this study. (W)

6. If you agree to participate in this interview, you must answer all questions that I ask you. (W)

10. If you begin this interview, you must complete it. (W)

Research sponsorship: In the interest of clarity, it was deemed necessary to point out that although project staff were concerned about complainant satisfaction with the rights complaint process, they bore no connection to the office responsible for implementing programs to protect the rights of patients requiring inpatient psychiatric hospitalization. Clarification of certain administrative aspects of the research was aimed at presenting staff and patients with a clearer perspective of the goals of project staff and a more realistic view of what might reasonably be expected as a result of the study. It was believed that this would help subjects to understand both that they did not need to fear reprisals because of participation or receive privileges or specific benefits from participation.

Questions designed to assess subject understanding of the research sponsorship facet included:

2. The people who work on this project do not work for the Office of Recipient Rights. (R)

14. This project is being paid for by the Office of Recipient Rights in Lansing. (W).

Construction of the Informed Consent Statement and Questionnaire. The aim of the researcher was to present appropriate information and the invitation to ask questions about the study in an effort to secure informed participation in the research study. Several revisions were required in order to accomplish that goal.

The initial draft of the Informed Consent Statement indicated that this research project had two main goals: (1) to assess the extent to which subjects could make an informed judgment about participating in a research study and (2) to assess the level of

satisfaction with the rights complaint process. The discussion of the dual purpose, however, made the form unduly long and confusing to respondents. Because the assessment of satisfaction with an aspect of the quality of service received was selected to serve as the research intervention of the study, it seemed more appropriate to focus primarily on discussion of that in the Informed Consent Statement. This approach not only seemed to simplify the task, but also served to make it more comparable to that usually encountered by prospective subjects of research studies.

Question also arose about the placement of the Informed Consent Questionnaire, e.g., whether it would be best administered prior to or after signing the Consent Form. Because the questionnaire directly related to the consent process, it seemed most appropriate to ask respondents to complete the questionnaire before being asked to sign the Consent Form. At the end of the Informed Consent Statement, it was decided that respondents would be asked to answer additional questions to assess how well the interviewer had explained the study. Indication that respondents were willing to answer the questions was viewed as an informal agreement to continue the interview procedure. From this perspective, the (1) Informed Consent Statement, (2) Informed Consent Questionnaire, and (3) Consent Form comprised the consent process.

The materials comprising the consent process required extensive revision after the first pre-test at Ypsilanti Regional Psychiatric Hospital in November, 1980. These were again pre-tested at the Michigan Institute for Mental Health in January and February, 1981.

Pre-tests were conducted with the patients and staff of the two aforementioned psychiatric hospitals and a small sample of college undergraduates at Michigan State University. The pre-tests were helpful in identifying awkward and confusing phrasing of questions, wording which did not read well in a conversational tone and pinpointing bureaucratic snares which might hamper data collection activities.

Measurement of the Concept of Informed Consent. A basic assumption underlying this study was that the decision to participate in a research study may be characterized as more or less informed, i.e., that informed consent exists on a continuum. It was theorized that the extent to which schizophrenics and normals differ in their ability to give informed consent could be crudely evaluated by using a unidimensional measure. A global informed consent score was, therefore, computed for schizophrenic and normal subjects based on the number of correctly answered items on the Informed Consent Questionnaire.

It was also hypothesized that within and between group differences might be observed by comparing performance on the various theoretically specified aspects of the informed consent concepts: the purpose of the research, the procedures involved, the risks, the benefits, the voluntary nature of participation, and research sponsorship. Certain facets included more items than others. This was done in an effort to keep the length of the Informed Consent Questionnaire to a minimum while providing greater weight for the more difficult facets. This was in accord with Cooke's (1982) view

based on a review of consent forms submitted to Institutional Review Boards that certain aspects of informed consent were more complex than others. Table 4 shows the items used to assess the various aspects of informed consent and the possible range of scores for each.

Table 4

Informed Consent Indices

Index	Items	Range of Index
Global	1-18	0-18
Purpose	1, 5, 7, 8, 18	0-5
Procedure	3, 12, 15	0-3
Risk	11, 13, 17	0-3
Benefit	9, 16	0-2
Voluntariness	4, 6, 10	0-3
Research sponsorship	2, 14	0-2

Consent Form

The Consent Form provided a brief summary statement of the information imparted in the Informed Consent Statement. It served as documentation that the interviewer had communicated the information necessary for potential subjects to make an informed judgment about whether to participate in the study. With the exception of the request to review patients' hospital records, the patient and staff versions of the Consent Form were identical. (See Appendix A-3 and B-3 for patient and staff versions of the Consent Form.)

Rights Complaint Survey

The Rights Complaint Survey consisted of a structured interview designed by the study author to assess complainant satisfaction with various aspects of the rights complaint process. Subjects were queried, for example, about their satisfaction with such things as the assistance provided by the hospital Rights Office staff in filing a rights complaint, the thoroughness of the complaint investigation, the length of time taken to resolve the complaint, perceived positive and negative changes believed to have resulted from filing the complaint, and satisfaction with the manner in which the complaint was finally resolved. Subjects were also asked to evaluate the adequacy of the explanation they were given describing the study after questions concerning the rights complaint process were answered. The same Rights Complaint Survey was administered to both patients and staff. (A copy of the survey may be found in Appendix -4.)

Assessment of Satisfaction with the Rights Complaint Process as the Research Procedure. The assessment of complainant satisfaction with the rights complaint process, as measured by the Rights Complaint Survey, was selected as the research procedure or vehicle through which this study might be implemented. This seemed to be an appropriate vehicle for several reasons. Consonant with the current interest in consumerism, it seemed legitimate to query those for whom the rights protection system was created about their satisfaction with it. This goal seemed of particular importance given that the rights system is predicated on such assumptions as patients know their rights, how to use the system, and are capable and willing to use it in cases of perceived violations. Importantly, the risk to subjects of this procedure was likely to be minimal or nonexistent, given the provisions in place to protect the privacy of subjects.

In addition to serving as a research procedure which justified the participation of those hospitalized as schizophrenic, as mandated by federal guidelines (DHEW, 1978a, 1978b; DHHS, 1981), it was hoped that this study would help to identify inadequacies in fundamental aspects of the rights protection system. Those who chose to participate had the opportunity to express their satisfactions and dissatisfactions with and suggestions for change of the rights system. It was believed that these opinions and suggestions might serve as the basis for effecting necessary changes in a system ultimately aimed at insuring that patients are provided the best care possible.

Aside from having practical applicability, the assessment of satisfaction with an aspect of the service provided to psychiatric

inpatients was a topic with which subjects were believed to be familiar and, conceivably, one with which they were likely to possess a fair measure of interest. While generalizations about the selective attention of schizophrenics are difficult to make (Schneider, 1978), it was felt that it was of basic importance that the research task of this study be one with which subjects possessed some degree of familiarity and personal interest as well as one that might not be viewed as detrimental or harmful. This was deemed necessary so as to limitedly interfere with subjects' ability to comprehend the information provided during the consent process. Significantly, during the pretest phase, many subjects seemed tolerant of the relatively lengthy consent procedure because it provided the opportunity to discuss their feelings about the rights complaint process.

Finally, assessment of complainant satisfaction provided a common procedure for comparing schizophrenics and normals (i.e., both groups had filed rights complaints in response to perceived violations which had been investigated and resolved). The comparison group of normals provided a context within which to interpret the responses of schizophrenics.

Construction of the Survey Instrument. A review of selected literature (Albers, 1977; Justice and McBee, 1978; Larsen, et al., 1979; Scheirer, 1978; Zusman and Slawson, 1972) on the satisfaction of those receiving mental health services revealed that studies concerned with this issue seemed potentially useful, but suffered from major flaws. First, client satisfaction studies generally failed to differentiate between the various dimensions of satisfaction. Secondly, and related to the first problem, client satisfaction ratings

have tended to be too global to provide a meaningful estimate. Third, client satisfaction measures have often been used as the sole (and, consequently, inadequate) measure of evaluation (Justice and McBee, 1978; Kaufman, Sorenson, and Raeburn, 1979). Without an appropriate frame of reference or corroborating data, it has been difficult to know what the findings of such studies mean.

In constructing the Rights Complaint Survey, effort was made to improve upon some of the limitations of previous client satisfaction studies. Questions were developed to assess satisfaction both with various aspects of the process filing a complaint (e.g., whether complainants were satisfied with the information provided and the assistance given in filing the complaint, etc.) as well as with the outcome or resolution status of the complaint.

The semi-structured interview was believed to be the most appropriate questionnaire format to assess client satisfaction. Freeman and Simmons (1970) have emphasized the potential usefulness of the survey method and the structured interview in investigations involving the mentally ill. They point out that the successful use of the survey with the mentally ill, not unlike other populations, is primarily dependent upon the use of sound research techniques. These authors also note the importance of the background and training of the interviewers when conducting studies involving the mentally ill.

The semi-structured interview provided a uniform stimulus for patients and staff and the opportunity for capturing the diversity of response of these groups. Some questions attempted to elicit general assessments, but probe questions made it possible to obtain clarification of the meaning of these responses. The interview also

provided the opportunity for face-to-face contact which was believed to be a vital element in interactions with those suffering from mental illness.

As with the consent material, the survey was pretested with patients and staff at two public psychiatric hospitals, Ypsilanti Regional Psychiatric Hospital and the Michigan Institute for Mental Health. Pretests of the Rights Complaint Survey resulted in the selection of the specific satisfaction elements which users of the system considered relevant and in making the phrasing of the survey more conversational and amenable to the population selected for study.

Scoring the Survey Instrument. Specific response options were presented for some questions; others were open-ended. In addition to substantive response categories, responses to open-ended questions were classed as general, irrelevant, or incoherent. Responses classed as general included unspecific responses where the respondent restated the basic premise of a question and failed to provide elaboration of the response after the interviewer asked appropriate probe questions. Responses classed as irrelevant were those which did not seem to specifically address the question posed. Responses considered incoherent were those which did not seem to address the question posed or the research task in a clearly discernible way.

Interviewer Observations Form

After completion of the Rights Complaint Survey, interviewers were instructed to record their general observations of subjects and to rate them on specific indices. Interviewers were asked to note their general impressions of the subjects and the wards where patients

resided and staff worked. They were also asked to note the number and nature of interruptions during the interview as well as subjects' attitude toward and interest in the interview procedure. These assessments were collected for both patients and staff.

Interviewers were instructed to make additional ratings of schizophrenics. They were asked to rate the degree of difficulty involved in keeping their attention focussed on interview topics, their seeming understanding of the questions posed, and their reality orientation. Interviewer ratings of respondents are summarized in Table 5. (A copy of the Patient Interviewer Observations Form may be found in Appendix A-5; the staff version be found in Appendix B-4.)

Patient Background Information Form

Patients who agreed to participate in the study were asked to permit the interviewer to review their hospital record to collect basic demographic information. Information concerning age, sex, race, marital status, educational background, primary and secondary psychiatric diagnoses, prognosis, length of present hospitalization, and the type, dosage, and frequency of medication(s) was obtained form patients' hospital records. (A copy of the Patient Background Information Form is shown in Appendix A-6.)

Staff Background Information Form

Staff who agreed to participate in this study were asked to complete a brief background information form. They were asked to supply such information as age, sex, race, marital status, educational background, present job classification and level, length of

Table 5

Interviewer Ratings of Respondents

Variable	Schizophrenic Percent	Nonschizophrenic Percent
Interruptions during interview		
None	67.2	70.2
One or more	23.0	20.7
Interest in survey		
Very interested	18.6	28.3
Moderately interested	39.2	50.0
Slightly interested	26.5	10.9
Seemingly not interested	2.9	5.4
Obviously bored or distracted	3.9	5.4
Attitude toward interview procedure		
Quite positive	16.7	37.0
Cooperative	56.9	48.9
Neutral	13.7	7.6
Somewhat uncooperative	2.9	1.1
Hostile or suspicious	1.0	5.4
Difficulty keeping on topic		-
Very difficult	3.9	
Somewhat difficult	25.5	
No real problem	60.8	
Understanding of questions		-
Understood all	36.3	
Understood most	43.1	
Misunderstood many	11.8	
Reality orientation		-
Very confused, disordered	5.9	
Somewhat disordered	27.5	
Not very disordered	57.8	
Length of consent procedure		
Mean	12.6 mins	7.6 mins

Note. Percentages may not total 100 due to missing information.

time in their present jobs, length of employment at the hospital, and length of state employment. (See Appendix B-5 for a copy of the Staff Background Information Form.)

Procedure

Requests for Hospital Participation and Appointment of Liaisons

The directors of the six psychiatric hospitals selected to participate in this study were asked to appoint a staff person with whom the researcher might work to make the necessary arrangements for completing the study. The liaison assisted with such tasks as helping the interviewer gain access to appropriate hospital records to determine which of the list of patients and staff who had rights complaints resolved were still residents or employees of the hospitals and the wards to which they were currently assigned. Hospital liaisons were asked to notify the wards of the anticipated study dates, secure a room where interviews might be conducted in privacy, and assist with other scheduling arrangements necessary to complete the study.

Training of Interviewers

Psychology independent study students enrolled at Michigan State University were recruited to assist with data collection activities. Those selected were given instruction in interview administration, the importance of maintaining confidentiality and the provisions made to protect the privacy of subjects, how to

direct subjects' attention, establish rapport, etc. The Interviewer's Manual (1976) published by the Institute for Social Research of the University of Michigan was used as a guide in this training.

Interviewer training also included the discussion of some of the possible responses to problems that might arise during the period of data collection. Examples of such situations included: patients' refusal to sign the consent form or complete the interview procedure, patients' requests for the interviewer to remedy a situation, patients' requests for matches, money, etc.

The interviewers were informed about the general aspects of the study and important aspects of the rights system to make it possible for them to respond intelligently to potential questions about them. They were not told of the specific hypotheses of the study so as not to bias the outcome of the results.

The Interview Procedure

Interviewers approached potential subjects about participation in the study on their hospital wards. Ward supervisors were asked by the hospital liaison to provide a room on the wards where patients resided and staff worked to conduct the interviews. The ward supervisors were also asked to provide assistance by locating and introducing the interviewer to selected subjects.

After a brief introduction, interviewers were instructed to give potential subjects a copy of the Informed Consent Statement (which they were told they could keep if they would like). The statement given to the subjects bore the name of the interviewer

and the address and telephone number of the researcher's office. Subjects were asked to follow along as the interviewer read it aloud. The statement attempted to impart the information necessary for potential subjects to make an informed decision about whether to participate in the study.

After the interviewer read the Informed Consent Statement and answered any questions, potential subjects were asked if they were willing to answer questions to let the interviewer know how well the study had been explained. Those who agreed to continue were given a copy of and administered the Informed Consent Questionnaire. Interviewers were instructed to record whether responses were correct or incorrect and whether subjects consulted the Informed Consent Statement when answering questions.

When all questions had been asked and responses recorded, the interviewer gave subjects a copy of the Consent Form and asked them to follow along as the interviewer read it aloud. Interviewers then read the brief statement of the Consent Form and asked potential subjects to sign it if they were interested in participating in the study. This form reiterated (for no less than the third time) that participation in the study was voluntary and that a decision to participate, or not, would not affect the services they received; or, with respect to staff, the services provided to the person(s) on those behalf a complaint was filed or their jobs. The interviewer explained that their signatures would show that they had granted permission to be interviewed.

Interviewers were instructed to present the signed Consent Forms of patients who agreed to participate in the study to the ward supervisors when requesting patients' hospital records for review. Information concerning patients' history of psychiatric hospitalization and demographics was abstracted from their hospital records. Staff who agreed to participate in the study were asked to complete brief background information forms. Interviewers were also asked to rate respondents on several variables after concluding the interview, such as the respondent's attitude toward and seeming interest in participating in the study.

The consent process included the Informed Consent Statement, Informed Consent Questionnaire, and Consent Form. The Rights Complaint Survey was considered the research intervention, i.e., what patients were being asked to consent to do. Those subjects who consented to participate were administered the Rights Complaint Survey. Some questions were structured, others were semi-structured. The responses to structured questions were printed on cards which were shown to subjects as the questions were read. Subjects were instructed to choose the answer that best expressed how they felt. Those who refused to sign the Consent Form were not administered the Rights Complaint Survey and background information was not collected. The Informed Consent Questionnaire data of those who refused to sign the Consent Form or later withdrew consent after beginning the survey were not included in the analyses of this study.

Subjects were allowed as much time as they required. The average length of the consent process was 10.5 minutes. Patients averaged 13

minutes while staff averaged eight. The time required to complete the entire interview procedure ranged from eight to 50 minutes, with a staff average of 18 and a patient average of 30 minutes.

RESULTS

Hypotheses

Hypotheses I, II, III, IV, and V were confirmed, as predicted. Hypothesis VI was stated in the null because of conflicting literature. The finding of statistically significant differences resulted in a rejection of the null hypothesis. The specific predictions and the statistic used to test each follow.

Hypothesis I

It was hypothesized that the mean global informed consent scores of schizophrenics (i.e., mean number of items answered correctly on the Informed Consent Questionnaire) were significantly lower than those of nonschizophrenics. The results of a one-way analysis of variance showed a significant difference in the global informed consent scores of schizophrenic and nonschizophrenic groups, $F(1, 192) = 143.316$, p .001. Nonschizophrenics had a significantly higher mean global informed consent score ($M = 16.67$, $SD = 2.02$) than the schizophrenic group ($M = 11.65$, $SD = 3.65$). The proportion of questions answered correctly was .93 for nonschizophrenics as compared to .65 for schizophrenics.

Hypothesis II

It was predicted that schizophrenics would obtain significantly lower scores than nonschizophrenics on each of the facets of informed consent which comprised the global score (e.g., purpose, procedure,

Table 5

Analysis of Variance of Informed Consent Scale Scores of Schizophrenics and Nonschizophrenics

Variables	Schizophrenics M	Nonschizophrenics M	F-Ratio
Purpose	3.49	4.71	117.873*
Procedure	2.28	2.87	47.834*
Risk	2.46	2.90	24.630*
Benefit	.74	1.53	52.361*
Voluntariness	1.71	2.83	71.765*
Research sponsorship	.98	1.84	96.633*

Note. df = 1, 192

*$p < .001$.

risk, benefit, voluntariness, and research sponsorship). The results of a one-way analysis of variance of scale scores are presented in Table 5. It is shown that schizophrenics scored significantly lower on all scales than normals.

Hypothesis III

It was predicted that group membership would account for a greater portion of the variance in informed consent scores than subjects' education, attitude toward, or interest in the research procedure. This hypothesis was, in part, posited as a test of the success of efforts to limit the effect of education by increasing the readability of information provided to subjects to secure informed participation.

Table 6

Stepwise Multiple Regression of Global Informed Consent on Group Membership, Attitude, Education, and Interest

Variable	Multiple R	R^2	Beta
Group membership	.6461	.4175	-.4170
Attitude	.6901	.4762	-.2107
Education	.7151	.5113	.2516
Interest	.7157	.5122	-.0424

This hypothesis was tested by a stepwise multiple regression with forward inclusion (Nie, Hull, Jenkins, Steinbrenner, and Bent, 1975) of the indicated predictor variables on global informed consent scores. In the forward stepwise procedure, the variable having the highest partial correlation with the criterion was entered in the regression equation at successive steps.

As shown by the R^2 in Table 6, group membership accounted for the greatest portion of the variance (42 percent) in informed consent scores. The attitudes of subjects toward the research procedure (i.e., whether they were cooperative or hostile and suspicious) was entered in the equation at the second step and accounted for an additional 5.9 percent of the variance. Education accounted for an additional 3.5 percent of the variance at the third step. The subjects' interest in the research procedure variable did not meet the minimum statistical criteria for inclusion in the stepwise analysis.

Hypothesis IVa

A negative correlation between global informed consent scores and length of the present psychiatric hospitalization was predicted in an effort to explain differences in the performance of schizophrenics. A correlation of -.22 was found between the length of the present hospitalization and global informed consent scores. The observed correlation was significant at the .05 level.

Hypothesis IVb

A negative correlation between the global informed consent scores of schizophrenics and the duration of all psychiatric hospitalizations was also predicted. A correlation of -.25 was found between the length of total psychiatric hospitalizations and global informed consent scores. This correlation was significant at the .05 level.

Hypothesis V

The prognostic assessments of treating physicians were hypothesized to be positively correlated with the global informed consent scores of schizophrenics. A correlation of .31 was found. This correlation was significant at the .01 level.

Hypothesis VI

It was predicted that there was no difference in the proportion of schizophrenics and nonschizophrenics who refused to participate in this study. The difference of proportion test, or z statistic. (Fleiss, 1981) was used to compare refusal rates. Differences in the proportion of refusals for the two groups were found to be

significant, $z^2 = 8.76$, $p < .01$, two-tailed, resulting in a rejection of the null hypothesis. Notably 21 percent of the schizophrenics approached about participation in this study refused. This is compared to a two percent refusal rate for nonschizophrenics.

The Effect of Differences in Group Demographics

While the intent of the design of this study was to select groups similar in demographic characteristics, the realities imposed by available patient and staff populations were such that this was not possible. As reported earlier, the groups differed significantly on race, marital status, and education variables. It was, therefore, necessary to assess the extent to which these differences were predictive of informed consent.

Analysis of variance was used to assess the relationship between the dichotomous variables of race and marital status and global informed consent score. Regression analysis was used to assess the relationship of education, a continuous variable, to informed consent. These analyses were completed for individual groups and for the total sample.

Marital status was found to significantly correlate with the global informed consent score of the total sample, although not with individual groups. A significant relationship between education and informed consent was found to exist for schizophrenics, nonschizophrenics, and the total sample. Race was not found to correlate with global informed consent score. These relationships are summarized in Table 7

Table 7

Demographic Characteristics and Informed Consent

Variable	Schizophrenics df	Schizophrenics F-Ratio	Nonschizophrenics df	Nonschizophrenics F-Ratio	Sample df	Sample F-Ratio
Race	1, 100	.010	1, 89	.127	1, 191	3.129
Marital status	1, 99	1.781	1, 87	.536	1, 188	20.133**
Education	1, 99	11.433*	1, 88	7.336*	1, 189	107.363**

Note. The error term degrees of freedom vary due to missing information.

*$p < .01$. **$p < .001$.

Additional Findings

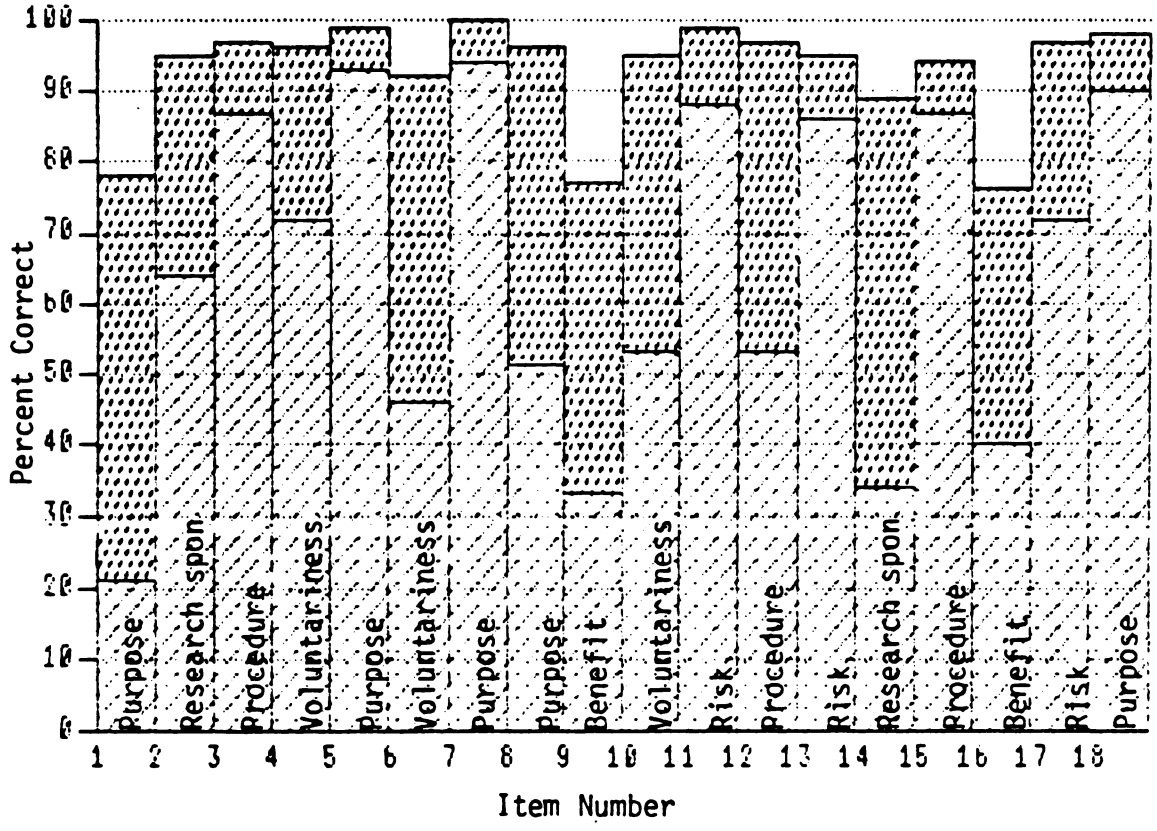
Additional analyses were completed to further elucidate the factors predictive of informed consent. Analyses were also completed to determine whether certain aspects of informed consent were better understood than others and to provide a normative framework within which to interpret the results.

Comparison of Group Performance on Informed Consent Questionnaire Items

Figure 1 provides a comparision of percent correct responses by item for schizophrenics and nonschizophrenics. Analysis of the relationship between schizophrenic and nonschizophrenic rankings of correctly answered questions using Spearman's rho revealed a strong positive correlation ($r_s = .847$), suggesting that the level of difficulty of questions was similarly perceived by both groups.

Figure 1

Percent Correct Responses by Item of Schizophrenics and Nonschizophrenics



Note. For all questions, nonschizophrenics answered a higher percentage of questions correctly than schizophrenics. The upper part of each bar represents the cumulative percentage of correct responses of nonschizophrenics. The percentages of correct responses of schizophrenics have been superimposed on nonschizophrenic scores. The percent scores of schizophrenics are represented by the lower portions of the bars.

Table 8

Analysis of Variance of Informed Consent Questions of Schizophrenics and Nonschizophrenics

Item No.	Informed Consent Construct	Schizophrenics M	Nonschizophrenics M	F-Ratio
1	Purpose	.21	.78	95.552**
2	Research sponsorship	.64	.95	31.205**
3	Procedure	.87	.97	5.864*
4	Voluntariness	.72	.96	21.914**
5	Purpose	.93	.99	4.126*
6	Voluntariness	.46	.92	62.621**
7	Purpose	.94	1.00	5.691*
8	Purpose	.51	.96	63.219**
9	Benefit	.33	.77	45.919**
10	Voluntariness	.53	.95	53.387**
11	Risk	.88	.99	9.146*
12	Procedure	.53	.97	62.921**
13	Risk	.86	.95	3.798*
14	Research sponsorship	.34	.89	87.474**
15	Procedure	.87	.94	2.122
16	Benefit	.40	.76	28.996**
17	Risk	.72	.97	24.872**
18	Purpose	.90	.98	4.926*

Note. df = 1, 192

*$p < .05$. **$p < .001$.

Analysis of variance of the mean group scores of schizophrenics and nonschizophrenics on individual items on the Informed Consent Questionnaire revealed statistically significant differences on all but one item. That item concerned a statement of the procedures required for participation. Although not statistically significant, comparison of the performance of groups on the item in question were in the expected direction with schizophrenics scoring lower than nonschizophrenics. The informed consent dimension assessed by each item and the corresponding F-Ratio are presented in Table 8.

Group Classification by a Stepwise Discriminant Function of Informed Consent Scale Scores and Individual Items

A stepwise discriminant function analysis was used to classify subjects based on informed consent scale scores. It was possible to correctly identify 82 percent of the sample based on four of the six informed consent constructs: purpose, voluntariness, benefit, and research sponsorship. Risk and procedure did not significantly differentiate the groups. Approximately 75 percent of the schizophrenics were correctly classified as compared to 90 percent of the nonschizophrenics. These results are shown in Table 9.

Significantly, purpose and research sponsorship were the constructs which contributed most to the discriminant function with standardized coefficients of .48 and .47, respectively. Voluntariness ranked third, with a coefficient of .24, followed by benefit with a coefficient of .19. The canonical correlation indicated that 48 percent of the variance was accounted for by the four discriminating constructs. Wilks' lambda was .53, $X^2(4, \underline{N} = 194) = 121.96$, $\underline{p} < .0001$.

Table 9

Classification of Schizophrenics and Nonschizophrenics by a Stepwise Discriminant Function Using Informed Consent Scale Scores

		Predicted Group Membership	
Actual Group	n	Schizophrenics	Nonschizophrenics
Schizophrenics	102	76 74.5%	26 25.5%
Nonschizophrenics	92	9 9.8%	83 90.2%

81.97% Overall Correct Group Classification

It should be pointed out that controversy exists about whether standardized discriminant function coefficients should be used to infer the extent to which variables contribute in differentiating groups. Klecka (1980) indicates that it is possible to make such inferences, while the most recent User's Manual of the Statistical Package for the Social Sciences (1986) seems to suggest otherwise.

The 18 informed consent items were also used to assess how well schizophrenics and nonschizophrenics might be differentiated based on performance. In this instance, the group membership of 80 percent of the schizophrenics and 87 percent of the non-schizophrenics was correctly predicted. These results are presented in Table 10.

Table 10

Classification of Schizophrenics and Nonschizophrenics by a Stepwise Discriminant Function Using Informed Consent Questionnaire Items

		Predicted Group Membership	
Actual Group	n	Schizophrenics	Nonschizophrenics
Schizophrenics	102	82 80.4%	20 19.4%
Nonschizophrenics	92	12 13.0%	80 87.0%

83.5% Overall Correct Group Classification

Ten of the 18 informed consent questions were found to significantly discriminate between schizophrenics and nonschizophrenics. The content of the items which contributed most to the discriminant function dealt with purpose, research sponsorship, voluntariness, and procedure, with standardized coefficients of .41, .41, -.30, and .29, respectively. The stardardized coefficients of significant informed consent items are shown in Table 11. Fifty-two percent of the variance was accounted for as indicated by the canonical correlation. Wilks' lambda was .48, $X^2(10, N = 194) = 138.51$, $p < .0001$.

Table 11

Standardized Discriminant Coefficients of Significant Informed Consent Questionnaire Items

Item	Coefficient
The purpose of this project is to solve rights complaints (Purpose-Wrong)	.41
This project is being paid for by the Office of Recipient Rights (Research sponsorship-Wrong)	.41
Everyone who is asked must participate in this study (Voluntariness-Wrong)	-.30
You must ask questions about this project (Procedure-Wrong)	.29
If you agree to participate in this interview, you must answer all questions that I ask you (Voluntariness-Wrong)	.24
The questions I will be asking you are part of a research project (Purpose-Right)	.21
This study will definitely benefit you (Benefit-Wrong)	.21
It you begin this interview, you must complete it (Voluntariness-Wrong)	.16
One part of this project is to find out how well I've explained to you what this project is about (Purpose-Right)	.14
The people who work on this project do not work for the Office of Recipient Rights (Research sponsorship-Right)	.12

Alternative Definitions of Informed Consent

Subjects' scores on the Informed Consent Questionnaire were analyzed in several ways to reflect alternative definitions of informed consent. The findings demonstrated, as predicted, that schizophrenics performed more poorly than did nonschizophrenics. Question remained, however, about what meaning should be ascribed to these findings, that is, to what extent subjects should be considered informed or uninformed participants in the research.

Percent Above Chance Predictions. Percent above chance predictions were made in an effort to empirically assess what constituted being an informed participant in this study. It seemed appropriate to evaluate the extent to which global informed consent scores might have been obtained by chance. Responses to the Informed Consent Questionnaire were either right or wrong which, based on the theory of expectations, gave respondents a 50 percent chance of obtaining a correct answer to a given question. Theoretically, if subjects guessed answers to all questions, they were expected to answer 50 percent of the questions (i.e., nine of the 18 items). Assuming this as the base for comparison, approximately one-third of the schizophrenics correctly answered nine or fewer questions (i.e., the expected value under the hypothesis of chance guessing). Only 3.2 percent of the nonschizophrenics answered nine or fewer questions.

Table 12 shows percent above chance predictions from the least (i.e., 10 items correct, one above chance prediction) to the most stringent criteria (i.e., all 18 items correct). It

Table 12

Percent Above Chance Predictions of Global Informed Consent Scores of Schizophrenics and Nonschizophrenics

Items Correct Above Chance Prediction	Percent Above Chance Prediction	Percent Informed Schizophrenics	Percent Informed Nonschizophrenics
10	11.1	67.6	96.8
11	22.2	61.7	96.8
12	33.3	49.0	96.8
13	44.4	37.2	95.7
14	55.6	29.4	93.5
15	66.7	18.6	90.2
16	77.8	12.7	85.9
17	88.9	9.8	70.7
18	100.0	4.9	43.5

may be noted that as the standard for being informed increased, the percentage of those who were informed dramatically decreased. If, for example, it were decided that subjects must answer five additional questions than those which might have been answered correctly by guessing (56 percent above chance prediction), only 29 percent of the schizophrenics would be considered informed. This is in comparison to 94 percent of the nonschizophrenics. Only five percent of the schizophrenic sample would be considered informed if the most stringent test of requiring correct responses to all 18 questions were employed. Forty-four percent

of the nonschizophrenics answered all 18 questions correctly.

Within Group Comparisons as the Standard. The extent to which subjects were informed participants in this research was also considered a normative question--one answered in relation to how well they did when compared with others in their same group. The rationale underlying this approach was that the standard for judging whether subjects were informed must be based on the average performance of those belonging to the same group.

Thirty-seven percent of the schizophrenic sample answered fewer than the average number of questions answered correctly by other members of their group (i.e., less than 11 items). Forty-nine percent of the schizophrenics scored at or above their group norm, but below the norm of the nonschizophrenic group (i.e., 11 to 15 questions correct). Fourteen percent of the nonschizophrenics scored below the average for their group (i.e., 16 questions correct). Three of the 14 percent scored below the schizophrenic norm.

A Normative Definition Based on Differential Weighting. Yet another approach to answering the question of what constituted informed consent concerned an assessment of whether certain aspects of informed consent were more important than others. The federal government implicitly subscribes to the position that all aspects of informed consent are of equal importance (DHEW, 1978a, 1978b; DHHS, 1981). The position advanced here, however, was that while the communication of all the necessary information is required to insure informed participation, greater effort should be used to insure that subjects understand certain information. Specifically,

an understanding of the risks involved and that participation was voluntary seemed basic.

Percentages were computed of schizophrenics and nonschizophrenics who correctly answered all risk and voluntariness questions to assess the extent to which they might have been informed participants. Twenty-six percent of the schizophrenics and 84 percent of the nonschizphrenics provided correct answers to all of the items on both scales. Not surprisingly, those subjects who gave correct responses to all risk and voluntariness questions were likely to have done well on the other questions. Table 13 shows the total number of items answered correctly by these subjects.

Table 13

Performance of Schizophrenics and Nonschizophrenics Meeting Normative Criteria for Informed Consent

	Schizophrenics		Nonschizophrenics	
Items Correct	n (26)	%	n (77)	%
12	2	2.0	-	-
13	2	2.0	-	-
14	3	2.9	2	2.2
15	7	6.9	2	2.2
16	5	4.9	13	14.1
17	2	2.0	20	21.7
18	5	4.9	40	43.5

Note. Percentages reflect the numbers of subjects in total sample of each group.

Differentiation of High and Low Performance Schizophrenics

A stepwise discriminant function analysis was performed to determine what variables differentiated those schizophrenics who scored at or above the mean global level of nonschizophrenics (i.e., 16 to 18 items correct) from those who did not. The following eight variables were entered in the equation: education, prognosis, the duration of all psychiatric hospitalizations, and interviewer ratings of subjects' attitude toward the research procedure, understanding of the questions, reality orientation, difficulty keeping their attention focussed on the task, and the length of time required to complete the consent procedure. Four of these variables were shown to have discriminating ability:

Table 14

Classification of High and Low Performance Schizophrenics by a Stepwise Discriminant Function

		Predicted Group Membership	
Actual Group	n	Group I[a]	Group II[b]
Group I[a]	72	56 77.8%	16 22.2%
Group II[b]	11	1 9.1%	10 90.9%

79.52% Overall Correct Group Classification

Note. 19 subjects had at least one missing discriminating variable. a = schizophrenics answering 15 or fewer questions correct; b = schizophrenics answering 16-18 questions correct.

prognosis, understanding of the questions, education, and length of the consent procedure, accounting for 38 percent of the variance in global informed consent scores. The standardized coefficients for these variables were -.60, -.50, .50, and -.27, respectively.

Those schizophrenics who scored at or above the mean global level of nonschizophrenics tended to have a good prognosis, a better understanding of the meaning of the questions asked concerning the consent procedure, more education, and required less time to complete the consent procedure. As may be seen in Table 14, 80 percent of the schizophrenics were correctly classified based on the aforementioned four variables. Wilks' lambda was .76, $X^2(4, \underline{N} = 83) = 24.41$, $\underline{p} < .0001$.

DISCUSSION

The purpose of the present investigation was to examine the extent to which hospitalized schizophrenics were able to make an informed choice to participate in a research study. The study in which subjects were asked to participate essentially involved no risk and the limited likelihood of direct benefit. Consent materials were designed to require a sixth grade reading level in an effort to increase the comprehensibility of information for those with limited formal education.

The results are reviewed in relation to three topical areas: a comparison of the performance of schizophrenics and nonschizophrenics on a test of their ability to give informed consent; explanations for variations in this performance; and, an evaluation of the performance of schizophrenics and nonschizophrenics using alternative standards of informed consent. Specific hypotheses and additional findings are discussed as they relate to these areas. The implications of the results are discussed in terms of the current literature, instrumentation, and sampling limitations. Directions for future research are also advanced.

The Results and Their Implications

Schizophrenic and Nonschizophrenic Differences in Informed Consent

As predicted, the mean global (Hypothesis I) and subscale (Hypothesis II) informed consent scores of schizophrenics were

found to be significantly lower than those of nonschizophrenics. Comparison of the performance of the two groups on individual consent items revealed similar results. Schizophrenics, again, performed more poorly than nonschizophrenics.

The magnitude of the difference in group performance was further demonstrated by a retroactive classification of subjects according to informed consent scale scores and individual items using a stepwise discriminant function analysis. Eighty-two percent of the subjects were correctly classified using scale scores. The scales which best seemed to differentiate schizophrenics and nonschizophrenics were purpose, voluntariness, benefit, and research sponsorship. Eighty-four percent of the subjects were correctly classified using actual questionnaire items. Significantly, the items which best seemed to differentiate study groups were purpose, research sponsorship, and voluntariness. It should be pointed out that some statisticians (Klecka, 1980; Nie, et al., 1975) indicate that standard discriminant function coefficients can be used to infer the extent to which variables contribute in differentiating groups. The recent User's Guide for the Statistical Package for the Social Sciences (1986), however, suggests that caution must be exercised in interpreting the individual contribution of coefficients.

These results, consistent with other research (Appelbaum, Roth, and Lidz, 1982; Grossman and Summers, 1980), raise questions about the reliability of informed consent procedures with schizophrenics. It appears that schizophrenics are unable to understand a substantial

portion of the information provided to secure informed consent to participate in research. Even such critical information as the freedom to withdraw may not be understood. Adequate comprehension cannot be assumed even when subjects are provided with a written explanation of relevant information which they have been encouraged to follow as it is read to them, are encouraged to ask questions, or sign a statement indicating that they have been informed of pertinent information concerning the study.

Anxiety (Epstein and Lasagna, 1969) and the difficulty of information forms (Grundner, 1980) have been cited as reasons underlying the inability of medical patients to recall information presented during consent procedures. These explanations, however, would seem to account only to a limited extent for the poor performance of schizophrenics. The statement of information designed for this study was written to be appropriate for the minimum educational level of the current sample. The research in which they were asked to participate involved a relatively simple task of answering questions about a subject with which they possessed some degree of familiarity. It is, thus, suggested that while anxiety may have had a general effect upon performance, it seems unlikely that it was anxiety alone which accounted for the difficulty subjects displayed in comprehending the information included in the informed consent document.

Two dilemmas are evinced by these findings. First, question arises about how a patient, who does not possess a full understanding of what the research consists, can participate in research on a voluntary basis. The second dilemma concerns current social

policies, legal trends, and treatment practices as reflected in mental health legislation and recent court decisions. There has been increasing recognition that autonomy and responsibility reside in the individual's own decisions, even if the individual is mentally ill. The results of this study indicate that a significant portion of the patients did not or could not act on their own behalf in an autonomous, responsible manner.

Explanations for Variations in Informed Consent

Schizophrenics and nonschizophrenics were compared on several variables in an effort to explain group differences in informed consent. Within group differences were also examined for schizophrenics in an effort to explain why certain members of that group performed better than others. The results of between group comparisons are presented first.

Between Group Comparisons

Schizophrenics and nonschizophrenics were compared on selected demographic characteristics (e.g., age, race, sex, marital status, and education) to determine the extent to which group differences in informed consent were related to differences in group characteristics. Membership in one group or the other, interviewer assessments of respondents' interest in and attitude toward the interview, participation rates, the length of time required to complete the informed consent procedure, and the relative difficulty of questions based on a rank-order of the percentage of questions answered correctly were also examined in an effort to explain differences in informed consent scores.

Demographic Characteristics. The study groups differed significantly on race, marital status, and education variables. Race was not found to account for group differences in informed consent. Education and marital status, however, were found to be predictive of informed consent. Schizophrenics have generally been described as having a lower level of social functioning which is reported to have an insidious inception early in life and is reflected in a lack of educational achievement and a disturbance in psychosexual development (Zigler and Phillips, 1968). The fact that significantly fewer schizophrenics had never married is viewed as being indicative of the latter. To this end, it is not singleness per se that is believed to relate to informed consent. Singleness, rather, is viewed as an artifact of schizophrenic illness.

It was not unexpected, then, that significantly more of the schizophrenics had never married and completed fewer years of schooling than the nonschizophrenics; or, that those schizophrenics who functioned at a higher level (as indicated by their having completed more years of schooling and a greater ability to develop and sustain an intimate relationship), were more likely to be informed participants in the research. Research shows that higher functioning schizophrenics are more likely to have experienced an acute course of illness and a better prognosis than lower functioning schizophrenics (Zigler and Phillips, 1968).

Group Membership. The results demonstrated that group membership (i.e., whether a subject was schizophrenic or nonschizophrenic) was a better predictor of performance than education or subjects'

attitude toward or their interest in the research procedure (Hypothesis III). Group membership alone explained 42 percent of the variance in informed consent scores. The additive effect of group membership, subjects' attitude toward the research procedure, and education accounted for 51 percent of the variance in informed consent scores. The lack of explanatory power of education was not surprising given efforts to mediate the effects of this variable.

Participation Rates. The statistically significant difference in participation rates (Hypothesis VI) between schizophrenics and nonschizophrenics raises question about the extent to which these differences may have accounted for differences in the performance of the two groups. All nonschizophrenics who began the interview completed it. Two percent refused participation. On the other hand, slightly more than half (53 percent) of the schizophrenics who met the study inclusion criteria completed the interview procedure. Twenty-one percent of those approached about participation refused. About one-fourth of those who initially consented to complete the interview failed to do so. Although the characteristics of those comprising these two groups were not formally analyzed, the anecdotal reports of interviewers revealed that those patients who initially agreed to participate and later withdrew consent were performing poorly.

Other research (Mills, et al., 1983; Rhodes, 1980) also indicates that psychiatric patients who tend to complete interview procedures are more likely to be among the higher functioning. In a previous study by the present investigator (Rhodes, 1980), those patients most capable of filing rights complaints (a prerequisite for participation in this study) were found to be those who suffered least from

psychiatric and physical debilitation. It may, thus, be argued that the findings of this study represent an upwardly biased estimate of the ability of schizophrenics to give informed consent to participate in research. Notably, the schizophrenics included in this study were considered legally competent. In Addition, schizophrenics were not approached about participation who had an Axis II diagnosis of organicity, mental retardation, or a history of alcohol or drug abuse to avoid a potential source of ambiguity. Those suffering from severe physical illness were also excluded from participation.

Length of the Consent Procedure. The length of time required to compelte the consent procedure was found to be predictive of the informed consent score of schizophrenics. The more time required to complete the consent procedure, the less likely subjects were to understand the information presented.

In general, schizophrenics averaged five minutes, or 63 percent, longer to complete the consent procedure than nonschizophrenics. More debilitated subjects exhibited a greater tendency to make idiosyncratic associations and indulge in irrelevant conversation and, consequently, require more in the way of explanations or repeated instruction. The relatively longer time required by schizophrenics to complete tasks has been attributed to an attentional deficit. The longer reaction time, noted especially in chronic schizophrenics, has been ascribed to an inability by these patients "to select the material relevant for optimal response" (Shakow, 1962).

The extended time required by schizophrenics to complete tasks has implications for the design of future studies. Numerous

researchers (Broen, 1968; Broen and Storms, 1966; Buss and Lang, 1965; Chapman, 1956, 1958, 1961; Shimkunas, 1970) have discussed the attentional deficits thought to be characteristic of schizophrenia. Yet, this issue seems to have been limitedly regarded in studies involving this population. Given the presumed limited ability of schizophrenics to attend, it would seem that efforts to assess their ability to perform at an optimum level should be kept brief. When longer procedures are required, it may be necessary to schedule the completion of these over several appointments.

Response Patterns. Analysis of the rankings of correctly answered questions for schizophrenics and nonschizophrenics on the Informed Consent Questionnaire revealed a strong positive correlation. This suggests that if an item was difficult for nonschizophrenics, it was likely to be difficult for schizophrenics. Conversely, if an item was easy for nonschizophrenics, it was likely to be found easy by schizophrenics. In short, the item difficulty pattern was similar for both groups, with schizophrenics making more errors than nonschizophrenics. Notably, Chapman and his coworkers (Boland and Chapman, 1974; Chapman, 1956, 1958, 1961; Rattan and Chapman, 1973) have characterized the cognitive deficit thought to typify schizophrenia as an "exaggerated normal error tendency."

Within Group Comparisons

Demographic and interviewer assessment variables were analyzed to determine which of these were predictive of the informed consent scores of schizophrenics. No predictions were made concerning the variables which might be correlative of informed consent among nonschizophrenics.

As predicted, shorter lengths of present (Hypothesis IVa) and total psychiatric hospitalizations (Hypothesis IVb) and a good prognosis (Hypothesis V) were found to be correlative of a higher global informed consent score among schizophrenics. These findings are consistent with the work of Knight, et al. (1979), McEvoy, et al. (1981), and Zigler and Phillips (1968). In their research, as well, higher functioning schizophrenics tended to require a shorter hospital stay and were evaluated by treating physicians as having a good probability of return to their premorbid status.

Hypotheses were not specifically formulated, but effort was made to determine what characteristics differentiated those schizophrenics who scored at or above the mean global informed consent score of nonschizophrenics from those who did not. Perhaps not surprisingly, those schizophrenics with a good prognosis, more education, who were rated by interviewers as having a good understanding of the questions posed, and required less time to complete the interview procedure were more likely to score at or above the mean global informed consent scores of nonschizophrenics

Other Explanations for Variations in Informed Consent

It seemed plausible that variables other than those considered in this study better explain between and within group differences in informed consent. Assessment of the ability of subjects to comprehend reading materials, for example, might have better explained differences in performance. In this study, the highest level of education attained was presumed to be an indication of subjects' ability to comprehend material. The increased readability of consent materials was aimed

at making greater the likelihood that those with little formal education would be able to understand the information provided.

Despite the fact that none of the subjects had less than six formal years of education, it is likely that some functioned below the level that the highest year of schooling completed would tend to indicate (Berg and Hammitt, 1980). The material presented, which required a mere sixth grade reading level, may have been too difficult for some. Assessment of subjects' ability to comprehend written material might have provided a better indication of the reading level that should have been used to obtain consent.

In addition, although the length of psychiatric hospitalization may be considered a proxy measure for the degree of debilitation of schizophrenics, formal assessment of the degree of psychopathology might have provided a better explanation for why certain schizophrenics performed more poorly than others. Assessment of both the degree of thought and affective disorder might have provided illuminating information about the characteristics of subjects who seemed informed versus those who did not.

The ability to comprehend written materials and assessment of the degree of psychopathology are but two variables which might be considered as predictive of differences in performance. There may, of course, be others, e.g., the presence of visual or auditory handicaps, the degree of attention deficit, etc.

Choosing the Standard: Informed Versus Uninformed Consent

Normative and empirical tests were conducted to determine what meaning should be ascribed to the performance of the study groups.

One test of whether subjects were informed consisted of evaluating performance in relation to the specific group norm. In this instance, 37 percent of the schizophrenics scored below the norm of their sample. Fourteen percent of the nonschizophrenics scored below their norm. This obviously seems to be a poor standard. It seems more reasonable to assess how well schizophrenics did in relation to persons presumed to be functioning normally. Eighty-seven percent of the schizophrenics scored below the average of nonschizophrenics and, so, might be considered uninformed.

Another test concerned the performance of schizophrenics and nonschizophrenics on two scales considered to be basic in making a decision to participate in research. First, it seemed that subjects should possess an accurate understanding of the risks involved for participation. Secondly, it seemed of vital importance that subjects understand that participation was voluntary, that they were not obliged to participate if they did not choose and, if they agreed to participate, that they had the right to revoke participation at any time prior to the completion of the research procedure.

When this test was employed, i.e., correct responses on all risk and voluntariness questions, 26 percent of the schizophrenics might be considered informed as opposed to 84 percent of the nonschizophrenic sample. This test reflects a narrow definition of informed consent in that only an understanding of certain aspects was required. While risk and voluntariness may well be the most important dimensions of informed consent, an understanding of other

aspects may be required to fully understand these. For example, in order to understand the amount of risk involved in participation in a research study, it would seem necessary for a subject to understand the procedures involved and be able to evaluate whether any benefits which might accrue were offset by any risks. Depending on the study, it is conceivable that the disclosure of information other than that which is usually conveyed might be necessary for a subject to make an informed decision for or against participation.

Yet another test consisted of assessing whether subjects scored better than they might have by chance. Approximately 68 percent of the schizophrenics answered one item more than the number they might have correctly answered had they simply guessed. This was compared to 97 percent for normals. If more stringent criteria of requiring correct responses to all questionnaire items were used, five percent of the schizophrenics in comparison to 44 percent of the nonschizophrenics might be considered informed.

The poor performance of schizophrenics in this study, as demonstrated by the various proposed standards, tends to indicate that as a group they were not informed participants. It may well be that their performance is more dire than it appears in that none of the proposed standards provided evidence of subjects' motivations for agreeing to participate in this research. In addition to understanding a certain modicum of information, an assessment of true competence would seem to require that subjects be able to articulate rational reasons in support of their decision. If this standard were employed, is is likely that the performance of schizophrenics would be poorer than that demonstrated.

To be sure, evidencing a choice to participate fulfills the requirement for a minimum standard of competence. It is conceivable, however, that the reasons underlying a subject's choice to participate, even one who met the most stringent test of correctly answering all questionnaire items, may not be rational. It also seems possible that a patient may be able to understand discrete aspects of the information provided without having a complete grasp of all of the information required to be fully informed. In short, schizophrenic subjects may pass one test of competency, but fail another. This problem has been documented by others (Appelbaum, Roth, and Lidz, 1982) and is discussed further later.

Unresolved Issues in the Examination of Informed Consent

The meaning of this study must be interpreted in the context of fundamental unresolved issues in the area of informed consent. The empirical support of the study hypotheses would tend to indicate that relatively few schizophrenics are able to give informed consent. This conclusion must be regarded to some extent, however, as tentative given the lack of clarity that surrounds three fundamental, and potentially overlapping, elements of informed consent. These three elements--competency, understanding, and voluntariness, form the basis of the legal doctrine of informed consent. While it seems generally agreed that they must be present for a legally valid consent, there is widespread disagreement about their meaning.

Elements of a Legally Valid Consent

It is obvious that the disclosure of information is necessary for a valid consent, i.e., one must know to what one is consenting.

Federal regulations describe the circumstances under which this consent must be obtained and enumerate areas considered pertinent for consent to be informed. These regulations specify that the information provided should be presented in simple language (DHHS, 1981). The recognition that certain classes of subjects may not be able to comprehend information because of a compromised status is specifically addressed. The federal guidelines do not address, however, what should be understood for a decision to be valid. Nor is it clear what effort should be made to ascertain whether understanding has taken place. Despite this lack of clarity, there seems to exist widespread agreement that for consent to be truly informed, a subject must, first, be competent (or, at least, not be incompetent) to give informed consent; be provided with and understand certain relevant information; and, exercise a free choice to participate that lasts throughout the study. These elements are considered fundamental. Yet, debate continues to rage about what constitutes competency, understanding, and voluntariness.

Competency. Competency implies that a person is able to use information to the same extent that a "reasonable" person would. If a patient is not "competent" or of "sound mind," the decision may be considered invalid. What a "reasonable" person would understand and how it is that it may be determined that a person is incompetent to make a "rational" decision may often be unclear, particularly in the case of the mentally ill who are presumed to be of uncertain competence, at best (Meisel, Roth, and Lidz, 1977).

In order to discuss the issues surrounding competency, major tests commonly used to assess it warrant brief description. Several tests of competency have been proposed in the literature (Appelbaum and Roth, 1982; Culver and Gert, 1980; Friedman, 1975; Goldstein, 1978; Meisel, Roth, and Lidz, 1977; Miller, 1981; Roth, Meisel, and Lidz, 1977; Stanley and Stanley, 1981); others may be readily inferred from judicial commentary (Kaimowitz vs. Michigan Department of Mental Health). Roth and his colleagues (1977) have summarized five tests that may be used to assess competency. They seem to be generally inclusive of those proposed by others. Although there tends to be overlap, these tests may be grouped into the following categories:

1) making a choice which suggests that the competent patient is one who simply evidences a preference. This test does not focus on the quality of the patient's decision but, rather, on the presence or absence of a decision.

2) making a choice similar to that which a "reasonable" person would make. Here the "reasonableness" of the decision, as opposed to the process involved in making the decision, is emphasized.

3) making a choice based on "rational" reasons. The quality or nature of the decision-making process must be examined.

4) making a choice that is reflective of a generalized ability to understand relevant information. The focus, here, is on whether a patient manifests an adequate ability to understand the information provided. The extent to which various elements are weighed or figure in the final decision is not considered important.

5) making a choice that is based on an actual understanding of the information disclosed. This test implies that effort has been made to ascertain whether a patient has understood the issues involved in the decision made.

The difficulty involved in making a distinction between "rational" and "irrational" reasons, what a "reasonable" versus

"unreasonable" person would choose (words frequently used in discussions of competency) seems obvious. Question arises about the validity of assuming that the reasons a patient gives for having made a certain choice are, in fact, the actual reasons underlying that decision. Question also arises about what should be done when a patient makes a "reasonable" decision for "irrational" reasons. Moreover, assuming that level of understanding may be objectively assessed, the specific level of understanding that constitutes being informed remains at issue. Some would argue, however, that attempts to assess actual understanding are inadequate in that a patient's ability to recall information rather than to understand it is what is likely being measured (Meisel, Roth, and Lidz, 1977).

An additional problem with respect to competency is that, in theory, it is an independent variable that determines whether or not a patient's decision should be honored. In practice, however, this seems to be dependent upon the interplay of other variables, e.g., the relationship of risk to benefit, and the valence of the patient, i.e., whether he/she consents to or refuses what is being proposed (Roth, Meisel, and Lidz, 1977). Of course, a basic problem is what to do when a patient passes one test of competency, but fails another. More recently, Schwartz and Blank (1986) have convincingly argued that since the conditions from which competency derives (i.e., the patient's clinical condition and the risks and benefits inherent in the decision the patient is asked to make) shift during the course of illness, effort must be made to continually reassess competency using the aforementioned standards.

Understanding. Judicial decisions which have involved psychiatric patients provide distinct indication of the confusion that surrounds the

concept of understanding. It has been implicitly assumed that a person who is competent and is a free agent to whom information has been disclosed will, in fact, understand the information provided and, therefore, make a reasoned decision (Meisel, Roth, and Lidz, 1977). In general, the requirement seems to be that information be communicated, not that patients understand it. Patients are expected to understand that which a "reasonable" person would understand. The courts have failed to clarify what a particular patient must understand in order for a decision to be considered valid. Of interest is that the courts have used "inform" and "understand" interchangeably (Meisel, Roth, and Lidz, 1977). Obviously, the act of informing does not insure that one will understand the information that has been imparted. As a result, it is not clear what effort should be made to ascertain the level of understanding.

In an effort to resolve some of the confusion that enshrouds the concept of informed consent, Meisel and his colleagues (1977) formulated objective and subjective models. On the one hand, understanding is not considered to be an essential part of a valid consent. This has been termed the objective model. This model has focussed on the congruence, or lack thereof, between the decision an actual patient would make and that of a hypothetical reasonable person. Assuming that there has been adequate disclosure of information and the patient is acting voluntarily, the patient's generalized ability to function as an objectively reasonable person is considered determinative of a valid decision. In this case, the patient's subjective understanding is considered to have no bearing on the validity of the decision.

On the other hand, however, the validity of a decision to accept or refuse participation in research may be based on a patient's understanding of the information supplied. Here the fact that the patient may be psychotic, retarded, on medication, or similarly compromised may be related to the validity of the decision. This model is, of course, more subjective and the determination, therefore, more difficult to make. This author believes that understanding as well as making a decision for rational reasons, not the least of which is because one is a free agent, are intrinsic elements of a valid consent.

Voluntariness. In order to be a free agent, patients must believe in their own freedom, that they have the right to make decisions which effect them. They must also be free from coercion, unfair persuasions, and inducements. Although there may be neither overt nor covert coercion in the research setting, it is possible that a schizophrenic may not be able to act voluntarily because he/she has experienced a disturbance of volition, a commonly accepted symptom of the illness (American Psychiatric Association, 1980; Bleuler, 1911; Kraepelin, 1919/1975). A schizophrenic may evidence a tendency to make the kind of decision that a "reasonable" person would make and understand what a "reasonable" person would likely understand and yet not be able to act voluntarily because he/she does not feel that he/she has the right to make a decision different than that which has been proposed.

Instrumentation

The problems which were encountered in the design of instru-

mentation for this study were similar to those faced by other researchers concerned with the question of the ability of psychiatric patients to give informed consent. For example, the Informed Consent Questionnaire used in this study to assess understanding may, in fact, have provided a better measure of subjects' ability to recall information. The question of whether understanding versus recall has been measured would seem to be an issue confronting others attempting an empirical assessment of informed cosent of the mentally disabled, as well. A minimal amount of retention of information is, of course, a prerequisite for genuine understanding. While the lack of short-term recall may be viewed as evidence of a lack of genuine understanding, the converse may not be so. Although the recall of information is basic to understanding it, the ability to recall what one has been told may not in and of itself be reflective of genuine understanding. There is also the possibility that subjects who gave correct responses to the Informed Consent Questionnaire may have done so arbitrarily, i.e., a correct response may simply have reflected chance guessing. Perhaps an open-ended questionnaire might have provided a better estimate of subjects' ability to understand the information disclosed to secure informed consent. Of course, this might have increased the tendency of schizophrenics to make idiosyncratic associations.

To simply evidence a choice to participate fulfills only a minimal level of competence. It would seem necessary to evaluate the extent to which subjects were able to provide rational reasons for their choice. Questionnaire items might have been included

which were designed to assess the motivations underlying a decision to participate in the study.

Further, it may be argued that the examination of subjects' ability to appreciate the nature of their illness was also necessary in a study of this kind. The position may be taken, for example, that unless a subject understands the nature of his/her illness and the need for treatment that he/she is unable to give a valid consent. Information concerning the presenting problem of patients and their level of current functioning might also have helped to identify the variables predictive of informed as opposed to uninformed consent with schizophrenics.

Subject Sampling

Problems evidenced in the selection of subjects for this study also seemed similar to those experienced by other researchers concerned with this area. The process of selecting subjects for research studies generally introduces factors that may bias outcome. In this study, the selection of subjects who had previously filed a rights complaint very likely resulted in a potential pool of subjects which included a disproportionate number of the higher functioning schizophrenics. The markedly poorer performance of those who failed to complete the interview procedure was noted in the anecdotal reports of interviewers. How those who refused participation outright might have performed is less clear. The reports of others (Marder, et al., 1983) would tend to suggest, however, that they, also, would likely have performed poorly. There is reason to believe that the subjects on whom this research

was based were the more highly functioning schizophrenics. The research of other investigators has also very likely been based on higher functioning psychiatric patients. Lower functioning patients would seem to be less able to attend to details and to comprehend such basic information as that required for participation. These patients, consequently, would be more likely to refuse or prematurely terminate participation.

Little is known about the effects of the use of psychotropic medication on the ability of patients who serve as subjects to give informed consent. Because 99 percent of the schizophrenics who participated in this study were receiving psychotropic medication at the time of the study, it was not possible to compare the performance of patients receiving such medication with those who were not. It was assumed that the medication facilitated subjects' performance. It is conceivable, however, that certain subjects were rendered too lethargic to participate in a meaningful way.

Suggestions for Further Research

There is much to learn about informed consent, not the least of which is the ability of the mentally ill to give it. The need for empirically based information is clear. Such information could help greatly to answer important ethical and public policy questions. If federal guidelines are to accomplish what was initially intended, i.e., to protect human subjects from unwilling and potentially harmful involvement in research while respecting their autonomy, more must be known about the ability of schizophrenics,

who served as the specific focus of this study, and the mentally ill, in general, to give informed consent.

As a first step in resolving the conceptual and methodological confusion that surrounds the concept of informed consent, future research studies must delineate the standards used to define informed consent. This is to say that researchers must be explicit about how informed consent is viewed conceptually and how these conceptions will be operationalized. In determining the standards to be used to assess whether subjects will be considered informed participants (or refusers, for that matter), norms may or may not be based on the performance of a control group. Both approaches may, in fact, be useful in establishing a standard of acceptable performance. Some basic caveats must be adhered, however.

When norms are not to be based on the performance of a specific group, careful thought must be given to how the standard against which subjects will be evaluated should be selected. The literature lends relatively little direction. It is not clear, for example, whether a subject is informed who is presumed to understand 90 as opposed to 75 percent of the information provided, whether a "rational" decision should constitute being informed, or whether the articulation of "rational" reasons in support of one's decision should be the standard. In order to facilitate the comparability of studies, the rationale for the selection of the standard must be thoroughly documented.

If a comparison group is to be used as the standard, the selection of an appropriate control group is an absolute necessity. When the control group is not carefully selected, researchers may tend to

over- or underestimate the ability of schizophrenics to be informed and, therefore, draw erroneous conclusions about the need for, or lack thereof, of special precautions for insuring their protection. The rationale for the selection of controls should be thoroughly discussed.

One of the major criticisms of previous studies is that the mentally ill have been regarded as a homogeneous group. The mentally ill would seem to differ in potentially significant ways. In fact, considerable variability would seem to exist among those given the same psychiatric diagnosis. Wing (1978) has pointed out that "chronic schizophrenia" includes syndromes of a wide range of types and severity, consisting of both intrinsic and reactive components. Van Praag (1977) suggests that if the heterogeneity subsumed under the rubric of schizophrenia is to be understood, future studies must attempt to select those with similar characteristics, e.g., length of psychiatric hospitalization, treatment effects, paranoid, and affective symptomatology or to control for differences such as these which are likely to confound associations. The use of such dimensions may serve to better explain differences in the ability of schizophrenics to give informed consent. Attempt should also be made to understand how the limitations demonstrated by schizophrenics compare with those suffering from other types of mental disability.

Finally, researchers conducting future studies must attempt to identify the factors that are correlative of poor performance, beyond the simple statement of obvious gross sample characteristics. Effort must be made to understand what sample characteristics as well as methodological variables effect subject performance. A possible artifact of what has been presumed to be subjects' inability to

understand information may be related to who transmits the information and in what manner. Researchers must be more sensitive to how these variables may facilitate or inhibit performance. To this end, researchers must explore different ways of improving the performance of subjects. While certain psychiatric patients may never possess a meaningful understanding of the information provided to secure informed consent, there are others who may be better able to comprehend information through improvised procedures or repeated follow-up measures. Ultimately, it may be necessary for researchers to routinely incorporate a test into the study design to assess the extent to which subjects comprehend the information that is conveyed. Greater effort must be taken to make the language of information statements and consent forms understandable to prospective subject populations. Care must be exercised to make these explanations as brief and as concrete as possible.

SUMMARY AND CONCLUSIONS

This study investigated the hypothesis that legally competent hospitalized schiozphrenics do not fully understand the information provided to secure informed consent to participate in research. All participating schizophrenics had been diagnosed according to the third edition of the Diagnostic and Statistical Manual of Mental Disorders and had been resident in a public psychiatric hospital for a minimum period of six months. None showed evidence of retardation, organicity, substance abuse, or severe physical illness. Ninety-nine percent were on a regimen of psychotropic medication at the time of the study.

The ability of schizophrenics to give informed consent was compared with that of nonschizophrenics who were selected from among the staff of the facilities of which the schizophrenic subjects were patients. Only those who had filed a complaint alleging a violation of patient rights were approached about participation. Subject satisfaction with the rights complaint process served as the vehicle through which it was possible to implement this study, i.e., subjects were asked to participate in a research study concerned with their satisfaction with the rights complaint process. The study essentially involved no risk and a limited likelihood of direct benefit.

A written information statement was presented to subjects to secure informed consent. Developed according to federal guidelines,

this statement included information concerning the purpose, procedure, risk, benefit, voluntariness, and research sponsorship of the study. They were asked to read the statement silently as it was read aloud to them in a conversational tone. Those who agreed to participate were then asked to answer questions to assess how well they understood the information. The Flesch Readability Scale was used to reduce the complexity of the Informed Consent Statement. The resulting form was determined to be "fairly easy" to read, requiring a sixth grade education.

As predicted, schizophrenics and nonschizophrenics were found to differ in their ability to understand the information provided to secure informed consent. This difference was indicated when performance was compared on the various dimensions of informed consent, e.g., purpose, procedure, risk, benefit, voluntariness, and research sponsorship, as well as on the individual items comprising these dimensions.

The magnitude of the difference in performance of the two groups was further demonstrated by a retroactive classification of subjects using a stepwise discriminant function analysis. The linear combination of variables in the discriminant function differentiated schizophrenics and nonschizophrenics with 82 percent accuracy using the scales and 84 percent accuracy when individual items were used.

In an effort to explain between group variance in performance, it was hypothesized that group membership, that is, whether a subject

was schizophrenic or nonschizophrenic, was a better predictor of informed consent than subjects' education, their attitude toward or interest in the research procedure. This prediction was confirmed, with group membership accounting for 42 percent of the variance.

Other hypotheses concerned within group variation in the performance of schizophrenics. As predicted, the length of both the current and total psychiatric hospitalizations and prognosis were correlative of informed consent. In short, those schizophrenics who required a more limited term of psychiatric hospitalization, whether current or previous, and who were diagnosed as having a better prognosis, were more likely to understand the information provided to secure informed consent.

Finally, it was hypothesized that there would be no difference in the proportion of schizophrenics and nonschizophrenics who would refuse participation in the study. This hypothesis was rejected. Significantly, more schizophrenics refused participation than nonschizophrenics. This hypothesis was stated in the null because of conflicting literature. On the one hand, schizophrenics have been described as acquiescent and yeasaying and, on the other, as negativistic and noncompliant. Although subjects were not queried about the reasons for refusal, the anecdotal reports of interviewers suggest that this group would very likely have been numbered among the poor performers. This possibility suggests that the results of this study would have been more dire had these persons completed the consent procedure.

Formal hypotheses were not made, but additional analyses were completed in an effort to further explain variations in the performance of subjects. It seemed useful, for example, to examine the length of time required to complete the consent procedure and the relationship between certain demographic characteristics of the subjects and their ability to give informed consent. Analyses were also completed to determine the extent to which certain aspects of informed consent were better understood than others.

The length of time required to complete the consent procedure was found to be predictive of the informed consent score of schizophrenics. Those schizophrenics who were more likely to obtain a high score were more likely to require a shorter consent procedure than those who obtained lower scores. Significantly, greater variability in the length of time required to complete the consent procedure was noted for schizophrenics. On an average, however, they required 63 percent longer than nonschizophrenics to complete the informed consent procedure.

Although the intent of this study was to select subjects similar in demographic characteristics, analysis of such variables revealed that this was not the case. The study groups differed significantly on race, marital status, and education variables. It was, therefore, necessary to assess the relationship of these variables to informed consent score. Race was not found to be predictive of informed consent score. Marital status was found to be related to the informed consent score of the combined sample of subjects, although not for individual groups. Ever married

subjects were found to have a higher score than never married subjects. This finding is believed to be related to the fact that significantly more schizophrenics had never married. Education was found to be predictive of the informed consent scores of the individual groups as well as the combined sample. In all cases, subjects with more education tended to have a higher informed consent score. A stepwise multiple regression analysis of education and other selected variables, however, demonstrated that education tended to be minimally predictive of the informed consent score of subjects. Importantly, this analysis revealed that being schizophrenic or nonschizophrenic tended to account for the difference in performance. It is believed that the effects of education were mediated to some extent by the application of the Flesch Readability Scale.

Although effort was directed toward making all aspects of informed consent understandable for the subject population, the findings of this study indicate that it was possible to significantly differentiate the study groups based on their responses to certain aspects of informed consent. Purpose, research sponsorship, benefit, and voluntariness were the elements which differentiated schizophrenics and nonschizophrenics. This is believed to be attributed to the fact that certain aspects did not lend themselves as easily to explanation as others. The explanations concerning these elements may have been more difficult for schizophrenics because they were more abstract and required greater conceptual ability to understand. The procedures required for participation (i.e., to answer questions) and the fact that

essentially no risk was involved in this study would seem to suggest that these aspects were more concrete. It is conceivable, of course, that these elements may be more abstract in certain studies, particularly those in which participation involves more than minimal risk.

Effort was also made to identify the characteristics which differentiated schizophrenics who scored at or above the mean global informed consent score of nonschizophrenics from those who did not. In general, the high performance schizophrenics had a better prognosis, a better understanding of the questions asked to determine whether they were informed, more education, and required less time to complete the consent procedure.

Several standards were proposed for determining whether subjects were informed participants in this study in an effort to provide a normative framework within which to interpret the findings. The group performance of subjects was evaluated in relation to how they might have faired by simple chance guessing, in comparison to group norms, and as a result of the differential weighting of certain aspects of informed consent.

The findings confirm those of other studies concerned with the competence of psychiatric patients to give informed consent. Using the least (i.e., correct responses to the same or greater number of questionnaire items as their group norm) to the most stringent (i.e., correct responses to all questionnaire items) standard proposed in this study, 37 to 95 percent, of hospitalized schizophrenics might be considered consenting, but not informed, participants in this study. It should be pointed out that the most stringent test

proposed makes no assessment of whether the decision to participate was a rationale and truly voluntary one. These would seem to be important elements of a valid consent. Moreover, given the likelihood that the most debilitated schizophrenics were least likely to have completed the procedure for participate or to have been included in the subject pool, there is reason to believe that even greater numbers of schizophrenics might have been found incompetent to give informed consent if it had been possible to employ the same test with a randomly selected population of schizophrenics.

Despite unresolved theoretical issues and methodological limitations, this study raises serious question about the ability of legally competent hospitalized schizophrenics to give informed consent to participate in research, as required by law. The moral prescriptive of respect for persons is two pronged: it requires that the autonomy of subjects be acknowledged but, also importantly, that subjects with diminished capacity be protected.

The autonomy of the individual is, of course, acknowledged when he/she is extended the opportunity to participate in a research study. But when a legally competent person who lacks the capacity to appreciate the risks involved in participation, respect for autonomy would seem to warrant protection, including the exclusion from potentially harmful activities. In other cases, relatively little protection may be required, such as insuring that activities are undertaken freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. But even when direct benefit is anticipated, subjects should understand clearly the extent of risk and the voluntary

nature of participation. If there is to be conformity with the substance, rather than the mere form, of federal guidelines regulating research with those who suffer from mental disability, researchers must assume greater responsibility for the protection of subjects who exhibit a diminished capacity.

In addition to the presentation of relevant information that has been adapted to the capacities of the subject population, this protection must be manifested in the form of an active effort to ascertain the level of understanding of the information that has been provided to secure informed consent. This may mean, of course, that considerable numbers of prospective subjects may be excluded from participation in certain types of studies. It will insure, however, that those who participate are informed volunteers, a praiseworthy accomplishment indeed.

APPENDICES

APPENDIX A

A-1. Patient Informed Consent Statement

A-2. Patient Informed Consent Questionnaire

A-3. Patient Consent Form

A-4. Rights Complaint Survey (same for patients and staff)

A-5. Patient Interviewer Observations Form

A-6. Patient Background Information Form

APPENDIX A-1

P INTERVIEWER FORM

INFORMED CONSENT STATEMENT

TIME CONSENT PROCEDURE STARTED:_____

I'd like to give you this to read. GIVE PATIENT A COPY OF THE INFORMED CONSENT STATEMENT.* It's yours to keep, if you'd like. It describes the project that I'm here to talk to you about today. I'd like for you to follow along as I read it out loud. Okay?

[I'm (Interviewer's Name) from the Michigan Department of Mental Health in Lansing. I'm working on a research project which is being paid for by the National Institute of Mental Health in Washington, D.C. Although the staff of this project do not work for the Office of Recipient Rights, we are concerned with how well rights complaints are handled. To find this out, I'd like to ask some questions of you and others who've had a complaint settled.

First, I want to tell you about our project. While I'm describing it to you and even when I've finished, feel free to ask any questions that you may have about it. I'll try to answer all of your questions as best I can.

The purpose of this project is to see how well rights complaints are handled. If you agree to participate in this project, I will ask you some questions about the last rights complaint for which you received a final report. Or, if there is another complaint for which you received a final report that you can remember better, then I'll ask some questions about that one. Also, if you agree to participate in this project, I would like to review your hospital record. This is so that I may get some basic things like the date you came to this hospital and the date you came to this ward.

Your decision to participate, or not, is voluntary. This means that you do not have to be interviewed if you don't want to. This also means that you can end this interview at any time, if for any reason, you would like to. Participation in this project will take about half an hour of your time. Your decision to participate will have no effect on the services you receive from this hospital.

The people who work on this project have made every effort to make sure that this research does not involve any risk for you. All the information you provide will be used for research purposes only and will be kept confidential. This means that no one other than the people who work on this project will see your answers.

Your answers will be combined with the answers of many others to help us learn how people feel about the way rights complaints are handled. Depending on the answers that you and others provide, changes may be made in the way complaints are dealt with. This project may not benefit you directly, but it is possible that patients and staff at this hospital may benefit in the long-run from what we learn.

As another important part of this research project, we want to find out how well I've communicated to you what it is we're studying. So the first questions I have will be about the things we've just read together. Before we go on, do you have any questions about this project? Are you willing to answer some questions that will let me know how well I've explained what this study is about?] IF PATIENT ANSWERS "YES," CONTINUE. IF PATIENT ANSWERS "NO," TERMINATE INTERVIEW.

*The Informed Consent Statement given to patients includes the information enclosed within the brackets.

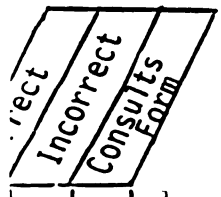
APPENDIX A-2

P FORM

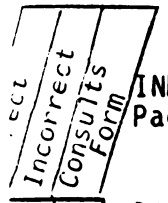
INFORMED CONSENT QUESTIONNAIRE

In order to see how well I've communicated what we're studying, I'd like to read some statements to you. After each one, please tell me whether the statement is right or wrong, based on what I've just told you about our project. After you've told me whether each statement is right or wrong, I'll go back and correct anything that I may not have made clear to you. Do you have any questions?

INTERVIEWER: ASK ALL QUESTIONS, NOTING WHETHER RESPONSES ARE CORRECT OR INCORRECT AND WHETHER RESPONDENT CONSULTS THE INFORMED CONSENT STATEMENT. WHEN YOU'VE FINISHED THE LIST, GO BACK AND CLARIFY ALL INCORRECT RESPONSES. BE SURE TO RECORD ALL COMMENTS AND/OR QUESTIONS OF RESPONDENT AND YOUR RESPONSE(S).



1. The purpose of this project is to solve rights complaints. (W)
2. The people who work on this project do not work for the Office of Recipient Rights. (R)
3. You may interrupt me to ask questions about this project at any time if you want to. (R)
4. Everyone who is asked must participate in this study. (W)
5. The purpose of this project is to find out how well rights complaints are handled. (R)
6. If you agree to participate in this interview, you must answer all questions that I ask you. (W)
7. The questions I will be asking are part of a research project. (R)
8. The purpose of this project is to learn how to file a rights complaint. (W)
9. This study will definitely benefit you. (W)
10. If you begin this interview, you must complete it. (W)
11. This study will probably not involve any risk for you. (R)
12. You must ask questions about this project. (W)
13. Only the people working on this project will see the answers that you may provide. (R)



INFORMED CONSENT QUESTIONNAIRE
Page 2

14. This project is being paid for by the Office of Recipient Rights in Lansing. (W)

15. Your participation on this project will involve being interviewed about your experiences with the rights complaint process. (R)

16. All of the patients and staff at this hospital will receive direct benefits from this study. (W)

17. Your responses to this interview will be shown to the staff on your ward. (W)

18. One part of this project is to find out how well I've communicated to you what the project is about. (R)

19. I will be asking to see your hospital record if you agree to participate in this study. (R)

Now, I'm going to read you a statement. INTERVIEWER: GIVE COPY OF CONSENT FORM TO POTENTIAL SUBJECT. If you agree to be interviewed about the way rights complaints are handled, I'd like for you to sign this statement when I've finished reading it. This will show that you've given me permission to interview you.

"I agree to be interviewed about my experiences with filing a rights complaint. I also give my permission to have my hospital record reviewed for this project. I understand that the people working on this project have made every effort to make sure that no risk is involved for me. I understand that the information I am providing will be used for research purposes only and will be kept confidential. I have had the opportunity to ask questions about this study and have had them answered."

TIME CONSENT PROCEDURE ENDED: _____

GLR

APPENDIX A-3

P Form

CONSENT FORM

I, _____, agree to be interviewed about my experiences with filing a rights complaint. I also give my permission to have my hospital record reviewed for this project. I understand that the prople working on this project have made every effort to make sure that no risk is involved for me. I understand that any information that I provide will be used for research purposes and seen only by the people working on this project. Personal benefit may not result from my taking part in this study, but knowledge may be gained that will benefit others. I understand that taking part in this study is voluntary and that I may withdraw at any time without penalty or loss of benefits or services. I have had the opportunity to ask questions about this study and had them answered to my satisfaction.

Signature _____

Date _____

Hospital _____

City _____

APPENDIX A-4

RIGHTS COMPLAINT SURVEY

Date of Interview_____

Complainant Type_____

Hospital_____

Ward_____

Program Type_____

Interviewer Name_____

TIME INTERVIEW STARTED:_____

Now, I'd like to ask you some questions about your experiences with the rights complaint process. I'm interested in your honest opinions, whether they are positive or negative.

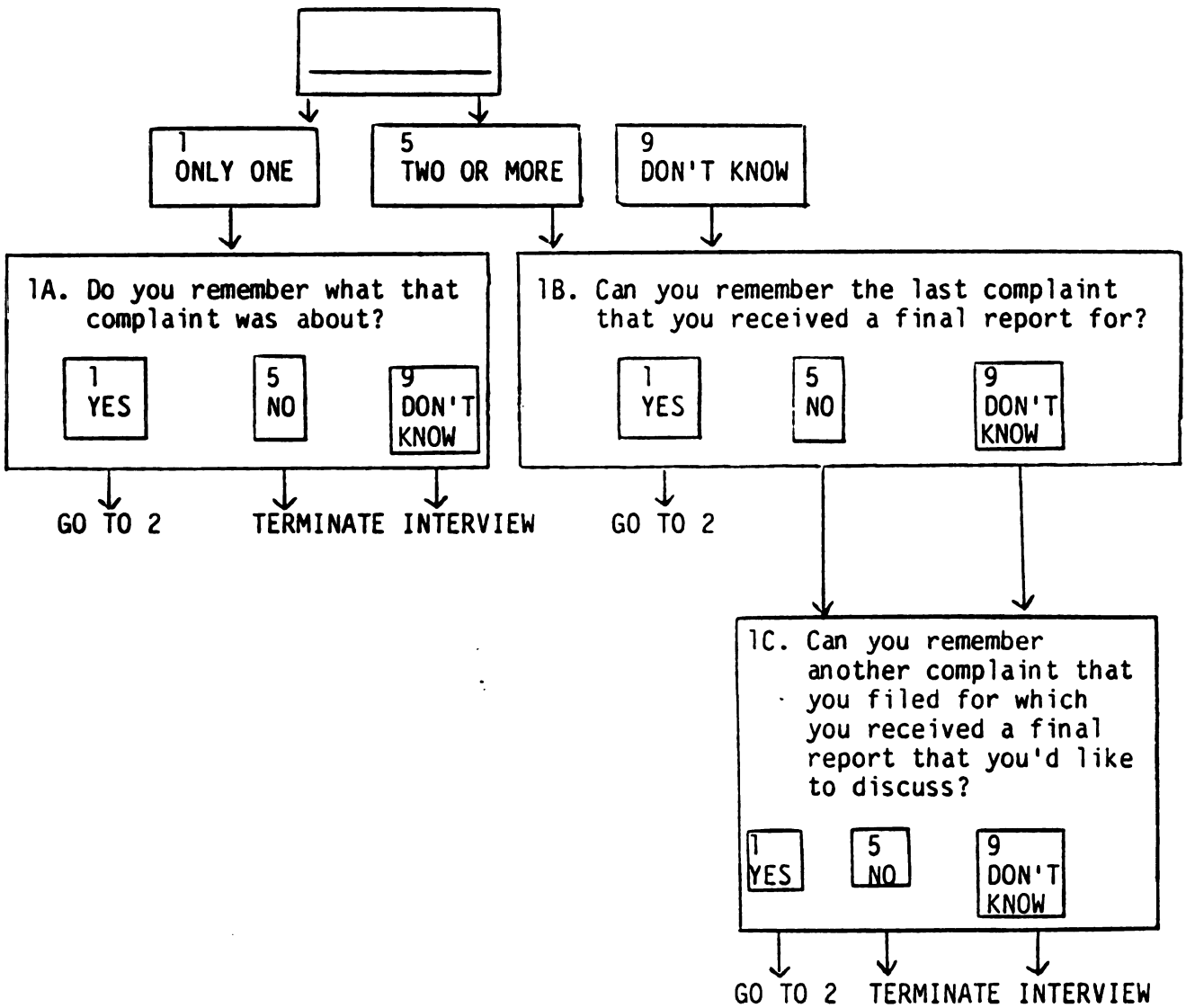
For some questions, I'll show you a card with some possible answers. I'd like for you to choose the answer that comes closest to describing how you feel.

If you've filed more than one complaint, please answer the questions on the basis of the last complaint for which you received a final report. If there is another complaint, however, for which you received a final report that you can remember better, then I'll ask some questions about that one.

Are you ready to begin?

INTERVIEWER: RECORD ALL QUESTIONS ASKED AND/OR COMMENTS MADE AND YOUR RESPONSE(S) IN MARGINS NEAR THE QUESTION WHERE INTRODUCED.

1. First, about how many rights complaints have you filed?



2. Could you tell me what that complaint was about? PROBE TO ASCERTAIN SUFFICIENT EXPLANATION OF COMPLAINT TO BE ABLE TO CATEGORIZE TYPE. IF ABUSE DESCRIBED, PROBE TO ASCERTAIN IF PATIENT TO PATIENT, STAFF TO PATIENT, PATIENT TO STAFF, ETC.

3. About how many months ago did you file this complaint?

____ MONTHS	9 DON'T KNOW

4. And about how many months ago did you receive the final report for that complaint?

____ MONTHS	9 DON'T KNOW

5. Did you talk to anyone from the Recipient Rights Office at this hospital about your complaint?

1 YES	5 NO → GO TO 11	9 DON'T KNOW → GO TO 11

6. Who did you talk to?

1 RIGHTS ADVISOR	2 ASSISTANT RIGHTS ADVISOR	3 RIGHTS OFFICE SECRETARY	9 DON'T KNOW

7. How courteous was that person (were they) to you?

1 EXTREMELY COURTEOUS	2 VERY COURTEOUS	3 SOMEWHAT COURTEOUS	4 NOT TOO COURTEOUS	5 NOT COURTEOUS AT ALL	9 DON'T KNOW

8. How helpful was that person's (their) advice in filing your complaint?

1 EXTREMELY HELPFUL	2 VERY HELPFUL	3 SOMEWHAT HELPFUL	4 NOT TOO HELPFUL	5 DEFINITELY NOT HELPFUL	9 DON'T KNOW

9. In filing this complaint, did you receive as much help as you wanted from the person (people) you spoke to in the Rights Office?

1 YES → GO TO 10

5 NO

9 DON'T KNOW → GO TO 10

9A. In what ways could he/she (they) have been more helpful? PROBE FOR AN ELABORATION OF GENERAL STATEMENTS OR COMMENTS.

_____

_____

_____

_____

_____

_____

_____

10. How would you rate the overall quality of service you received from the person (people) that you talked to in the Rights Office--excellent, very good, good, fair, or poor?

1 EXCELLENT	2 VERY GOOD	3 GOOD	4 FAIR	5 POOR	9 DON'T KNOW
GO TO 11	GO TO 11	GO TO 11			GO TO 11

10A. Why have you rated the service as (fair/poor)? PROBE TO ASCERTAIN SPECIFIC REASON(S) FOR FAIR OR POOR SERVICE RATINGS.

_____

_____

_____

_____

_____

_____

_____

_____

11. Who helped you most to understand the procedure for filing a rights complaint?

01 RA	02 ASST RA	03 RO SEC	04 ANO PT	05 ATTN RN	06 PSYCHI	07 PSYCHO	08 SW	09 OTHER HOSP STAFF

10 R	11 RTS BOOKLET	99 DON'T KNOW

_____

(IF R LISTS OTHER THAN THOSE ABOVE, PROBE TO ASCERTAIN WHETHER PERSON IS FRIEND, RELATIVE, COMMUNITY LEADER, COMMUNITY GROUP, ETC.

12. To

[1
VE

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13. Ho
co

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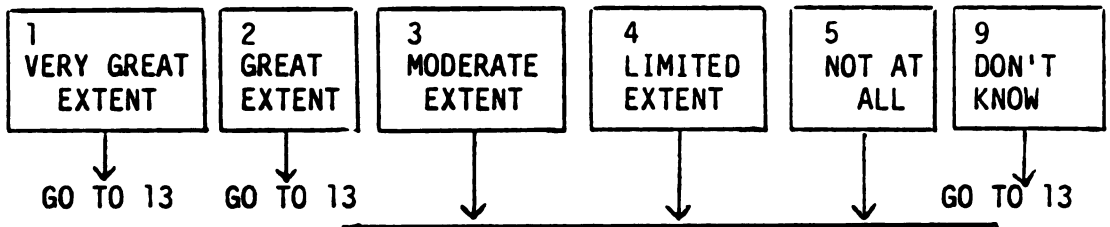
S

14. H

[T

S

12. To what extent do you feel your complaint was thoroughly investigated?



12A. In what ways could it have been investigated more thoroughly? PROBE TO ASCERTAIN SPECIFIC REASON(S) FOR FEELING THAT COMPLAINT WAS MODERATELY, LIMITEDLY, OR NOT AT ALL INVESTIGATED.

_____

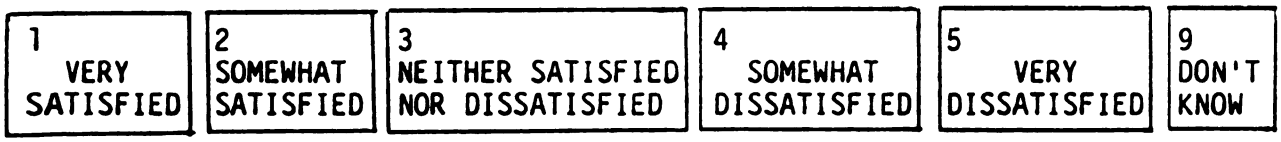
_____

_____

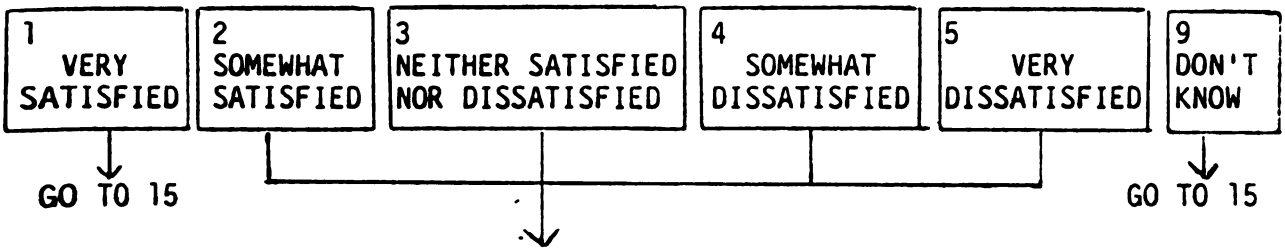
_____

_____

13. How satisfied were you with the amount of time it took to resolve that complaint?



14. How satisfied were you with the way your complaint was finally settled?



14A. Whey weren't you more satisfied? PROBE TO ASCERTAIN SPECIFIC REASON(S) FOR DISSATISFACTION.

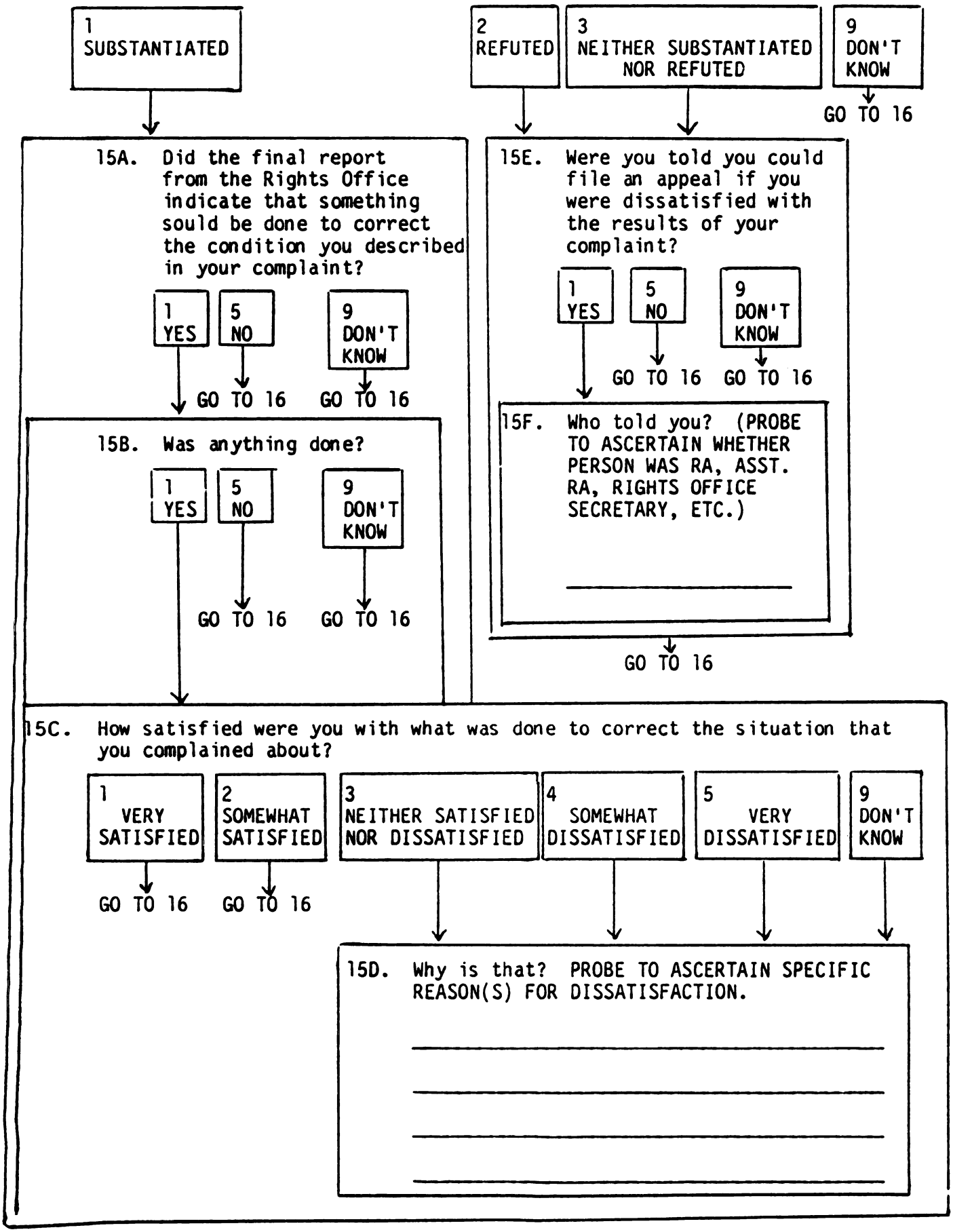
_____

_____

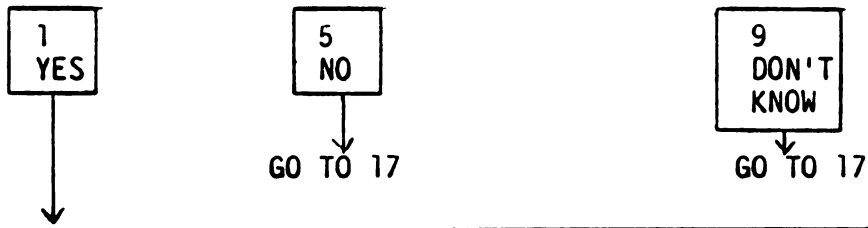
_____

_____

15. In the final report from the Rights Office, was this complaint substantiated, refuted, or neither substantiated nor refuted?

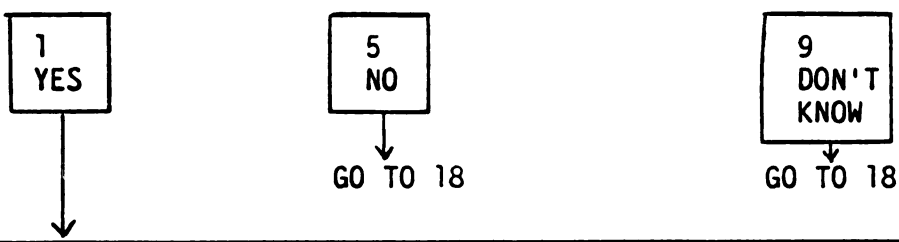


16. Did filing this complaint lead to any positive changes for you?



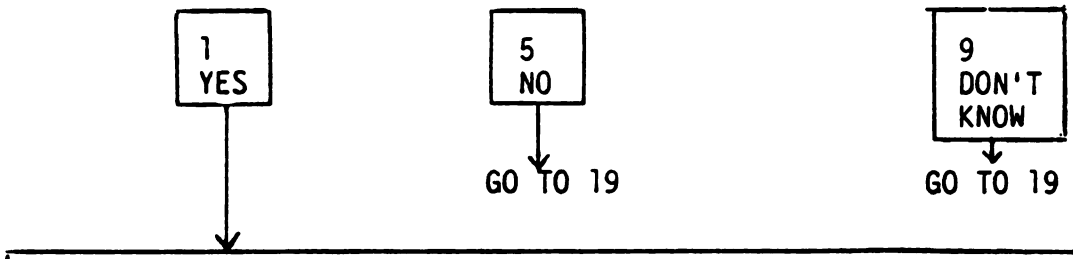
16A. Would you tell me a little about the positive changes that resulted from your filing that rights complaint? PROBE FOR AN ELABORATION OF GENERAL STATEMENTS OR COMMENTS ABOUT PERCEIVED POSITIVE CHANGES.

17. Did filing this complaint lead to any problems for you?



17A. Would you tell me a little about the problems that resulted from your filing that rights complaint? PROBE FOR AN ELABORATION OF GENERAL STATEMENTS OR COMMENTS ABOUT PERCEIVED PROBLEMS.

18. Do you think anything about the rights complaint procedures needs to be changed?



18A. What changes would you suggest? PROBE FOR AN ELABORATION OF SPECIFIC COMMENTS OR SUGGESTIONS.

_____

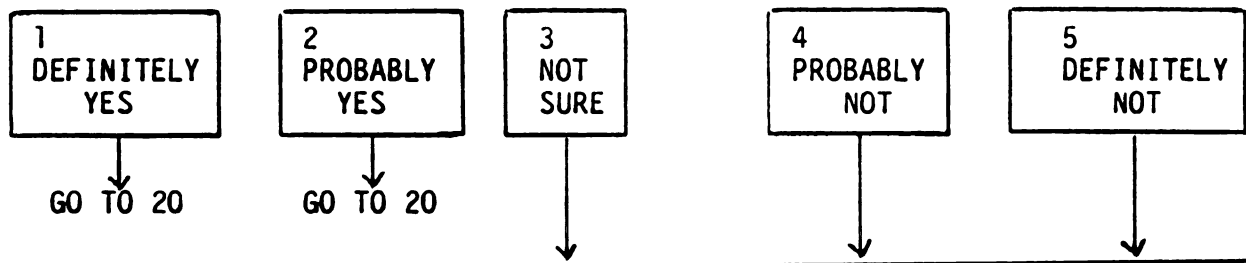
_____

_____

_____

_____

19. If you thought it necessary, would you file another rights complaint?



19A. Why (would/might) you not file another complaint? PROBE FOR SPECIFIC REASON(S).

_____

_____

_____

_____

_____

_____

20. Do you have any other comments or suggestions that you'd like to make about the way rights complaints are handled? PROBE FOR AN ELABORATION OF GENERAL COMMENTS OR SUGGESTIONS.

_____

_____

_____

_____

_____

21. I'd like to ask you just two last questions. Was participating in this research project easier, harder, or about what you expected?

1 EASIER	2 AS EXPECTED	3 HARDER
	GO TO 22	

21A. In what ways was it (easier/harder)? PROBE FOR AN ELABORATION OF GENERAL COMMENTS.

_____

_____

_____

_____

_____

22. Now that you've about completed this interview, how well do you think this project was explained to you?

1 EXTREMELY WELL	2 VERY WELL	3 FAIRLY WELL	4 NOT SO WELL	5 NOT WELL AT ALL

That was the last question. Thank you very much for your help.

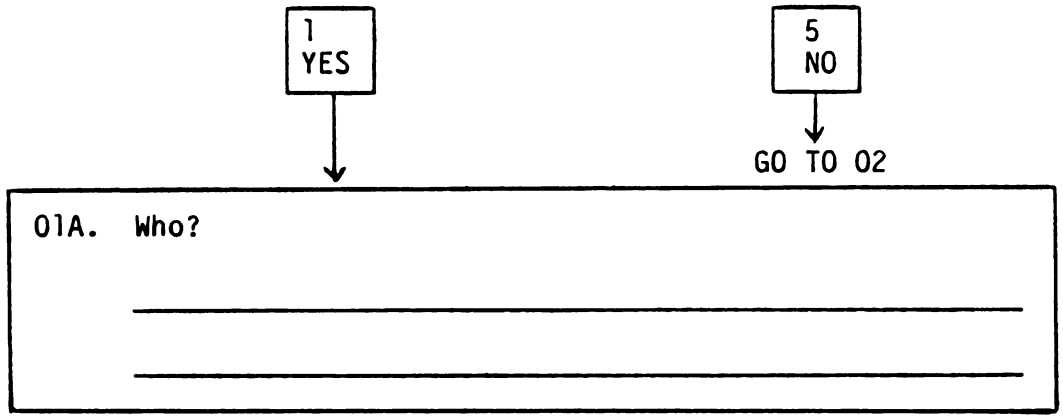
TIME INTERVIEW ENDED: _____

GLR

APPENDIX A-6

INTERVIEWER OBSERVATIONS

O1. Was anyone else present during the interview?



O2. Interruptions during the interview:

1	2	3	4	5
NONE	ONE	A FEW	A GOOD MANY	CONSTANTLY

O3. Respondent's interest in the interview:

1	2	3	4	5
VERY INTERESTED	MODERATELY INTERESTED	SLIGHTLY INTERESTED	SEEMINGLY NOT INTERESTED	OBVIOUSLY BORED

O4. Respondent's attitude toward the interview:

1	2	3	4	5
QUITE POSITIVE	COOPERATIVE	NEUTRAL	SOMEWHAT UNCOOPERATIVE	HOSTILE OR SUSPICIOUS

O5. How difficult was it keeping the R on the interview topics?

1	2	3
VERY DIFFICULT	SOMEWHAT DIFFICULT	NO REAL PROBLEM

06. How well did the R seem to understand the questions?

1	2	3
UNDERSTOOD ALL QUESTIONS	UNDERSTOOD MOST QUESTIONS	MISUNDERSTOOD MANY QUESTIONS

07. How would you describe the R's reality orientation?

1	2	3
VERY CONFUSED, DISORDERED	SOMEWHAT DISORDERED	NOT VERY DISORDERED

08. Should this interview be included in the main data analysis?

1	2	3
YES	MAYBE	NO

APPENDIX A-5

PATIENT BACKGROUND INFORMATION FORM

1. DMH Identifier _____

2. Birthdate ____/____/____

3. Sex

   (1) ☐ Male

   (2) ☐ Female

4. Race

   (1) ☐ American Indian

   (2) ☐ Black

   (3) ☐ Oriental/Asian

   (4) ☐ Spanish Surnamed

   (5) ☐ White

   (6) ☐ Other (please specify) _____

5. Marital Status

   (1) ☐ Married

   (2) ☐ Separated

   (3) ☐ Divorced

   (4) ☐ Widowed

   (5) ☐ Single (never married)

6. Education Level (record highest grade completed)

   _____

7. Most recent DSM-III Axis I diagnosis

   _____

PATIENT BACKGROUND INFORMATION FORM
Page 2

8. Most recent DSM-III Axis II diagnosis

_____

9. Prognosis

(1) ☐ Good

(2) ☐ Fair

(3) ☐ Guarded

(4) ☐ Poor

10. Date of present hospitalization ____/____/____

11. Date of present ward assignment ____/____/____

12. Number of previous psychiatric hospitalizations

None	1	2	3	4	5	6+

13. Total length of time of psychiatric hospitalizations

(1) ☐ Less than 3 months

(2) ☐ At least 3, but less than 6 months

(3) ☐ At least 6, but less than 12 months

(4) ☐ At least 1, but less than 3 years

(5) ☐ At least 3, but less than 5 years

(6) ☐ More than 5 years

14. Type, dosage, and frequency of administration of medication(s)

_____

_____

_____

APPENDIX B

B-1. STAFF INFORMED CONSENT STATEMENT

B-2. STAFF INFORMED CONSENT QUESTIONNAIRE

B-3. STAFF CONSENT FORM

B-4. STAFF INTERVIEWER OBSERVATIONS FORM

B-5. STAFF BACKGROUND INFORMATION FORM

APPENDIX B-1

S INTERVIEWER FORM

INFORMED CONSENT STATEMENT

TIME CONSENT PROCEDURE STARTED:_____

I'd like to give you this to read. GIVE STAFF A COPY OF THE INFORMED CONSENT STATMENT* It's yours to keep, if you'd like. It describes the project that I'm here to talk to you about today. I'd like for you to follow along as I read it out loud. Okay?

[I'm (Interviewer's Name) from the Michigan Department of Mental Health in Lansing. I'm working on a research project which is being paid for by the National Institute of Mental Health in Washington, D.C. Although the staff of this project do not work for the Office of Recipient Rights, we are concerned with how well rights complaints are handled. To find this out, I'd like to ask some questions of you and others who've had a complaint settled.

First, I want to tell you about our project. While I'm describing it to you and even when I've finished, feel free to ask any questions that you may have about it. I'll try to answer all of your questions as best I can.

The purpose of this project is to see how well rights complaints are handled. If you agree to participate in this project, I will ask you some questions about the last rights complaint for which you received a final report. Or, if there is another complaint for which you received a final report that you can remember better, then I'll ask some questions about that one.

Your decision to participate, or not, is voluntary. This means that you do not have to be interviewed if you don't want to. This means that you can end this interview at any time, if for any reason, you would like to. Participation in this project will take about half an hour of your time. Your decision to participate will have no effect on your job or the service provided to the person on whose behalf you filed a rights complaint.

INFORMED CONSENT STATEMENT
Page 2

The people who work on this project have made every effort to make sure that this research does not involve any risk for you. All the information you provide will be used for research purposes only and will be kept confidential. This means that no one other than the people who work on this project will see your answers.

Your answers will be combined with the answers of many others to help us learn how people feel about the way rights complaints are handled. Depending on the answers that you and others provide, changes may be made in the way complaints are dealt with. This project may not benefit you directly, but it is possible that patients and staff at this hospital may benefit in the long-run from what we learn.

As another important part of this research project, we want to find out how well I've communicated to you what it is we're studying. So the first questions I have will be about the things we've just read together. Before we go on, do you have any questions about this project? Are you willing to answer some questions that will let me know how well I've explained what this study is about?] IF STAFF ANSWERS "YES," CONTINUE. IF STAFF ANSWERS "NO," TERMINATE INTERVIEW.

*The Informed Consent Statement given to staff includes the information enclosed within the brackets.

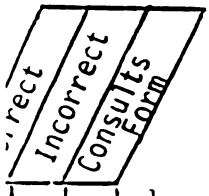
APPENDIX B-2

S FORM

INFORMED CONSENT QUESTIONNAIRE

In order to see how well I've communicated what we're studying, I'd like to read some statements to you. After each one, please tell me whether the statement is right or wrong, based on what I've just told you about our project. After you've told me whether each statement is right or wrong, I'll go back and correct anything that I may not have made clear to you. Do you have any questions?

INTERVIEWER: ASK ALL QUESTIONS, NOTING WHETHER RESPONSES ARE CORRECT OR INCORRECT AND WHETHER RESPONDENT CONSULTS THE INFORMED CONSENT STATEMENT. WHEN YOU'VE FINISHED THE LIST, GO BACK AND CLARIFY ALL INCORRECT RESPONSES. BE SURE TO RECORD ALL COMMENTS AND/OR QUESTIONS OF RESPONDENT AND YOUR RESPONSE(S).



1. The purpose of this project is to solve rights complaints. (W)
2. The people who work on this project do not work for the Office of Recipient Rights. (R)
3. You may interrupt me to ask questions about this project at any time if you want to. (R)
4. Everyone who is asked must participate in this study. (W)
5. The purpose of this project is to find out how well rights complaints are handled. (R)
6. If you agree to participate in this interview, you must answer all questions that I ask you. (W)
7. The questions I will be asking are part of a research project. (R)
8. The purpose of this project is to learn how to file a rights complaint. (W)
9. This study will definitely benefit you. (W)
10. If you begin this interview, you must complete it. (W)
11. This study will probably not involve any risk for you. (R)
12. You must ask questions about this project. (W)
13. Only the people working on this project will see the answers that you may provide. (R)

Incorrect Consults Form

INFORMED CONSENT QUESTIONNAIRE
Page 2

14. This project is being paid for by the Office of Recipient Rights in Lansing. (W)

15. Your participation on this project will involve being interviewed about your experiences with the rights complaint process. (R)

16. All of the patients and staff at this hospital will receive direct benefits from this study. (W)

17. Your responses to this interview will be shown to the staff on your ward. (W)

18. One part of this project is to find out how well I've communicated to you what the project is about. (R)

Now, I'm going to read you a statement. INTERVIEWER: GIVE COPY OF CONSENT FORM TO POTENTIAL SUBJECT. If you agree to be interviewed about the way rights complaints are handled, I'd like for you to sign this statement when I've finished reading it. This will show that you've given me permission to interview you.

"I agree to be interviewed about my experiences with filing a rights complaint. I understand that the people working on this project have made every effort to make sure that no risk is involved for me. I understand that the information I am providing will be used for research purposes only and will be kept confidential. I have had the opportunity to ask questions about this study and have had them answered."

TIME CONSENT PROCEDURE ENDED: _____

GLR

APPENDIX B-3

S Form

CONSENT FORM

I, _____, agree to be interviewed about my experiences with filing a rights complaint. I understand that the people working on this project have made every effort to make sure that no risk is involved for me. I understand that any information that I provide will be used for research purposes and seen only by the people working on this project. Personal benefit may not result from my taking part in this study, but knowledge may be gained that will benefit others. I understand that taking part in this study is voluntary and that I may withdraw at any time without penalty or loss of benefits or services. I have had the opportunity to ask questions about this study and had them answered to my satisfaction.

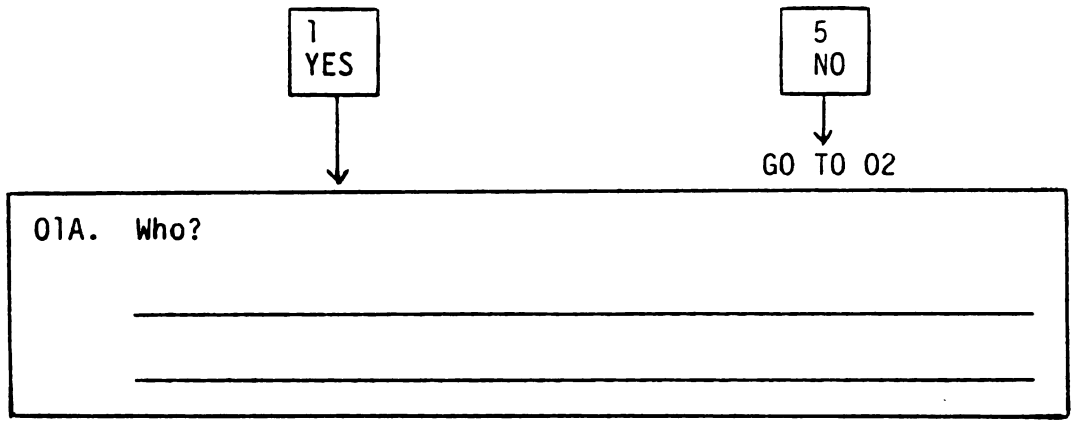
Signature _____

Date _____

APPENDIX B-4

INTERVIEWER OBSERVATIONS

O1. Was anyone else present during the interview?



O2. Interruptions during the interview:

1	2	3	4	5
NONE	ONE	A FEW	A GOOD MANY	CONSTANTLY

O3. Respondent's interest in the interview:

1	2	3	4	5
VERY INTERESTED	MODERATELY INTERESTED	SLIGHTLY INTERESTED	SEEMINGLY NOT INTERESTED	OBVIOUSLY BORED

O4. Respondent's attitude toward the interview:

1	2	3	4	5
QUITE POSITIVE	COOPERATIVE	NEUTRAL	SOMEWHAT UNCOOPERATIVE	HOSTILE OR SUSPICIOUS

APPENDIX B-5

STAFF BACKGROUND INFORMATION FORM

Please answer each of the questions listed below.

1. Birthdate ____/____/____

2. Sex

   (1) ☐ Male

   (2) ☐ Female

3. Race

   (1) ☐ American Indian

   (2) ☐ Black

   (3) ☐ Oriental/Asian

   (4) ☐ Spanish Surnamed

   (5) ☐ White

   (6) ☐ Other (please specify) _____

4. Marital Status

   (1) ☐ Married

   (2) ☐ Separated

   (3) ☐ Divorced

   (4) ☐ Widowed

   (5) ☐ Single (never married)

5. Education Level (record highest grade completed)

   _____

STAFF BACKGROUND INFORMATION FORM
Page 2

6. Present job classification and level

_____

7. Length of time in present job classification and level

_____

8. Length of time employed at this hospital

_____

9. Length of time in state service

_____

REFERENCES

REFERENCES

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