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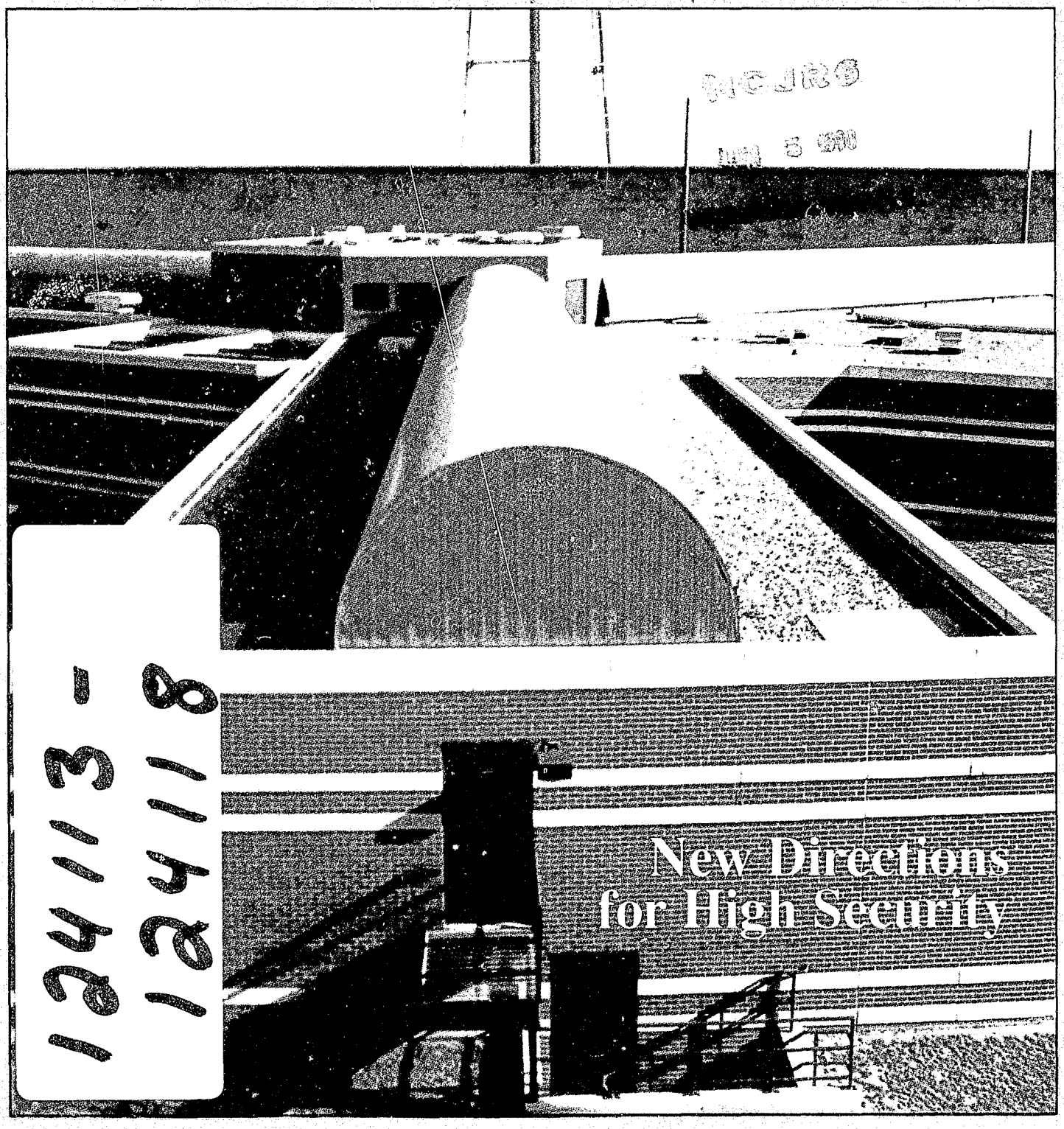

New Directions for High Security

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Protecting Prisoners in Research

A reasonable approach

Harriet Lebowitz

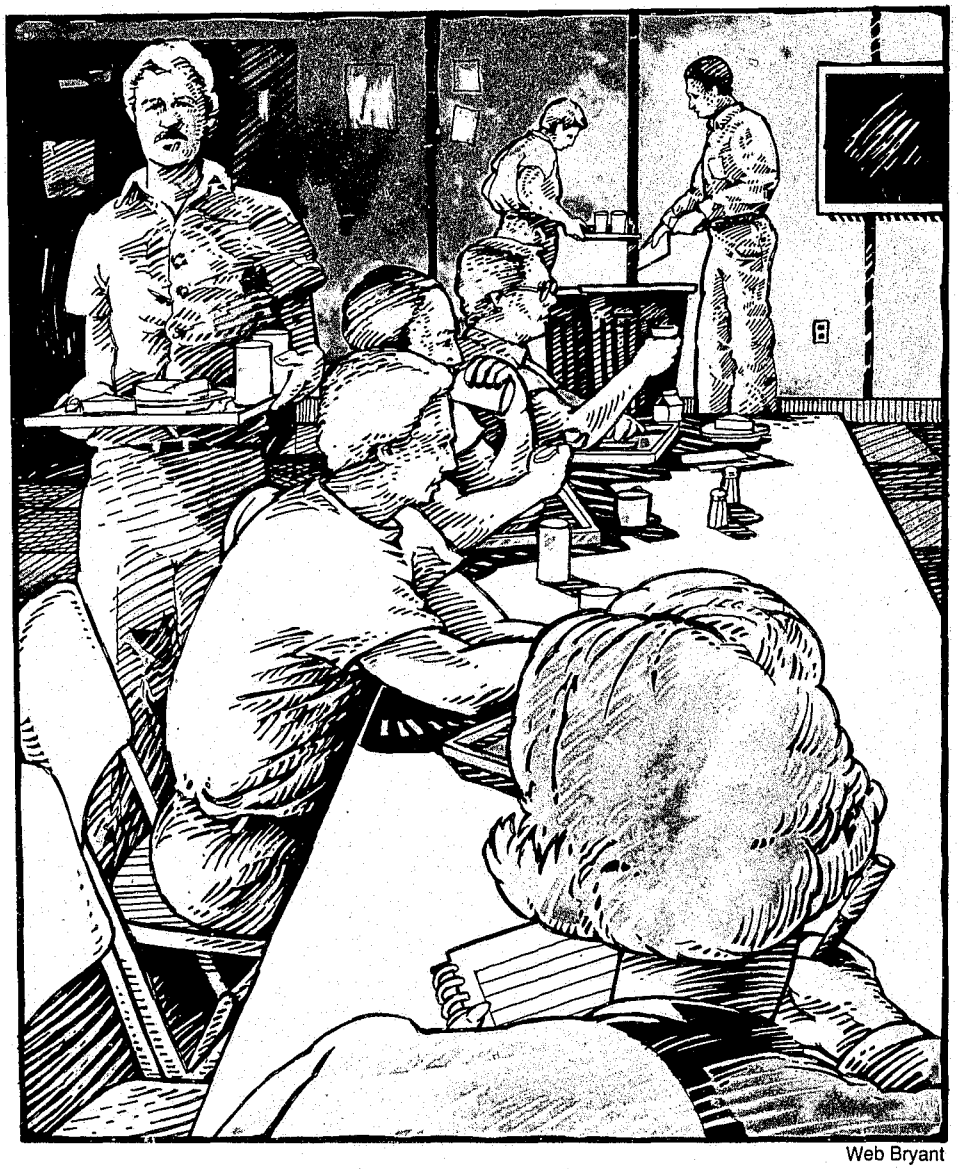
Picture yourself as a prison system administrator who reviews research proposals. Would you approve the following studies?

■ In the first, a graduate student wants to interview inmates about the types of television programs they prefer. The student wants to see if there is any relationship between television program choices and inmate offense categories. For example, he wants to know whether drug offenders prefer *Geraldo* or *Jeopardy*.

■ In the second study, one of the physicians on your staff wants to investigate the relationship of level of sugar in inmates' diets to misconduct in the institution. The physician proposes to include very low levels of sugar in one unit's diet; another unit with a similar population would be given a moderate level of sugar; and a third unit would be given high levels of sugar.

■ Finally, a drug company would like to test an experimental cold remedy on volunteer inmates. Two experimental groups would receive medication; a control group would be given placebos. Each person would be monitored for 2 weeks in a hospital setting. Would you, as a prison administrator, approve that research project?

This article discusses how these proposals might be viewed under the U.S. Department of Health and Human Services (HHS) and Federal Bureau of Prisons (BOP) regulations on protection of research subjects. Before explaining the policies of these two Federal agencies, a sense of why they were developed may be helpful.



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Background

Before 1940, prisoners in the United States seldom participated in biomedical research that had no reasonable expectation of improving the health or well-being of the research subjects. Beginning in World War II, however, large numbers of prisoners participated in voluntary research programs to develop treatments for diseases common to American soldiers. After the war, the growth of biomedical research and the imposition of requirements for testing drug safety led to increased participation of prisoners in such research. The major advantage in involving prisoners was the opportunity to monitor subjects in a controlled environment at a low cost.

Since the 1960's, the ethical propriety of prisoner participation in research has been under scrutiny. Among the events that focused public attention on the issue was the 1973 publication of *Kind and*

Usual Punishment by the investigative journalist Jessica Mitford, in addition to congressional hearings on the topic in the same year. The hearings, which addressed problems associated with prisoners as research subjects, pointed to danger, exploitation, secrecy, and difficulties in obtaining informed consent.

In the mid-1970's, the Director of the Federal Bureau of Prisons determined that "continued use of prisoners in any medical experimentation should not be permitted"; he ordered that participation by Federal prisoners be phased out. At about the same time, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to develop ethical guidelines for research involving human subjects and to make recommendations for the application of these guidelines to research conducted or supported by the Department of Health, Education and Welfare (now Health and Human Services) and other Federal agencies. Special groups of subjects, such as children and prisoners, were to receive additional study and consideration. The commission held hearings, called in consultants, conducted site visits to prisons, and surveyed research participants and nonparticipants.

The commission produced a series of recommendations on guidelines for research with the public and with prisoners. Many of the recommendations were incorporated into Federal regulations covering research sponsored by HHS. Since these regulations serve as a model to other Federal agencies, including the BOP, I will summarize some of them here.

HHS regulations

Permissible types of research. HHS regulations[1] specify that biomedical and behavioral research (defined as a systematic investigation designed to develop or contribute to generalizable knowledge) involving prisoners may be permitted if it falls into one of three categories.

The major advantage in involving prisoners was the opportunity to monitor subjects in a controlled environment at a low cost.

The first category involves the study of the possible causes, effects, and processes of incarceration and of criminal behavior; *or* it involves prisons as institutional structures or prisoners as incarcerated persons; *or* it involves practices that have the intent and reasonable probability of improving the health or well-being of the subjects; *and* it involves no more than minimal risk (in other words, the risks of harm are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of healthy people) and no more than inconvenience to the subjects. I call this category *Minimal Risk.*

This research would typically include studies of sociological and psychological variables associated with prisoners or prisons, and would usually involve administering questionnaires or interview schedules to prisoners or prison staff. Analyzing data from inmate or prison files might also be part of the research. This category of research would also include evaluations of programs to improve well-being—stress management, for example.

The second category of permissible research involves more than a minimal risk and investigates conditions that particularly affect prisoners as a class (for example, hepatitis—which is more prevalent in prisons than elsewhere—alcoholism, drug addiction, and sexual assault). Such research is permitted, provided that the head of the department consults with appropriate experts and publishes notice in the *Federal Register* of the intent to approve the research. This category I call *Conditions Particularly Affecting Prisoners/More Than Minimal Risk.*

If a vaccine is being tested, then the project would fall into the "more than minimal risk" category. However, if only the incidence of hepatitis is to be studied, and there are no additional blood tests required than what normally would be performed during routine exams, such a study would not fall in this category, but would probably fall into the first category of minimal risk.

The last category of permissible research involves the study of practices—both innovative and accepted—that pose more than minimal risk but have the intent and reasonable probability of improving the health or well-being of the subjects. If the study includes control groups that may not benefit from the research, the head of the agency would be required to consult appropriate experts and publish notice in the *Federal Register* of the intention to approve the research. I call this category *Improve Health or Well-Being/More Than Minimal Risk.* Administering experimental drugs in a systematic way

to improve terminal conditions of cancer patients would fall into this category.

All other research would probably not be permitted. For example, National Institutes of Health researchers would probably not be permitted to test an experimental chicken pox vaccine or investigate the effects of experimentally controlled sleeplessness on reaction time; similarly, researchers may not be permitted to test the effects of prolonged weightlessness on inmate subjects.

Review committee composition. According to HHS regulations, a research project must receive the approval of a human subjects review committee (called Institutional Review Boards, or IRB's, by HHS) before the research may begin and periodically thereafter. The human subjects review committee is a key group in ensuring that research subjects are protected.

The human subjects review committee itself must meet certain criteria of membership. Each committee must have at least five members, the majority of whom have no association with the prison(s) involved. The members must have varying backgrounds and not be associated with conducting the research. The committee must include representatives of racial/cultural groups, representatives of both sexes, at least one nonscientist (perhaps a lawyer or ethicist), at least one person with professional competence to review research activities, and an inmate or inmate representative.

Minimum requirements for studies. If a study falls into one of the three permissible categories noted earlier, the human subjects review committee looks for the following minimum requirements centering around fairness, voluntary informed consent, and confidentiality.

The enticement of better conditions (and perhaps monetary incentive) reduces the ability of the potential subject to make a "voluntary" decision.

- First, the committee determines whether risks to subjects are *minimized and reasonable in relation to anticipated benefits.* For example, in studies where there are no direct benefits to the subject, there should be minimal risk to the subject. However, matching risks and benefits becomes more complex when risks increase. To ensure the voluntary nature of subject participation, any possible advantages to the subject should not be of such magnitude that the subject cannot objectively weigh the risks and advantages. For example, if the general living conditions, medical care, quality of food, or opportunities for earning money at the prison are inadequate, the potential subject may be willing to participate in a fairly risky study if the conditions at the research site are significantly better.

The enticement of better conditions (and perhaps monetary incentive) reduces the ability of the potential subject to make an objective "voluntary" decision. The review committee needs to evaluate whether the subjects can make such a "voluntary" decision under the circumstances. The committee will need to be sure that participants know that their parole status will not be affected by participation or nonparticipation in the study, and that risks involved are commensurate with risks that would be accepted by nonprisoner volunteers.

- Second, the committee determines whether *selection of subjects is equitable.* For example, if stress management techniques are being taught to a sample of volunteers, the research design should specify how subjects are selected; random selection would help ensure that inmates or prison authorities could not intervene so that certain "favorites" are placed in the experimental group.

- Third, the committee determines that *informed consent requirements are met.* An informed consent statement presented to each subject will cover such topics as who is conducting the study, the purposes of the project, the procedures, the risks and benefits, confidentiality, and voluntary participation. The committee also evaluates whether the informed consent statement and other explanations to subjects during the course of the study are presented in understandable language.

- Fourth, the committee determines whether *monitoring of the research, including followup, is specified and appropriate* to ensure the safety of subjects.

- Fifth, the committee determines whether there are *adequate provisions to protect the privacy* of subjects and the confidentiality of data.

After the committee determines that the study falls into a permissible research category and that it meets minimum requirements of fairness and voluntary informed consent, and once the committee specifies any appropriate additional requirements, the project must receive approval from the head of the department. Most projects that present more

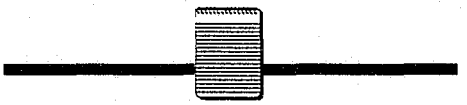
than minimal risk also require review by a national panel of ethical and technical experts. The intent to conduct the project must also be announced in the *Federal Register*. Once all these requirements are met, the study may begin.

BOP policy

In developing research policy, the BOP has followed the intent of HHS regulations, but the BOP and HHS policies differ somewhat. The primary difference is that the BOP limits the type of research permitted to *minimal risk research*.[2]

The BOP does not permit biomedical or drug research. The result is a simpler research review process, because one of the most difficult phases in the human subjects review committee evaluation process—the complicated risk-versus-benefit analysis—is virtually eliminated. To help ensure that inmate participation in research is "voluntary" (without undue inducement), the only incentives permitted, according to policy, are sodas and snacks at the test setting.

With minimal risk research, the review process is also simpler because most proposals can receive "expedited review." Under BOP policy, a process called "expedited review" may be permissible, providing that the research presents "minimal risk," neither manipulates the subject's behavior nor involves stress to the subject, does not involve a medical procedure, and is not of a sensitive nature. Expedited review requires review of a proposal by the chairperson of the review committee, rather than by the entire committee. Here the chairperson exercises the same authority as the full committee. Expedited review obviously takes less time than review by the full committee and, therefore, is one of the elements of the BOP's "reasonable" approach to proposal review and protection of research subjects. The vast majority of research proposals submitted to the BOP fall into this category.



The BOP does not permit biomedical or drug research. The result is a simpler review process.

The BOP review process attempts to examine the same elements described in HHS regulations; that is, it includes the assessment of risks, privacy, fairness, informed consent, and the other safeguards. As with HHS regulations, the BOP requires that the head of the department (in this case the Director of the BOP) must approve the study before it may begin. Besides factors relevant to protection of subjects, BOP policy also has additional requirements. For most projects, approval by a warden and regional director is necessary. In making their decisions, these individuals might consider additional factors, such as the extent to which the project might interfere with institutional operations.

Issues to consider

Obviously, not everyone agrees that BOP regulations regarding protecting human subjects are appropriate. One issue concerning the BOP policy on research is the *extent of review* the proposal receives. I am unaware of anyone who contends that the Bureau should perform more stringent reviews. However, there is a legitimate argument that if a person wants to administer an anonymous questionnaire to inmates at an institution, and there is minimal risk involved, and the warden agrees to the study, then the researcher should be able to proceed without undergoing the entire review process. Most of the time it is likely that prospective researchers and prison administrators carefully consider the requirements of voluntary informed consent and confidentiality, which would be the key issues in studies of this nature. However, it is possible that on occasion these protections would be ignored if the review process were not in place.

The review process is a control measure that is worth the time and effort. It raises consciousness and sensitivity. If we eliminate the review process, it is conceivable that more and more research would be conducted with inadequate safeguards. Even research that involves only the gathering of data from inmate files by staff members could compromise privacy and lead to risks in an institutional setting; such proposals need to be reviewed to ensure that the researchers will build in protections for subjects who might be placed at direct or indirect risk.

Another issue that inmates raise is the *amount of incentive* to participate in a study. Some question why inmates cannot receive money in exchange for their participation. If the study involves minimal risk, they suggest, then the inmate could receive a small amount of money, perhaps in line with the amount that can be earned in prison industries. The BOP policy of limiting incentives to sodas and snacks is primarily to promote fairness and minimize complicated issues. It is too complicated to decide on an amount of money, credit it to the inmate's account, and contend with other inmates who may protest that they were not selected for the study or challenge the amount of incentive because on another project inmate participants received more money. Clearly, incentives limited to

sodas and snacks given at the "test" session eliminate these criticisms and are probably more "fair" in the long run.

To approve or disapprove?

Now that I have reviewed some of the key elements in HHS and BOP policies, I am prepared to discuss the three research proposals mentioned earlier.

Recall the graduate student who wants to relate inmate television program choices to inmate offense category. If the student's purpose is to compare prisoner with nonprisoner program choices so as to further describe "prisoners" as a group, and if the project meets all the other requirements, HHS and the BOP would probably approve the project. It falls into the "minimal risk" category.

Next, there was the study in which a drug company would test an experimental cold remedy on experimental groups while giving a placebo to a control group. This drug research could possibly be approved under HHS regulations if a secretarial panel were convened and the secretary accepted a recommendation to proceed with the research, but would not be permitted under BOP regulations, as it involves "more than minimal risk."

The study by the physician on the relationship of sugar in diets to misconduct might be approved by both HHS and BOP. It is a difficult decision. A major question for the BOP to consider is whether the research is minimal risk. If low, medium, and high amounts of sugar were all within the normal range that the inmates usually consume, there is a possibility that it would be considered minimal risk. "Is it practical to conduct the study?" is another question. Would you need to be deceptive and not tell the inmates you were conducting a study and initiate the diets without their knowledge? If so, the project would not be approved by the BOP, since deception is not compatible with BOP policy.

Somewhere between informed consent and deception is incomplete disclosure.

Somewhere between informed consent and deception is incomplete disclosure; if the researcher told the inmates the type of study they were participating in, but admitted that they would not be told which sugar level group they were in, that could be called "incomplete disclosure." This may be permitted by the BOP if the procedure in question was not placing the subject in any danger.

Another question is "Would the low sugar group be getting a sugar substitute?" If so, could the substitute be harmful and could that throw the study into the "more than minimal risk" category? In that case, the project could not be approved by the BOP. Due to the number of complicated issues involved, this proposal would definitely be reviewed by the full human subjects review committee. Perhaps an acceptable proposal could be worked out.

Conclusion

For some proposals, the decision regarding approval or disapproval is clear; for others, issues must be discussed and resolved. A close working relationship between the researcher and the review committee staff can sometimes help to resolve issues so that research may proceed with appropriate protection of human subjects.

In this article, I have attempted to increase the reader's awareness of issues related to protecting prisoners in research, categorize permissible research with prisoners, and spell out minimal requirements for research according to HHS and BOP regulations. Minimal risk research should be encouraged. The needs of researchers can usually be satisfied while taking reasonable approaches to safeguarding subjects. ■

Harriet Lebowitz is a Senior Research Analyst, Office of Research and Evaluation, Federal Bureau of Prisons. This article is based on a paper delivered to the American Society of Criminology in November 1988 in Chicago, Illinois.

Notes

[1] HHS regulations for prisoners in research are found in the Code of Federal Regulations, Title 45, Part 46, Subparts A and C. My objective here is to summarize the general intent of the regulations. For specifics, it is necessary to consult the regulations themselves.

[2] Guidelines for conducting research in the Federal Bureau of Prisons are found in the Code of Federal Regulations, Title 28, Part 512.

References

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