An Evaluation of "Informed Consent" with Volunteer Prisoner Subjects

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"Informed consent" sets a goal for investigators experimenting with human subjects, but little is known about how to achieve or evaluate it in an experiment. In a 3-year, double-blind study with incarcerated men, we attempted to provide a "free and informed consent" and evaluated our efforts with an unannounced questionnaire administered to subjects after they completed the experiment. At that time, approximately two-thirds had sufficient information for an informed consent, but only one-third was well informed about all key aspects of the experiment and one-third was insufficiently informed to give an informed consent. We found that institution- or study-based coercion was minimal in our experiment. From our evaluation of the questionnaire and experience at the study institution, we conclude that an experiment with human subjects should be designed to include an ongoing evaluation of informed consent, and active attempts should be made to avoid or minimize coercive inducements. Experiments with significant risk, which require a long duration and/or large sample size relative to the institution's population, should probably not be performed on prisoner subjects. The experimenter should be independent of the penal institution's power structure. Presenting and explaining a consent form to volunteers on one occasion is probably an inadequate procedure for obtaining and maintaining an informed consent.

INTRODUCTION

Until recently, scrutiny of experiments involving human subjects was made principally by investigators who focused on questions of methodology, i.e., data reliability and reproducibility, rather than questions of ethics. As a result, the ethical problems of protection of human subjects have been neglected compared to the methodological problems, and the principal source of experience drawn upon in the current examination of research ethics, and for guidelines for human experimentation (1), has been the common law regulating physician-patient relationships (2). The ideas about research ethics which have resulted are summarized in the concept of informed consent, which establishes criteria for the protection of the experimental subject. Key aspects of informed consent are that the subject is aware he is participating in an experiment and knows its objects or goals; that he understands the risks and benefits of his participation; and that he is neither forced to participate nor subject to punishment for withdrawal of his participation.

Prisoners are frequently employed as subjects of pharmacological and other experiments and are especially vulnerable to coercion and limited information. The possibility of achieving a "free and informed consent" in prisoner research has been denied by some observers, who assert that the nature of a penal institution inevitably compromises informed consent (3). Others stress that a researcher must understand the unique institutional and personal factors influencing prisoners (4–6) and have suggested that investigators who are aware of and sensitive to these factors can provide the basis for a free and informed consent (4,5). Evidence and opinion on ethical and legal aspects of prison research has been outlined effectively by Katz (7), and im-

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important aspects of motivations and rewards for prisoner subjects are discussed by Ayd (8).

In this paper we report the results of our evaluation of informed consent in a 3-year study of the antiaggressive effect of lithium carbonate (9), conducted with inmates of the principal Connecticut Correctional Institution for men under 21 years of age. The results and conclusions are based on our observations during the study and on answers to a questionnaire routinely given to subjects upon termination of the experiment. The unannounced questionnaire contained 11 simply phrased questions dealing with issues we viewed as relevant to informed consent.

The evaluation was prompted by the controversy about informed consent with prisoner subjects, which emphasizes the need for information based on actual experience with the problems of conducting research in prisons. We hope this study will help clarify some problems of informed consent with captive subjects and will aid other investigators in designing ongoing evaluations of informed consent within their primary research objectives.

**DESCRIPTION OF LITHIUM EXPERIMENT**

The experiment was designed to compare the effect of lithium carbonate versus placebo in modifying the frequency of threatening or violent behavior and/or reducing angry affect in a heterogeneous group of incarcerated male delinquents (9). It was an outgrowth of work on the modification of violent behavior by lithium in chronically assaultive men reported by Sheard (10,11) and confirmed by others (12).

The experiment operated on a 5-month regime: a drug-free control month, followed by up to 3 months with single daily doses of either sustained-release lithium carbonate (Priadel) or identical-appearing placebo administered under double-blind conditions, and concluded with a drug-free control month. During medication, blood samples were obtained weekly for serum lithium levels and clinical tests (13). Subjects continued with their usual institutional routine, except for the 0.5 to 2 hr per week during which they performed study tasks; they received no privileges or amenities within the institution. Subjects were paid at the rate of $3.75 per week, whether or not they completed the experiment. Those who completed or whose termination was beyond their control (e.g., transfer to another institution) received a bonus of $2.50 per week (gross rate of pay, $6.25 per week, for a maximum payment of $125.00 for 5 months). The pay rate was equivalent to monthly remuneration for the best-paying inmate jobs at the study institution during our experiment (October 1972–June 1975).

All subjects signed consent forms and an identical form was also signed by a parent or the legal guardian of subjects under 18 years old. The consent form was as follows.

The purpose of this project is to test whether lithium (which is a simple chemical element) can help the control of impulsive and aggressive behavior. This is why you have been asked to volunteer. In order to see if lithium has any good effects it is necessary to compare it with a placebo (a substance which works by suggestion only). You will not know which of the two agents you are getting. You may notice symptoms such as nausea, hand tremors, headaches, diarrhea, constipation, or dryness of the mouth, which we will try to avoid as much as possible, and can treat early if they occur. Repeated clinical interviews, psychological behavioral testing and a weekly blood test will be performed to follow your progress. Should there be any indication that it is not in your best interest to continue the treatment, the medicine will be discontinued. You are free to discontinue the trial should you wish to do so, and there will be no penalty to you for so doing. Participation in this experimental treatment program will not influence your status in the correctional institution.
Criteria of acceptability for the experiment were: (i) conviction for a serious assaultive crime (e.g., manslaughter, murder, rape, assault); a history of chronic assaultive behavior; or a history of chronic impulsive antisocial behavior; (ii) freedom from psychosis; (iii) good physical health with absence of illness contraindicating lithium treatment; (iv) ability to comprehend the written material used in the study; (v) sentence of sufficient duration to insure time for completion of the study. Subjects taking psychoactive medication (e.g., tranquilizers) were not accepted for the program unless medication was discontinued with the consent of the prescribing physician. All subjects accepted for the study were given a physical examination before receiving medication.

Inmates were referred to the experiment by the institutional counseling staff, to whom we had described the experiment and admissions criteria. On interview, the study was described, and a referral's suitability was determined by a staff psychiatrist and the senior investigator. Subjects were not given the consent form until they had 2–4 weeks of contact with the study staff and had received a detailed explanation of the program. All staff members who had contact with the subjects were blind to the medication for the duration of the experiment (9, 14).

SUBJECTS AND INFORMED CONSENT QUESTIONNAIRE

The men reported on here \(N = 58\) received the questionnaire on informed consent when they left the study. There was no other criterion for selection of these subjects. Of this group, 44 (76%) completed the entire study, 10 (17%) quit, 2 (3.5%) were dropped for noncooperation, and 2 were lost due to transfer. The sample represents 67% of all subjects who completed the study and 55% of all subjects who quit. Average age 1 month before receiving medication was 19.1 years; average vocabulary-based IQ (15) was 90.0; average Memory-For-Designs brain damage score (16) was 2.8 (normal range: 0–4); 34 subjects (58.6%) were white, 19 (32.8%) black, and 5 (8.6%) Hispanic. Thirty-five (62.5%) received lithium carbonate and 21 (37.5%) received placebo; 2 subjects had received no medication when they left the study. Thirty-nine (67.2%) had been arrested and/or convicted for a crime of violence.

The questionnaire, which was not anonymous, was administered to each subject at his final staff contact; a staff member was available to offer assistance to subjects with poor verbal skills. An analysis of response in terms of drug and status (complete, quit, etc.) would not have been possible with an anonymous questionnaire. The directions were: "This is not a test. We want to know your answers so we can improve the Program. Answer every question that applies to you. If you don't know how to spell a name, write in what sounds right to you." All subjects had received partial or complete payment from the study and were aware that remuneration was not in jeopardy when they got the questionnaire. Since subjects were interviewed after completing the study, and since our staff members had no authority to impose institutional punishments and had no poststudy commitments, we feel that the subjects answered candidly. In scoring, ambiguities due to the limited language skills of many subjects were taken into consideration. Because a staff member was available to answer questions during completion of the questionnaire, we believe all subjects understood the questionnaire items. Staff members never hinted at answers or provided information which would influence subjects’ responses.

INFORMATION FOR THE VOLUNTEER SUBJECTS

In part, informed consent establishes criteria for informing the subjects about participation in an experiment. To evaluate this aspect of informed consent, we must
compare the output (answers on questionnaire) with the input (routine study information). Our standard format, presented by the same staff member in a reproducible manner throughout the study, was as follows.

All referrals received a detailed presentation within their first 2 weeks with the experiment, generally during their first staff contact. Each was given a printed description of the study which included its purpose, the age and medication requirements, an outline of the experiment, the names of the drugs involved, the requirement of blood samples, and the payment schedule. This was always supplemented with a 0.5–1-hr oral presentation.

The oral presentation stressed that the study was experimental and was not a treatment program. Lithium carbonate was described, as was its history in the treatment of manic–depressive illness and its availability by prescription (to stress that the drug itself was not experimental). The pilot use of lithium in the treatment of aggressive behavior was outlined and the subject told that, while we felt lithium did help some men control aggressive behavior, we knew that it did not help all men; the purpose of the experiment was to prove whether or not it worked, and with whom. We stressed that we could therefore not promise any benefits related to the drug. The placebo effect was discussed as well as the reasons for a double-blind design. It was made clear that neither our staff at the jail nor the subject would know which drug he received, and because of the double-blind we could not guarantee that a subject would receive lithium even if he wanted to try the medication to improve his behavior. We asserted that the only benefits we could be sure of were remuneration, an opportunity to have a change of routine, and contact with noninstitutional people. It was stressed that we were neither part of the jail staff nor affiliated with the Department of Corrections.

Each subject was assured that his records would be kept strictly confidential and was told that we made no poststudy commitments and refused to be involved in parole or probationary considerations. We discussed payment, pointing out explicitly that money was paid for weeks completed, with a bonus for completion of the full program, which meant that quitting would result in reduced remuneration and that this was the only penalty for quitting the experiment. We stressed that the subject was free to terminate at any time.

We described side effects, pointing out that because of the placebo effect subjects might experience side effects on either lithium or placebo, but that symptoms were more likely, and longer lasting, with lithium. Subjects were told that no one experiences all the side effects and some subjects would experience none, and the purpose and necessity of the weekly blood sample were explained. Side effects described included headache, loss of appetite, thirst, dryness of mouth, increased urinary frequency, hand tremor, and gastrointestinal disturbances; a description was given in words familiar to the subject. In addition to this presentation of side effects, each subject completed a weekly symptom check list which included the symptoms described above (13).

The possibility of lithium intoxication ("overdose") with symptoms of increased tremor, stumbling and loss of coordination, confusion and stupor was mentioned, but it was stressed that taking weekly blood samples would greatly minimize the possibility of intoxication and that intoxication and unpleasant side effects could be dealt with by reducing dose or stopping medication. We concluded by encouraging the subject to question the staff about matters of concern or interest to him throughout the study.
RESULTS

The summarized results for all subjects are presented in Table 1 in which the questions are given as they appeared on the questionnaire. To evaluate our subjects’ comprehension of the key aspects of the experiment, we examine answers to the first six questions in Table 1. A total of 18 subjects (31.6%) answered all Questions 1–6 completely and correctly. Virtually all (97%) knew that lithium (carbonate) was the drug being tested and virtually all (98%) were aware of the correct payment. Most (82%) knew that lithium and a placebo (“sugar pill”) were the two drugs available (an additional 5 subjects (9%) named one of these). The two subjects who did not give the name of the study drug deserve comment. Both answered very few questions (3/11 for a subject who was dropped and 6/11 for a subject who quit), and it is probable that, had they been more motivated to respond, they would have given the correct answer. This follows from the fact that our experiment was known for nearly three years at the host institution as the “Lithium Program,” so that the name of the medication we studied was known to nearly all inmates and staff, as we had intended.

Question 2 gives an opportunity to evaluate the subjects’ understanding of their role in the study and its purpose. Most of the subjects (71%) gave an answer which clearly indicated the experimental nature of the study: “to experiment the drug (sic) with different types of people” and “to find out if the drug can work on violent

| Table 1 | Responses to Informed Consent Questionnaire |
| --- | --- |
| Question | Total answers | Responses [N(%)]| |
| Correct | Incorrect |
| 1. What is the name of the drug we are testing? | 58 | 56(96.6) | 2(3.4) |
| 2. What is the purpose of this program? | 59 | 42(71.2) | 17(28.8) |
| 3. How much does the program pay? | 57 | 27(47.4) | 30(52.6) |
| 4. Why do we take blood samples? | 57 | 55(98.2) | 1(1.8) |
| 5. What are some side effects from this drug? (Drug in Question 1) | 57 | 34(60.7) | 22(39.0) |
| 6. If you got medication every day, you got one of two possible drugs. What are their names? | 54 | | |
| None | One | Two | Three or more |
| 20(35.1) | 10(17.5) | 16(28.1) | 11(19.3) |
| Correct drugs named | | | |
| 5(9.26) | 5(9.26) | | 44(81.5) |
| 7. Why did you volunteer for this program? | 64 | | |
| Money | Self-help | Miscellaneous | Parole |
| 27(42.2) | 22(34.4) | 12(18.8) | 3(4.69) |
| Yes | No | | |
| 1(1.8) | 55(98.2) | 0(0) | |
| 8. Did you feel forced to join the program? If you did, how? | 56 | | |
| 32(56.1) | 18(31.6) | 7(12.3) |
| 9. Did the program do you any good? If it did, how? | 56 | | |
| 14(24.6) | 41(71.9) | 2(3.5) |
| 10. Did the program do you any harm? If it did, how? | 57 | | |
| 46(83.6) | 4(7.3) | 5(9.1) |
| 11. Do you think we were honest about the program? | 55 | | |
| | | | |
people" are typical. However, nine men (15%) gave no indication of an experiment and eight (13.5%) simply said they did not know the purpose of the study.

Only 47% of the subjects indicated the importance of aggressive behavior in the experiment. A good answer was "to experiment w(ih) lithium to see if it controls violent or other types of behavior related to violence." A more typical answer was "to detummen wheather (sic) or not it (lithium) can help level a person's temper off." A typical answer not indicating aggression was "to try to find out how lithium helps people." That only half of the subjects indicated aggression is unexpected since our experiment had a reputation in the institution for selecting violence-prone men as shown by inmates who approached staff members in the corridors with advertisements of aggressive prowess. Also, the study explicitly investigated aggressive behavior in terms of both admissions criteria and routine weekly questions about violent behavior.

A majority of subjects (61%) correctly indicated that the blood sample was required to monitor lithium levels in the blood. Typical incorrect answers suggested prior experience with drug abuse programs: "to make sure I didn't take any other drugs"; "to make sure were taken (sic) the lithium."

With regard to side effects, 65% gave at least one correct side effect of the medication as described by the staff, but only 19% could give three or more, and 35% gave no correct side effects (although many subjects reported symptoms they had experienced while on the study). Most common side effects given were shakiness or tremor (N = 14), headache (N = 13), and stomach cramps or pains (N = 8) (13).

To evaluate motivation, we consider Question 7. The largest group of responses (42% of total) indicated money; 34% indicated self-improvement, and only 4.7% (3 subjects) gave help at the parole board as a consideration. The remainder of responses (19%) indicated interest in the study (N = 6), chance of getting high (N = 2), seeing psychiatrist (N = 1), and variety (N = 1) as reasons for joining.

Questions 8–11 give the subjects' evaluation of the study. Virtually all (96%) denied that they "felt forced" to join, and a large majority (84%) said that the staff had been honest; 7% felt we had been dishonest, and 9% were unsure, usually because they were concerned with long-term effects of the medication which could not be evaluated at the time they received the questionnaire. Over half (56%) felt that they received benefits. Of these men, 29 (94%) gave reasons. Increased self-knowledge or self-control (most frequently expressed as "slowed me down some") accounted for 20 of the responses (69%); contact with staff for 5 (17%), increased knowledge for 2 (7%), and money for 2. Nearly 25% of the subjects reported that the study did them some harm, 4% were unsure, and 72% reported they were not harmed. All the subjects (N = 14) who felt harmed gave reasons: 12 were side effects, and 2 were adverse (paradoxical) effects on behavior. Half of the subjects who felt harmed quit the experiment.

Table 2 compares study completers and noncompleters. Of 12 noncompleters, 10 quit the study and 2 were dropped for noncooperation; they are combined because they have in common that they were unwilling to participate in the study as required. Table 2 presents only comparisons which were significantly different; there were no significant differences among any of the other questionnaire or demographic data discussed above.

Many more noncompleters were on lithium and they were significantly younger than the completers. With respect to information and attitudes about the experi-
ment, the groups were similar. However, 67% of the noncompleters reported that the program did them some harm, compared to 13% of the completers.

In 2 1/2 years, 159 individuals were referred to the study, of whom 101 joined. Fifty-three subjects completed the entire study and 14 completed at least 1 month on medication. A total of 18 subjects quit, 14 while on medication and 4 before receiving it. Six subjects were dropped for various reasons. The subjects who quit gave these reasons: side effects (N = 10), disliked study procedures (N = 3), suspicious of staff (N = 2), no reason available (N = 3). Twenty-five of the original referrals were unsuitable and 14 others refused to participate in the experiment in any way. The subjects who refused to participate gave these reasons: disliked any kind of medication (N = 4), not interested (N = 3), refused being “guinea pigs” (N = 2), disliked blood samples (N = 1), felt study was not appropriate for him (N = 1). Finally, a few subjects showed impatience and disinterest during the presentation of the study or the explanation of the consent form.

**DISCUSSION**

We administered the questionnaire to the subjects when they terminated, usually 4 months after they received detailed information about the experiment. We chose to administer the questionnaire at that time in order to get candid appraisals of the study. Because the subjects were not questioned when they signed the consent form, we cannot conclude how much they knew about the experiment at that time, although it seems likely that questioning them shortly after the oral presentation would have resulted in a higher percentage of correct answers on Questions 1–6 (Table 1).

We have defined the key aspects of informed consent as follows: A subject should know he is participating in an experiment and understand its objects or goals; he should understand the risks and benefits of participation; and he should not be forced to participate. In order to evaluate the success of informed consent, we will deal with information, coercion, and motivation separately.
Information

With respect to information, Questions 1, 2, and 6 (Table 1) deal with the experimental nature of the study, the drug being tested, the use of a placebo, and the object of the experiment. Table 1 shows that over two-thirds of the subjects correctly answered each of these questions, with the exception that only one-half specifically indicated aggressive behavior in their answers. As discussed in Results, the importance of aggressive behavior was so explicit in the study and widely known at the institution that it is unlikely that only half of the subjects were aware of it.

With respect to risks and benefits, Question 3 gives the principal benefit (payment) and Question 5, the risk (side effects). Virtually all subjects correctly described payment, and two-thirds could identify at least one side effect described in the informational presentation. In addition, nearly two-thirds correctly described the reason for the blood sample, which is related to risks of participation.

Based on the results above, we conclude that approximately two-thirds of the subjects had the information necessary for an informed consent to our experiment at the time of testing.

Apparent lack of information was evident in several areas. Of 17 subjects (29%) who did not correctly answer Question 2, 8 reported that they had no understanding of the purpose of the study and 9 did not indicate its experimental nature. One-third of the subjects gave no correct lithium side effects and did not give a correct explanation for the blood samples. Thus, approximately one-third had inadequate information on the nature and purpose of the study and on risk at the time of testing.

It is possible that the subjects would have been better informed if we employed a second presentation of key aspects of the study. This could have been accomplished by administering Questions 1-6 to each subject before he started medication, giving a second explanation of all questions the subject answered incorrectly. This procedure would help insure that no subject received medication without understanding the key aspects of the experiment, although no formal presentation can guarantee that a subject will employ the information in reaching a decision to participate.

Coercion

Even if adequately informed, a subject cannot make a free consent if coerced by threats to his safety, quality of life, or parole or release possibilities. We found no indication of systematic coercion or that the subjects perceived themselves as forced to join the study. For example, 14 of the 159 individuals we interviewed (8.8%) refused outright to participate. Since nearly 1 in 10 men refused any contact with the study, the referrals obviously perceived and exercised freedom of choice to join. In addition, 98% of the subjects answered they did not "feel forced" to join the study (Question 8, Table 1). The single subject who felt forced quit the program after 6 weeks on medication (placebo). Because inmates were candid in their criticisms of coercion and authority in the institution, and because the question was simple and direct, we believe the subjects felt themselves free from external pressure to join the experiment.

These results indicate substantial freedom from coercion to join, and they reflect our efforts to avoid pressuring subjects and reflect noninterference by the jail administration. However, some subjects may not have answered Question 8 honestly because an affirmative answer was defended against or denied as a result of a need to maintain a tough self-image.

Freedom to terminate is important to self-esteem and to an ongoing free and in-
formed consent. Of the 101 men who agreed to join the study, 18 quit and, of the 80 men who received medication, 16 (20%) quit and specified side effects or adverse effects on behavior as their reasons. Since 1 out of every 5 men who took medication not only perceived but exercised the option to quit, coercion, if present, was not important enough to override motives of self-protection or comfort.

Motivation

An informed subject with a free choice to join or continue an experiment might be so strongly motivated to achieve rewards contingent upon participation that need for the rewards overrides considerations of safety. In prison, the most important motivations are early release, improved living conditions in a "research unit" (4), and money.

With respect to release, only 3 subjects indicated parole considerations as their motivation for joining the study. Because there was pressure to join self-help programs run by jail staff at the study institution in order to achieve favorable parole evaluation, this is an important result. It demonstrates that a practice on noninvolvement with the parole board can be made clear to, and be understood by, volunteer subjects. This result is consistent with the conclusion of Wells (17), based on a review of the literature on motives for volunteering among prisoners, that "relatively few believe, popular misconceptions notwithstanding, that volunteering will enhance parole possibilities."

Bach-Y-Rita (4) has pointed out that in some prisons experimental subjects receive better treatment or enjoy better living conditions than other prisoners. Since participation in the experiment had no effect on the prisoners' status in the institution, and since there was no "research unit," such factors played no part in our study.

Money was the most important motive indicated by the subjects (42%), and virtually all subjects correctly described the payment schedule. We cannot evaluate the extent to which money may have induced subjects to remain on the study against their better judgment. We attempted to minimize this by paying all subjects; no one was denied payment for his time for any reason. Further, if subjects chose, they were paid on a monthly basis so there was no need to take medication or to complete the experiment in order to earn some money. However, we paid inmates at a rate comparable to the best-paying jobs at the jail. Since most of our subjects did not aspire to or qualify for these jobs, the rate of pay may have been very attractive. In addition, the bonus may have been a strong inducement. Since 1 out of 5 subjects quit, such monetary considerations clearly did not override subjects' judgment, however.

The only other important motivation for joining was self-improvement (34% of the reasons given). Since our program was experimental, we attempted to discourage subjects from joining because they felt the medication or the staff could offer them successful treatment. That one-third gave self-improvement as a motive may mean that we failed, and the subjects expected benefits we could not validly offer. However, closer examination suggests that the men giving self-improvement as an answer were motivated by their own designs and were not misled by our presentation. Twenty-two of the 57 subjects who answered Question 9 gave self-help as a motive. Fifteen of these (68%) reported some benefits from the study compared to 17/35 (48.6%) who did not seek benefits ($\chi^2(1) = 1.39$, N.S.). Since those who both sought and perceived benefits from the study were evenly divided between lithium carbonate and placebo (lithium, 8 subjects; placebo, 7), their benefits reflect their own motivation for self-improvement. Because many inmates were sincerely concerned about
personal change and growth, it is not surprising that subjects indicated self-improve-
ment as a motivation for joining the study. And, since most (84%) of the subjects felt
we were honest about the study, with only 7% indicating they felt us to be dishonest,
they did not feel that the experiment staff misled them.

**Benefits and Harm**

Finally, we examine subjects’ appraisals of benefits and harm. Over half of the sub-
jects reported some benefits; most gave increased self-control and self-knowledge.
Fully one-fourth of the subjects reported harm, usually from side effects. Of the sub-
jects who quit, virtually all received lithium carbonate and overwhelmingly reported
harm (side effects) when compared to the completers. While motivated to join pri-
marily by money, benefits were perceived in personal terms of self-control or growth.
Risks were perceived as related specifically to drug effects. Two subjects were
unsure if the program had harmed them because they were not confident of our
assurance that there were no long-term consequences of receiving lithium carbonate.

**CONCLUSIONS**

The results presented above show that approximately two-thirds of the subjects
had sufficient information on the nature and purpose of the experiment and its risks
and benefits to make an informed consent at the time of testing, 4 months after com-
mencement of the experiment; fully one-third, however, did not. As administered in
the “medium security” host institution, this study seems to have been relatively free
from coercion to join, or to remain on medication, as shown by the significant number
of men who refused to join, who reported that they had not felt forced to join, and
who exercised their option to quit, and as shown by the very small number who gave
parole as a consideration for joining. Therefore, it was possible to achieve a free and
informed consent with a majority of the prisoners in our study.

Based on our evaluation of the questionnaire responses and our impressions during
the experiment, we are certain that an explanation of the consent form on one occa-
sion only would have been entirely inadequate for an informed consent. Some men
displayed indifference during our explanation of the study or consent form by inter-
rupting or asserting disinterest. In such cases, it may be the best policy to exclude
subjects willing to accept risk, but unwilling to understand it, since in such subjects
the informational requirement of informed consent cannot be met.

In order to insure that subjects have the information required for an informed
consent, a questionnaire of the type we employed could be made mandatory before
participation involving risk begins. Subjects incorrectly answering key questions
could then receive additional information or be excluded from the experiment. The
latter alternative requires that the investigator or advisory committee thoroughly
and fairly present the experiment, but neither drill nor induce the subject to cram for
the questionnaire.

We chose to question subjects at the end of their participation to evaluate what
they had in fact learned, rather than offering a pass-or-fail test which would evaluate,
at worst, what they could memorize without understanding. We feel that an evalua-
tion of key aspects of informed consent should be a part of every experiment invol-
ving risk to human subjects. Such an evaluation could serve to improve the educa-
tional routine, to identify coercive factors influencing subjects, and to provide the in-
formation needed to clarify the problems of prisoner participation in research.

In order to minimize coercive pressures on subjects, experiments must be designed
*from the outset* so that they will not trap subjects (for example, by refusing payment
if a subject does not complete an experiment or by conducting an experiment in an institution in which the parole board considers participation in a medical experiment to be particularly meritorious. Our evaluation of coercion and our experience at the host institution suggest that the conditions for a free consent would be compromised at an institution where jail administration or staff view an experiment as part of their correctional repertory or as useful for reasons of security.

An earnest effort to avoid coercion and to describe risks may appear to or actually cause an unacceptable dropout rate which may pose a serious problem for the completion of a successful experiment. This may place pressures on the investigator to reorder priorities in the study in order to maximize the number of subjects available. Because of this problem, we believe experiments involving significant risk, and requiring either long study periods or a large sample size relative to the institution’s population, should generally not be undertaken with incarcerated subjects.

Finally, the investigator must be familiar with the power structure of the host institution and remain independent of it in order to minimize institution-based pressures on research subjects.

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