The effect of information redundancy and format upon comprehensibility of consent information to chronic alcoholics

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The effect of information redundancy and format upon comprehensibility of consent information to chronic alcoholics

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The effect of information redundancy and format upon comprehensibility of consent information to chronic alcoholics

by

Kenneth Raymond Mills

A Dissertation Submitted to the Graduate Faculty in Partial Fulfillment of the Requirements for the Degree of DOCTOR OF PHILOSOPHY Department: Psychology Major: Psychology

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For the Graduate College

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1992

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DEDICATION

This work is dedicated with love to Susan, Joss, Travis, and Caity. Without their love and support it could not have been accomplished. I hope that in the future I will be able to make up for the countless nights that they spent without a husband and a father while this study was being completed.

This dissertation is also dedicated with love to my father, Harold Mills, who taught me that you can accomplish anything if you work at it hard enough, and to my mother, Louise Mills, whose faith in her son's abilities has often exceeded his own.
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INTRODUCTION

In our complex, technological, and rather impersonal society, individuals often find themselves involved in activities directed by others, about which they know very little. Just as often, individuals may feel that they have not been afforded an adequate opportunity to agree to their own participation. Informed consent is the voluntary agreement of a person to participate in treatment, research, or any other activity, based upon an adequate understanding of salient aspects of that activity. The concept of informed consent has gradually developed through the evolution of both case law and biomedical ethics.

It is generally agreed that informed consent procures are required whenever intrusion, risk, or questionable purposes are evident in a participatory activity (Beauchamp & Childress, 1979). The provision of informed consent to both research and treatment has become accepted practice in medicine and psychology. Further, it follows that as medical or research procedures become more intrusive or risky, the argument to provide informed consent becomes more compelling. A good example of an intrusive medical and psychological procedure is intensive treatment for chemical dependency. In chemical dependency treatment, patients are confronted by both professional staff and fellow patients about their behavior, attitudes, and honesty. Physical freedom is often curtailed (inpatient and residential treatment), privacy is invaded (no closed doors in patient rooms allowed, mandatory urinalysis), and the significant
discomfort of detoxification is experienced by a sizable portion of the treatment population.

In informed consent, "consent" refers to the voluntariness of the person's agreement to participate. "Informed" refers to the provision of pertinent information about the activity and the understanding of that information by the person who is considering involvement. Beauchamp and Childress (1979) state that "the information element of informed consent refers to adequate disclosure of information and adequate comprehension by patients or subjects of what is disclosed" (p. 66). Inherent in the provision of fully informed consent is the assumption that the subject or patient has adequately understood the information offered to him or her. The usual and customary procedure for provision of informed consent is the presentation of a printed consent form along with the request that the subject or patient read it and sign a statement indicating agreement to participate (Grundner, 1980; Morrow, 1980). Paradoxically, while informed consent procedures are clearly indicated for individuals who are in treatment for alcohol dependency, research suggests that their chronic excessive use of alcohol often results in cognitive impairment which may limit their ability to comprehend consent information, as commonly presented in written form.

Several researchers have investigated methods which offer potential enhancement of consent information by patients and subjects. In an analysis of the dynamics of reading, Adams (1982) noted that highly coherent text material contains greater redundancy of information than
less coherent material. Some researchers (e.g., Miller & Willner, 1974; Taub & Baker, 1983) have incorporated increased redundancy into designs of consent information, intended to enhance comprehension and recall.

Another promising and innovative technique is the use of videotaped presentations of consent information (Barbour & Blumenkrantz, 1978; Tymchuk, Ouslander, & Rader, 1986). Through the use of video format, the potential limiting effects of poor reading ability and short attention span may be overcome.

The goal of this study was to investigate the effects of these two promising techniques on comprehension when used in the presentation of consent information to chronic alcoholics. The study investigated the effect of information redundancy and media format upon the comprehension of consent information by persons in treatment for chronic alcohol dependency. Consent information was presented to subjects via two formats, printed information sheets and a videotaped presentation. Each of the two formats was presented either with a single delivery of each element of consent information or with each element of consent information presented twice. The goal of the study was to clarify the potential contribution of these factors toward the provision of fully informed consent by alcoholics in both the research and treatment settings. In addition to an analysis of the effects of the two variables of main interest, the relationship of several other independent variables to comprehension of the consent information was examined.
REVIEW OF THE LITERATURE

A Brief History of Informed Consent

The Beginnings of Informed Consent

The doctrine of informed consent to treatment is of relatively recent origin, yet its roots extend as far back as the Code of Hammurabi. Written in the 18th century B.C., this code included the first recorded cultural effort to protect patients from unskilled or fraudulent doctors (Hammurabi, 1960). Although sanctions were limited to the practice of surgery, exacting penalties for therapeutic failure, this recognition of medicine as a special undertaking, carrying with it special obligations, signaled the beginning of the long evolution of medical ethics.

Codified regulation of medical practice was more stringent under the Egyptian Pharaohs. Egyptian physicians provided treatment in strict accordance with officially approved written protocols. If they deviated from accepted practice, and their patient died, they were subject to the death penalty (Carrick, 1985).

Under ancient formulations, the rights of patients were protected, albeit in a limited fashion, by harsh regulation of physician behavior. These regulations, however, took no note of the patient as a partner in his or her medical treatment. Instead, the patient was viewed as a passive recipient of purchased services.

By the Classical Age of Greece, physicians enjoyed the status of craftsmen, seen to be in command of a specialized body of knowledge. In Homer's time (c. 850 B.C.), the physician held social status similar to the
spear maker and the singer (Carrick, 1985). Interestingly, ethical constraints on physicians in ancient Greece, as during later Roman times, were largely voluntary, with few behaviors proscribed by law.

The earliest, and certainly the most familiar, complete code of medical ethics was the so-called Hippocratic Oath. Scholars no longer attribute its authorship to the historical individual Hippocrates but instead suggest an origin which is partly of the Hippocratic school, partly Pythagorean (Carrick, 1985). Like earlier pronouncements, this oath (See Appendix A) did not directly address the concept of consent to treatment. It did contain, however, promises to "keep (the sick) from harm and injustice" and to "come for the benefit of the sick, remaining free of all intentional injustice." This concern for justice, although apparently not reflective of actual medical practice at the time, marked an important development in medical ethics.

During the Roman Era, although the medical profession was certainly familiar with the Hippocratic tradition, little attention was paid to medical ethics. A notable exception was the influence of pagan humanism in the writings of popular medical theorists, such as Libanius (Polani, 1983). Even Galen (c. A. D. 138-201), the celebrated Roman physician and prolific author, left little written evidence of a concern with ethical practice.

Interestingly, while few records exist of Roman concerns with overtly ethical medical issues, significant attention was paid to medical etiquette. Since formal medical training and certification of doctors would not be instituted in Italy for almost a thousand years, the maintenance of proper
professional behavior and decorum would allow patients to differentiate between sincere, dedicated physicians and charlatans, whose practice was often marked by braggadocio and flamboyant self-promotion. Thus, proper professional etiquette could be seen as an important way in which to address the ethical issue of development of trust between patient and medical practitioner.

During the early Middle Ages, professional medicine in the Western world was often controlled by governmental decree. Concepts of ethical practice were beginning to appear but were still rudimentary in nature. In Italy, under the Ostrogoth Cassiodorus (c. A. D. 550), a small sense of physician/patient partnership was indicated by the governmental encouragement of patients to ask, and of their physicians to answer, appropriate medical questions (Smith, 1979).

The concurrent development of medicine in the Arabic world was characterized by significant advancements in practical and scientific aspects but evidenced little expansion upon current, minimal, ethical precepts. Even the writings of Avicenna (c. A. D. 1000), arguably the greatest figure of Arabic medicine, showed minimal focus on medical ethics (Gutas, 1988). Medicine in the Arabic world was not devoid of ethical direction, however. Judaic ethicists were especially active during this period. Most notable was Moses ben Maimon (a.k.a. Maimonides, c. A. D. 1100) whose writings on the Law and morality (e.g., Maimonides, 1956) laid important groundwork for later developments in Jewish medical ethics.
The late Middle Ages saw the emergence of the School of Medicine in Salerno, Sicily. The requirements of the Salernitan School, extensive formal education, public examination, and professional licensure, were endorsed and enforced by Pope Frederick II and subsequent pontiffs (Polani, 1983). While no significant changes in the ethical relationship between doctor and patient are attributable to this school, its rise to prominence permanently established the concept of rigorous professional training for physicians and established a framework for the inclusion of ethical professional requirements, such as informed consent to treatment.

The Protestant Reformation heralded the beginning of a significant concern with ethics in Western philosophy. Although none of his 95 theses pertained to medicine, Luther exemplified the intense interest in questions of religion and personal morality that was manifested by philosophers and theologians in the early sixteenth century. The burgeoning cultural emphasis upon personal responsibility and individual freedom served to create a new view of the worth of the individual and gave form to the concept of autonomy as an inherent value of personhood.

Seventeenth and eighteenth century philosophers continued a focus upon religious questions, most notably the Ontological Argument (the argument that the concept of God implies his existence), yet against this theocentric background, the perceived intrinsic value of humankind, and human thought, grew. Rationalists from Descartes (1596-1650) through Spinoza (1632-1677) to Leibniz (1646-1716) attempted to construct complete moral and metaphysical systems based upon logic and rational
argument (Coppleston, 1963). British empiricist Locke (1632-1704) condemned paternalistic concepts such as the divine right of kings, while Rousseau (1712-1778) argued for a social order which reflected humankind's basic goodness. Clearly, in eighteenth century Europe, the stage was set for a precise articulation of the ethical precepts governing human interaction. These precepts were enunciated by Immanuel Kant (1724-1804) who synthesized the Rationalism of Leibniz and the Skepticism of Hume into a deontological ethical system, the culmination of which was the Categorical Imperative: "...I ought never to act except in such a way that I can also will that my maxim should become a universal law" (Kant, 1964, p. 70). Most relevant to the concept of informed consent was the Practical Imperative, a special case of the Categorical Imperative which related to interpersonal behavior: "Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end" (Kant, 1964, p. 96).

Kant's affirmation of human worth implied the respect for individual dignity and autonomy upon which the concept of informed consent is based. Indeed, it has been argued that the primary function of informed consent is the maintenance of patient autonomy (Engelhardt and McCullough, 1981).

The acceptance of a personal right of autonomy is the sine qua non of the doctrine of informed consent. The traditional Anglo-Germanic respect for individual privacy and autonomy influenced not only the writings of
Rousseau and Kant but also the development of the ethical stance of the
Christian Church. Positing earthly life as sacred, but also as a precursor
to a more important afterlife, Catholic ethical tradition has consistently set
limits upon the "right" of physicians to encroach upon the autonomy of the
individual in order to preserve mortal life (Sloane, 1983). In contrast,
Jewish philosophy has maintained a focus upon earthly human life,
considering it to be the ultimate expression of God's handiwork and,
therefore, sacred and to be preserved at all costs (Jakobovits, 1983).
Consequently, the right to refuse medically needed treatment has not
usually been recognized in the Jewish tradition. This dialectic between
Jewish paternalism and Christian individualism foreshadowed a similar
tension in current medical ethics, which appropriately finds its focus in the
concept of informed consent.

Beauchamp and Childress (1979) have suggested that the modern
health care professional must take into consideration several ethical
concepts when considering professional action. Included in these
concepts are:

a) Autonomy: The right of individuals to determine their own course
   of action, in congruence with their own chosen plans.

b) Nonmaleficence: The obligation not to harm people.

c) Beneficence: The duty of persons to help others.

d) Justice: The requirement that benefits, burdens, goods, and
   services be distributed equitably.
e) Informed consent: The right of the patient to have knowledge of and consent to a particular treatment before it is administered. The potential and inherent conflict among the first four of these concepts is most clearly evidenced in the actualization of informed consent. The paternalism often implied by beneficence may serve to limit patient autonomy. Nonmaleficence, similarly, may serve to limit to the patient disclosure of potentially injurious information, thereby diminishing autonomy. Conversely, full respect of patient autonomy could result in certain subpopulations selecting less effective treatments, thereby diminishing justice.

Informed Consent as a Legal Doctrine

Since the French enlightenment, Kant, and the subsequent progressive secularization of society, significant developments in health care ethics have been manifested most decisively in legal doctrine and legislation.

Modern informed consent doctrine, while philosophically rooted in the concept of autonomy, developed directly from the common-law rule that a physician is subject to "liability in tort" to the patient for any unauthorized operation (Ludlam, 1978). Informed consent rulings in the United States were first seen at the beginning of the current century. Ludlam notes that early cases (e.g., Mohr v. Williams [1905], Pratt v. Davis [1906], Rolater v. Strain [1913]) found that unless a patient consented expressly or implicitly to a medical operation, the performance of such an operation would constitute an actionable act of battery by the physician.
In his decision on Schoendorff v. Society of New York Hospitals (1914)—in which a tumor was removed from a patient's abdomen without her consent—Judge Cardoza observed:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages...This is true, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained" (Quoted in Ludlam, 1978, p. 20).

Subsequent legal decisions (e.g., Natanson v. Kline, 1960) enunciated the duty of the physician to warn the patient of potential risks of treatment. In Mitchell v. Robinson (1960) a similar duty to disclose risk was adjudged in a case regarding physical injuries suffered as a result of insulin shock treatments. While still primarily concerned with somatic injury, this case dealt with issues at the juncture of medical and psychiatric treatment and served as a harbinger of the eventual expansion of the informed consent doctrine to include psychiatric and psychological practice. As was exemplified in the recent case of Osherhoff v. Chestnut Lodge (Malcom, 1988), the courts clearly consider informed consent to apply to the provision of psychotherapy.

Initially, courts found physicians to be responsible to disclose to patients the type and amount of information that a "reasonable medical practitioner" (Natanson v. Kline, 1960) would disclose or that would reflect
the common practice of competent physicians. This criterion came to be known as the "professional standard." Current trends, however, are to impose a more rigorous standard of the scope of required information to be disclosed to the patient, encompassing all significant risks and relevant alternatives. Known as the "material risk" standard, this criterion was first articulated in Canterbury v. Spence (1972) and Cobbs v. Grant (1972). It is noteworthy that in moving from a profession-based standard to a consumer-based standard, the courts have acted to increase the perceived value of personal autonomy and have decreased the paternalistic options of health care professionals.

The courts have held that in certain situations, physicians are fully or partially exempt from a "duty to disclose" risks to patients. Included in these are (Ludlam, 1978):

b) When the patient is already aware of the risk. (Canterbury v. Spence, 1972)
c) When existence of the risk is "common knowledge." (Wilkinson v. Vesey, 1972)
d) When the risk only results from improper performance of the medical procedure. (Mull v. Emory University, 1966)
e) When the risk is not generally known to the profession at the time of the procedure. (Trogun v. Fruchtman, 1973)
f) When the patient requests to not be informed. (Canterbury v. Spence, 1972)
e) In cases of medical emergency. (Canterbury v. Spence, 1972)
h) In cases in which full disclosure would cause the patient's condition to worsen, physically or mentally. Known as "therapeutic privilege" (Salgo v. Leland Stanford Jr. University Board of Trustees, 1957), this concept allows the practitioner to inform the patient less than fully, as long as there would be a clearly predictable injurious result of full disclosure and as long as the practitioner does not withhold information merely to assure the patient's compliance with a particular treatment. In such cases, the physician's duty to "above all, do no harm" is held to supersede respect for the patient's autonomy.

The Current Status of Informed Consent

Originally conceived as pertaining to the therapeutic relationship between physician and patient, the applicability of the informed consent process has expanded over the past few decades to include most professional relationships between patients and professionals in the health care arena.

The acceptance of an ethical mandate to provide informed consent is not universal, however. Physicians have been slow to endorse the concept, possibly concerned about an erosion of professional prerogative. Laforet (1976) brands informed consent as a "legalistic fiction that destroys good patient care and paralyzes the conscientious physician" (pp. 1584-1585), asserting that the integrity of the physician is the most effective safeguard of patient well-being. In a similar sentiment, Ingelfinger (1980) declares that "authoritarianism, paternalism, and
domination are the essence of the physician's effectiveness" (p. 135). In psychology, the potential incompatibility of fully informed consent with many therapeutic techniques has been noted (Widiger & Rorer, 1984). Several authors (e.g., Finney, 1987; Mahler, 1986; Trice, 1986a & b) have pointed out that fully informed consent in the research setting may unduly affect the validity of outcome data.

Notwithstanding these objections, prior informed consent to participation in professionally mediated activities has become increasingly seen as the right of the individual. Ironically, medical associations have been reticent to include a right to informed consent-to-treatment in their codes of professional conduct. In its 1983 Declaration of Geneva (See Appendix B), the World Medical Association neglects to mention informed consent in particular, or patients' rights in general, although a pledge of confidentiality is included in this update of the Hippocratic Oath. The American Medical Association, on the other hand, specifies in its Principles of Medical Ethics (See Appendix C) that physicians "shall respect the rights of patients," although these rights are not enumerated.

The American Hospital Association has been more proactive on the subject of patients' rights, however. In its 1973 Patient Bill of Rights (See Appendix D), the right of a patient "to receive from his (sic) physician information necessary to give informed consent..." is clearly asserted.

Interestingly, the apparent reticence of the community of physicians to embrace informed consent as it applies to medical treatment is not evident in the areas of medical research and experimentation. Perhaps as a
reaction to the horrors of Nazi medical experimentation during World War II, a clear consensus has emerged regarding the necessity for truly voluntary and informed subject consent to medical research.

The earliest formal reaction to Nazi "research" atrocities came as a set of standards for medical research behavior, embedded within a judgment against a group of German doctors at the War Crimes Tribunal in Nuremberg, Germany in 1947. Known as the Nuremberg Code (See Appendix E), its initial, and most strident, statement is that "the voluntary consent of the human subject is absolutely essential." In its Declaration of Helsinki (See Appendix F), the World Medical Association asserts a similar requirement for the physician to obtain prior voluntary consent from the research subject, although it allows for the possible omission of informed consent procedures in some instances in which research is combined with professional care.

Psychology and Informed Consent

Informed Consent and Psychological Treatment

The mandate for ethical psychological treatment developed as an expansion of ethical requirements for psychiatric treatment, which in turn developed from ethical requirements for medical treatment. This developmental process was rather slow, however, and it was not until 1951 that the American Psychological Association published its first Ethical Code for clinical and consulting psychologists. The current version of "Ethical Principles of Psychologists of the American Psychological Association" (1989) reflects the increased concern of the profession over
issues of consumer rights, including the right to prior informed consent (Nagy, 1988). Principle 6, titled "Welfare of the Consumer," states, "Psychologists fully inform consumers as to the purpose and nature of an evaluative, treatment, educational, or training procedure, and they freely acknowledge that clients, students, or participants in research have freedom of choice with regard to participation" (American Psychological Association, 1989, p. 393).

In August, 1992, the Council of Representatives of the American Psychological Association adopted a revised "Ethical Principles of Psychologists and Code of Conduct", which will take effect December 1, 1992 (American Psychological Association, in press). This newly revised codification of professional principles delineates much more specifically than the 1989 "Principles" the concern of the Association that clients be afforded opportunity for appropriate prior consent. Section 4.02(a), "Informed Consent to Therapy", specifically states "Psychologists obtain appropriate informed consent to therapy or related procedures, using language that is reasonably understandable to participants."

Ethical codes for counselors (American Association for Counseling and Development, now the American Counseling Association, 1988), psychiatrists (American Psychiatric Association, 1986), marriage and family therapists (American Association of Marriage and Family Therapy, 1985), and social workers (National Association of Social Workers, 1979) all speak to the need for provision of informed consent.
In *Making health care decisions: A report on the ethical and legal implications of informed consent in the patient-practitioner relationship* (1982), the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommends the provision of informed consent in all but a very limited category of treatment interactions, including a recommendation of informed consent for psychological treatment.

Writers have noted the overwhelming ethical (Coyne, 1976; Handlesman, Kemper, Kesson, McLain, & Johnsrud, 1986; Hulteng, 1988) and legal (Epstein, Steingarten, Weinstein, & Nashel, 1977; Noll, 1976; Sadoff, 1974) arguments for the provision of informed consent in psychotherapy. Especially in light of the increasing use of deception (paradox) in psychotherapy, the importance of the provision of informed consent to treatment has become a major ethical and legal focus (Brown & Slee, 1986; Henderson, 1987; Martin, 1986). Failure to provide adequate informed consent to treatment exposes the psychotherapist to considerable risk of litigation (Bray, Shepherd, & Ray, 1985; Malcolm, 1986; Pope, Simpson, & Weiner, 1978). The mandate to provide a consent opportunity is seen as extending to include mental patients (Meisel, 1983; Schwitzgebel, 1975) and children (Glenn, 1980), although Kaser-Boyd and her associates (Kaser-Boyd, Adelman, Taylor, & Nelson, 1986) have suggested that in the case of children, determinations of competency to consent be based upon the capacities of the child. Some therapists (Jensen, Josephson, & Frey, 1989) have even begun to use the
informed consent procedure as a method to establish trust and deflect clients' resistance to therapy.

**Informed Consent and Psychological Research**

For most of the recorded history of psychological thought, "informed consent to participation in psychological research" was a phrase with little meaning. Traditionally, psychology was an aspect of philosophy, and was speculative in nature. The gradual "scientification" of psychology was heralded by the publishing of *Elemente der Psychophysik* by Gustav Fechner in 1860, a treatise concerned with the measurement of sensory experiences. The focal point of the foundation of psychology as an experimental science came in 1879 with Wilhelm Wundt's establishment of the first laboratory of psychology at the University of Leipzig. Recognizing the pivotal importance of Wundt's work, Titchener (cited in Klein, 1970) referred to Wundt as not only the founder of experimental psychology, but of psychology itself.

Yet, even with the development of Wundt's laboratory, "informed consent" remained irrelevant in experimental psychology. The introspective method championed by Wundt and his followers involved trained observers reporting upon simple mental processes they observed in themselves. Thus, the experimenters were their own subjects, rendering consent to participate a moot point.

With the rise of behaviorism, introspection gave way to more objective scientific observation in the laboratory and the field. While the concept of informed consent to participation now became applicable, little attention
was actually paid to obtaining it. A review of some of the major works on
the history of scientific psychology (Klein, 1970; Hearst, 1979; Reisman,
1976) yielded no references at all to the concept of informed consent.

As the incorporation of deception in psychological research
increased, the need for informed consent became more apparent.
Participation in research could no longer always be considered innocuous
and without risk. The “post-experimental stress disorder” experienced by
many of the participants in Milgram’s studies of obedience (1963) was of
concern to many professionals. Zimbardo (1975) stopped a simulated
prison experiment after only 6 of a planned 14 days, after several
instances of depression, extreme anxiety and psychosomatic illness
occurred in the subject group. Gradually, the concept of providing
potential subjects of psychological research an informed decision on
participation has gained ground both legally and in professional ethics.
The Belmont report (National Commission for the Protection of Human
Subjects of Biomedical and Behavioral Research, 1978) recommended
the provision of informed consent to participants in research. The Federal
Policy for the Protection of Human Subjects (U. S. Department of Health
and Human Services, 1991) implemented that recommendation as part of
Federal Law. The current version of the Ethical Principles of
Psychologists of the American Psychological Association (1989)
addresses the need for informed consent in research through Principle 9d.
“...The investigator informs the participants of all aspects of the research
that might reasonably be expected to influence willingness to participate
and explains all other aspects of the research about which the participants inquire" (American Psychological Association, 1989, p. 394). The upcoming revision of the "Principles" (American Psychological Association, in press) delineates this requirement even more clearly. Section 6.11(a), "Informed Consent to Research", specifies "Psychologists use language that is reasonably understandable to research participants in obtaining their appropriate informed consent."

A decade prior to the implementation of current Federal guidelines on informed consent, Kimmel (1979) noted with concern the steady increase in governmental regulation of human subjects research. The increasing expectancy that informed consent will be provided to potential subjects has been resisted by some researchers, especially those involved in research which utilizes deception. Several writers (Dill, Gilden, Peter, & Hanselka, 1982; Finney, 1987; Trice, 1987) have asserted that the provision of informed consent to participants, especially in studies of subject reaction to experimentally induced stressors, has a significant effect upon subject performance. Other authors (Wiener & Erker, 1986) contend that, in studies involving deception, results are unaffected by the provision of informed consent. Oliansky (1991) has argued that the use of deception itself is unethical and impractical in most research situations, while Christensen (1988) asserted that participants in studies involving deception didn't mind being deceived or having their privacy violated and actually enjoyed the research experience more than participants in non-deceptive research.
Trice (1986a) informed a group of student volunteers of a withdrawal-without-prejudice policy, a few days before a planned meeting. He found that significantly fewer members of this group showed up for the meeting and stayed for testing than subjects who were informed of the policy at the time of the meeting, immediately prior to testing.

Smith (1976) foresaw these difficulties and suggested that some research designs are incompatible with fully informed consent. Linsey (1984) suggested that it is the task of the profession to create new and innovative research designs which will allow for the protection of subjects' rights, including the provision of informed consent. Addressing this issue, Brod and Feinbloom (1990) designed a standardized verbal consent procedure which provided adequate information to geriatric subjects for a truly informed consent decision, while at the same time avoiding the high refusal rates often seen with geriatric subjects when written consent is required.

Overall, the provision of prior informed consent for both treatment and research participation has become the standard of practice, both ethically and legally. Actual professional behavior, however, may often fail to achieve that standard. Malcom (1988) has noted that many physicians consider the concept to be "an unworkable myth" (p. 59). In her doctoral dissertation, Witkin (1985) found that applied psychologists often decided to withhold information from therapy clients and had only a superficial awareness of the ethical ramifications of their actions. In a review of studies published in nine social psychology journals, Adair, Dushenko, and
Lindsay (1985) found that the proportion of studies that reported obtaining informed consent from subjects was negligible. While the Court, major professional organizations, and the public at large (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982) have the expectation that the autonomy of consumers will be respected through the provision of informed consent procedures, that expectation has yet to be fulfilled.

Informed Consent in the Treatment of Alcoholism

As noted above, provision of fully informed consent has been seen to be an ethical imperative in both the treatment of research subjects and the provision of clinical services. Pragmatic difficulties, however, are sometimes encountered in the application of this ethical and legal mandate. Complications may arise from idiosyncratic characteristics of certain subject or client populations. Chronic alcoholics constitute an example of a population with whom the provision of informed consent is potentially complicated by recipient characteristics.

Of the various therapeutic interventions offered to the public by the health-care community, inpatient/residential treatment for alcoholism is one of the most all-encompassing and psychologically intrusive. Such treatment incorporates psychotherapy, medical and pharmacological management, and behavior modification techniques to effect significant change in deeply embedded addictive behaviors. Participants are encouraged to adopt major, permanent changes in most aspects of their lifestyles. Programs usually provide treatment and supervision on a 24
hour basis for a period of a few weeks to several months in duration. The average length of stay in inpatient treatment has shortened in recent years, subsequent to reimbursement limitations imposed by third party payers. Inpatient treatment lasting only 21 days is rapidly becoming commonplace, although traditional 4 week programs abound. In consideration of the intensity and duration of this type of treatment, little question exists as to the ethical and legal imperative for the provision of informed consent to treatment.

Ironically, participation in this all-encompassing medico/psychological intervention is seldom truly voluntary. Patients often enter treatment as a result of court order, family pressure, or employer ultimatum. A commonly held opinion among addiction professionals is that no one enters treatment voluntarily, but that every patient has been "forced" into treatment by the environmental and personal results of their addictive behaviors. Thus, patients in alcoholism treatment can be considered to possess limited autonomy as a result of their prior addictive behaviors. As Dyer (1982) has noted, however, limited autonomy implies neither limited competency nor a limitation on the patient's right to self determination within the context of environmentally imposed constraints. The provision of informed consent to treatment, including an appraisal of the risks and benefits of both consent and refusal, would appear to be indicated in such cases of limited autonomy.

Valid informed consent consists of three elements: information, voluntariness, and competency (National Commission for the Protection of
Human Subjects of Biomedical and Behavioral Research, 1978).

Information, meaningful data presented to the patient, and competency, the ability of the patient to make a personally valid treatment decision, interact in the function of comprehension, the patient's understanding of proffered information. Limitations of rationality or cognitive complexity do not in themselves bespeak limitations in the patient's competency for treatment decisions (Dyer, 1982). They do, however, limit the patient's ability to understand consent information. If that information is presented in a manner which is unintelligible, or otherwise noncommunicative, to the patient, comprehension will be similarly limited and the consent process will lack validity. The mere presentation of a consent form, with no provisions to insure comprehension of the information by the patient, may constitute no more than a legalistic exercise (Brady, 1979). In a survey of adult patients in a chemical dependency treatment program, Mills (1990) found not only that recall for the content of consent forms was poor, but that approximately half of the respondents reported never reading the forms in the first place. Levine (1984) has asserted that the principle of distributive justice requires that special protection be provided to those who are relatively incapable of protecting their own interests in the informed consent process. He suggests that comprehension of consent information can be increased by either limiting the subject pool to the most intelligent or by introducing procedures to enhance the comprehensibility of consent information. Limitation of subject pool is not a viable option, however, in the treatment setting. Therefore, enhancement of
comprehensibility of consent information would appear to be the appropriate means to increase comprehension in situations in which a significant proportion of the subjects (or patients) experience a limitation of their ability to understand customarily presented information.

Cognitive Impairment in Chronic Alcoholics

There is evidence that alcoholics in treatment constitute a population who, because of their higher than average potential for cognitive impairment, could experience difficulty in comprehending consent information as customarily provided.


Impairment in short term visual memory has been noted by several researchers (Donat, 1986; Markowitsch, Kessler, & Denzler, 1986; Ryan & Lewis, 1988; Salmon, Butters, & Schuckit, 1986). While some authors assert that similar deficits in short term verbal memory are apparent
(Cermak, 1987; Ryan & Lewis, 1988), most (Butters & Brandt, 1985; Donat, 1986; Grant, Adams, & Reed, 1979) suggest that verbal encoding remains resistant to change and that findings of impaired short term verbal memory in chronic alcoholics are confounded by factors of cognitive clouding and visuointegrative compromise.

Alcoholism treatment programs usually begin with a short, 2-3 day, detoxification period for most patients (McCready, 1987). Informed consent is seldom requested from acutely intoxicated individuals because of the obvious disruption of cognitive processes during intoxication. The acutely intoxicated patient experiences confusion (Lex, Greenwald, Lukas, & Slater, 1988) and significantly impaired short term memory (Mello, 1973), including both registration and recall.

During the withdrawal period, patients experience clouding of the sensorium, disturbance of consciousness, anxiety, mood disturbances, and various somatic symptoms (Gross & Lewis, 1973).

Malloy, Noel, Rogers, Longabaugh, and Beattie (1989) have noted the negative treatment implications of severe neuropsychological impairment and have suggested that in such cases early placement in a supervised living setting may be more efficacious than intensive substance abuse treatment. For the majority of patients, however, the degree of neuropsychological impairment experienced serves to handicap, rather than to eliminate, their capacity to benefit from treatment. Most treatment programs wait until the patient has progressed beyond the initial detoxification period before initiation of the formal informed consent
process for the full treatment regimen. It is questionable, however, that the patient is able at this point to adequately comprehend customarily presented consent information. While the overt signs of acute intoxication are no longer apparent during the immediate post detoxification period, the data strongly suggest that chronic alcoholics at this stage are experiencing severe compromise of cognitive function (Claiborne & Greene, 1981; Parsons, 1987a, 1987b). Vocabulary level does not appear deteriorated (Goldman, 1987), a finding which may explain the appearance of reading in the absence of true comprehension. Clouding of consciousness, concentration difficulties, visuoperceptual impairment, visual and verbal learning impairments, and memory defects may all be experienced by the recently detoxified chronic alcoholic (Ellenberg, Rosenbaum, Goldman, & Whitman, 1980; Kish, Hagen, Woody, & Harvey, 1980). Ellenberg and associates suggest that both verbal and visuospatial learning evidence significant recovery within two weeks, although visuospatial impairment may last longer in long term alcoholics. Within three weeks, Kish and associates note recovery of function in short term memory and attention, visuospatial analysis/synthesis, abstract thinking, visual memory, and serialization ability. Goldman (1983) states that deficits in verbal learning appear to remit as early as one month after detoxification, although Yohman, Parsons, and Leber (1985) found significant differences between alcoholics and controls on verbal, abstracting/problem solving, and perceptual motor tasks at seven weeks after detoxification. At 13 months they noted no difference between controls and alcoholics on verbal tasks.
Brandt, Butters, Ryan, and Bayog (1983) similarly found performance on several tests of neuropsychological function to be significantly better for alcoholics with long term sobriety (> 5 years) than for those with intermediate (1-3 years) and short-term (1-2 months) sobriety.

Although several authors have noted some recovery over time of cognitive function in abstinent alcoholics, provision of a protracted (2-4 week) detoxification period prior to the initiation of the consent process is not a workable option for alcoholism treatment centers. Neither is limiting services to alcoholics who have been sober for one month prior to entering treatment. A viable alternative, therefore, would appear to be modification of informed consent procedures in order to enhance comprehension of salient information by prospective patients, despite their potential cognitive limitations.

Comprehension of Consent Information

Written Consent Forms

Perhaps as a response to ever-increasing documentation requirements in both research and treatment settings, utilization of a written consent form, containing an enumeration of salient information along with a signature line upon which the subject/patient may indicate consent, has become standard practice. Often, however, signatories do not understand major portions of that to which they have consented (O'Connor, 1981; Silva & Sorrell, 1984, 1988). Several stimulus variables affect the comprehensibility of these forms, especially as administered to recently
detoxified alcoholics, including: vocabulary difficulty, familiarity, readability, textual coherence, schema, and redundancy.

The most basic variable affecting text comprehensibility is vocabulary difficulty. If readers are unaware of the meaning of constituent words, they are less likely to understand the attempted communication. Comprehension does not manifest a simple inverse proportionality to vocabulary difficulty, however. While word understanding is important for text understanding, simplifying vocabulary significantly below a reader's functional level does not necessarily increase comprehensibility over text written at his or her vocabulary level. For example, for a subject with a seventh grade vocabulary, text written with a second grade vocabulary would not necessarily be more comprehensible (i.e., would not more effectively communicate information) than text written with a sixth grade vocabulary. In fact, such oversimplification of wording could diminish the complexity of information communicated. Additionally, vocabulary simplification would not appear to differentially enhance comprehension by chronic alcoholics, as compared to normals, since vocabulary function appears resistant to compromise in long-term drinkers (Goldman, 1987).

Freebody and Anderson (1983) point out that familiarity accounts for almost three times as much variance in comprehension as vocabulary level. If the concepts presented in the text have been encountered before, the reader is likely to manifest a higher level of understanding than when confronted with unfamiliar concepts and terminology. While it is not possible in the clinical setting to control for prior exposure to consent-to-
treatment information, it is possible to avoid specialized terminology and parochial usage of otherwise familiar phrases. As with vocabulary, differential enhancement of understanding for chronic alcoholics would not be expected.

"Readability" has often been seen as a function of word length (in syllables), sentence length, and word familiarity. Several studies (e.g., Baker & Taub, 1983; Grundner, 1980; Morrow, 1980) have substantiated the high level of reading difficulty presented by typical informed consent forms utilized in the provision of health services and health research. Eaton and Holloway (1980) observed increased comprehension of patient information materials written at a fifth grade reading level as compared to materials written at a tenth grade level. Similarly, Tymchuk, Ouslander, and Rader (1986) found that comprehension by elderly subjects of a list of client rights was significantly higher for a simplified written version than for the version of standard difficulty.

Anderson and Armbruster (1986) assert that the "textual coherence" of written communication is the most important contributor to comprehensibility. Emphasizing the structural aspects of text, they suggest that by presentation of data within commonly accepted and familiar structural formats (e.g., listings, comparisons, temporal sequences, cause/effect relationships, etc.) comprehension is enhanced. Explicitly "signaling the structure" (p. 155) is suggested, including introductory statements, summary statements, pointer words, and textual cues, such as underlining. Clarification of structure would appear to be
especially beneficial to the cognitively clouded, recently detoxified alcoholic.

Another important characteristic of comprehensible text is the early presentation of a "schema": a meaningful context for the facts presented subsequently. Wilson and Anderson (1986) suggest that a schema is a conceptual structure that provides "slots that can be instantiated with specific information from a text" (p. 33). In the absence of a meaningful conceptual framework, the text presents merely "data" which only becomes comprehensible information as a meaningful interrelationship is developed by the reader. The clouded consciousness and impaired concentration experienced by recently detoxified alcoholics (Ellenberg et al., 1980; Oscar-Berman, 1987; Kish et al., 1980) reduce the ability of these readers to independently derive schema. Initial, clear presentation of schema would, therefore, appear to enhance comprehensibility of text for all readers, but especially for cognitively impaired, recently detoxified alcoholics.

Several theorists (Just & Carpenter, 1980; LaBerge & Samuels, 1974; Miller & Kintsch, 1980) emphasize that immediate memory capacity is a major determinant of text comprehension. Schwartz (1984) has suggested that poor readers have difficulty maintaining information in short-term memory. An implication of these findings is that strategies which facilitate immediate memory function may enhance comprehension. Adams (1982) offers tangential support of this concept by noting that highly coherent text offers many more sources of redundancy than less
coherent text. As has been indicated previously, attention and immediate
memory function often appear impaired in recently detoxified alcoholics.
Provision of multilevel redundancy of information in consent procedures
may increase comprehension for this population.

One method which provides redundancy is repeated exposure to the
same material. Miller and Willner (1974) suggested that subsequent to
reading the consent information, patients complete a short quiz on its
content. If answers to the quiz demonstrated an inadequate
comprehension of the material, remedial action could be taken, including
discussing the missed items with the subject or requiring them to reread
the consent form. Taub and Baker (1983) utilized the second option in
their study of the effect of repeated testing upon the comprehension of
informed consent materials by elderly subjects. Essentially a mastery
level teaching paradigm, each subject read a sheet of consent information,
then completed a short quiz. If any quiz items were missed, the subject
was tutored on the answers to those particular items and the quiz was
subsequently readministered. If the subject again missed any items, the
process was repeated. If after three administrations of the information
sheet the subject still was unable to answer all quiz items correctly, he or
she was considered to be unable to understand the information presented.
They found that this multtrial approach was effective in increasing
comprehension of informed consent information in elderly volunteers.
Congruent with earlier work (Taub, Kline, and Baker, 1981), it was noted
that while comprehension was enhanced for subjects at all levels of
vocabulary proficiency, subjects with higher fluency evidenced higher comprehension than those with lower fluency.

The method of repeated administration appears effective in increasing memory for presented material, however it does not address the comprehensibility, as such, of the initial presentation of consent information. Taub and Baker (1983) admit that test repetition measures "rote learning rather than actual understanding (p. 137), but point out that it is doubtful that subjects are "capable of providing informed consent if they cannot find the correct answers after repeated testing and feedback." A major drawback of this technique in the clinical setting, however, is the considerable amount of staff and patient time involved in repeated administration and testing.

**Video Presentation**

Another potentially effective method of presentation of consent information is video. Similar to printed consent forms, videotaped presentation is standardized across subjects and requires much less staff time than individual tutorial sessions. Through the use of videotaped lectures/presentations, salient information can be presented audibly to subjects, avoiding the potentially confounding effects of reading impairments.

Although video presentation would appear to potentially enhance comprehension of consent information in poor readers, and thereby increase overall comprehension in an impaired population, Tymchuk, Ouslander, and Rader (1986) found that video presentation alone did not
significantly differ in effectiveness from standard written text presentation of Patient Rights information for a normal elderly population. The implication of their findings was that a change in presentation format, from print to video, did little to increase comprehension, notwithstanding the circumvention of any impediment to understanding caused by impaired reading abilities. Their findings may not be generalizable to recently detoxified, nonelderly, alcoholics, however. While some researchers have likened the cognitive impairments experienced by chronic alcoholics to those found in an elderly population (the "premature aging theory"; Markowitsch, Kessler, and Denzler, 1986), most have recognized the cognitive impairments which accompany chronic alcohol abuse to be more numerous and of greater severity than the concomitants of normal aging (Svanum and Schladenhauffen, 1986).

Barbour and Blumenkrantz (1978) asserted that when presented in addition to the standard written consent form, an informative videotape facilitated the achievement by patients of an adequate level of understanding of consent information. Such an additive presentation afforded not only substantial redundancy of exposure but also communicated an enhancement of meaningful structure into which the pertinent consent data could be fit.
PURPOSE

Rationale for Present Study

It appears that chronic alcoholics would benefit from many of the same modifications of standard informed consent presentations as the normal population, including simplified vocabulary level, avoidance of jargon, and enhanced readability. Presentation of the information in a meaningful context, utilizing commonly understood structural forms, would be seen as an effective aid to comprehension for all subjects, but especially for those experiencing some degree of cognitive clouding.

In consideration of the significant impairment of attention, concentration, and short term memory which has been noted in recently detoxified alcoholics, it is suggested that an increase in information redundancy would significantly increase comprehension of consent information in that subject group. To test this, a sample of chronic alcoholics recently admitted to treatment was presented with standard research consent information, varying among subjects in the amount of redundancy of salient information.

The emergence of the written consent form as the primary mode of consent information presentation occurred prior to the development and proliferation of video cassette recording. This new technology allows presentation of consent information in a manner which more closely approximates the ideal of a face to face tutorial than the standard written consent form. Video presentation can provide the image of a presenter along with the personalizing touch of a human voice. Additionally, video
lecture presentation of consent information eliminates the potential confounding effect of impaired reading ability in subjects. To test the effect of presentation mode upon comprehension of consent information, information was presented in two formats: a printed consent form and a videotaped lecture. Level of information redundancy varied as follows:

1. Simple informed consent presented.
2. Informed consent with enhanced redundancy presented.

The printed consent form was written at the seventh grade reading level, utilized familiar structural formats in order to enhance textual coherence, and avoided the use of jargon and specialized terminology. Two levels of written consent information were utilized:

1) Simple written consent information.
2) Simple written consent information with an illustrative elaboration following each element of consent information.

The video conditions consisted of short presentations in which the presenter answered questions from an off-camera voice by stating verbatim elements of consent information from the printed form. Two levels of video consent information were presented:

1) Simple video consent information.
2) Simple video consent information with an illustrative elaboration following each element of consent information.

This study was a 2 X 2 complete factorial experiment (format [printed, video] X redundancy [single, enhanced]) with equal cell size. A
randomized group design was used, with 20 participants for each treatment. (See Figure 1.).

Subsequent to presentation of the experimental level and type of consent information, subjects completed a short written quiz to assess their comprehension of the information.

**Figure 1. Experimental design**
The content of the basic elements of informed consent presented in the various formats and levels of redundancy fulfilled all pertinent ethical and statutory requirements, including regulations promulgated by the U. S. Department of Health and Human Services (1991, pp. 28016-28017). While the actual consent information presented pertained to the proposed research study, and not to the chemical dependency treatment experience itself, it is felt that the findings of this study will generalize readily to the presentation of both research and clinical consent information and will help both researchers and clinicians design more efficient and effective consent procedures for cognitively impaired individuals.

Hypotheses

The following hypotheses were advanced:

**Hypothesis 1:** Enhanced redundancy of presented information will result in a higher level of comprehension of the material, as reflected in a higher score on the Comprehension Quiz, than unitary presentation of the information (Simple condition).

**Hypothesis 2:** Video presentation of the stimulus information will result in a higher level of comprehension of the material, as reflected in a higher score on the Comprehension Quiz, than presentation via a printed format.

**Hypothesis 3:** Enhanced redundancy of presented information will result in a higher level of recall of the material, as reflected in a higher score on the Comprehension Posttest, than unitary presentation of the information (Simple condition).
Hypothesis 4: Video presentation of the stimulus information will result in a higher level of recall of the material, as reflected in a higher score on the Comprehension Posttest, than presentation via a printed format.
METHOD

Subjects

The stimulus conditions were presented to a total of 105 subjects. Of that number, 12 declined without comment to continue after reading or viewing the consent information. Another 4 subjects terminated participation, stating that they felt the process would take up too much of their time. Three subjects quit without comment after beginning the Questionnaire. One subject quit when he discovered that he was unable to read the Questionnaire.

Of the remaining 85 subjects, 3 were deleted from the study because of WRAT-R reading subtest scores below the seventh grade level. In order to balance cells for gender, one Simple Video female subject and one Enhanced Printed male subject were randomly deleted from the study, leaving 4 equal cells of 20 subjects each, with 15 males and 5 females in each cell.

Sixty males and twenty females were included in the data set, with a mean age of 29.91 (s.d. = 7.99), a mean level of educational attainment of 12.68 years (s.d. = 1.99, when attainment of a G. E. D. is held equivalent to high school graduation) and a mean reading level of second semester of 11th grade.

Volunteers were recruited from among clients in their first 21 days of inpatient or intensive outpatient treatment for alcohol, or alcohol and other drug, dependency. All volunteers were enrolled in treatment at one of five
Central Iowa chemical dependency treatment programs (Appendix G)
Subjects were 18 to 53 years old, inclusive, had maintained at least 72 hours of continuous sobriety prior to participation, and had completed any pharmacologically based detoxification prior to participation. Subjects with significant hearing loss or visual impairment were excluded from participation. Information on hearing loss and visual impairment was obtained both informally from the subject and from medical records available in the treatment setting. Demographic information for the sample is presented in Tables 1 and 2.

Subjects were seen either individually or in a small group setting for testing, which lasted a half hour or less. The stimulus/testing paradigm was essentially administered individually, even in the small group setting. Administration of the stimulus and the testing procedures were identical in both individual and group administrations. No interaction among subjects occurred during the sessions.

Research (Taub, 1979; Taub, Kline, & Baker, 1981) suggests individual vocabulary facility and years of education to be potent variables in predicting subject comprehension of informed consent material. Taub, Kline, & Baker (1981) have asserted that those with low vocabulary and little education may require special methods of informed consent. Potential subjects in this study were screened to assess their level of vocabulary function. All participants were administered the Reading subtest of the Wide Range Achievement Test - Revised (WRAT-R) (Jastak & Wilkinson, 1984). Since the stimulus material was written at the
Table 1. Age of subjects

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Mean 29.91  Median 29.00
Mode 29.00  Std dev 7.99
Minimum 18.00  Maximum 53.00
Table 2. Years of formal education of subjects

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<td>13.8</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
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</tbody>
</table>

Mean 12.68
Mode 12.00
Median 12.00
Std dev 1.99
Maximum 16.00

\(^a\) Actual years of formal education completed are listed for the 17 subjects who earned a G.E.D.

seventh grade level of difficulty, subjects scoring below seventh grade reading proficiency were excluded from the study.

Similarly, subjects were asked their level of educational attainment. Those subjects who had completed fewer than 7 grades of formal education, not including special programming for learning impaired students, were excluded from the study. (Completion of a certificate of
General Educational Development was considered the equivalent of 12 years of formal education.

Stanley, Guido, Stanley, and Shortell (1984) found that elderly patients (62 years of age and older) demonstrated significantly poorer comprehension of consent information than a younger (average age = 33.7 years) sample of patients. They concluded that geriatric patients may exhibit some impairment in their competency to give informed consent. Similar results were obtained by Taub, Baker, and Sturr (1986) who noted that comprehension of informed consent material seemed to vary directly with education and inversely with age. They noted an especially low comprehension rate among elderly patients with little education. In order to control for the effects of age on assessed comprehension in the current study, participation was limited to clients aged 18 to 61 years, inclusive.

Procedure

Overview

All subjects were presented with consent information about the study through one of the four stimulus conditions: Simple Printed (SP), Simple Video (SV), Enhanced Printed (EP), or Enhanced Video (EV). Each subject then completed a short demographic questionnaire, a quiz over the content of the consent information, and was administered the Reading subtest of the WRAT-R. One week later, subjects were again administered the quiz over the content of the consent information.
Randomization of Condition

Subjects were assigned to treatment conditions through the use of a random drawing procedure. Tokens of identical size and shape were marked to indicate each of the specific treatment conditions. Twenty tokens of each condition were placed into an envelope marked "Males", yielding a total of 80 tokens in the container. An additional twenty tokens of each condition were placed into an envelope marked "Females". After each subject's initial agreement to participate in the study, the experimenter drew a token from the container marked with their gender in order to determine treatment assignment. In the case of group administration, the experimenter drew a token from the container marked with the gender of the majority of the group. (Subsequent to each testing session, contents of each container were adjusted to accurately reflect remaining subjects needed.) After the initial 80 subjects had been tested, groups were not balanced for gender. At that time, a determination was made as to the additional subjects needed, by gender and treatment category, to achieve balance. These additional subjects were then assigned to treatments as available.

Staffing

Initial testing sessions were facilitated by the primary investigator. One-week posttests were administered by the primary investigator in the majority of cases. The only exceptions were for subjects who participated at the Center for Addictions Recovery and the Mid-Eastern Council on Chemical Abuse. For subjects at those locations, posttests were
administered by staff counselors at the end of regularly scheduled counseling sessions. The staff counselors who administered the posttests did not have access to the information contained therein. Completed quiz sheets were immediately inserted into manila envelopes and put aside for pickup by the primary investigator.

Stimulus Materials

Each stimulus condition included 25 items of salient information about the study, for a total of 30 possible units of information (some items contained more than one unit of information). Each item began with a heading statement, phrased as a question in the first person. The text of the item itself was phrased as an answer to the heading question. Content of the consent stimuli was congruent with applicable federal, professional, and Iowa State University requirements. (For a detailed description of the rationale for item inclusion, please refer to Appendix H.)

Description of Printed Consent Information

Printed consent information was presented at two levels of redundancy: simple and enhanced.

Simple printed information.

The simple printed information condition utilized five pages of standard consent information (Appendix I) printed at 10 characters per inch with a Courier font. The information form was written at a seventh grade level of reading difficulty, as assessed by both the Fry Readability Scale (Fry, 1968, Spadaro, Robinson, & Smith, 1980) and the Flesch Readability Formula (Flesch, 1948, 1974), as outlined in Appendix J. Grundner (1978,
1980) has asserted that these formulas are particularly well suited for use in analysis of the readability of consent forms.

Enhanced printed information.

The enhanced printed information condition utilized seven pages of consent information, printed in the same size and font as the simple condition (Appendix K). Content differed only in the addition of an illustrative elaboration after each element of consent information. As with the simple condition, text was written at the seventh grade level of reading difficulty.

Description of Video Consent Information

Video consent information was presented at two levels of redundancy: simple and enhanced.

Simple video information.

The simple video information condition utilized a short videotaped presentation of a female spokesperson. The spokesperson was unaware of the nature or hypotheses of the study. A male off-camera voice read the topic headings as questions. The spokesperson responded with essentially a verbatim rendering of the topic content found in the print version of the information sheet for the "Simple" condition, changing only a few words, in order to reflect viewing, rather than reading, the material (see Appendix L).

Enhanced video information.

The enhanced video information condition utilized a similar videotaped presentation of the spokesperson, dressed identically. A male off-camera
voice read the topic headings as questions. The spokesperson responded with essentially a verbatim rendering of the topic content found in the print version of the information sheet for the "Enhanced" condition, changing only a few words, in order to reflect viewing, rather than reading, the material (see Appendix M).

Videotaped presentations were in full color, recorded on VHS HQ format at standard speed, and presented using a full-sized television screen. Care was taken to assure that all participating subjects were able to clearly see and hear the taped presentation.

**Production of video stimuli.**

The scripts for each of the two video taped presentations were essentially verbatim reproductions of the corresponding printed versions. The only difference in content consisted of slight wording changes to reflect watching and listening to the stimulus, rather than reading it. An off-camera male voice read the section headings, each of which was in the form of a question (e. g., "What is the nature of this study?"), and the on-camera presenter stated the explanatory response (e. g., "The nature of this study is research.").

A total of 34 sample videotaped presentations were initially produced; 17 for each condition. Videos were recorded in full color on standard 1/2" VHS format using a combination camera/videocassette recorder. The distribution of the initial video presentations was as follows:

- **Male presenter #1:** 5 simple versions, 5 enhanced versions
- **Male presenter #2:** 3 simple versions, 3 enhanced versions
Female presenter #1: 6 simple versions, 6 enhanced versions
Female presenter #2: 3 simple versions, 3 enhanced versions

The sample videotapes were then reviewed by a certified media specialist, a doctoral level psychologist, and the experimenter. Tapes were subjectively rated on clarity of presentation, accuracy of presentation, and freedom from distraction. By consensus, two tapes by female presenter #1 were chosen as the most acceptable presentations of the two consent information scripts.

The length of the Simple Video presentation was 233 seconds. The Enhanced Video presentation lasted 364 seconds.

**Individualized Treatment**

Treatments were administered on either an individual basis or within a small group (2 - 5 persons). Even in the small group setting, however, administration of the stimulus and the testing was essentially individual. Subsequent to the provision of orientation information and an opportunity to agree to or decline participation (see below), subjects were randomly assigned to one of the four treatment conditions.

**Informed Consent Procedures**

Inasmuch as all experimental treatments were presentations of consent information, subjects in this study received full consent information along with an opportunity to agree to or decline participation, prior to administration of test protocols. Because informed consent is itself the treatment of study, however, the provision of full consent information prior to the administration of the experimental treatments would confound
the results of post-treatment testing. Yet, involvement of subjects in experimental treatment prior to being given the opportunity to make an informed choice regarding participation appears to violate clear ethical guidelines.

Benjamin Freedman (1982) defined "ignorant consent" as "that offered under less information than that used by the reasonable person in arriving at a decision" (p. 4). He suggested that, in certain circumstances, such consent could be valid, although he failed to delineate the parameters of those circumstances. In order to address this problem in a manner which would satisfy ethical requirements yet have little or no impact upon test results, orientation information was read to all potential subjects at the beginning of each meeting. The orientation statement provided a basic description of the study and allowed potential subjects an opportunity to make an initial decision to participate or not, based upon minimally adequate information.

Individuals were read the following orientation statement:

"We are conducting a study on communication with people in treatment for alcohol abuse or dependency. If you decide to participate, you will be provided some information. Then you will be asked to answer some questions. A week from today, you'll be asked to answer a few more short questions. After you finish, you will be provided with detailed information about the study. I will need your written permission to include you in the study and I will not collect any materials from you until I receive your written permission."
"In order to participate in this study you must be 18 to 61 years old, inclusive, in treatment for alcohol abuse or dependency, and you must have been sober for at least the last 72 hours. Also, you must not be currently taking any medication, other than vitamin supplements, to aid in detoxification.

"We appreciate you listening to this information. If you do not wish to participate, please say so now. If you would like to help, we will begin in a few minutes."

Information presented during the initial orientation was not included in the data tested for during the assessment phase. It is felt that the information provided at this stage was enough to allow a "reasonable person" to make a decision upon further participation, especially with the knowledge that their data would only be used after they had given their written permission. Subsequent to the presentation of orientation information and the provision of an opportunity to decline to participate, subjects were randomly assigned to treatment conditions. After presentation of the experimental treatment, subjects were again given the choice to participate or decline, and were requested to sign a consent sheet (Appendices N & O) before testing.

The information presented to all subjects after completion of the delayed testing phase consisted of a printed description of the study (Appendix P) along with an open-ended question and answer session.
Measures

Initial Assessment of Informed Consent Comprehension

Taub, Baker, Kline, and Sturr (1987) suggest that subjects should retain access to the consent information during testing. Otherwise, they assert, assessment results will reflect recall, not comprehension. While it is recognized that short term recall can be a confounding element in this type of comprehension assessment, it is argued that the short recall interval involved in immediate post-exposure testing does not significantly interfere in the assessment of functional comprehension. By necessity, informed consent is a process which requires holistic comprehension. Agreement, or refusal, to participate is given after an adequate understanding of a body of salient information is obtained, not given serially upon understanding of each of the component parts. Sequential comprehension of individual components of information, in the absence of an ability to appreciate the whole, is inadequate for valid consent. Consequently, recall was considered to be an integral part of comprehension, for the purposes of this study. Subjects were administered the Questionnaire and Informed Consent Quiz (Appendix Q) immediately after exposure to the experimental condition (i.e., immediately after exposure to consent information). Because the intent of the Informed Consent Quiz was to assess comprehension, and not merely rote recall, a short answer format was used, rather than multiple choice. Each test item consisted of a topic heading from the Information Sheet. (All topic headings on the information sheet were written in the form of a question.)
There were 25 items, for a total of 30 possible points (some items were multi-point).

Each subject was given a copy of the Informed Consent Quiz. The following instructions were read by the facilitator:

"Please write your name and the requested information in the space provided on the first page only. When you're done with the questions on the first page, please stop and look up."

After the subject completed the first page (which was the demographic questionnaire) the tester read the following statement, "This quiz will ask you several questions about this very study that we're doing today. Each question is followed by a space in which you may write the answer. Please answer each question.

"You will have up to 15 minutes to answer these questions. I'll tell you when the time is up. Ready? Begin."

After the subject completed the quiz, or after the 15 minute testing period had elapsed, the facilitator asked the subject to place the Informed Consent Quiz protocol aside, making sure that he or she had provided the identifying information requested at the beginning of the questionnaire.

Protocols were assigned temporary subject numbers, and the demographic questionnaire sections of each protocol were detached from the body of the tests prior to scoring. Tests were scored utilizing the Informed Consent Quiz Answer Key (Appendix R). Responses which were substantially similar in content to the answer given in the Key were considered correct.
In order to calculate interscorer reliability, 30 test protocols, selected at random, were scored by both the primary investigator and an associate, utilizing the Answer Key. The associate was blind to the hypotheses of the study and was unaware of the results of the investigator's scoring of the sample protocols. Interscorer reliability was calculated to be .9836 ($p < .01$, 2-tailed). As a result of the high degree of interrater reliability, the primary investigator, blind to experimental condition, acted as scorer for the comprehension instrument administered to all subjects.

The tests were initially scored by the primary investigator and the initial, temporary scores were recorded. To enhance accuracy of scoring, the tests were rescored one week later. At that point, final scores were recorded for the protocols.

Assessment of Vocabulary Function

Immediately after completion of the Informed Consent Quiz, subjects were administered the Reading subtest of the Wide Range Achievement Test - Revised (WRAT-R, Jastak & Wilkinson, 1984), a task involving recognizing and naming letters and pronouncing words of increasing difficulty out of context. This WRAT-R yields a score which was converted to a grade level rating for the purpose of eligibility determination. The score was converted to a standard score for purposes of comparison and analysis.

Delayed Assessment of Informed Consent Comprehension

Seven days after the initial exposure to the experimental treatment, subjects met again with the facilitator or a staff person for retesting. They
were again administered the Informed Consent Quiz, with the facilitator following essentially identical procedures. Subsequent to completion of the retesting procedure, subjects were given a printed descriptive summary of the study along with the opportunity to ask the facilitator any questions about the study. Subjects were given the opportunity to request copies of the results upon completion of the study.

Data Analysis

Design

This study is a 2 X 2 complete factorial experiment (redundancy [single, enhanced] X format [printed, video]) with equal cell size. A randomized group design was used, with 20 participants for each treatment. Because of the randomized assignment of subjects to treatment conditions, a significant cohort effect was not expected. The dependent variables of interest in this study were the scores on the initial Comprehension Quiz and the Posttest.

Since treatment levels of redundancy and format were not selected randomly, a fixed-effect analysis of variance (ANOVA) was used to test the significance of the effects of both treatment variables on initial comprehension. A similar ANOVA was planned to examine the effects of the treatment variables upon delayed performance. As will be noted, however, not enough posttests were completed to allow analysis for one-week recall. Appropriate descriptive statistics regarding obtained demographic data are provided.
To provide further insight into the relationship among cognitive function, demographic variables, and comprehension, several relationships were examined, including those: between initial test scores and posttest scores, between score on the WRAT-R Reading subtest and performance on the comprehension test, between age and performance on the comprehension test, between gender and performance on the comprehension test, and between educational level and performance on the comprehension test.

Data analysis was performed on an Apple Macintosh Classic II computer with an Applied Engineering 68882 floating-point math coprocessor installed. The software packages utilized were SPSS, Version 4.0 (SPSS, 1990a) and SPSS Advanced Statistics (SPSS, 1990b).

This research was approved by the Iowa State University Human Subjects Review Committee.
RESULTS

Preliminary Analyses

Power Analysis

A power analysis of the ANOVA design, a 2 X 2 complete factorial experiment with 20 subjects in each cell, was undertaken, utilizing the master table found in Kraemer & Thiemann's (1987) informative work on statistical power analysis in research. The results indicated a power (5% level, 2-tailed) of 99% for a large effect size (.80 s.d.) and a power of 65% for a moderate effect size (.50 s.d.).

Internal Consistency of the Test

Cronbach's alpha, a measure based upon the internal consistency of the test items, was calculated at $\alpha = .74$.

Effect of Gender upon Comprehension Scores

An analysis of variance was performed to ascertain the effect of gender upon initial comprehension scores (Table 3). No significant effect [$F(1,78) = 1.60, p = .21$] was noted. Analyses were, therefore, collapsed across gender.

Inferential Analyses

Immediate Comprehension

Hypothesis Testing

An analysis of variance was performed to determine the effects of the two independent variables of primary concern (redundancy and format) upon initial comprehension score (Table 4). Results of the analysis showed no significant effect from Redundancy [$F(1, 76) = .09, p \leq .77$],
Table 3. Analysis of variance of comprehension score by gender

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>d.f.</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>22.82</td>
<td>1</td>
<td>22.82</td>
<td>1.60</td>
<td>.21</td>
</tr>
<tr>
<td>Within Groups</td>
<td>1113.13</td>
<td>78</td>
<td>14.27</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Format $[F(1, 76) = 1.11, p < .30]$, or an interaction of the two variables $[F(1, 76) = .88, p < .35]$. Neither Hypothesis 1 (Enhanced redundancy of presented information will result in a higher level of comprehension of the material, as reflected in a higher score on the Comprehension Quiz, than unitary presentation of the information ) nor Hypothesis 2 (Video presentation of the stimulus information will result in a higher level of comprehension of the material, as reflected in a higher score on the Comprehension Quiz, than presentation via a printed format.) was supported by the results of the analysis.
Table 4. Analysis of Variance of comprehension score by redundancy by format

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>DF</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Effects</td>
<td>17.45</td>
<td>2</td>
<td>8.73</td>
<td>.60</td>
<td>.55</td>
</tr>
<tr>
<td>REDUNDANCY</td>
<td>1.25</td>
<td>1</td>
<td>1.25</td>
<td>.09</td>
<td>.77</td>
</tr>
<tr>
<td>FORMAT</td>
<td>16.20</td>
<td>1</td>
<td>16.20</td>
<td>1.11</td>
<td>.30</td>
</tr>
<tr>
<td>2-Way Interactions</td>
<td>12.80</td>
<td>1</td>
<td>12.80</td>
<td>.88</td>
<td>.35</td>
</tr>
<tr>
<td>REDUNDANCY X FORMAT</td>
<td>12.80</td>
<td>1</td>
<td>12.80</td>
<td>.88</td>
<td>.35</td>
</tr>
<tr>
<td>Explained</td>
<td>30.25</td>
<td>3</td>
<td>10.08</td>
<td>.69</td>
<td>.56</td>
</tr>
<tr>
<td>Residual</td>
<td>1105.70</td>
<td>76</td>
<td>14.55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1135.95</td>
<td>79</td>
<td>14.38</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Comparison of Scores by Site of Administration**

Subject data were collected at five different treatment centers in the state of Iowa (Appendix G). A one-way analysis of variance of the effect of site upon initial comprehension test score (Table 5) indicated inequality of population means ($F(4, 75) = 3.39, p < .01$). In order to identify the significant differences among population means, a Scheffé multiple comparison procedure was used. The Scheffé procedure is conservative for pairwise comparisons of means and requires larger differences between means for significance than most of the other methods (Gravetter & Wallnau, 1988). The results of the Scheffé procedure suggest a significant difference between the population means of site 3 (CFARI) and site 5 (MECCA). Three subjects were tested at site 5, yielding the highest mean test result of the 5 sites. The mean test result for site 5 was 7.67 points (2.52 s.d.) above the mean test result for site 3, the lowest mean. The mean score for site 5 was 5.92 points (1.79 s.d.) above the mean test result for site 2, the second highest mean score.

In order to examine the potential effect upon the overall analysis of the data by the three site 5 scores, a revised data set of 77 subjects was created which did not include the site 5 scores. An analysis of variance was performed to determine the effects of the two independent variables of primary concern (redundancy and format) upon initial comprehension score (Table 6). Results of this analysis were equivalent to the results of the ANOVA performed upon the entire 80 subject data set. The decision
Table 5. Analysis of variance of comprehension score by site of administration

<table>
<thead>
<tr>
<th>SOURCE</th>
<th>D.F.</th>
<th>SUM OF SQUARES</th>
<th>MEAN SQUARES</th>
<th>F RATIO</th>
<th>F PROB.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BETWEEN GROUPS</td>
<td>4</td>
<td>173.93</td>
<td>43.48</td>
<td>3.39</td>
<td>.01</td>
</tr>
<tr>
<td>WITHIN GROUPS</td>
<td>75</td>
<td>962.02</td>
<td>12.83</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>79</td>
<td>1135.95</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FREQUENCY OF TREATMENT TYPE BY SITE OF ADMINISTRATION

| S     | S | E | E | T | P | V | P | V | T | R | D | R | D | T | O | T | O | T | O | T | O | T | O | T | O |
| Mean  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 17.00a | SITE 3 | 8 | 15 | 1 | 5 | 29 |
| 18.33 | SITE 4 | 0 | 0 | 0 | 3 | 3 |
| 18.54 | SITE 1 | 9 | 5 | 11 | 12 | 37 |
| 18.75 | SITE 2 | 1 | 0 | 7 | 0 | 8 |
| 24.67a | SITE 5 | 2 | 0 | 1 | 0 | 3 |
| TOTAL | 20 | 20 | 20 | 20 | 80 |

aScheffé multiple comparison procedure indicates sites 3 and 5 significantly different at the .05 level.
Table 6. Analysis of Variance of comprehension score by redundancy by format, eliminating data from site #5

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>DF</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REDUNDANCY</td>
<td>.06</td>
<td>1</td>
<td>.06</td>
<td>.01</td>
<td>.95</td>
</tr>
<tr>
<td>FORMAT</td>
<td>3.31</td>
<td>1</td>
<td>3.31</td>
<td>.25</td>
<td>.62</td>
</tr>
<tr>
<td>2-Way Interactions</td>
<td>20.53</td>
<td>1</td>
<td>20.53</td>
<td>1.53</td>
<td>.22</td>
</tr>
<tr>
<td>REDUNDANCY X FORMAT</td>
<td>20.53</td>
<td>1</td>
<td>20.53</td>
<td>1.53</td>
<td>.22</td>
</tr>
<tr>
<td>Explained</td>
<td>23.89</td>
<td>3</td>
<td>7.96</td>
<td>.59</td>
<td>.62</td>
</tr>
<tr>
<td>Residual</td>
<td>980.06</td>
<td>73</td>
<td>13.43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1003.95</td>
<td>76</td>
<td>13.21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

was therefore made to include data from the three site 5 subjects in the study.

Confidence in the Null Hypothesis

Power analysis of the ANOVA design (Kraemer & Thiemann, 1987) indicates a power of 99% for a large effect size (.80 s.d.) and a power of 65% for a moderate effect size (.50 s.d.). A cautious interpretation of the data suggests acceptance of the equivalency of the four tested treatments, for large effects on immediate comprehension, as measured by the Comprehension Quiz.
One-Week Recall

Data Collection Difficulties

Assessment of recall of consent information at the one-week follow-up point was hampered severely by programmatic factors. Several subjects failed to attend scheduled posttest sessions due to:

a) dropping out of treatment,

b) loss of insurance coverage, resulting in discontinuation of treatment,

c) early completion of treatment,

d) failure of hospital staff to notify the patient of their appointment,

e) voluntarily quitting the study.

Of the 80 subjects involved in the study, only 28 completed posttests. As a result of the paucity of posttest data, the data were not analyzed to test Hypothesis 3 (Enhanced redundancy of presented information will result in a higher level of recall of the material, as reflected in a higher score on the Comprehension Posttest, than unitary presentation of the information) or Hypothesis 4 (Video presentation of the stimulus information will result in a higher level of recall of the material, as reflected in a higher score on the Comprehension Posttest, than presentation via a printed format.).

Relationship of Immediate Comprehension Scores to Posttest Scores

As noted previously, difficulties were experienced in obtaining full participation in the follow-up portion of the study. Only 35% of the posttests were completed. Although initially planned to occur at exactly
one week after the initial testing, the amount of time from initial testing to posttest ranged from 7 to 14 days. Results involving posttests should, therefore, be interpreted with care and regarded as general descriptives.

Attrition of the posttest sample due to extraneous factors could skew the data. To test the independence of "dropping out", an analysis was performed, comparing the initial comprehension scores of the 28 subjects who successfully completed the posttest to the initial comprehension scores of 28 randomly selected subjects who failed to complete the posttest. The results ($t_{[27]} = .04, p = .97$) indicated no significant differences between the samples, suggesting that failure to complete the posttest was randomly distributed.

The relationship between initial Comprehension Quiz scores and posttest scores was examined, collapsing across cells. Examination of a scatterplot of the two scores (Figure 2) revealed a positive association between initial comprehension score (SCORE1) and posttest score (SCORE2).

Pearson correlation coefficients were calculated to quantify the strength of the association (Table 7). A significant correlation ($r = .65$, $p = .00$) was noted between initial Comprehension Quiz scores and posttest scores.

Results also suggest that if subjects remember consent information immediately subsequent to its presentation, they are likely to remember it after approximately one week. A 2-tailed, paired-sample t-test
Figure 2. Scatterplot: Comprehension scores with posttest scores

(SCORE1 = immediate comprehension test
SCORE2 = one week follow-up test)
Table 7. Correlation between initial comprehension score (SCORE1) and posttest score (SCORE2)

<table>
<thead>
<tr>
<th></th>
<th>SCORE1</th>
<th>SCORE2</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE1</td>
<td>1.00</td>
<td>.65**</td>
</tr>
<tr>
<td>SCORE2</td>
<td>.65**</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Significant at p ≤ .05 (2-tailed).
** Significant at p ≤ .01 (2-tailed).

(t (27) = .34, p = .73) indicated no significant differences between initial test scores and posttests (Table 8).

Two potential confounds are noted, however, which may affect the validity of these observations regarding initial test/posttest correlation. The nature of chemical dependency treatment is such that most subjects spent many hours each day in close proximity to other patients in the treatment program, some of whom were subjects. Although subjects were requested at the end of both testing sessions to not share information about the study with other current or potential subjects, some information sharing may have occurred.

A second, and potentially more serious confound, results from the experimental design. The information about which subjects were tested in the Comprehension Quiz was specific, descriptive information about the study. At the time of posttesting, subjects had already participated in one
Table 7. T-test, SCORE1 versus SCORE2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number of Cases</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE1</td>
<td>28</td>
<td>18.46</td>
<td>3.04</td>
<td>.57</td>
</tr>
<tr>
<td>SCORE2</td>
<td>28</td>
<td>18.29</td>
<td>3.48</td>
<td>.66</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(Difference) Mean</th>
<th>(Difference) Standard Deviation</th>
<th>2-tail t Value</th>
<th>Degrees of Freedom</th>
<th>2-tail Prob.</th>
</tr>
</thead>
<tbody>
<tr>
<td>.18</td>
<td>2.75</td>
<td>.52</td>
<td>.65</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.34</td>
<td>27</td>
<td>.73</td>
</tr>
</tbody>
</table>
testing session, and had an opportunity to consider their experience over the one-week interim. The experience of participation itself may have provided subjects with pertinent information regarding the study. Such information as the voluntariness of participation, activities required of subjects, and confidentiality of data may have been conveyed by the participation experience. This learning dynamic may have served to offset potential forgetting of information tested for in the posttest.

Effect of Reading Variables

Effect of WRAT-R Reading Subtest Performance on Comprehension Score

Subjects were administered the Reading subtest of the WRAT-R as a screening instrument. Language proficiency may be seen as an essential component of comprehension of consent information. To investigate this, a scatterplot was constructed, plotting comprehension scores against WRAT-R standard scores. (Figure 3). A small positive association between the two variables seemed apparent. In order to quantify the strength of the association, Pearson correlation coefficients were calculated (Table 9). These calculations confirmed a small, but significant association between comprehension score and WRAT-R standard score ($r = .23, p \leq .05$).

WRAT-R standard scores reflect subject performance relative to his or her age norm group. Comprehension scores, however, reflected raw, not age standardized, scores. The salient measurement was how much of the consent information the subject comprehended, not how well they did
Figure 3. Scatterplot: Comprehension scores with WRAT-R standard scores

80 cases plotted.
Table 9  Correlation between comprehension score and WRAT-R Reading subtest standard score

<table>
<thead>
<tr>
<th>SCORE</th>
<th>WRAT SS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE</td>
<td>1.00</td>
</tr>
<tr>
<td>WRAT SS</td>
<td>.23*</td>
</tr>
</tbody>
</table>

* Significant at p ≤ .05 (2-tailed)
** Significant at p ≤ .01 (2-tailed)

relative to their peers. Level of vocabulary function, in an absolute sense, may significantly affect comprehension of consent information, regardless of its relationship to the vocabulary performance of the norming population. Therefore, a second scatterplot was constructed, plotting comprehension scores against WRAT-R raw scores (Figure 4). A small positive association, quite similar to that between comprehension scores and WRAT-R standard scores, was apparent. A Pearson correlation coefficient was calculated (Table 10), confirming a small, but significant, positive association (r = .25, p ≤ .05).

Since the printed conditions of consent information relied heavily upon reading ability, the possibility of an interaction between format and WRAT-R performance was investigated (Tables 11 and 12). Regression analysis failed to support a significant interaction between WRAT-R standard
Figure 4. Scatterplot: Comprehension scores with WRAT-R raw scores

60 cases plotted.
Table 10. Correlation between comprehension score and WRAT-R Reading subtest raw score

<table>
<thead>
<tr>
<th>SCORE</th>
<th>WRAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00</td>
<td>.25*</td>
</tr>
<tr>
<td>.25*</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Significant at \( p \leq .05 \) (2-tailed)
** Significant at \( p \leq .01 \) (2-tailed)

Table 11. Multiple regression table, WRAT-R standard score, format, and their interaction

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE B</th>
<th>( \beta )</th>
<th>t</th>
<th>Significance of t</th>
</tr>
</thead>
<tbody>
<tr>
<td>WRAT-R SS</td>
<td>.15</td>
<td>.13</td>
<td>.43</td>
<td>1.17</td>
<td>.25</td>
</tr>
<tr>
<td>FORMAT</td>
<td>4.07</td>
<td>7.47</td>
<td>.54</td>
<td>.55</td>
<td>.59</td>
</tr>
<tr>
<td>INTERACTION (Constant)</td>
<td>-.05</td>
<td>.08</td>
<td>-.60</td>
<td>-.62</td>
<td>.54</td>
</tr>
</tbody>
</table>
Table 12. Multiple regression table, WRAT-R raw score, format, and their interaction

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE B</th>
<th>β</th>
<th>t</th>
<th>Significance of t</th>
</tr>
</thead>
<tbody>
<tr>
<td>WRAT-R</td>
<td>.17</td>
<td>.14</td>
<td>.44</td>
<td>1.25</td>
<td>.22</td>
</tr>
<tr>
<td>FORMAT</td>
<td>2.84</td>
<td>5.53</td>
<td>.38</td>
<td>.51</td>
<td>.61</td>
</tr>
<tr>
<td>INTERACTION</td>
<td>-.05</td>
<td>.09</td>
<td>-.45</td>
<td>-.62</td>
<td>.54</td>
</tr>
<tr>
<td>(Constant)</td>
<td>8.31</td>
<td>8.81</td>
<td></td>
<td>.94</td>
<td>.35</td>
</tr>
</tbody>
</table>

scores and format ($t = -.62, p = .54$). Similarly, for WRAT-R raw scores, no significant interaction with format was supported ($t = -.62, p = .54$).

Relationship of Time-to-Read-Stimulus to Comprehension Scores in Printed Conditions

Subjects were given up to fifteen minutes to read consent information in the printed conditions. The range of actual times-to-read was from 84 seconds to 375 seconds. Careful reading of material may take longer than cursory examination, but may also result in higher comprehension. To examine the relationship between time-to-read and comprehension score, a scatterplot of scores with their corresponding times-to-read was constructed (Figure 5). No discernible relationship between the two variables was apparent. Pearson correlation coefficients were calculated, confirming the lack of apparent relationship (Table 13).
Figure 5. Scatterplot: Comprehension scores with time to read printed stimuli (in seconds)
Table 13. Correlation between comprehension score and reading time

<table>
<thead>
<tr>
<th></th>
<th>SCORE</th>
<th>TIME TO READ</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE</td>
<td>1.00</td>
<td>-.14</td>
</tr>
<tr>
<td>TIME TO READ</td>
<td>-.14</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Significant at $p \leq .05$ (2-tailed)

** Significant at $p \leq .01$ (2-tailed)

Effect of Education upon Comprehension Scores

**Holding G. E. D. Equivalent to HS Degree**

Subjects in this study reported completion of from 9 to 16 years of formal education. Seventeen subjects had completed certificates of general educational development (G. E. D.), customarily accepted as equivalent of high school completion. Pearson correlation coefficients were calculated to ascertain the relationship of educational attainment to initial comprehension scores. G. E. D. completion was held equal to completion of 12 years of education for purposes of this analysis (Table 14.). The results showed no apparent significant relationship between educational level (with G. E. D. = 12 years) and comprehension scores ($r = .11$)
Table 14. Correlation between comprehension score and years of education, with attainment of a GED = 12 years

<table>
<thead>
<tr>
<th>SCORE</th>
<th>YEARS OF EDUCATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE</td>
<td>1.00</td>
</tr>
<tr>
<td>YEARS OF EDUCATION</td>
<td>.11</td>
</tr>
<tr>
<td></td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Significant at $p \leq .05$ (2-tailed)

** Significant at $p \leq .01$ (2-tailed)

**Actual Years of Educational Attainment**

Completion of a G. E. D. may not indicate true high school equivalency, however. In order to more completely investigate the potential effect of education, another correlation was performed to ascertain the relationship of educational attainment to initial comprehension scores. In this second correlation, the education variable reflected the actual number of years of formal education completed, notwithstanding possible completion of a G. E. D. (Table 15). Results of this analysis also indicated no overall significant relationship of educational attainment to initial comprehension scores ($r = .13$).
Table 15. Correlation between comprehension score and actual years of education

<table>
<thead>
<tr>
<th>SCORE</th>
<th>YEARS OF EDUCATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE</td>
<td>1.00</td>
</tr>
<tr>
<td>YEARS OF EDUCATION</td>
<td>.13</td>
</tr>
</tbody>
</table>

* Significant at $p \leq .05$ (2-tailed)

** Significant at $p \leq .01$ (2-tailed)

Interaction of Format and Education

A major difference between the two formats of information presentation used in this study was the requirement for the printed format that the subject be able to read the document for understanding whereas an ability to read was not necessary for the stimulus presentation phase of the video format. Level of educational attainment may reflect ability to read, understand, and retain printed material. Thus, an interaction of educational attainment and format could be expected, with years of educational attainment positively related to printed format scores, but not necessarily video format scores. Appropriate ANOVAs were performed to analyze for possible interaction between education and format. No significant main effect from educational level ($F(7, 66) = 1.38, p = .23$) or significant interaction between format and educational level.
(F(5, 66) = 1.49, p = .21) was found when the education variable reflected actual years of formal education completed (Table 16).

When attainment of a G.E.D. was held equivalent to 12 years of formal education, a borderline interactive effect was noted (F(3, 68) = 2.41, p = .08, Table 17). Although it is tempting to speculate on the implications of the suggested interactive effect, such speculations must be tempered by the borderline significance of the findings.

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>DF</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FORMAT</td>
<td>146.66</td>
<td>8</td>
<td>18.33</td>
<td>1.36</td>
<td>.23</td>
</tr>
<tr>
<td>ED</td>
<td>22.04</td>
<td>1</td>
<td>22.04</td>
<td>1.64</td>
<td>.21</td>
</tr>
<tr>
<td>2-Way Interactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FORMAT X ED</td>
<td>100.42</td>
<td>5</td>
<td>20.08</td>
<td>1.49</td>
<td>.21</td>
</tr>
<tr>
<td>Explained</td>
<td>247.07</td>
<td>13</td>
<td>19.01</td>
<td>1.41</td>
<td>.18</td>
</tr>
<tr>
<td>Residual</td>
<td>888.88</td>
<td>66</td>
<td>13.47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1135.95</td>
<td>79</td>
<td>14.38</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 7. Analysis of Variance of SCORE1 by format and years of education, with attainment of a GED held equal to 12 years

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>DF</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Effects</td>
<td>74.74</td>
<td>8</td>
<td>9.34</td>
<td>.66</td>
<td>.72</td>
</tr>
<tr>
<td>FORMAT</td>
<td>21.88</td>
<td>1</td>
<td>21.88</td>
<td>1.55</td>
<td>.22</td>
</tr>
<tr>
<td>ED</td>
<td>58.54</td>
<td>7</td>
<td>8.36</td>
<td>.59</td>
<td>.76</td>
</tr>
<tr>
<td>2-Way Interactions</td>
<td>101.92</td>
<td>3</td>
<td>33.97</td>
<td>2.41</td>
<td>.08</td>
</tr>
<tr>
<td>FORMAT X ED</td>
<td>101.92</td>
<td>3</td>
<td>33.97</td>
<td>2.41</td>
<td>.08</td>
</tr>
<tr>
<td>Explained</td>
<td>176.67</td>
<td>11</td>
<td>16.06</td>
<td>1.14</td>
<td>.35</td>
</tr>
<tr>
<td>Residual</td>
<td>959.28</td>
<td>68</td>
<td>14.11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1135.95</td>
<td>79</td>
<td>14.38</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Effect of Age upon Comprehension Scores

Subjects in this study ranged from 18 to 53 years of age. To investigate the possible relationship between subject age and comprehension score, a scatterplot was constructed, plotting comprehension scores against subject age (Figure 6). No discernible relationship between the variables was apparent. Pearson correlation coefficients were calculated, confirming the lack of apparent relationship (Table 18).
Figure 6. Scatterplot: Comprehension scores with subject age
Table 18. Correlation between comprehension score and age

<table>
<thead>
<tr>
<th>SCORE1</th>
<th>AGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE1</td>
<td>1.00</td>
</tr>
<tr>
<td>AGE</td>
<td>-.19</td>
</tr>
</tbody>
</table>

* Significant at $p \leq .05$ (2-tailed)

** Significant at $p \leq .01$ (2-tailed)

Item Analysis

The quiz was constructed of 25 questions, paralleling the structure of the stimulus information, containing a total of 30 scorable points (some items contained more than one element of information). Each question was followed by 5 blank lines, allowing the subject adequate room to answer the question as fully or as briefly as desired. Quizzes were scored utilizing the Scoring Criteria and procedures enumerated in Appendix R. Table 19 details descriptive statistics for each item.

Questions 16 through 20 were answered correctly by all subjects, in all conditions. The questions, with the correct answers in parenthesis, are listed below.

Question 16: “Do you have to take part in the study?” (No)

Question 17: “Will you be penalized if you refuse to take part in the study?” (No)
Table 19. Descriptive statistics for quiz items

<table>
<thead>
<tr>
<th>Question</th>
<th>Mean</th>
<th>Std Dev</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>.31</td>
<td>.47</td>
</tr>
<tr>
<td>Q2</td>
<td>.29</td>
<td>.46</td>
</tr>
<tr>
<td>Q3A</td>
<td>.71</td>
<td>.46</td>
</tr>
<tr>
<td>Q3B</td>
<td>.44</td>
<td>.50</td>
</tr>
<tr>
<td>Q4A</td>
<td>.19</td>
<td>.39</td>
</tr>
<tr>
<td>Q4B</td>
<td>.25</td>
<td>.44</td>
</tr>
<tr>
<td>Q4C</td>
<td>.05</td>
<td>.22</td>
</tr>
<tr>
<td>Q5A</td>
<td>.39</td>
<td>.49</td>
</tr>
<tr>
<td>Q5B</td>
<td>.09</td>
<td>.28</td>
</tr>
<tr>
<td>Q6</td>
<td>.48</td>
<td>.50</td>
</tr>
<tr>
<td>Q7</td>
<td>.22</td>
<td>.42</td>
</tr>
<tr>
<td>Q8</td>
<td>.90</td>
<td>.30</td>
</tr>
<tr>
<td>Q9</td>
<td>.76</td>
<td>.43</td>
</tr>
<tr>
<td>Q10</td>
<td>.94</td>
<td>.24</td>
</tr>
<tr>
<td>Q11</td>
<td>.99</td>
<td>.11</td>
</tr>
<tr>
<td>Q12</td>
<td>.87</td>
<td>.33</td>
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<tr>
<td>Q13</td>
<td>.83</td>
<td>.38</td>
</tr>
<tr>
<td>Q14</td>
<td>.79</td>
<td>.41</td>
</tr>
<tr>
<td>Q15A</td>
<td>.26</td>
<td>.44</td>
</tr>
<tr>
<td>Q15B</td>
<td>.45</td>
<td>.50</td>
</tr>
<tr>
<td>Q16</td>
<td>1.00</td>
<td>.00</td>
</tr>
<tr>
<td>Q17</td>
<td>1.00</td>
<td>.00</td>
</tr>
<tr>
<td>Q18</td>
<td>1.00</td>
<td>.00</td>
</tr>
<tr>
<td>Q19</td>
<td>1.00</td>
<td>.00</td>
</tr>
<tr>
<td>Q20</td>
<td>1.00</td>
<td>.00</td>
</tr>
<tr>
<td>Q21</td>
<td>.96</td>
<td>.19</td>
</tr>
<tr>
<td>Q22</td>
<td>.45</td>
<td>.50</td>
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<tr>
<td>Q23</td>
<td>.19</td>
<td>.39</td>
</tr>
<tr>
<td>Q24</td>
<td>.76</td>
<td>.43</td>
</tr>
<tr>
<td>Q25</td>
<td>.67</td>
<td>.47</td>
</tr>
</tbody>
</table>
Question 18: "Will you lose any benefits if you refuse to take part in the study?" (No)

Question 19: "Will you be penalized if you quit the study after you've started?" (No)

Question 20: "Will you lose any benefits if you quit the study after you've started?" (No)

Questions 16-20 all deal with the subject of voluntariness, and as such may essentially be asking different aspects of the same question. Since the items have zero variance, statistical interpretation is limited, however. Additionally, only two subjects missed Question 21, which also pertained to voluntariness and the subject's right to quit at any time ("If you quit the study, what kind of reason must you give?" [None]). Because of their similarity, presentation of the stimulus information for these items may have constituted an extreme example of information redundancy. Additionally, voluntariness as an essential component of research participation may be common knowledge among members of the sampled population. The lack of a no-treatment control group in this study precludes support for that conclusion, however.

Items 8, 10, and 11 all were answered correctly over 90% of the time. The questions are listed below. (Since answer criteria for these items are more complex than for items 16-21, the reader is referred to Appendix R for details of scoring.)

Question 8: "To what extent, if any, is your participation confidential?"
Question 10: "To what extent is what you tell us confidential?"

Question 11: "Will the questionnaire and quizzes have your name on them?"

These items focus on confidentiality of participation and the resulting identifying data and may be seen to reflect the effect of multiple presentations of similar informative statements about confidentiality. Also, they may possibly tap into another common belief about research participation.

Questions 4C and 5B were answered correctly less than 10% of the time. Each reflects part of a multi-element item. Their text is listed below.

Question 4. "What will you have to do?" (Part C refers to the activity of taking another quiz one week after the initial meeting.)

Question 5. "What will the quizzes be about?" (Part B refers to the vocabulary assessment.)

These question sub-parts appeared to assess memory for information elements which were idiosyncratic for the study and had little relevance to concepts of participant rights. Additionally, as sub-parts of information items, they may have "competed for hierarchical space" in subject memory paradigms for the overall items. Thus, the posttest may have been recalled more poorly because of its perceived temporal distance and lower relevance to the task at hand. The vocabulary assessment may have been recalled more poorly because of an apparent lack of relevance to the overall gestalt of the study.
All items except 4C, 11, and 16-21 (see above) correlated positively and significantly with overall test score (Table 20). When a Pearson correlation coefficient was calculated between individual items and the sum of the scores on all the other items, however (Table 21, "Corrected item-total correlation"), the relationship of individual items to the others was seen to range from a low of zero for the 5 items with zero variance (16-20) to a high of .54 for Item 1 ("What is the nature of this study? [Research]).

Cronbach's alpha, a measure based upon the internal consistency of the items, was calculated at $\alpha = .74$. 
Table 20. Correlation of individual quiz items with total comprehension score

<table>
<thead>
<tr>
<th>Item</th>
<th>Total score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>.62**</td>
</tr>
<tr>
<td>Q2</td>
<td>.59**</td>
</tr>
<tr>
<td>Q3A</td>
<td>.38**</td>
</tr>
<tr>
<td>Q3B</td>
<td>.40**</td>
</tr>
<tr>
<td>Q4A</td>
<td>.35**</td>
</tr>
<tr>
<td>Q4B</td>
<td>.38**</td>
</tr>
<tr>
<td>Q4C</td>
<td>.20</td>
</tr>
<tr>
<td>Q5A</td>
<td>.57**</td>
</tr>
<tr>
<td>Q5B</td>
<td>.23*</td>
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<tr>
<td>Q6</td>
<td>.30**</td>
</tr>
<tr>
<td>Q7</td>
<td>.49**</td>
</tr>
<tr>
<td>Q8</td>
<td>.30**</td>
</tr>
<tr>
<td>Q9</td>
<td>.35**</td>
</tr>
<tr>
<td>Q10</td>
<td>.29**</td>
</tr>
<tr>
<td>Q11</td>
<td>.16</td>
</tr>
<tr>
<td>Q12</td>
<td>.45**</td>
</tr>
<tr>
<td>Q13</td>
<td>.54**</td>
</tr>
<tr>
<td>Q14</td>
<td>.57**</td>
</tr>
<tr>
<td>Q15A</td>
<td>.29**</td>
</tr>
<tr>
<td>Q15B</td>
<td>.29*</td>
</tr>
<tr>
<td>Q16</td>
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<td>Q17</td>
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<td>Q18</td>
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<td>Q19</td>
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</tr>
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<td>Q20</td>
<td>.00</td>
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<td>Q21</td>
<td>.15</td>
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<tr>
<td>Q22</td>
<td>.36**</td>
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<td>Q23</td>
<td>.25*</td>
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<tr>
<td>Q24</td>
<td>.35**</td>
</tr>
<tr>
<td>Q25</td>
<td>.33</td>
</tr>
</tbody>
</table>

" . " is printed if a coefficient cannot be computed

* Significant at $p \leq .05$ (2-tailed)

** Significant at $p \leq .01$ (2-tailed)
Table 21. Item-total statistics

<table>
<thead>
<tr>
<th>SCALE</th>
<th>SCALE</th>
<th>CORRECTED</th>
<th>ALPHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEAN</td>
<td>VARIANCE</td>
<td>ITEM TOTAL</td>
<td>CORRELATION</td>
</tr>
<tr>
<td>Q1</td>
<td>17.93</td>
<td>12.32</td>
<td>.54</td>
</tr>
<tr>
<td>Q2</td>
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<td>17.53</td>
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<td>.26</td>
</tr>
<tr>
<td>Q3B</td>
<td>17.80</td>
<td>13.07</td>
<td>.27</td>
</tr>
<tr>
<td>Q4A</td>
<td>18.05</td>
<td>13.44</td>
<td>.25</td>
</tr>
<tr>
<td>Q4B</td>
<td>17.99</td>
<td>13.25</td>
<td>.27</td>
</tr>
<tr>
<td>Q4C</td>
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<td>.14</td>
</tr>
<tr>
<td>Q5A</td>
<td>17.85</td>
<td>12.43</td>
<td>.47</td>
</tr>
<tr>
<td>Q5B</td>
<td>18.15</td>
<td>13.90</td>
<td>.15</td>
</tr>
<tr>
<td>Q6</td>
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<td>.50</td>
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<td>.18</td>
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<td>17.79</td>
<td>13.49</td>
<td>.16</td>
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<td>Q17</td>
<td>17.24</td>
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Alpha = 0.74
DISCUSSION

This study investigated the effect of information repetition and media format upon comprehension and recall of consent information in a sample of chronic alcoholics. Relationships between several other variables and information comprehension were also examined.

The findings did not support the effectiveness of redundant information presentation to increase comprehension of consent material in the sampled population. Neither did they support the effectiveness of video format over print format in the presentation of consent information. No significant interactive effects were noted.

Equivalency of Print and Video Formats

The lack of significant difference in the four conditions is itself, however, a finding of value. As noted earlier, a power analysis of the ANOVA design, calculated at the 5% level (2-tailed), indicated that the probability of a correct acceptance of the null hypothesis, for a large effect size (.80 s.d., or 2.43 points on the initial consent quiz), was 99%. Thus, relative equivalency of the treatments is suggested.

Provision of informed consent in chemical dependency treatment is difficult in most instances. Patients are sometimes acutely intoxicated. If sober, they may be experiencing the cognitive clouding that often occurs during the acute post-detoxification period. Many patients are placed into treatment involuntarily, or “semi-voluntarily”, and exhibit a high level of uncooperativeness. Even for cooperative, cognitively intact, patients, the first few days of treatment are complicated, confusing, and disorienting.
Provision of treatment information, including that required for the patient to provide truly informed consent to remain in treatment, is traditionally through printed handbooks or sign-off sheets. As noted by Mills (1990), patients often read these sheets only cursorily, if at all. The finding that video format presentation of consent information is at least as effective as traditional print methods gives treatment programs more flexibility in presentation of this important information. Additionally, utilization of a video format would allow programs to present consent information to large groups of patients at the same time.

Initial presentation of important treatment information via video format, followed up by presentation of printed material with a sign-off sheet for documentation purposes, would be one possible innovative implementation of these findings. In this paradigm, exposure to the information could be assured, through monitored presentation of video information. Although patients would always have the option of not paying attention to the proffered video information, to do so would require an active decision on their part to ignore the material. Conversely, in order to be exposed to printed information, patients must make an active decision to read the material. Thus, in the video paradigm, patient inaction would result in exposure to the information, while in the print paradigm, patient inaction would result in nonexposure to the information. Considering the volitional inertia exhibited by many patients during the initial weeks of chemical dependency treatment, video presentation of information could
facilitate communication of important treatment information in the clinical setting.

Analogous to the presentation of clinical information, presentation of research consent information to alcoholics in treatment, or in acute post-detoxification status, can be quite difficult. Research information may hold little interest for the subject who finds himself or herself in treatment for a chronic, life threatening illness, especially when complicated by cognitive clouding and emotional upheaval. Video presentation of consent information as an acceptable option in research with alcoholics would provide needed flexibility and many of the same benefits of facilitation of communication noted in the discussion of presentation of clinical information.

Recall of Consent Information

Significant correlative findings between initial test results and posttests support an interpretation that initial level of consent information comprehension is positively related to level of long-term recall of the material. Further, t-test results suggest that, once learned, recall tends to remain stable, at least during the first week. Considering that most chemical dependency treatment lasts only about one month, adequate recall of consent material during that time empowers the patient as an active partner in health care decision making. In light of the findings, clinicians would be urged to emphasize facilitation of comprehension of important, consent-related material during the initial phases of treatment.
Reading Ability and Comprehension of Consent Information

Results suggest a small, but significant, correlation between vocabulary level and comprehension of consent material ($r = .25, p \leq .05$). Although statistical significance was observed, it is noted that this correlation only accounted for approximately 6% of the score variance, not a finding of clinical significance. Since the stimulus material was constructed at the 7th grade level of reading difficulty, effects of vocabulary ability may have been suppressed. The practical significance of these findings may decrease as treatment facilities rewrite consent information, emphasizing enhancement of readability and reduction of an historically high difficulty level. At this time, however, results suggest that patients with low vocabulary function or poor reading ability be provided with ancillary assistance in comprehension of important consent-related material.

ANOVA results did not support a differential effect for vocabulary function for print versus video format. Even if programs utilize video presentation of consent information, it would be prudent to provide assistance to poor readers in order to enhance comprehension of the material.

Educational Level and Comprehension of Consent Information

No significant effects of educational level on consent information comprehension were noted. This finding seems to support the practice of simplification and clarification of presented material. Although no comparison data is available, it is tempting to speculate that educational
level may have been a significant factor in comprehension had the material been written at the post-graduate level, an all-too-common occurrence.

**Age and Gender**

No effects of either age or gender on comprehension were noted. It is stressed, however, that the sample consisted of patients between the ages of 18 and 53, inclusive. Thus, the potential confounds of youth, and senior status were avoided. It would be unwise to extrapolate these findings to include youthful or elderly populations, considering the special needs and problems which appear in each.

**Limitations of the Study**

While providing an adequate assessment of the effects of the target variables, several limitations were noted in both research design and implementation.

The lack of a no-treatment control group left open the question of preexisting knowledge about consent information. The core of consent material consists of elements of confidentiality and voluntariness. As was noted in the previous section, these were precisely the areas in which subjects scored the highest. In the absence of a control group, the etiology of this scoring differential remains unknown.

Difficulty with follow-up data prevented the testing of the two hypotheses regarding posttest performance. The dynamics of chemical dependency treatment (and the behaviors of chemically dependent patients) are significantly different than those found in the usual research
setting. More care should have been taken to insure the collectability of posttests.

The video stimuli used in this study were selected on the basis of their "neutrality." Several subjects referred to them as "boring." Video is an immensely flexible and creative medium. In fact, subjects may be more critical of the interest level of video presentations than of print presentations because they have come to expect video presentations to be both interesting and informative. Utilization of more sophisticated production facilities, and incorporation of a "level of interest" variable would have been quite useful.

Conclusions

Although results did not support the hypotheses of increased comprehension of consent material through the utilization of increased information redundancy and substitution of a video format instead of the usual printed one, findings were useful, both clinically and in the research setting. As discussed in the preceding section, potential equivalency of video and print formats in the efficiency of presentation of consent information to alcoholics provides clinicians and researchers with more flexibility by adding an option which easily allows for group and monitored presentation of information. The negligible effects on performance of educational level, vocabulary level, gender, and age (within the stated limits) lend support to the hope that patients and subjects throughout a wide range of demographic characteristics and cognitive ability can be
effectively provided with salient information about their treatment or the research in which they participate.

Future research in this area is certainly indicated, especially in the incorporation of interest and production variables into video consent presentation. As interactive video programs become more sophisticated and plentiful, through the use of personal computers with attached video disc systems, another potentially fruitful avenue of consent research opens.

The question is no longer whether or not to provide meaningful consent information to subjects and patients, but rather in what manner the most effective and efficient presentation of that information can be made.
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ACKNOWLEDGMENTS

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This research could not have been completed without the full cooperation and assistance of the clients and staff members of Powell Chemical Dependency Center (day and evening programs), Center for Addictions Recovery, Substance Abuse Treatment Unit of Central Iowa, and Mid-Eastern Council on Chemical Abuse.

The insight, assistance, and collegial support afforded me through my association with Dr. Susan Isbill and Mr. Phillip Wolfe were invaluable.

Finally, I acknowledge and appreciate the support of Dr. Joyce Keen, Director of the Department of Clinical Psychology at Iowa Methodist Medical Center, whose flexibility allowed me to take considerable time away from my clinical responsibilities in order to complete this project.
APPENDIX A. HIPPOCRATIC OATH

(Carrick, 1985, pp. 69-70)
THE HIPPOCRATIC OATH

P1 I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

P2 To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art- if they desire to learn it- without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but to no one else.

P3 I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

P4 I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art.

P5 I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.
P6 Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

P7 What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about.

P8 If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.
APPENDIX B: DECLARATION OF GENEVA
(from Carrick, 1985, p. 193)
DECLARATION OF GENEVA
WORLD MEDICAL ASSOCIATION
AMENDED, 1983

At the time of being admitted as a member of the medical profession:

I solemnly pledge myself to consecrate my life to the service of humanity;
I will give to my teachers the respect and gratitude which is their due;
I will practice my profession with conscience and dignity;
The health of my patient will be my first consideration;
I will respect the secrets which are confided in me, even after the patient has died;
I will maintain by all the means in my power, the honor and the noble traditions of the medical profession;
My colleagues will be my brothers;
I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient;
I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;

I make these promises solemnly, freely, and upon my honor.
APPENDIX C: PRINCIPLES OF MEDICAL ETHICS

AMERICAN MEDICAL ASSOCIATION

(from Carrick, 1985, p. 188)
The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients, but also to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.

II. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.
V. A physician shall continue to study, apply, and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.

VII. A physician shall recognize a responsibility to participate in activities contributing to an improved community.
APPENDIX D: PATIENT'S BILL OF RIGHTS
(from Carrick, 1985, pp. 189-191)
The American Hospital Association presents a Bill of Rights with the expectation that observance of these rights will contribute to more effective patient care and greater satisfaction for the patient, his physician, and the hospital organization. Further, the Association presents these rights in the expectation that they will be supported by the hospital on behalf of its patients, as an integral part of the healing process. It is recognized that a personal relationship between the physician and the patient is essential for the provision of proper medical care. The traditional physician-patient relationship takes on a new dimension when care is rendered within an organizational structure. Legal precedent has established that the institution itself also has a responsibility to the patient. It is in recognition of these factors that these rights are affirmed.

1. The patient has the right to considerate and respectful care.

2. The patient has the right to obtain from his physician complete current information concerning his diagnosis, treatment, and prognosis in terms the patient can be reasonably expected to understand. When it is not
medically advisable to give such information to the patient, the information should be made available to an appropriate person in his behalf. He has the right to know by name the physician responsible for coordinating his care.

3. The patient has the right to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment. Except in emergencies, such information for informed consent should include, but not necessarily be limited to the specific procedure and/or treatment, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care or treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information. The patient also has the right to know the name of the person responsible for the procedures and/or treatment.

4. The patient has the right to refuse treatment to the extent permitted by law, and to be informed of the medical consequences of his action.

5. The patient has the right to every consideration of his privacy concerning his own medical care program. Case discussion, consultation, examination, and treatment are confidential and should be conducted discreetly. Those not directly involved in his care must have the permission of the patient to be present.
6. The patient has the right to expect that all communications and records pertaining to his care should be treated as confidential.

7. The patient has the right to expect that within its capacity a hospital must make reasonable response to the request of a patient for services. The hospital must provide evaluation, service and/or referral as indicated by the urgency of the case. When medically permissible, a patient may be transferred to another facility only after he has received complete information and explanation concerning the needs for and alternatives to such a transfer. The institution to which the patient is to be transferred must first have accepted the patient for transfer.

8. The patient has the right to obtain information as to any relationship of his hospital to other health care and educational institutions insofar as his care is concerned. The patient has the right to obtain information as to the existence of any professional relationships among individuals, by name, who are treating him.

9. The patient has the right to be advised if the hospital proposes to engage in or perform human experimentation affecting his care or treatment. The patient has the right to refuse to participate in such research projects.
10. The patient has the right to expect reasonable continuity of care. He has the right to know in advance what appointment times and physicians are available and where. The patient has the right to expect that the hospital will provide a mechanism whereby he is informed by his physician or a delegate of the physician of the patient's continuing health care requirements following discharge.

11. The patient has the right to examine and receive an explanation of his bill regardless of the source of payment.

12. The patient has the right to know what hospital rules and regulations apply to his conduct as a patient.

No catalogue of rights can guarantee for the patient the kind of treatment he has a right to expect. A hospital has many functions to perform, including the prevention and treatment of disease, the education of both health professionals and patients, and the conduct of clinical research. All these activities must be conducted with an overriding concern for the patient, and, above all, the recognition of his dignity as a human being. Success in achieving this recognition assures success in the defense of the rights of the patient.
APPENDIX E: CODE OF NUREMBERG

These standards of medical behavior were pronounced as part of a rendering of judgment against defendants at a War Crimes tribunal on August 19, 1947, in Nurnberg, Germany. (Dunstan & Seller, 1983, pp.115-117)
THE NUREMBERG CODE

Permissible medical experiments:

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all
inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in
those experiments where the experimental physicians also serve as the subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable
cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
APPENDIX F: DECLARATION OF HELSINKI

This Code of Ethics on Human Experimentation was originally authored by the World Medical Association in 1964 in a meeting in Helsinki, Finland. The current version of this Code - which became known as the Declaration of Helsinki - resulted from a revision in 1975 (Dunstan and Seller, 1983, pp. 118-122).
THE DECLARATION OF HELSINKI

Recommendations guiding medical doctors in biomedical research involving human subjects.

Introduction.

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic or prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies a fortiori to biomedical research.
Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may effect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every doctor in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.
I. Basic Principles.

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific tradition.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment, and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she
should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.
II. Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient- including those of a control group, in any- should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the
extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic Biomedical Research Involving Human Subjects
(Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers—either healthy persons or patients—for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interests of science and society should never take precedence over considerations related to the well-being of the subject.
APPENDIX G: PARTICIPATING TREATMENT PROGRAMS
Chemical dependency treatment programs involved in the study were:

1) Powell Chemical Dependency Center (PCDC)
   Iowa Methodist Medical Center
   1200 Pleasant Street
   Des Moines, Iowa 50309

2) Powell Chemical Dependency Center Evening Outpatient Program
   (PCDC-E)
   Iowa Methodist Medical Center
   1200 Pleasant Street
   Des Moines, Iowa 50309

3) Center for Addictions Recovery, Inc. (CFARI)
   511 Duff Avenue
   P. O. Box 1721
   Ames, Iowa 50010

4) Substance Abuse Treatment Center of Central Iowa (SATUCI)
   19 West State Street
   Marshalltown, Iowa 50158
5) Mid-Eastern Council on Chemical Abuse (MECCA)

430 Southgate Avenue

Iowa City, Iowa 52240
APPENDIX H: RATIONALE FOR CONSENT CONTENT
RATIONALE FOR CONSENT CONTENT

Consent information provided to subjects in this research contained 25 individual items. The content of consent information was developed in congruence with federal statute (Department of Health and Human Services, 1991), the Ethical Principles of Psychologists of the American Psychological Association (American Psychological Association, 1990), and regulations of the Department of Psychology and the Graduate College of Iowa State University. A breakdown of the rationale for inclusion of each item follows. Material which was included in only the enhanced redundancy conditions appears in italics. The slight wording changes which were presented in the video information conditions appear in parentheses. In cases of specific redundancy of Federal regulations, professional principles, or University policies, only the Federal regulation is specified as the rationale for inclusion of the consent item.

Item 1: What is the nature of this study?

This is a research study. *Its* nature is research.

Rationale for inclusion: 45 CFR Part 46.116(a)1, "A statement that the study involves research."
Item 2: What is the purpose of this study?

The purpose is to study different ways of giving information to clients in alcohol treatment. We’re looking at how well different ways of presenting information work.

Rationale for inclusion: 45 CFR Part 46.116(a)1, “...an explanation of the purposes of the research...”

Item 3: How much of my time will it take?

Participation in this study takes about a half hour today and about fifteen minutes next week. Thirty minutes of your time will be needed today. Fifteen minutes of your time will be needed next week.

Rationale for inclusion: 45 CFR Part 46.116(a)1, “...the expected duration of the subject’s participation...”

Item 4: What will I have to do?

You will be asked to read (see) this information. We’ll ask you to read (look at) this form (video). It will take less than ten minutes. That is, reading it (looking at it) will take ten minutes or less. Then you will be asked to complete two short quizzes. Both quizzes will be rather
brief. Next week you’ll be asked to complete another short quiz. In seven days we’d like you to take one more short quiz. 4

Rationale for inclusion: 45 CFR Part 46.116(a)1, “...a description of the procedures to be followed...”

Item 5: What will the quizzes be about?

Two of the quizzes will ask questions about this study, itself. They will ask questions about what you are reading (watching) right now. The other will be a vocabulary quiz. It will test how well you know words.

Rationale for inclusion: 45 CFR Part 46.116(a)1, “...a description of the procedures to be followed...”

Item 6: Are there risks or discomforts?

Risks to you are small. This is not a very risky study. You may get bored or frustrated. That is, risks may include boredom and frustration.

Rationale for inclusion: 45 CFR Part 46.116(a)2, “A description of any reasonably foreseeable risks or discomforts to the subject.”
Item 7: What will this study help?

This study will help us design more effective ways of presenting information to clients. It will help us to get information to clients more efficiently.

Rationale for inclusion: 45 CFR part 46.116(a)3, “A description of any benefits to the subject or to others which may reasonably be expected from the research.”

Item 8: To what extent, if any, is my participation confidential?

Only the tester and the project director will know that you have helped. Only the tester and the project director will know that you have been in the study.

Rationale for inclusion: 45 CFR Part 46.116(a)5, “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.”

Item 9: What will happen to the quiz and the questionnaire sheets?

The tester will collect your quiz and questionnaire sheets. He will gather them up when you are done. They will be kept in a locked file
by the project director. *He will make sure they are kept in a locked cabinet.*

Rationale for inclusion: 45 CFR Part 46.116(a)5, "A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained."

(Iowa State University) **Department of Psychology** ethical principles and policies relevant to research with human participants, General ethical principles. III. Confidentiality, "...All nonanonymous data are to be stored in locked files to which only investigator-supervised, restricted access (consistent with the confidentiality provisions existing at the time data were collected) is permissible."

**Item 10:** To what extent is what I tell you confidential?

Your answers on the questionnaire and quizzes will be kept confidential. *What you tell us will be kept private.* It will not be seen by treatment center staff. *None of the treatment center staff will have access to this information.*
Rationale for inclusion: 45 CFR Part 46.116(a)(5), “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.”

Item 11: Will the questionnaire and quizzes have my name on them?

Sheets will be coded with a number, not your name. A special number, not your name, will be put on your answer sheets. Only the tester and the project director will know which sheets are yours. Only the tester and the project director will know which name goes with which number. Within a week after you finish the last quiz, the code numbers will be removed. In seven days or less after you complete the last quiz, your code numbers will be removed.

Rationale for inclusion: 45 CFR Part 46.116(a)(5), “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.”

Item 12: Who can I speak to if I have questions about the study?

If you have any questions about this study, please speak with the tester. If you’d like to ask about this study, please speak with the tester.
Rationale for inclusion: 45 CFR Part 46.116(a)7, "An explanation of whom to contact for answers to pertinent questions about the research..."

American Psychological Association (1990) Ethical principles of psychologists, Principle 9.d, “The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explains all other aspects of the research about which the participants inquire.”

Item 13: Who can I speak to if I have questions about my rights?

If you have any questions about your rights, please speak with the tester. If you have any questions about the treatment that you’re entitled to, please speak with the tester.

Rationale for inclusion: 45 CFR Part 46.116(a)7, “...and research subjects' rights...”

Item 14: Who can you speak to if I feel that I have been injured?

If you feel that you have been injured, please speak with the tester. If you’ve been hurt, please speak with the tester.
Rationale for inclusion: 45 CFR Part 46.116(a)7, "...and whom to contact in the event of a research-related injury to the subject..."

Item 15: “How can I contact the project director?”

You may also contact the project director at this address:

Ken Mills
Department of Clinical Psychology
Iowa Methodist Medical Center
1200 Pleasant Street
Des Moines, Iowa 50309
(515) 241-6834

If you'd like to contact the project director (Ken Mills of Iowa Methodist Medical Center) you may do so at the above address.

Rationale for inclusion: 45 CFR Part 46.116(a)7, “An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject...”

Item 16: “Do I have to take part in the study?”

Taking part in the study is voluntary. You decide on your own.
Rationale for inclusion: 45 CFR Part 46.116(a)8, “A statement that participation is voluntary…”

Item 17: Will I be penalized if you refuse to take part in the study?

If you refuse to take part, there will be no penalty. *Nothing bad will happen to you if you decide to not take part.*

Rationale for inclusion: 45 CFR Part 46.116(a)8, “…refusal to participate will involve no penalty…”

Item 18: Will I lose any benefits if I refuse to take part in the study?

You will not lose any benefits in the treatment program if you refuse to take part. *You will not lose anything if you decide to not take part.*

Rationale for inclusion: 45 CFR Part 46.116(a)8, “…or loss of benefits to which the subject is otherwise entitled…”

Item 19: Will I be penalized if I quit the study after I’ve started?

If you quit the study after you’ve started, you will receive no penalty. *Nothing bad will happen to you if you quit the study at any time.*
Rationale for inclusion: 45 CFR Part 46.116(a),8, "...and the subject may discontinue participation at any time without penalty ..."

Item 20: Will I lose any benefits if I quit the study after I've started?

You will not lose any benefits in the treatment program if you quit at any time. You will not lose anything if you decide to quit after you've started.

Rationale for inclusion: 45 CFR Part 46.116(a)8, "...or loss of benefits to which the subject is otherwise entitled."

Item 21: If I quit the study, what kind of reason must I give?

If you quit the study, you need not give a reason. You don't have to explain to anyone if you quit the study.

Rationale for inclusion: (Iowa State University) Department of Psychology ethical principles and policies relevant to research with human participants. General ethical principles, I. Informed consent. "...The participant may withdraw from a study without giving a specific reason for refusal to participate or for withdrawal of consent to continue participation."
Item 22: How many subjects are in this study?

About 120 subjects are involved in this study. That is, about 120 people will take part in the study.

Rationale for inclusion: 45 CFR Part 46.116(b)6, “The approximate number of subjects involved in the study.”

Item 23: What will you tell me about the study after I finish?

After you finish the last quiz, the tester will give you a complete written description of the study and will answer any questions that you have. As soon as you’re done with the last quiz, the tester will hand you a printed summary of the study and will answer your questions.

Rationale for inclusion: American Psychological Association (1990) Ethical principles of psychologists, Principle 9.h, “After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen.”

Item 24: How can I find out about the final results of the study?
You may have a description of the results of this study sent to you. You can receive a report on how it comes out if you would like. If you would like to get a copy of these results, please tell us. If you’d like to know how the study comes out, let us know.

Rationale for inclusion: American Psychological Association (1990) Ethical principles of psychologists, Principle 9.d, “The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explains all other aspects of the research about which the participants inquire.”

American Psychological Association (1990) Ethical principles of psychologists, Principle 9.h, “After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen.”

Item 25: When do you expect the study to be finished?

We expect the study to be completed in six months or less. In half a year, or less, we expect the study to be finished.”
Rationale for inclusion: American Psychological Association (1990) *Ethical principles of psychologists*, Principle 9.d, "The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate..."
APPENDIX I: CONSENT INFORMATION, "SIMPLE, PRINTED" CONDITION
WHAT IS THE NATURE OF THIS STUDY?

This is a research study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose is to study different ways of giving information to clients in alcohol treatment.

HOW MUCH OF MY TIME WILL IT TAKE?

Participation in this study takes about a half hour today and about fifteen minutes next week.

WHAT WILL I HAVE TO DO?

You will be asked to read this information. It will take less than ten minutes. Then you will be asked to complete two short quizzes. Next week you'll be asked to complete another short quiz.

WHAT WILL THE QUIZZES BE ABOUT?

Two of the quizzes will ask questions about this study, itself. The other will be a vocabulary quiz.

(CONTINUED ON NEXT PAGE)
ARE THERE RISKS OR DISCOMFORTS?

Risks to you are small. You may get bored or frustrated.

WHAT WILL THIS STUDY HELP?

This study will help us design more effective ways of presenting information to clients.

TO WHAT EXTENT, IF ANY, IS MY PARTICIPATION CONFIDENTIAL?

Only the tester and the project director will know that you have helped.

WHAT WILL HAPPEN TO THE QUIZ AND QUESTIONNAIRE SHEETS?

The tester will collect your quiz and questionnaire sheets. They will be kept in a locked file by the project director.

TO WHAT EXTENT IS WHAT I TELL YOU CONFIDENTIAL?

Your answers on the questionnaire and quizzes will be kept confidential. It will not be seen by treatment center staff.

(CONTINUED ON NEXT PAGE)
WILL THE QUESTIONNAIRE AND QUizzes HAVE MY NAME ON THEM?

Sheets will be coded with a number, not your name. Only the tester and the project director will know which sheets are yours. Within a week after you finish the last quiz, the code numbers will be removed.

WHO CAN I SPEAK TO IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions about this study, please speak with the tester.

WHO CAN I SPEAK TO IF I HAVE QUESTIONS ABOUT MY RIGHTS?

If you have any questions about your rights, please speak with the tester.

WHO CAN I SPEAK TO IF I FEEL THAT I HAVE BEEN INJURED?

If you feel that you've been injured, please speak with the tester.

(CONTINUED ON NEXT PAGE)
HOW CAN I CONTACT THE PROJECT DIRECTOR?

You may also contact the project director at this address:

Ken Mills
Department of Clinical Psychology
Iowa Methodist Medical Center
1200 Pleasant Street
Des Moines, Iowa 50309
(515) 241-6834

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in the study is voluntary.

WILL I BE PENALIZED IF I REFUSE TO TAKE PART IN THE STUDY?

If you refuse to take part, there will be no penalty.

WILL I LOSE ANY BENEFITS IF I REFUSE TO TAKE PART IN THE STUDY?

You will not lose any benefits in the treatment program if you refuse to take part.

WILL I BE PENALIZED IF I QUIT THE STUDY AFTER I'VE STARTED?

If you quit the study after you've started, you will receive no penalty.

(CONTINUED ON NEXT PAGE)
WILL I LOSE ANY BENEFITS IF I QUIT THE STUDY AFTER I'VE STARTED?

You will not lose any benefits in the treatment program if you quit at any time.

IF I QUIT THE STUDY, WHAT KIND OF REASON MUST I GIVE?

If you quit the study, you need not give a reason.

HOW MANY SUBJECTS ARE IN THIS STUDY?

About 120 subjects are involved in this study.

WHAT WILL YOU TELL ME ABOUT THE STUDY AFTER I FINISH?

After you finish the last quiz, the tester will give you a complete written description of the study and will answer any questions that you have.

HOW CAN I FIND OUT ABOUT THE FINAL RESULTS OF THE STUDY?

You may have a description of the results of this study sent to you. If you would like to get a copy of these results, please tell us.

WHEN DO YOU EXPECT THE STUDY TO BE FINISHED?

We expect the study to be completed in six months or less.
APPENDIX J: READABILITY ANALYSES OF PRINTED STIMULI
READABILITY ANALYSIS

Readability analyses of both the simple and enhanced versions of the printed stimuli were completed. Analyses were performed on an Apple IIe computer, utilizing software provided by the Heartland Area Education Agency, Johnston, Iowa.

Grade Level

Simple Printed:

- Flesch: 7.2
- Fry: 6.9

Enhanced Printed:

- Flesch: 6.9
- Fry: 6.7
APPENDIX K: CONSENT INFORMATION, "ENHANCED, PRINTED" CONDITION
WHAT IS THE NATURE OF THIS STUDY?

This is a research study. It's nature is research.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose is to study different ways of giving information to clients in alcohol treatment. We're looking at how well different ways of presenting information work.

HOW MUCH OF MY TIME WILL IT TAKE?

Participation in this study takes about a half hour today and about fifteen minutes next week. Thirty minutes of your time will be needed today. Fifteen minutes of your time will be needed next week.

WHAT WILL I HAVE TO DO?

You will be asked to read this information. We'll ask you to read this form. It will take less than ten minutes. That is, reading it will take ten minutes or less. Then you will be asked to complete two short quizzes. Both quizzes will be rather brief. Next week you'll be asked to complete another short quiz. In seven days we'd like you take one more short quiz.

(CONTINUED ON NEXT PAGE)
WHAT WILL THE QUIZZES BE ABOUT?

Two of the quizzes will ask questions about this study, itself. They will ask questions about what you are reading right now. The other will be a vocabulary quiz. It will test how well you know words.

ARE THERE RISKS OR DISCOMFORTS?

Risks to you are small. This is not a very risky study. You may get bored or frustrated. That is, risks may include boredom and frustration.

WHAT WILL THIS STUDY HELP?

This study will help us design more effective ways of presenting information to clients. It will help us to get information to clients more efficiently.

TO WHAT EXTENT, IF ANY, IS MY PARTICIPATION CONFIDENTIAL?

Only the tester and the project director will know that you have helped. Only the tester and the project director will know that you have been in the study.
WHAT WILL HAPPEN TO THE QUIZ AND QUESTIONNAIRE SHEETS?

The tester will collect your quiz and questionnaire sheets. He will gather them up when you are done. They will be kept in a locked file by the project director. He will make sure they are kept in a locked cabinet.

TO WHAT EXTENT IS WHAT I TELL YOU CONFIDENTIAL?

Your answers on the questionnaire and quizzes will be kept confidential. What you tell us will be kept private. It will not be seen by treatment center staff. None of the treatment center staff will have access to this information.

WILL THE QUESTIONNAIRE AND QUIZZES HAVE MY NAME ON THEM?

Sheets will be coded with a number, not your name. A special number, not your name, will be put on your answer sheets. Only the tester and the project director will know which sheets are yours. Only the tester and the project director will know which name goes with which number. Within a week after you finish the last quiz, the code numbers will be removed. In seven days or less after you complete the last quiz, your code numbers will be removed.

(CONTINUED ON NEXT PAGE)
WHO CAN I SPEAK TO IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions about this study, please speak with the tester. If you’d like to ask about this study, please speak with the tester.

WHO CAN I SPEAK TO IF I HAVE QUESTIONS ABOUT MY RIGHTS?

If you have any questions about your rights, please speak with the tester. If you have any questions about the treatment that you’re entitled to, please speak with the tester.

WHO CAN I SPEAK TO IF I FEEL THAT I HAVE BEEN INJURED?

If you feel that you've been injured, please speak with the tester. If you've been hurt, please speak with the tester.

HOW CAN I CONTACT THE PROJECT DIRECTOR?

You may also contact the project director at this address:

Ken Mills
Department of Clinical Psychology
Iowa Methodist Medical Center
1200 Pleasant Street
Des Moines, Iowa 50309
(515) 241-6834

(CONTINUED ON NEXT PAGE)
If you'd like to contact the project director (Ken Mills of Iowa Methodist Medical Center) you may do so at the above address.

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in the study is voluntary. You decide on your own.

WILL I BE PENALIZED IF I REFUSE TO TAKE PART IN THE STUDY?

If you refuse to take part, there will be no penalty. Nothing bad will happen to you if you decide to not take part.

WILL I LOSE ANY BENEFITS IF I REFUSE TO TAKE PART IN THE STUDY?

You will not lose any benefits in the treatment program if you refuse to take part. You will not lose anything if you decide to not take part.

WILL I BE PENALIZED IF I QUIT THE STUDY AFTER I'VE STARTED?

If you quit the study after you've started, you will receive no penalty. Nothing bad will happen to you if you quit the study at any time.

(CONTINUED ON NEXT PAGE)
WILL I LOSE ANY BENEFITS IF I QUIT THE STUDY AFTER I'VE STARTED?

You will not lose any benefits in the treatment program if you quit at any time. You will not lose anything if you decide to quit after you've started.

IF I QUIT THE STUDY, WHAT KIND OF REASON MUST I GIVE?

If you quit the study, you need not give a reason. You don't have to explain to anyone if you quit the study.

HOW MANY SUBJECTS ARE IN THIS STUDY?

About 120 subjects are involved in this study. That is, about 120 people will take part in the study.

WHAT WILL YOU TELL ME ABOUT THE STUDY AFTER I FINISH?

After you finish the last quiz, the tester will give you a complete written description of the study and will answer any questions that you have. As soon as you're done with the last quiz, the tester will hand you a printed summary of the study and will answer your questions.

(CONTINUED ON NEXT PAGE)
HOW CAN I FIND OUT ABOUT THE FINAL RESULTS OF THE STUDY?

You may have a description of the results of this study sent to you. You can receive a report on how it comes out if you would like. If you would like to get a copy of these results, please tell us. If you'd like to know how the study comes out, let us know.

WHEN DO YOU EXPECT THE STUDY TO BE FINISHED?

We expect the study to be completed in six months or less. In half a year, or less, we expect the study to be finished.
APPENDIX L: CONSENT INFORMATION, "SIMPLE, VIDEO" CONDITION
TEXT OF "SIMPLE, VIDEO" CONDITION.

(This text will be read by the actors in the video format presentation. The content is virtually identical with that of the "Simple, Printed" condition, with the exception of references to hearing the information, rather than reading it.)

OFF CAMERA VOICE: WHAT IS THE NATURE OF THIS STUDY?
ANNOUNCER: This is a research study.

OFF CAMERA VOICE: WHAT IS THE PURPOSE OF THIS STUDY?
ANNOUNCER: The purpose is to study different ways of giving information to clients in alcohol treatment.

OFF CAMERA VOICE: HOW MUCH OF MY TIME WILL IT TAKE?
ANNOUNCER: Participation in this study takes about a half hour today and about fifteen minutes next week.

OFF CAMERA VOICE: WHAT WILL I HAVE TO DO?
ANNOUNCER: You will be asked to hear this information. It will take less than ten minutes. Then you will be asked to complete two short quizzes. Next week you'll be asked to complete another short quiz.
OFF CAMERA VOICE:  WHAT WILL THE QUIZZES BE ABOUT?
ANNOUNCER:  Two of the quizzes will ask questions about this study, itself. The other will be a vocabulary quiz.

OFF CAMERA VOICE:  ARE THERE RISKS OR DISCOMFORTS?
ANNOUNCER:  Risks to you are small. You may get bored or frustrated.

OFF CAMERA VOICE:  WHAT WILL THIS STUDY HELP?
ANNOUNCER:  This study will help us design more effective ways of presenting information to clients.

OFF CAMERA VOICE:  TO WHAT EXTENT, IF ANY, IS MY PARTICIPATION CONFIDENTIAL?
ANNOUNCER:  Only the tester and the project director will know that you have helped.

OFF CAMERA VOICE:  WHAT WILL HAPPEN TO THE QUIZ AND QUESTIONNAIRE SHEETS?
ANNOUNCER:  The tester will collect your quiz and questionnaire sheets. They will be kept in a locked file by the project director.
OFF CAMERA VOICE: TO WHAT EXTENT IS WHAT I TELL YOU
CONFIDENTIAL?
ANNOUNCER: Your answers on the questionnaire and quizzes will
be kept confidential. They will not be seen by treatment center staff.

OFF CAMERA VOICE: WILL THE QUESTIONNAIRE AND QUIZZES
HAVE MY NAME ON THEM?
ANNOUNCER: Sheets will be coded with a number, not your name.
Only the tester and the project director will know which sheets are yours.
Within a week after you finish the last quiz, the code numbers will be
removed.

OFF CAMERA VOICE: WHO CAN I SPEAK TO IF I HAVE
QUESTIONS ABOUT THE STUDY?
ANNOUNCER: If you have any questions about this study, please
speak with the tester.

OFF CAMERA VOICE: WHO CAN I SPEAK TO IF I HAVE
QUESTIONS ABOUT MY RIGHTS?
ANNOUNCER: If you have any questions about your rights, please
speak with the tester.
OFF CAMERA VOICE: WHO CAN I SPEAK TO IF I FEEL THAT I HAVE BEEN INJURED?
ANNOUNCER: If you feel that you've been injured, please speak with the tester.

OFF CAMERA VOICE: HOW CAN I CONTACT THE PROJECT DIRECTOR?
ANNOUNCER: You may also contact the project director at this address:

Ken Mills
Department of Clinical Psychology
Iowa Methodist Medical Center
1200 Pleasant Street
Des Moines, Iowa 50309
(515) 241-6834

OFF CAMERA VOICE: DO I HAVE TO TAKE PART IN THE STUDY?
ANNOUNCER: Taking part in the study is voluntary.

OFF CAMERA VOICE: WILL I BE PENALIZED IF I REFUSE TO TAKE PART IN THE STUDY?
ANNOUNCER: If you refuse to take part, there will be no penalty.
OFF CAMERA VOICE: WILL I LOSE ANY BENEFITS IF I REFUSE TO TAKE PART IN THE STUDY?
ANNOUNCER: You will not lose any benefits in the treatment program if you refuse to take part.

OFF CAMERA VOICE: WILL I BE PENALIZED IF I QUIT THE STUDY AFTER I'VE STARTED?
ANNOUNCER: If you quit the study after you've started, you will receive no penalty.

OFF CAMERA VOICE: WILL I LOSE ANY BENEFITS IF I QUIT THE STUDY AFTER I'VE STARTED?
ANNOUNCER: You will not lose any benefits in the treatment program if you quit at any time.

OFF CAMERA VOICE: IF I QUIT THE STUDY, WHAT KIND OF REASON MUST I GIVE?
ANNOUNCER: If you quit the study, you need not give a reason.

OFF CAMERA VOICE: HOW MANY SUBJECTS ARE IN THIS STUDY?
ANNOUNCER: About 120 subjects are involved in this study.
OFF CAMERA VOICE: WHAT WILL YOU TELL ME ABOUT THE STUDY AFTER I FINISH?
ANNOUNCER: After you finish the last quiz, the tester will give you a complete written description of the study and will answer any questions that you have.

OFF CAMERA VOICE: HOW CAN I FIND OUT ABOUT THE FINAL RESULTS OF THE STUDY?
ANNOUNCER: You may have a description of the results of this study sent to you. If you would like to get a copy of these results, please tell us.

OFF CAMERA VOICE: WHEN DO YOU EXPECT THE STUDY TO BE FINISHED?
ANNOUNCER: We expect the study to be completed in six months or less.
APPENDIX M: CONSENT INFORMATION, "ENHANCED, VIDEO" CONDITION
TEXT OF "ENHANCED, VIDEO" CONDITION.

(This text is read by the actors in the video format presentation. The content is virtually identical with that of the "Enhance, Printed" condition, with the exception of references to hearing the information, rather than reading it.)

OFF CAMERA VOICE: WHAT IS THE NATURE OF THIS STUDY?
ANNOUNCER: This is a research study. It's nature is research.

OFF CAMERA VOICE: WHAT IS THE PURPOSE OF THIS STUDY?
ANNOUNCER: The purpose is to study different ways of giving information to clients in alcohol treatment. We're looking at how well different ways of presenting information work.

OFF CAMERA VOICE: HOW MUCH OF MY TIME WILL IT TAKE?
ANNOUNCER: Participation in this study takes about a half hour today and about fifteen minutes next week. Thirty minutes of your time will be needed today. Fifteen minutes of your time will be needed next week.

OFF CAMERA VOICE: WHAT WILL I HAVE TO DO?
ANNOUNCER: You will be asked to hear this information. We'll ask you to listen to this presentation. It will take less than ten minutes. That is, listening to it will take ten minutes or less. Then you will be asked to
complete two short quizzes. Both quizzes will be rather brief. Next week you'll be asked to complete another short quiz. In seven days we'd like you take one more short quiz.

OFF CAMERA VOICE: WHAT WILL THE QUIZZES BE ABOUT?
ANNOUNCER: Two of the quizzes will ask questions about this study, itself. They will ask questions about what you are reading right now. The other will be a vocabulary quiz. It will test how well you know words.

OFF CAMERA VOICE: ARE THERE RISKS OR DISCOMFORTS?
ANNOUNCER: Risks to you are small. This is not a very risky study. You may get bored or frustrated. That is, risks may include boredom and frustration.

OFF CAMERA VOICE: WHAT WILL THIS STUDY HELP?
ANNOUNCER: This study will help us design more effective ways of presenting information to clients. It will help us to get information to clients more efficiently.

OFF CAMERA VOICE: TO WHAT EXTENT, IF ANY, IS MY PARTICIPATION CONFIDENTIAL?
ANNOUNCER: Only the tester and the project director will know that you have helped. Only the tester and the project director will know that you have been in the study.
OFF CAMERA VOICE: WHAT WILL HAPPEN TO THE QUIZ AND QUESTIONNAIRE SHEETS?
ANNOUNCER: The tester will collect your quiz and questionnaire sheets. He will gather them up when you are done. They will be kept in a locked file by the project director. He will make sure they are kept in a locked cabinet.

OFF CAMERA VOICE: TO WHAT EXTENT IS WHAT I TELL YOU CONFIDENTIAL?
ANNOUNCER: Your answers on the questionnaire and quizzes will be kept confidential. What you tell us will be kept private. It will not be seen by treatment center staff. None of the treatment center staff will have access to this information.

OFF CAMERA VOICE: WILL THE QUESTIONNAIRE AND QUIZZES HAVE MY NAME ON THEM?
ANNOUNCER: Sheets will be coded with a number, not your name. A special number, not your name, will be put on your answer sheets. Only the tester and the project director will know which sheets are yours. Only the tester and the project director will know which name goes with which number. Within a week after you finish the last quiz, the code numbers will be removed. In seven days or less after you complete the last quiz, your code numbers will be removed.
OFF CAMERA VOICE: WHO CAN I SPEAK TO IF I HAVE QUESTIONS ABOUT THE STUDY?
ANNOUNCER: If you have any questions about this study, please speak with the tester. If you'd like to ask about this study, please speak with the tester.

OFF CAMERA VOICE: WHO CAN I SPEAK TO IF I HAVE QUESTIONS ABOUT MY RIGHTS?
ANNOUNCER: If you have any questions about your rights, please speak with the tester. If you have any questions about the treatment that you're entitled to, please speak with the tester.

OFF CAMERA VOICE: WHO CAN I SPEAK TO IF I FEEL THAT I HAVE BEEN INJURED?
ANNOUNCER: If you feel that you've been injured, please speak with the tester. If you've been hurt, please speak with the tester.

OFF CAMERA VOICE: HOW CAN I CONTACT THE PROJECT DIRECTOR?
ANNOUNCER: You may also contact the project director at this address:

Ken Mills
If you'd like to contact the project director (Ken Mills of Iowa Methodist Medical Center) you may do so at the above address.

OFF CAMERA VOICE:   DO I HAVE TO TAKE PART IN THE STUDY?
ANNOUNCER:    Taking part in the study is voluntary. You decide on your own.

OFF CAMERA VOICE:   WILL I BE PENALIZED IF I REFUSE TO TAKE PART IN THE STUDY?
ANNOUNCER:    If you refuse to take part, there will be no penalty. Nothing bad will happen to you if you decide to not take part.

OFF CAMERA VOICE:   WILL I LOSE ANY BENEFITS IF I REFUSE TO TAKE PART IN THE STUDY?
ANNOUNCER:    You will not lose any benefits in the treatment program if you refuse to take part. You will not lose anything if you decide to not take part.
OFF CAMERA VOICE: WILL I BE PENALIZED IF I QUIT THE STUDY AFTER I'VE STARTED?
ANNOUNCER: If you quit the study after you've started, you will receive no penalty. Nothing bad will happen to you if you quit the study at any time.

OFF CAMERA VOICE: WILL I LOSE ANY BENEFITS IF I QUIT THE STUDY AFTER I'VE STARTED?
ANNOUNCER: You will not lose any benefits in the treatment program if you quit at any time. You will not lose anything if you decide to quit after you've started.

OFF CAMERA VOICE: IF I QUIT THE STUDY, WHAT KIND OF REASON MUST I GIVE?
ANNOUNCER: If you quit the study, you need not give a reason. You don't have to explain to anyone if you quit the study.

OFF CAMERA VOICE: HOW MANY SUBJECTS ARE IN THIS STUDY?
ANNOUNCER: About 120 subjects are involved in this study. That is, about 120 people will take part in the study.

OFF CAMERA VOICE: WHAT WILL YOU TELL ME ABOUT THE STUDY AFTER I FINISH?
ANNOUNCER: After you finish the last quiz, the tester will give you a complete written description of the study and will answer any questions that you have. As soon as you're done with the last quiz, the tester will hand you a printed summary of the study and will answer your questions.

OFF CAMERA VOICE: HOW CAN I FIND OUT ABOUT THE FINAL RESULTS OF THE STUDY?
ANNOUNCER: You may have a description of the results of this study sent to you. You can receive a report on how it comes out if you would like. If you would like to get a copy of these results, please tell us. If you'd like to know how the study comes out, let us know.

OFF CAMERA VOICE: WHEN DO YOU EXPECT THE STUDY TO BE FINISHED?
ANNOUNCER: We expect the study to be completed in six months or less. In half a year, or less, we expect the study to be finished.
APPENDIX N: CONSENT SIGNOFF, PRINT CONDITIONS
Agreement to Participate in this Study:

Your signature below indicates that you have read and understood the information form and that you voluntarily agree to participate in the study described.

Signature of Participant                      Date

Signature of Witness                          Date
APPENDIX O: CONSENT SIGNOFF, VIDEO CONDITIONS
Agreement to Participate in this Study:

Your signature below indicates that you have seen, heard, and understood the presentation of information and that you voluntarily agree to participate in the study described.

_________________________  ____________
Signature of Participant      Date

_________________________  ____________
Signature of Witness         Date
APPENDIX P: COMPLETE DESCRIPTION OF STUDY
COMPLETE DESCRIPTION OF STUDY

This was a research study about the effectiveness of different ways of presenting information to clients in alcohol treatment. We compared written material and video material. Also, we looked at the effect of repeated information. To help in this study took about a half hour on the first day and about fifteen minutes a week later.

Subjects were asked to either read some information or watch a video. Each took less than ten minutes. Then they were asked to complete two short quizzes. One of the quizzes asked questions about this study, itself. The other was a vocabulary quiz. Seven days later, subjects were asked to complete another short quiz. The quizzes on the first day were given by Ken Mills, who was also the project director.

The vocabulary quiz helped us to be aware of any reading problems that the subjects might have. These problems could have influenced their responses on the other quizzes. Subjects' responses on the other quizzes gave us a measure of how effective the presentation of information was.

Risks to subjects were small. You might have been bored or frustrated.
The tester collected the test sheets after each testing session was done. They are kept in a locked file cabinet by the project director.

This research will help us design more effective ways of presenting information to clients.

All answers on the quizzes will be kept confidential. Sheets will be coded with a number, not your name. Only the project director will know which numbers go with which names. Within a week from the time you finish the last quiz, the numbers will be removed. After that, no one at all will be able to tell which sheets are yours.

If you have further questions about this study, your rights, or if you feel that you've been injured, please speak with the tester. You may contact the project director at this address:

Kenneth R. Mills  
Department of Clinical Psychology  
Iowa Methodist Medical Center  
1200 Pleasant Street  
Des Moines, Iowa 50309  

(515) 241-6834
Your participation has been voluntary and has not affected your relationship with staff of the treatment center. Your treatment will not be affected in any way. You will not gain or lose any privileges.

Please do not discuss this study with the other clients in treatment. If people know the content of the study before they participate, the results could be affected.

You may have a description of the results of this study sent to you. If you would like a copy, please give your name and address to the tester. It will be given to the project director and you will be sent a copy of the results when the study is finished. We expect the research to be completed in six months or less.

Thank you for your help!
"The effect of information redundancy and format."

Your signature below indicates that you have read and understood the information form and that you voluntarily agree to participate in the study described.

_________________________________________  __________________________
Signature of Participant Date

You are entitled to a general description of the results of this study. If you would like to receive a copy of these results, please print your name and address below. A description of our findings will be sent to you upon completion of this study (in about six months from now, or less).
APPENDIX Q: DEMOGRAPHIC QUESTIONNAIRE AND INFORMED CONSENT QUIZ
197

QUESTIONNAIRE

DO NOT WRITE YOUR NAME ON THIS OR ANY OTHER SHEET!

What is today's date?___________________________________________

When did you enter treatment?___________________________________

Are you in treatment for alcohol?_____ Other drugs?__________

How long has it been since you've had a drink?______________

Did you go through detoxification?______________________________

If so, when did you complete detox?__________________________

Are you taking any detox medication, other than vitamins?__

If so, what?_________________________________________________

How far did you go in school?___________________________________

Do you have a G.E.D.?________________________________________

What is your gender? (circle one) male female

What is your birth date? (month, year, and date)______________

Do you have any difficulty in hearing?__________________________

If so, how bad is it?________________________________________

Do you have any trouble with your vision?_______________________

If so, what is the trouble?____________________________________
1) WHAT IS THE NATURE OF THIS STUDY?


2) WHAT IS THE PURPOSE OF THIS STUDY?


3) HOW MUCH OF YOUR TIME WILL IT TAKE?


4) WHAT WILL YOU HAVE TO DO?

5) WHAT WILL THE QUIZZES BE ABOUT?

6) ARE THERE RISKS OR DISCOMFORTS?
7) WHAT WILL THIS STUDY HELP?


8) TO WHAT EXTENT, IF ANY, IS YOUR PARTICIPATION CONFIDENTIAL?


9) WHAT WILL HAPPEN TO THE QUIZ AND QUESTIONNAIRE SHEETS?


10) TO WHAT EXTENT IS WHAT YOU TELL US CONFIDENTIAL?

11) WILL THE QUESTIONNAIRE AND QUIZZES HAVE YOUR NAME ON THEM?

12) WHO CAN YOU SPEAK TO IF YOU HAVE QUESTIONS ABOUT THE STUDY?
13) WHO CAN YOU SPEAK TO IF YOU HAVE QUESTIONS ABOUT YOUR RIGHTS?


14) WHO CAN YOU SPEAK TO IF YOU FEEL THAT YOU HAVE BEEN INJURED?


15) HOW CAN YOU CONTACT THE PROJECT DIRECTOR?
16) DO YOU HAVE TO TAKE PART IN THE STUDY?

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

17) WILL YOU BE PENALIZED IF YOU REFUSE TO TAKE PART IN THE STUDY?

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

18) WILL YOU LOSE ANY BENEFITS IF YOU REFUSE TO TAKE PART IN THE STUDY?

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
19) WILL YOU BE PENALIZED IF YOU QUIT THE STUDY AFTER YOU'VE STARTED?


20) WILL YOU LOSE ANY BENEFITS IF YOU QUIT THE STUDY AFTER YOU'VE STARTED?


21) IF YOU QUIT THE STUDY, WHAT KIND OF REASON MUST YOU GIVE?
22) How many subjects are in this study?

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

23) What will we tell you about the study after you finish?

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

24) How can you find out about the final results of the study?

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________
25) WHEN DO WE EXPECT THE STUDY TO BE FINISHED?
APPENDIX R: SCORING CRITERIA, INFORMED CONSENT QUIZ
SCORING THE INFORMED CONSENT QUIZ

The purpose of consent information is to convey to the subject an understanding of salient aspects of the study. With that in mind, both the initial questionnaire and the posttest were constructed in a short answer format. This format does not reflect an emphasis upon rote memory, instead allowing the subject to describe his or her understanding of the information in his or her own words. Consequently, the adequacy of individual responses was not adjudged based upon the degree of verbatim restatement of the stimulus material. Rather, responses were evaluated based upon the understanding they reflected of the particular article of information involved.

The quiz was constructed of 25 questions, containing a total of 30 scorable points. Each question was followed by 5 blank lines, allowing the subject adequate room to answer the question as fully or as briefly as desired.

Scoring Criteria

Question 1: “What is the nature of this study?”

Relevant stimulus material (enhanced stimulus material appears in italics):
“This is a research study. Its’ nature is research.”
Credit was given for use of the word “research” in describing the study or a general description of the activity as a scientific endeavor, studying communication. Credit was not given for answers which stated or implied that the study was part of the treatment regimen.

**Question 2: “What is the purpose of this study?”**

Relevant stimulus material: “The purpose is to study different ways of giving information to clients in alcohol treatment. *We’re looking at how well different ways of presenting information work.*”

Credit was given for answers which described the purpose of the study as the examination of different ways of presenting information, or studying communication with clients. Credit was not given for answers which stated or implied that the purpose of the study was to improve clinical treatment.

**Question 3: “How much of your time will it take?”**

Relevant stimulus material: “Participation in this study takes about a half hour today and about fifteen minutes next week. *Thirty minutes of your time will be needed today. Fifteen minutes of your time will be needed next week.*”
This question was allotted two points: one point for the statement of the thirty minute interval during the first meeting and one point for the statement of the fifteen minute interval during the second session.

One credit was given for responses mentioning only the initial thirty minute session or stating that the overall duration of both sessions would be forty-five minutes. Two credits were given to responses which specified the duration of both the initial and posttest sessions. No credit was given for responses which specified inaccurate durations or generalities.

**Question 4: “What will you have to do?”**

Relevant stimulus material (video statements in parentheses): “You will be asked to read (see) this information. We’ll ask you to read (look at) this form (video). It will take less than ten minutes. That is, reading it (looking at it) will take ten minutes or less. Then you will be asked to complete two short quizzes. Both quizzes will be rather brief. Next week you’ll be asked to complete another short quiz. In seven days we’d like you to take one more short quiz.

Question 4 was allotted three points: one point for the required activity of reading the form, or watching the video; one point for the two required
quizzes during the first session; and one point for the single required quiz during the second session.

One point was given for mention of each of the required activities. Answers which stated only the total number of tests across both sessions received only one point for that portion of the answer. Answers which stated only that tests would be answered, without specifying a number, received no point for that portion of the answer.

**Question 5: “What will the quizzes be about?”**

Relevant stimulus material: "Two of the quizzes will ask questions about this study, itself. They will ask questions about what you are reading (watching) right now. The other will be a vocabulary quiz. It will test how well you know words.

Two credits were allotted to question 5. One credit was given for mention of each of the two quiz categories. Credit was not given for generalities or answers which stated or implied that the quizzes were clinical in nature.

**Question 6: “Are there risks or discomforts?”**
Relevant stimulus material: “Risks to you are small. This is not a very risky study. You may get bored or frustrated. That is, risks may include boredom and frustration.

One credit was given for answers which specified minor risks or which described the study as only minimally risky. Credit was not given for answers which stated that there were no risks at all involved in the study.

Question 7: “What will this study help?”

Relevant stimulus material: “This study will help us design more effective ways of presenting information to clients. It will help us to get information to clients more efficiently.“

One point credit was given for responses which described a facilitation of communication with clients. General statements, such as “help out in treatment” were given no credit.

Question 8: To what extent, if any, is your participation confidential?”

Relevant stimulus material: “Only the tester and the project director will know that you have helped. Only the tester and the project director will know that you have been in the study.”
One point credit was assigned to responses which described either a limitation of knowledge of participation to the tester and the project director, or substantial confidentiality regarding participation. General statements, such as “100% confidential”, were accepted. Since for all of the subjects the tester was also the project director, a statement that knowledge of participation was limited to either party was acceptable.

Question 9: “What will happen to the quiz and the questionnaire sheets?”

Relevant stimulus material: “The tester will collect your quiz and questionnaire sheets. He will gather them up when you are done. They will be kept in a locked file by the project director. He will make sure they are kept in a locked cabinet.”

Although the information given in the stimulus material relevant to this topic is rather specific, the question itself is quite general in nature. Therefore, one credit was given for responses which accurately described procedures to be undertaken with the quiz and questionnaire sheets. Accepted responses included, but were not limited to: “Locked up”, “be analyzed”, “be studied, then destroyed”, and “be reviewed by the project director.” Responses which stated or implied that the quiz and questionnaire sheets would be reviewed by treatment staff, or other
individuals beyond the described limits of confidentiality, were given no credit.

**Question 10: “To what extent is what you tell us confidential?”**

Relevant stimulus material: “Your answers on the questionnaire and quizzes will be kept confidential. *What you tell us will be kept private.* It will not be seen by treatment center staff. *None of the treatment center staff will have access to this information.*”

As in Question 8, one point credit was assigned to responses which described either a limitation of knowledge of participation to the tester and the project director, or substantial confidentiality regarding participation. General statements, such as “100% confidential”, were accepted. Since for all of the subjects the tester was also the project director, a statement that knowledge of participation was limited to either party was acceptable. Responses which stated or implied that treatment center staff would have access to the quiz and questionnaire sheets were given no credit.

**Question 11: “Will the questionnaire and quizzes have your name on them?”**

Relevant stimulus material: “Sheets will be coded with a number, not your name. *A special number, not your name, will be put on your answer*”
sheets. Only the tester and the project director will know which sheets are yours. *Only the tester and the project director will know which name goes with which number.* Within a week after you finish the last quiz, the code numbers will be removed. *In seven days or less after you complete the last quiz, your code numbers will be removed.*

One point credit was given to responses which accurately stated that subject names would not appear on the quiz and questionnaire sheets.

**Question 12: “Who can you speak to if you have questions about the study?”**

Relevant stimulus material: “If you have any questions about this study, please speak with the tester. *If you’d like to ask about this study, please speak with the tester.*”

One credit was given for responses which indicated that subjects could query the tester regarding aspects of the study. Since for all subjects, at the time of the initial testing, the tester was also the project director, a statement that questions could be directed to the project director was also acceptable. Responses which indicated that treatment counselors or hospital administrators could be asked about the study were not given credit.
Question 13: "Who can you speak to if you have questions about your rights?"

Relevant stimulus material: "If you have any questions about your rights, please speak with the tester. *If you have any questions about the treatment that you're entitled to, please speak with the tester.*"

One credit was given for responses which indicated that subjects could query the tester regarding their rights. Since for all subjects, at the time of the initial testing, the tester was also the project director, a statement that questions could be directed to the project director was also acceptable. Responses which indicated that treatment counselors, hospital administrators, or attorneys could be queried were given no credit.

Question 14: "Who can you speak to if you feel that you have been injured?"

Relevant stimulus material: "If you feel that you have been injured, please speak with the tester. *If you've been hurt, please speak with the tester.*"

One credit was given for responses which indicated that subjects could speak with the tester regarding possible injury. Since for all subjects, at the time of the initial testing, the tester was also the project director, a statement that subjects could speak with the project director was also
acceptable. Responses which indicated other resources in case of possible injury, such as attorneys, while ostensibly accurate, did not reflect an accurate understanding of the presented material and were given no credit.

Question 15: “How can you contact the project director?”

Relevant stimulus material: “You may also contact the project director at this address:

Ken Mills
Department of Clinical Psychology
Iowa Methodist Medical Center
1200 Pleasant Street
Des Moines, Iowa 50309
(515) 241-6834

If you’d like to contact the project director (Ken Mills of Iowa Methodist Medical Center) you may do so at the above address.”

Two points of credit were assigned to this question. One point was given if the name of the project director, or his identity as the tester, was stated. No credit for identity was given if only a first name was referenced. An additional point was given if an element of his address was accurately stated (e.g., Iowa Methodist Medical Center, phone number). If the
subject was tested at Iowa Methodist Medical Center, a statement that the
director could be contacted “here” was acceptable. General responses,
such as “by phone”, or “at his office”, or “in Des Moines” were not given
credit.

Question 16: “Do you have to take part in the study?”

Relevant stimulus material: “Taking part in the study is voluntary. You
decide on your own.”

One point of credit was given for responses which indicated a recognition
of the voluntary nature of participation in the study.

Question 17: “Will you be penalized if you refuse to take part in the
study?”

Relevant stimulus material: “If you refuse to take part, there will be no
penalty. Nothing bad will happen to you if you decide to not take part.”

One point of credit was given for responses which indicated a recognition
that no penalty would be imposed for refusal to participate.

Question 18: “Will you lose any benefits if you refuse to take part in
the study?”
Relevant stimulus material: "You will not lose any benefits in the treatment program if you refuse to take part. You will not lose anything if you decide to not take part."

One point of credit was given for responses which indicated a recognition that no benefits would be lost as a result of refusal to participate in the study.

Question 19: "Will you be penalized if you quit the study after you’ve started?"

Relevant stimulus material: "If you quit the study after you've started, you will receive no penalty. Nothing bad will happen to you if you quit the study at any time."

One point of credit was given for responses which indicated a recognition that no penalty would be meted out to subjects as a result of quitting the study before completion.

Question 20: "Will you lose any benefits if you quit the study after you've started?"
Relevant stimulus material: “You will not lose any benefits in the treatment program if you quit at any time. You will not lose anything if you decide to quit after you’ve started.”

One point of credit was given for responses which indicated a recognition that no benefit to subjects would be withheld or withdrawn as a result of quitting the study before completion.

Question 21: “If you quit the study, what kind of reason must you give?”

Relevant stimulus material: “If you quit the study, you need not give a reason. You don’t have to explain to anyone if you quit the study.”

One point of credit was given for responses which indicated a recognition that subjects could quit the study without giving a reason.

Question 22: “How many subjects are in this study?”

Relevant stimulus material: “About 120 subjects are involved in this study. That is, about 120 people will take part in the study.”

One point of credit was given only for responses which accurately specified the number of subjects to be 120. (Although in the final design,
the number of subjects was somewhat fewer than 120, this number was presented to all subjects as part of the stimulus material in order to maintain uniformity. At the time of full debriefing, subjects were informed of the smaller number of subjects expected to participate in the study.)

**Question 23:** “What will we tell you about the study after you finish?”

Relevant stimulus material: “After you finish the last quiz, the tester will give you a complete written description of the study and will answer any questions that you have. *As soon as you’re done with the last quiz, the tester will hand you a printed summary of the study and will answer your questions.*”

One point of credit was given for responses which indicated a recognition that a complete description of the study would be provided upon completion of subject participation, and/or that any subject questions about the study would be answered. Credit was not given for responses that indicated that the results of the study would be forthcoming immediately after the subject had completed his or her participation.

**Question 24:** “How can you find out about the final results of the study?”
Relevant stimulus material: "You may have a description of the results of this study sent to you. You can receive a report on how it comes out if you would like. If you would like to get a copy of these results, please tell us. If you'd like to know how the study comes out, let us know."

One point of credit was given to responses which indicated that the results of the study would be sent if requested. No credit was given to responses which stated that the results would be sent automatically.

Question 25: "When do we expect the study to be finished?"

Relevant stimulus material: "We expect the study to be completed in six months or less. In half a year, or less, we expect the study to be finished."

One point of credit was given to responses specifying that the study would be completed in six months, or less, or that it would be completed in six months. No credit was given for other time frames, or for the statement that the study would be completed in six months or more.
APPENDIX S: INSTITUTIONAL PERMISSIONS TO COLLECT DATA
August 27, 1991

Kenneth R. Mills  
Clinical Psychology  
Iowa Methodist Medical Center  

RE: R & I Grant Request #506  KRM: CONSENT  

Dear Ken:

Your proposal for a study on the effectiveness of different methods of consent information presentation was approved by the Research and Innovation Center Advisory Committee at its meeting on August 21, 1991. There was no question regarding the proposed materials to be reviewed by the subjects. Please forward a copy of the approval by the ISU Human Subjects Committee when it is received.

Also please forward to the committee the procedure you will follow regarding protection of the confidentiality of the patient in the interviewing process, accessing patient records, and reporting the results.

Should you have any questions or concerns regarding this approval please contact me at 283-6761. Best wishes in the conduct of your study. If I can be of any assistance in the course of the study, please call. The Committee looks forward to receiving a report of your study.

Sincerely,

Keith L. McRoberts, Ph.D., P.E.  
Director, Research and Innovation Center

KLM/cfw

cc: Juli Taylor, Accounting  
    Ivan Lyddon, IMHF  
    Joyce Keen, Clinical Psychology

LTR/AD07/KLM/MILLS
TO: Ken Mills  
Clinical Psychology  

FROM: Kathy Stone  
Powell CDC  

DATE: August 30, 1991  

RE: Research Proposal  

I have reviewed the proposal you sent me for a planned study on the effectiveness of different methods of presentation of consent information to chronic alcoholics. The proposal is very interesting and of potential benefit to Powell CDC staff and clients. You can count on our participation in the study.

Please contact me as your plans move forward so we can work out details.

Thanks!

KS/pc
September 28, 1992

Ken Mills
713 Ninth Street
Ames, Iowa 50010

Dear Ken:

This is a letter officially giving you permission to collect the research data for your study entitled “The effect of information redundancy and format upon comprehensibility of consent information in chronic alcoholics.”

It is our belief that this study will be of mutual benefit to you and to us. I hope your research will prove valuable.

Sincerely,

David A. Sahr,
Executive Director
October 16, 1992

TO WHOM IT MAY CONCERN:

The Substance Abuse Treatment Unit of Central Iowa Board of Directors have officially given Mr. Ken Mills permission to collect research data as needed.

Vickie F. Lewis
Director of Professional Services
September 30, 1992

To Whom it May Concern:

This letter is to verify that Ken Mills has received our permission to interview M.E.C.C.A. clients for the purpose of conducting research. Mr. Mills will initially interview clients on October 2nd, 1992, any subsequent appointments will be arranged through Fonda Frazier or with the clients themselves with our standing permission.

Sincerely,

Arthur J. Schut
Executive Director

Fonda Frazier, M.A., CAC III
Clinical Director