Report and
Recommendations

Research Involving Prisoners

The National Commission
for the Protection of
Human Subjects
of Biomedical and
Behavioral Research

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National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard, Avenue
Bethesda, Maryland 20016

October 1, 1976

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our Report and Recommendations: Research Involving Prisoners. Under Public Law 93-348, the Commission is charged to submit periodic reports to the President, the Congress and the Secretary of Health, Education, and Welfare on various aspects of research involving human subjects, including the participation of prisoners in biomedical and behavioral research.

The Commission's deliberations and recommendations to the Congress and the Secretary, on research involving prisoners, as well as a summary of background materials, are included in this volume. An appendix volume, containing materials reviewed by the Commission in its deliberations, will accompany the report.

The Commission has conducted extensive public deliberations on the issues surrounding the involvement of prisoners in research. These deliberations are reflected in our recommendations, which we hope will provide a useful resolution of this matter of public concern. We are grateful for the opportunity to prepare the report.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

October 1, 1976

The Honorable Nelson A. Rockefeller
President of the United States Senate
United States Senate
Washington, D.C. 20510

Dear Mr. President:

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October 1, 1976

The Honorable Carl Albert
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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October 1, 1976

Honorable David Mathews
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

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NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

MEMBERS OF THE COMMISSION

Kenneth John Ryan, M.D., Chairman
Chief of Staff
Boston Hospital for Women

Joseph V. Brady, Ph.D.
Professor of Behavioral Biology
Johns Hopkins University

Robert E. Cooke, M.D.
Vice Chancellor for Health Sciences
University of Wisconsin

Dorothy I. Height
President
National Council of Negro Women, Inc.

Albert R. Jonsen, Ph.D.
Associate Professor of Bioethics
University of California at San Francisco

Patricia King, J.D.
Associate Professor of Law
Georgetown University Law Center

Karen Lebacqz, Ph.D.
Consultant in Bioethics
Department of Health
Sacramento, California

David W. Louisell, J.D.
Professor of Law
University of California at Berkeley

Donald W. Seldin, M.D.
Professor and Chairman
Department of Internal Medicine
University of Texas at Dallas

Eliot Stellar, Ph.D.
Provost of the University and
Professor of Physiological Psychology
University of Pennsylvania

Robert H. Turtle, LL.B.
Attorney
VomBaur, Coburn, Simmons & Turtle
Washington, D.C.

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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SPECIAL CONSULTANT

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PREFACE

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established under the National Research Act (P.L. 93-348) to develop ethical guidelines for the conduct of research involving human subjects and to make recommendations for the application of such guidelines to research conducted or supported by the Department of Health, Education, and Welfare (DHEW). The legislative mandate also directs the Commission to make recommendations to Congress regarding the protection of human subjects in research not subject to regulation by DHEW. Particular classes of subjects that must receive the Commission's attention include children, prisoners and the institutionalized mentally infirm.

The duties of the Commission with regard to research involving prisoners are specifically set forth in section 202(a)(2) of the National Research Act, as follows:

> The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by....prisoners....The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary [DHEW] and involving....prisoners.... to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study the Commission shall make such recommendations to the Secretary as it determines appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him meets the requirements respecting informed consent identified by the Commission.

This responsibility is broadened by the provision (section 202(a)(3)) that the Commission make recommendations to Congress regarding the protection of subjects involved in research not subject to regulation by DHEW, such as research involving prisoners that is conducted or supported by other federal departments or agencies, as well as research conducted in federal prisons or involving inmates from such prisons.

To carry out its mandate, the Commission studied the nature and extent of research involving prisoners, the conditions under which such research is conducted, and the possible grounds for continuation, restriction or termination of such research. Commission members and staff made site visits to four prisons and two research facilities outside prisons that use prisoners, in order to obtain first-hand information on the conduct of biomedical research and the operation of behavioral programs in these settings. During the visits, interviews were conducted with many inmates who have participated in research or behavioral programs as well as with nonparticipants.

The Commission held a public hearing at which research scientists, prisoner advocates and providers of legal services to prisoners, representatives of the pharmaceutical industry, and members of the public presented their views on research involving prisoners. This hearing was duly announced, and no request to testify was denied. The National Minority Conference on Human Experimentation, which was convoked by the Commission in order to assure that viewpoints of minorities would be expressed, made recommendations to the Commission on research in prisons. In addition to papers, surveys and other materials prepared by the Commission staff, studies on the following topics were prepared

under contract: (1) alternatives to the involvement of prisoners; (2) foreign practices with respect to drug testing; (3) philosophical, sociological and legal perspectives on the involvement of prisoners in research; (4) behavioral research involving prisoners; and (5) a survey of research review procedures, investigators and prisoners at five prisons. Finally, at public meetings commencing in January 1976, the Commission conducted extensive deliberations and developed its recommendations on the involvement of prisoners in research.

Part I of this report contains the recommendations as well as the deliberations and conclusions of the Commission and a summary of background materials. The nature and extent of research involving prisoners are described in Part II. The activities of the Commission and reports that were prepared for it are summarized in Parts III and IV, respectively. An appendix to this report contains papers, surveys, reports and other materials that were prepared or collected for the Commission on various topics related to research involving prisoners. Most of such materials are summarized in Part IV of the report.

Glossary of Terms Used in this Report.

Phases of drug testing. FDA regulations require three phases for the testing of new drugs. Phase 1 is the first introduction of a new drug into humans (using normal volunteers), with the purpose of determining human toxicity, metabolism, absorption, elimination and other pharmacological action, preferred route of administration and safe dosage range. Phase 2 covers the initial trials on a limited number of patients for specific

disease control or prophylaxis purposes. Phase 3 involves extended clinical trials, providing assessment of the drug's safety and effectiveness and optimum dosage schedules in the diagnosis, treatment or prophylaxis of groups of subjects involving a given disease or condition. (Source: 21 C.F.R. 312.1)

Prison. "Any place for the confinement or rehabilitation of juvenile offenders or individuals charged with or convicted of criminal offenses" (42 U.S.C. 3781).

Prisoner. Any individual involuntarily confined in a prison.

Therapeutic research, nontherapeutic research. The Commission recognizes problems with employing the terms "therapeutic" and "nontherapeutic" research, notwithstanding their common usage, because they may convey a misleading impression. Research refers to a class of activities designed to develop generalizable new knowledge. Such activities are often engaged in to learn something about practices designed for the therapy of the individual. Such research is often called "therapeutic" research; however, the research is not solely for the therapy of the individual. In order to do research, additional interventions over and above those necessary for therapy may need to be done, e.g., randomization, blood drawing, catheterization; these interventions may not be "therapeutic" for the individual. Some of these interventions may themselves present risk to the individual--risk unrelated to the therapy of the subject. The Commission has employed the term "research on practices which have the intent and reasonable probability of improving the health or well-being of the subject" or variants of this term. Since the reports pre-

pared for the Commission by outside contractors or consultants generally employ, the terms in common usage, such terms have been retained in the summaries of those reports.

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PART I. DELIBERATIONS, CONCLUSIONS AND RECOMMENDATIONS

Chapter 1. Deliberations and Conclusions.

Introduction. Prior to 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. During World War II, however, large numbers of prisoners participated in voluntary research programs to develop treatment for infectious diseases that afflicted our armed forces. This involvement of prisoners was considered to be not only acceptable, but praiseworthy. Following the war, the growth of biomedical research and the imposition of requirements for testing drugs as to safety led to the increased use of prisoners. Their participation in biomedical research not related to their health or well-being has continued in this country to the present time. This participation is now primarily in phase 1 drug and cosmetic testing, which is conducted or supported by pharmaceutical manufacturers in connection with applications to the Food and Drug Administration for licensing new drugs. Other research of this sort in which prisoners participate, or have participated, includes studies of normal metabolism and physiology, conducted by the Public Health Service (PHS); studies of the prevention or treatment of infectious diseases, conducted or supported by the PHS and the Department of Defense; a study of the effects of irradiation on the male reproductive function, supported by the Atomic Energy Commission; and testing of the addictive properties of new analgesics by giving them to prisoners with a history of narcotic abuse, conducted at the Addiction Research Center in Lexington, Kentucky. (The involvement of federal prisoners in the Lexington program is scheduled to be phased out.*)

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* Letter dated March 1, 1976 to Honorable Robert W. Kastenmeier from Norman A. Carlson, Director, U.S. Bureau of Prisons.

Prisoners also participate in research on practices that have the intent and reasonable probability of improving their health or well-being. This research includes, for example, studies (supported by various components of DHEW and the Federal Bureau of Prisons) to develop methods to reduce the spread of infections, improve dental care, help the subjects stop smoking and remove tatoos. A major focus of this sort of research involving federal prisoners has been the development of new treatments for narcotic addiction.

A third type of research in which prisoners participate includes studies of the possible causes, effects and process of incarceration, and studies of prisons as institutional structures or of prisoners as incarcerated persons. Components of DHEW have undertaken research of this sort for such purposes as learning the etiology of drug addiction and deviant or self-destructive behavior, and the factors relating to parole performance and recidivism.

Research is also conducted on the methods of treatment or "rehabilitation" of prisoners. The National Institute of Mental Health, the Federal Bureau of Prisons, and the Law Enforcement Assistance Administration have supported research on the experimental treatment of aggressive behavior with drugs and aversive conditioning techniques, as well as behavior modification based upon depriving inmates of basic amenities which they must then earn back as privileges. Rehabilitative practices have not always been based upon prior scientific design and evaluation, however, despite the fact that there are few, if any, approaches to the treatment or rehabilitation of prisoners for which effectiveness has been clearly demonstrated.

Outside the United States prisoners do not generally participate in biomedical research. This exclusion may be ascribed in part to continuing concern

over experiments that were conducted on prisoners in Nazi concentration camps. Revelations of those experiments led to the enunciation of the Nuremberg Code (1946–1949), which required that human subjects of research "be so situated as to be able to exercise free power of choice" but did not expressly prohibit research involving civil prisoners. The Declaration of Helsinki, adopted by the World Medical Association in 1964 and endorsed by the American Medical Association in 1966, contained similar language that was subsequently deleted in 1975. Although little if any drug testing is conducted in foreign prisons, other kinds of research have been conducted in prisons throughout the world, such as studies dealing with the incidence and implications of chromosome abnormalities.

Since the 1960's, the ethical propriety of participation by prisoners in research has increasingly been questioned in this country. Among the events that have focused public attention on this issue was the publication of Jessica Mitford's book, Kind and Usual Punishment, in 1973. Eight states and the Federal Bureau of Prisons have formally moved to abandon research in prisons. The Health Subcommittee of the Senate Committee on Labor and Public Welfare held hearings (Quality of Health Care - Human Experimentation, 1973) on research involving prisoners in late 1973. Those speaking against the use of prisoners cited exploitation, secrecy, danger and the impossibility of obtaining informed consent as reasons to impose a prohibition or moratorium on the conduct of research in prisons. The advantages of using prisoners in research (e.g., 3 opportunity for close monitoring and controlled environment) and the procedures that are employed to protect prisoner participants were also described in the hearings. The Health Subcommittee held extensive

hearings on other areas of human experimentation as well, and reported the bill establishing this Commission with a mandate that included a directive to study and make recommendations concerning the involvement of prisoners in research.

More recently, the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice held hearings (Prison Inmates in Medical Research , 1975) on a bill (H.R. 3603) to prohibit "medical research" in federal prisons and prisons of states that receive certain federal support. Following these hearings, the Director of the Federal Bureau of Prisons determined that "continued use of prisoners in any medical experimentation should not be permitted," and he ordered that such participation by prisoners under federal jurisdiction be phased out.

Some of the more extreme behavioral programs have also raised questions. In her 1973 book, Jessica Mitford expressed concern about new approaches to "treatment" for offenders. Concurrently, others raised questions about the use of psychosurgery in prisons. In the early 1970's, the first challenges to behavior modification and aversive conditioning programs in prisons were argued in the courts, with mixed results. Most of the cases involved the right to refuse to participate in such programs, although prisoners have also petitioned for the right to be included in programs designed to alter sexually aggressive behavior.

Concern over behavior modification programs in prisons was expressed in a study, Individual Rights and the Federal Role in Behavior Modification (1974), prepared by the staff of the Constitutional Rights Subcommittee of the

Senate Judiciary Committee. The study contained information on a number of such programs and suggested that this Commission make use of the information in attempting to resolve the issues that they raised. It should be noted that a number of the "treatment" programs mentioned in the study are reported to have been discontinued.

General concerns. In conducting its investigations and studies, the Commission has noted and cannot ignore serious deficiencies in living conditions and health care that generally prevail in prisons. Nor can the Commission ignore the potential for arbitrary exercise of authority by prison officials and for unreasonable restriction of communication to and from prisoners. The Commission, although acknowledging that it has neither the expertise nor the mandate for prison reform, nevertheless urges that unjust and inhumane conditions be eliminated from all prisons, whether or not research activities are conducted or contemplated.

Ethical considerations about using prisoners as research subjects. There are two basic ethical dilemmas concerning the use of prisoners as research subjects: (1) whether prisoners bear a fair share of the burdens and receive a fair share of the benefits of research; and (2) whether prisoners are, in the words of the Nuremberg Code, "so situated as to be able to exercise free power of choice" -- that is, whether prisoners can give truly voluntary consent to participate in research.

These two dilemmas relate to two basic ethical principles: the principle of justice, which requires that persons and groups be treated fairly, and the principle of respect for persons, which requires that the autonomy of persons

be promoted and protected. Disproportionate use of prisoners in certain kinds of research (e.g. , phase 1 drug testing) would constitute a violation of the first principle; closed and coercive prison environments would compromise the second principle. It is within the context of a concern to implement these principles that the Commission has deliberated the question of use of prisoners as research subjects.

The Commission recognizes, however, that the application of these principles to the problem is not unambiguous. To respect a person is to allow that person to live in accord with his or her deliberate choices. Since the choices of prisoners in all matters except those explicitly withdrawn by law should be respected, as courts increasingly affirm, it seems at first glance that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. Indeed, systematic deprivation of this freedom would also violate the principle of justice, since it would arbitrarily deprive one class of persons of benefits available to others--namely, the benefits of participation in research.

However, the application of the principles of respect and justice allows another interpretation, which the Commission favors. When persons seem regularly to engage in activities which, were they stronger or in better circumstances, they would avoid, respect dictates that they be protected against those forces that appear to compel their choices. It has become evident to the Commission that, although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in

which they live compromise their freedom. The Commission believes, therefore, that the appropriate expression of respect consists in protection from exploitation. Hence it calls for certain safeguards intended to reduce the elements of constraint under which prisoners give consent and suggests that certain kinds of research would not be permitted where such safeguards cannot be assured.

Further, a concern for justice raises the question whether social institutions are so arranged that particular persons or groups are burdened with marked disadvantages or deprived of certain benefits for reasons unrelated to their merit, contribution, deserts or need. While this principle can be interpreted, as above, to require that prisoners not be unjustly excluded from participation in research, it also requires attention to the possibility that prisoners as a group bear a disproportionate share of the burdens of research or bear those burdens without receiving a commensurate share of the benefits that ultimately derive from research. To the extent that participation in research may be a burden, the Commission is concerned to ensure that this burden not be unduly visited upon prisoners simply because of their captive status and administrative availability. Thus it specifies some conditions for the selection of prisoners as a subject pool for certain kinds of research. In so doing, the Commission is not primarily intending to protect prisoners from the risks of research; indeed, the Commission notes that the risks of research, as compared with other kinds of occupations, may be rather small. The Commission's concern, rather, is to ensure the equitable distribution of the burdens of research no matter how large or small those burdens may be. The Commission is concerned that the status of being a prisoner makes possible the perpetration of certain systemic injustices. For example, the availability

of a population living in conditions of social and economic deprivation makes it possible for researchers to bring to these populations types of research which persons better situated would ordinarily refuse. It also establishes an enterprise whose fair administration can be readily corrupted by prisoner control or arbitrarily manipulated by prison authorities. And finally, it allows an inequitable distribution of burdens and benefits, in that those social classes from which prisoners often come are seldom full beneficiaries of improvements in medical care and other benefits accruing to society from the research enterprise.

Reflection upon these principles and upon the actual conditions of imprisonment in our society has led the Commission to believe that prisoners are, as a consequence of being prisoners, more subject to coerced choice and more readily available for the imposition of burdens which others will not willingly bear. Thus, it has inclined toward protection as the most appropriate expression of respect for prisoners as persons and toward redistribution of those burdens of risk and inconvenience which are presently concentrated upon prisoners. At the same time, it admits that, should coercions be lessened and more equitable systems for the sharing of burdens and benefits be devised, respect for persons and concern for justice would suggest that prisoners not be deprived of the opportunity to participate in research. Concern for principles of respect and justice leads the Commission to encourage those forms of inquiry that could form a basis for improvement of current prison conditions and practices, such as studies of the effects of incarceration, of prisons as institutions and of prisoners as prisoners, and also to allow research on practices clearly intended to improve the health or well-being of individual prisoners.

The Commission has noted the concern, expressed by participants at the National Minority Conference and by others, that minorities bear a disproportionate share of the risks of research conducted in prisons. This concern is fostered, in part, by evidence that prison populations are disproportionately nonwhite. Evidence presented to the Commission indicates that where research is done in prison, those prisoners who participate tend to be predominantly white, even in institutions where the population as a whole is predominantly nonwhite; further, those who participate in research tend to be better educated and more frequently employed at better jobs than the prison population as a whole. This evidence suggests that nonwhites and poor or less educated persons in prison do not carry a greater share of the burdens of research.

However, the evidence is inconclusive for two reasons: first, because it does not fully satisfy questions related to the risks of research; and second, because it raises questions of justice with respect to the equitable distribution of benefits (as well as burdens) of research.

With respect to risks, the Commission notes that different research projects carry different risks; it is possible, though the Commission has no evidence to this effect, that one race or another may participate in more research of higher risk. And of course, the ratio of nonwhites to whites participating in research and hence bearing the burdens of research may still be disproportionate when compared to the ratio of the populations as a who1e.

But the Commission also notes that those who participate in research consider the benefits sufficient to outweigh the burdens. Thus, the greater

participation of whites may mean that there is an inequitable distribution of benefits between racial groups. Hence the greater participation by whites does not necessarily resolve the issue of distributive justice.

Similarly, the Commission notes that less research is conducted in women's prisons. While the reasons for this may well be the same reasons that women in general are used less frequently than men as research subjects (e.g., the possibility of pregnancy), questions of distributive justice, similar to those raised above, may still need to be addressed with respect to participation in research by women prisoners.

Discussion. Among the issues discussed by the Commission are two on which no specific recommendations are made, but concerning which the considerations of the Commission should be expressed: (1) remuneration, and (2) alternatives to conducting research in prisons. (1) Remuneration is a subject that should be analyzed by human subjects review committees, in consultation with prison grievance committees and prison authorities. There are at least two considerations that must be balanced in the determination of appropriate rates for participation in research not related to the subjects' health or well-being. On the one hand, the pay offered to prisoners should not be so high, compared to other opportunities for employment within the facility, as to constitute undue inducement to participate. On the other hand, those who sponsor the research should not take economic advantage of captive populations by paying significantly less than would be necessary if nonprisoner volunteers were recruited. Fair solutions to this problem are difficult to achieve. One suggestion is that those who sponsor research pay the same rate for prisoners

as they pay other volunteers, but that the amount actually going to the research subjects be comparable to the rates of pay otherwise available within the facility. The difference between the two amounts could be paid into a general fund, either to subsidize the wages for all inmates within the prison, or for other purposes that benefit the prisoners or their families. Prisoners should participate in managing such a fund and in determining allocation of the monies. Another suggestion is that the difference be held in escrow and paid to each participant at the time of release or, alternatively, that it be paid directly to the prisoner's family.

A requirement related to the question of appropriate remuneration for participation in research is that prisoners should be able to obtain an adequate diet, the necessities of personal hygiene, medical attention and income without recourse to participation in research.

(2) Some of the Commission members endorse the alternative of permitting prisoners to participate in research provided it is conducted in a clinic or hospital outside the prison grounds, and provided also that nonprisoners participate in the same projects for the same wages. Other members of the Commission believe that such a mechanism would serve only to increase the disparity between the conditions within the prison and those within the research unit, thereby heightening the inducement to participate in research in order to escape from the constraints of the prison setting. All of the members of the Commission endorse the suggestion that the use of alternative populations be explored and utilized more fully than is presently the case. This may be especially important to permit drugs to continue to be tested, as required by current law and regulations of the FDA, during any period in which prisons have not satisfied the

conditions that are recommended for the conduct of such research. Increased utilization of alternative populations would have the added benefit of providing nonprisoner populations to participate in research projects along with prisoners, or in parallel with similar projects within prisons, in order to satisfy the general concern that prisoners not participate in experiments that nonprisoners would find unacceptable. The Commission also suggests that Congress and the FDA consider the advisability of undertaking a study and evaluation to determine whether present requirements for phase 1 drug testing in normal volunteers should be modified.

Conclusions. In the course of its investigations and review of evidence presented to it, the Commission did not find in prisons the conditions requisite for a sufficiently high degree of voluntariness and openness, notwithstanding that prisoners currently participating in research consider, in nearly all instances, that they do so voluntarily and want the research to continue. The Commission recognizes the role that research involving prisoners has played. It does not consider, however, that administrative convenience or availability of subjects is, in itself, sufficient justification for selecting prisoners as subjects.

Throughout lengthy deliberations, the strong evidence of poor conditions generally prevailing in prisons and the paucity of evidence of any necessity to conduct research in prisons have been significant considerations of the Commission. An equally important consideration has been the closed nature of prisons, with the resulting potential for abuse of authority. Some of the Commission members, who are opposed to research not related to the health or well being of prisoner-participants, have, however, agreed to permit it to be con-

ducted, but only under the following standards: adequate living conditions, separation of research participation from any appearance of parole consideration; effective grievance procedures and public scrutiny at the prison where research will be conducted or from which prospective subjects will be taken; importance of the research; compelling reasons to involve prisoners; and fairness of such involvement. Compliance with these requirements must be certified by the highest responsible federal official, assisted by a national ethical review body. The Commission has concluded that the burden of proof that all the requirements are satisfied should be on those who wish to conduct the research.

Chapter 2. Recommendations.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research makes the following recommendations on research involving prisoners, to:

(i) The Secretary, DHEW, with respect to research that is subject to his regulation, i.e., research conducted or supported under programs administered by him and research reported to him in fulfillment of regulatory requirements; and

(ii) The Congress, except as otherwise noted, with respect to research that is not subject to regulation by the Secretary, DHEW.

Recommendation (1): STUDIES OF THE POSSIBLE CAUSES, EFFECTS AND PROCESSES OF INCARCERATION AND STUDIES OF PRISONS AS INSTITUTIONAL STRUCTURES OR OF PRISONERS AS INCARCERATED PERSONS MAY BE CONDUCTED OR SUPPORTED, PROVIDED THAT (A) THEY PRESENT MINIMAL OR NO RISK AND NO MORE THAN MERE INCONVENIENCE TO THE SUBJECTS, AND (B) THE REQUIREMENTS UNDER RECOMMENDATION (4) ARE FULFILLED.

Comment: The Commission encourages the conduct of studies of prisons as institutions and prisoners as incarcerated persons. Because the inadequacies of the prisons may themselves be the object of such studies, the Commission has not set any conditions for the conduct of such research other than a limitation of this category to research that presents minimal or no risk and no more than mere inconvenience, and the requirements of Recommendation (4)

Studies of prisoners consisting of questionnaires, surveys, analyses of census and demographic data, psychological tests, personality inventories

and the like rarely involve risk and are essential for proper understanding of prisons and the effects of their practices. Research designed to determine the effects on general health of institutional diets and restricted activity, and similar studies that do not manipulate bodily conditions (except innocuously, e.g., obtaining blood samples) but merely monitor or analyze such conditions, also present little physical risk and are necessary to gain some knowledge of the effects of imprisonment. Such research is a necessary step toward understanding prison practices and alternatives, without which there can be no improvement.

Recommendation (2): RESEARCH ON PRACTICES, BOTH INNOVATIVE AND ACCEPTED, WHICH HAVE THE INTENT AND REASONABLE PROBABILITY OF IMPROVING THE HEALTH OR WELL—BEINGOF THE INDIVIDUAL PRISONER MAY BE CONDUCTED OR SUPPORTED, PROVIDED THE REQUIREMENTS UNDER RECOMMENDATION (4) ARE FULFILLED.

Comment: Research would fall under this recommendation if the practices under study are designed solely to improve the health or well-being of the research subject by prophylactic, diagnostic or treatment methods that may depart from standard practice but hold out a reasonable expectation of success. The Commission intends that prisoners not be discriminated against with respect to research protocols in which a therapeutic result might be realized for the individual subject. The committees that review all research involving prisoners should analyze carefully any claims that research projects are designed to improve the health or well-being of subjects and should be particularly cautious with regard to research in which the principal purpose of the practice under study is to enforce conformity with behavioral norms established by prison officials or even by society. Such conformity cannot be assumed to improve

the condition of the individual prisoner. If the review committee does not consider such claims to be sufficiently substantiated, the research should not be conducted unless it conforms to the requirements of Recommendation (3).

Recommendation (3): EXCEPT AS PROVIDED IN RECOMMENDATION (1) AND (2), RESEARCH INVOLVING PRISONERS SHOULD NOT BE CONDUCTED OR SUPPORTED, AND REPORTS OF SUCH RESEARCH SHOULD NOT BE ACCEPTED BY THE SECRETARY, DHEW, IN FULFILLMENT OF REGULATORY REQUIREMENTS, UNLESS THE REQUIREMENTS UNDER RECOMMENDATION (4) ARE FULFILLED AND THE HEAD OF THE RESPONSIBLE FEDERAL DEPARTMENT OR AGENCY HAS CERTIFIED, AFTER CONSULTATION WITH A NATIONAL ETHICAL REVIEW BODY, THAT THE FOLLOWING THREE REQUIREMENTS ARE SATISFIED:

(A) THE TYPE OF RESEARCH FULFILLS AN IMPORTANT SOCIAL AND SCIENTIFIC NEED, AND THE REASONS FOR INVOLVING PRISONERS IN THE TYPE OF RESEARCH ARE COMPELLING;

(B) THE INVOLVEMENT OF PRISONERS IN THE TYPE OF RESEARCH SATISFIES CONDITIONS OF EQUITY; AND

(C) A HIGH DEGREE OF VOLUNTARINESS ON THE PART OF THE PROSPECTIVE PARTICIPANTS AND OF OPENNESS ON THE PART OF THE INSTITUTION(S) TO BE INVOLVED WOULD CHARACTERIZE THE CONDUCT OF THE RESEARCH; MINIMUM REQUIREMENTS FOR SUCH VOLUNTARINESS AND OPENNESS INCLUDE ADEQUATE LIVING CONDITIONS, PROVISIONS FOR EFFECTIVE REDRESS OF GRIEVANCES, SEPARATION OF RESEARCH PARTICIPATION FROM PAROLE CONSIDERATIONS, AND PUBLIC SCRUTINY.

Comment: Detailed standards expressing the intent of the Commission with respect to Requirement (C) of this Recommendation are as follows:

(i) Public scrutiny. Prisoners should be able to communicate, without censorship, with persons outside the prison and, on a privileged, confidential basis, with attorneys, legal organizations which assist prisoners, the accrediting office which assists the certifying federal official or national ethical review body, the grievance committee referred to in paragraph (ii) below, and the human subjects review committee or institutional review board referred to in Recommendation (4). Each of such persons or organizations with whom prisoners should be able to communicate on a privileged, confidential basis should be able to conduct private interviews with any prisoner who so desires. The accrediting office, grievance committee and human subjects review committee or institutional review board should be allowed free access to the prison.

(ii) Grievance procedures. There should exist a grievance committee composed of elected prisoner representatives, prisoner advocates and representatives of the community. The committee should enable prisoners to obtain effective redress of their grievances and should facilitate inspections and monitoring by the accrediting office to assure continuing compliance with requirement (C).

(iii) Standard of living. Living conditions in the prison in which research will be conducted or from which subjects will be recruited should be adequate, as evidenced by compliance with all of the following standards:

(1) The prison population does not exceed designed capacity, and each prisoner has an adequate amount of living space;

(2) There are single occupancy cells available for those who desire them;

(3) There is segregation of offenders by age, degree of violence, prior criminal record, and physical and mental health requirements;

(4) There are operable cell doors, emergency exists and fire extinguishers, and compliance with state and local fire and safety codes is certified;

(5) There are operable toilets and wash basins in cells;

(6) There is regular access to clean and working showers;

(7) Articles of personal care and clean linen are regularly issued;

(8) There are adequate recreation facilities, and each prisoner is allowed an adequate amount of recreation;

(9) There are good quality medical facilities in the prison, adequately staffed and equipped, and approved by an outside medical accrediting organization such as the Joint Commission on Accreditation of Hospitals or a state medical society;

(10) There are adequate mental health services and professional staff;

(11) There is adequate opportunity for prisoners who so desire to work for remuneration comparable to that received for participation in research;

(12) There is adequate opportunity for prisoners who so desire to receive education and vocational training;

(13) Prisoners are afforded opportunity to communicate privately with their visitors, and are permitted frequent visits;

(14) There is a sufficiently large and well-trained staff to provide assurance of prisoners' safety;

(15) The racial composition of the staff is reasonably concordant with that of the prisoners;

(16) To the extent that it is consistent with the security needs of the prison, there should be an opportunity for inmates to lock their own cells; and

(17) Conditions in the prison satisfy basic institutional environmental health, food service and nutritional standards.

(iv) Parole . There should be effective procedures assuring that parole boards cannot take into account prisoners' participation in research and that prisoners are clearly informed that there is absolutely no relationship between research partcipation and determinations by their parole boards.

If an investigator wishes to present evidence of the importance and fairness of conducting a type of research on a prison population (requirements (A) and (B)) and proposes that the conditions of voluntariness and openness would be satisfied at a particular prison (requirement (C)), the case should be presented to the Secretary, DHEW (or the head of any other department or agency under whose authority the research would be conducted). Such official should seek the advice of an existing or newly created advisory body (such as the Ethical Advisory Board established within the Public Health Service) in determining whether to approve the type of research at the specific institution. Such official or advisory body should be assisted by an accrediting office, which makes inspections, certifies compliance with requirement (C), and monitors continuing compliance of any prison involved in research. In determining such compliance, the accrediting office should be guided by the above description of the Commission's intent in recommending requirement (C).

Recommendation (4) : (A) THE HEAD OF THE RESPONSIBLE FEDERAL DEPARTMENT OR AGENCY SHOULD DETERMINE THAT THE COMPETENCE OF THE INVESTIGATORS AND THE ADEQUACY OF THE RESEARCH FACILITIES INVOLVED ARE SUFFICIENT FOR THE CONDUCT OF ANY RESEARCH PROJECT IN WHICH PRISONERS ARE TO BE INVOLVED.

(B) ALL RESEARCH INVOLVING PRISONERS SHOULD BE REVIEWED BY AT LEAST ONE HUMAN SUBJECTS REVIEW COMMITTEE OR INSTITUTIONAL REVIEW BOARD COM— PRISED OF MEN AND WOMEN OF DIVERSE RACIAL AND CULTURAL BACKGROUNDS THAT IN— CLUDES AMONG ITS MEMBERS PRISONERS OR PRISONER ADVOCATES AND SUCH OTHER PER— SONS AS COMMUNITY REPRESENTATIVES, CLERGY, BEHAVIORAL SCIENTISTS AND MEDICAL PERSONNEL NOT ASSOCIATED WITH THE CONDUCT OF THE RESEARCH OR THE PENAL INSTI— TUTION; IN REVIEWING PROPOSED RESEARCH, THE COMMITTEE OR BOARD SHOULD CONSIDER AT LEAST THE FOLLOWING: THE RISKS INVOLVED, PROVISIONS FOR OBTAINING INFORMED CONSENT, SAFEGUARDS TO PROTECT INDIVIDUAL DIGNITY AND CONFIDENTIALITY, PRO— CEDURES FOR THE SELECTION OF SUBJECTS, AND PROVISIONS FOR PROVIDING COMPEN— SATION FOR RESEARCH—RELATEDINJURY.

Comment: The risks involved in research involving prisoners should be commensurate with risks that would be accepted by nonprisoner volunteers. If it is questionable whether a particular project is offered to prisoners because of the risk involved, the review committee might require that non— prisoners be included in the same project.

In negotiations regarding consent, it should be determined that the written or verbal comprehensibility of the information presented is appro— priate to the subject population.

Procedures for the selection of subjects within the prison should be fair and immune from arbitrary intervention by authorities or prisoners.

Compensation and treatment for research-related injury should be provided, and the procedures for requesting such compensation and treatment should be described fully on consent forms retained by the subjects.

Prisoners who are minors, mentally disabled or retarded should not be included as subjects unless the research is related to their particular condition and complies with the standards for research involving those groups as well as those for prisoners. (Recommendations concerning research participation of children and the institutionalized mentally infirm will hereafter be made by the Commission.)

There should be effective procedures assuring that parole boards cannot take into account prisoners' participation in research, and that prisoners are made certain that there is absolutely no relationship between research participation and determinations by their parole boards.

Recommendation (5): IN THE ABSENCE OF CERTIFICATION THAT THE REQUIREMENTS UNDER RECOMMENDATION (3) ARE SATISFIED, RESEARCH PROJECTS COVERED BY THAT RECOMMENDATION THAT ARE SUBJECT TO REGULATION BY THE SECRETARY, DHEW, AND ARE CURRENTLY IN PROGRESS SHOULD BE PERMITTED TO CONTINUE NOT LONGER THAN ONE YEAR FROM THE DATE OF PUBLICATION OF THESE RECOMMENDATIONS IN THE FEDERAL REGISTER OR UNTIL COMPLETED, WHICHEVER IS EARLIER.

PART II. BACKGROUND

Chapter 3. Nature of Research Involving Prisoners

Research activities involving prisoners may be divided into four broad categories: biomedical research not related to the health or well-being of the subject, biomedical research on practices intended to improve the health or well-being of the subject, social research, and behavioral research on practices intended to improve the health or well-being of the subject. The first category of research using prisoners mainly involves phase 1 testing of new drugs and testing of vaccines as to efficacy. Biomedical and behavioral research related to the health or well-being of the prisoner-participants generally involves the study of conditions associated with prisoners or prisons. In addition, innovative practices in prisons, intended to rehabilitate or treat prisoners, often have many attributes of behavioral research but are seldom introduced as such. The major controversy over participation of prisoners surrounds their use as subjects of biomedical research not related to their health or well-being and their unwilling involvement in experimental treatment or rehabilitative programs.

Biomedical research unrelated to the health or well-being of prisoner-participants was conducted in the United States only in isolated instances prior to the establishment in 1934 of a program at Leavenworth Prison to assess the abuse potential of narcotic analgesics; such research is now conducted at the Addiction Research Center in Lexington, Kentucky, although it was announced recently that the program will be terminated by the end of 1976. The current involvement of prisoners in biomedical research unrelated to their health or

well-being can be traced to three sources. First, during World War II, prisoners volunteered in large numbers for studies, such as those to develop effective anti-malarial drugs, which were viewed as contributing to the national interest. Reviews of these prison research activities by several state commissions resulted in their endorsement. In fact, prisoner participation in research was felt to be such a salutary experience that the American Medical Association formally opposed allowing persons convicted of particularly serious crimes to have the privilege of participating in scientific experiments. Second, the enthusiastic support of biomedical research by the government and the public following the war brought an enormous growth to research enterprises, and prisoners served as subjects in many of these new endeavors. Third, the thalidomide experience was followed by passage in 1962 of the Kefauver-Harris amendments to the Food and Drug Act, which established additional requirements for testing the safety and efficacy of all drugs to be sold in interstate commerce and thereby encouraged the continued use of prisoners in research. The phase 1 testing requirements established under these amendments required evaluation of the safety of new drugs in normal volunteers under controlled conditions, and prisoners became the population on which much of this testing was performed.

Innovative prison practices are often difficult to distinguish from what might be termed behavioral research on practices intended to improve the health or well-being of prisoner-participants. Since the early 1900's, innovations such as flexible sentences, indeterminate sentences, behavioral therapies during imprisonment, and parole and probation based on evidence of rehabilitation have been introduced into the prison system. These innovations have not generally included provisions for design, review and evaluation as research.

Frequently, though, the behavioral programs have had many characteristics of behavior modification research. Examples range from use of "therapeutic community" and reinforcement techniques in prison, to use of aversive conditioning (employing electric shock or drugs with unpleasant effects) in treating sex offenders or uncontrollably violent prisoners, to use of a structured tier system (token economy) in which a prisoner progresses from living conditions of severe deprivation to relative freedom and comfort as a reward for socially acceptable behavior. At the extreme of research or treatment designed to change behavior were castration for sexual offenders and psychosurgery for uncontrollable violence.

The peak of enthusiasm for the application of behavior modification techniques in the prison system was marked by the establishment of the Special Treatment and Rehabilitation Training (START) program in the Federal Bureau of Prisons, and the planning of a new federal prison at Butner, North Carolina, with research in applying behavioral modification throughout a prison as its primary purpose. The START program was abandoned, after 1½ years of operation, under considerable criticism and after some challenges in court. Similar activities led to a reevaluation of the programs planned for Butner, which opened in May 1976. It now offers a variety of vocational and academic courses as well as general counseling. Participation in these programs is voluntary, and changes in the program content will be introduced only with the approval of both the inmates and the staff.

Social research and psychological testing are also conducted in prisons. Projects include studies of the factors which may contribute to criminal

behavior (such as cytogenetic anomalies or socioeconomic and psychological stress), comparison of effectiveness of various rehabilitative programs in reducing recidivism, psychological assessment of criminals as compared with noncriminal counterparts, tracking the outcome of judgments concerning "dangerousness," and evaluating standards for determining competency to stand trial.

Examples of biomedical research on practices intended to improve the health or well-being of subjects in prisons are studies to reduce the spread of infections in crowded environments or to develop new methods of treating drug addiction. Other research, which may or may not be intended to benefit subjects, includes investigations to increase understanding of the nature and causes of narcotic or alcohol abuse and addiction.

Research conducted or supported by DHEW. Information was made available to the Commission by the Public Health Service (PHS) regarding all biomedical research projects involving prisoners that were conducted or supported since January 1, 1970. In addition, the National Institute of Mental Health (NIMH) provided information on all behavioral research with prisoners that was conducted or supported since July 1, 1971. A summary of this information follows.

Biomedical research with prisoners was conducted or supported by five of the six PHS agencies, the exception being the Health Resources Administration. The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) reported conducting over 40 intramural research projects in its testing facility at the Addiction Research Center in Lexington, Kentucky. These studies involved a wide range of activities, such as developing methods for detecting drugs of

abuse through urinalysis, studies of various properties of morphine and other narcotics, evaluations of methadone, studies of the effects of amphetamines, analysis of interactions of various drugs with narcotics, and assessment of the addictive or abuse potential and psychoactive effects of new drugs. ADAMHA also supported nine extramural studies involving prisoners, including studies of the XYY chromosome anomaly, assessment of clinical methods to predict episodic violence, study of the use of narcotic antagonists to treat addict inmates in a prison and in a work release program, and study of behavioral and biological correlates of alcoholism.

The Center for Disease Control reported three studies with prisoners; these involved vaccines and skin test studies for a parasitic disease. FDA conducted five studies with prisoners, all of which involved oral administration of a standard dose of a commercially available antibiotic (Penicillin or Tetracycline). FDA also supported three studies with prisoners (two evaluating skin sensitization by irritants and one studying cyclamates). In the Health Services Administration, research involving prisoners was conducted by physicians at one PHS hospital (13 studies of metabolic responses to prolonged bed rest) and by physicians and behavioral scientists at the Research Division, Bureau of Prisons (33 studies involving a wide range of activities, such as dental care, weight reduction and tattoo removal; many were behavioral and rehabilitative rather than biomedical in focus). Seven institutes of the National Institutes of Health reported support of a total of 19 research programs involving prisoners. This research included studies of vaccines (rubella, rubeola, cholera toxoid, influenza and other respiratory viruses, streptococcus testicular cell function, treatment of sun-induced skin conditions, responses

to infectious diseases (colds, cholera), pathogenesis of acne, and the effect of diet on blood pressure and lipids.

Behavioral research with prisoners conducted or supported by NIMH included psychological and social research studies of crime and delinquency, individual violence, institutionalization, and law-mental health interactions. Participation of prisoners as subjects in these studies was essential due to the nature of the inquiries. A small number of intramural studies conducted at St. Elizabeths Hospital were related to analysis of procedures used to determine competency to stand trial or assess dangerousness of criminally insane patients. Support was provided for 19 extra-mural studies, some of which had biomedical as well as behavioral components. This research included studies (1) to identify sources and patterns of criminal and delinquent behavior (the XYY syndrome, attitudes toward criminal behavior); (2) to develop, test or evaluate models for the prevention, treatment or remediation of criminal behaviors (prediction of violence, lithium treatment for aggressive behavior, impact of imprisonment on the families of black prisoners, perceptions of the minority prison community, effects of prison environment stress on physical and mental health of inmates and staff); and (3) to define and analyze critical issues in law and mental health interactions (due process in determination of criminal insanity, assessment of adequacy of treatment for offenders committed to mental institutions, release of dangerous mental patients, the impact of a "dangerousness" standard as the sole criterion for involuntary commitment). In addition, NIMH has been directed by Congress to study the factors contributing to homosexual rape in prisons.

Chapter 4. Extent of Research Involving Prisoners

The Commission obtained information from all fifty states and the Federal Bureau of Prisons on the policies of each toward research involving prisoners and whether or not research, if permitted, is being conducted. Also, the Pharmaceutical Manufacturers Association surveyed its members to assess the extent of pharmaceutical research involving prisoners. These surveys do not document what is generally considered to be a significant amount of social and behavioral research conducted by scholars and by the prison system itself.

Research in state and federal prisons. To ascertain the status of state laws, regulations and policies governing research involving prisoners, and to determine where such research is being conducted, state correctional agencies and the Federal Bureau of Prisons were surveyed during the summer of 1975. The following information is based on the reports received at the time from the state-wide agencies and the Bureau of Prisons. It should be noted that the policies and research activities of county and municipal jails were not surveyed.

1. Of the 21 states that permit biomedical research and the 23 states that permit behavioral research in prisons, studies are being conducted in the state prisons of only seven and five states, respectively.

2. Of the seven states in which biomedical research is conducted, all of the programs are unrelated to the health or well-being of the subjects and primarily involve drug and cosmetic testing.

3. Of the five states in which behavioral research is conducted, all of the programs are characterized as therapeutic in four states, and both therapeutic and nontherapeutic research (so characterized) in one state. No state reported conducting research programs involving behavior modification.

4. Eight states prohibit biomedical research: one by legislation, six by departmental policy, and one by moratorium; twenty-two have no specific policy.

5. Five states prohibit behavioral research: one by legislation, three by departmental policy, and one by moratorium; twenty-three have no specific policy.

6. Research is being conducted only in states that have specific legislation or departmental policies permitting and regulating it.

7. Information provided by the Federal Bureau of Prisons indicated that both biomedical and behavioral research are permitted by departmental policy. Biomedical research (limited to addiction research at Lexington) and behavioral research projects are being conducted.*

Participation of prisoners in pharmaceutical testing. The Pharmaceutical Manufacturers Association conducted a survey of its members to ascertain the extent to which they used prisoner volunteers as subjects for drug testing in 1975, with the focus primarily on phase 1 studies. Fifty-one companies, representing three-fourths of the members' annual expenditures for research and development, responded to the survey. Sixteen of the 51 used prisoners as subjects.

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* In March 1976, the Director of the Federal Bureau of Prisons announced that all biomedical research in federal prisons would be discontinued.

Of these 16 companies, 14 conducted phase 1 drug research with prisoners, employing a total of nearly 3600 prisoners in 100 protocols studying 71 substances. For nine companies, phase 1 testing represented their only use of prisoners as subjects. The percentage of phase 1 testing subjects who were prisoners ranged from 100% (one company) to 2%, with a median of 50% (an average could not be calculated from the data given). The companies listed a total of eight state and six county or municipal prisons as research sites. Ten companies used only minimum security prisons. No companies used detainees in their research. Other categories of volunteer subjects which the companies reported using in phase 1 studies included college students, medical students, company employees, residents of foreign countries, military personnel, members of fraternal organizations, medical personnel, and the general population.

Thirty-three of the 51 companies indicated that they had insurance policies or other mechanisms for compensating subjects who might be injured in research. (There was no determination of the extent to which such policies or other mechanisms would provide compensation in the absence of legal liability.)

PART III. ACTIVITIES OF THE COMMISSION

Chapter 5. Site Visits to Prisons

The Commission made a site visit to the State Prison of Southern Michigan at Jackson on November 14, 1975. In addition, groups of Commission members visited Washington State Penitentiary in Walla Walla, the Michigan Intensive Program Center at Marquette, and the California Medical Facility at Vacaville. Prior to the visits, Commission members were briefed by a former prison administrator, a former prisoner, and a director of research from a pharmaceutical manufacturing firm, regarding conditions to look for and questions that might be asked.

The State Prison of Southern Michigan at Jackson is the largest penitentiary in the United States, housing over 5000 residents. It is also the site of one of the largest nontherapeutic biomedical research operations, with special buildings on the grounds constructed by two pharmaceutical manufacturers (Parke-Davis and Upjohn) specifically to conduct phase 1 drug studies.

Commission members toured the prison facilities, including regular and honor cellblocks, prison industries, the prison infirmary, and the research buildings. They discussed prison procedures with the deputy warden, and research procedures with the vice-chairman of the committee that reviews each research protocol and with members of the research teams. Most of their visit was devoted to discussion of prison conditions and the research program with prisoners.

According to materials made available to the Commission, the research conducted at Jackson is primarily phase 1 drug testing, although some phase 2 studies and device testing are also performed. Research protocols must be reviewed and approved by the Protocol Review and Protection Committee (composed of five physicians in the community and at Michigan medical schools, two lawyers and a third lay member) and by the Director of the Department of Corrections. Annual reports of research performed are made to the Review and Protection Committee and the Department; any adverse reactions that occur are reported to the Committee immediately.

Information about the research program is included in the packet of information an inmate receives upon entering the prison; there is no additional recruitment or contact with the prisoners by the research personnel unless he requests information about participation. Then the program is described to him in a group meeting, and if he wishes to be considered for research he undergoes a physical examination and laboratory screening tests. Eligibility is contingent upon approval of the prison authorities and passing the screening tests; in addition, subjects must have an IQ of at least 70.

Those who qualify enter a common subject pool maintained for the two companies on a card file. When a new protocol is initiated, prisoners' cards are pulled from the front of the file, and the specific protocol is described to them. If they decline to enter the study, they reenter the pool. The studies are about equally divided between inpatient and outpatient trials. Pay is based on the procedures involved, according to a schedule devised by the Protection Committee and approved by the Department of Corrections, and is comparable to pay received in prison industries. Of the 5200 prisoners at Jackson,

approximately 800 are in the research subject pool. The Commission was advised that medical supervision is close, that a physician is present or on call in the immediate vicinity at all times, that a prisoner can discontinue participation in a project at any time,* and that no notation of his participation in research is made in his official prison record, so that the parole board is not advised of it.

Commission members talked with a representative sample of 80 prisoners both individually and in groups. The sample was selected by Commission staff from the master list of all prison residents, and included both research participants and nonparticipants who responded to an invitation to meet with the Commission. In addition, prisoners suggested by other inmates were interviewed in a group setting. Overall impressions from this experience were that prisoner-participants valued the research opportunity. In general, they felt that they were free to volunteer for or withdraw from the program at will and were given adequate information about research protocols. Nonparticipants expressed various reasons why research was not for them, but did not object to its being available for others.

Participants gave many reasons for volunteering for research, including better living conditions, need for a good medical evaluation, and desire to perform a worthwhile service to others, but it was clear that the overriding motivation was the money they received for participating. In fact, their strongest objection was that the pay for participation in research was held

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* A consent form provided as a sample for review contained a contrary implication. The drug company representatives readily acknowledged that this was a mistake, however, and they gave assurances that the form would be corrected.

down to levels comparable to prison industries. Other complaints focused on limitations to participation rather than on research excesses: if a prisoner stayed on an inpatient study for more than a week, he would lose his prison job seniority; prison officials were said to exclude certain prisoners arbitrarily; some prisoners did not seem to get called to participate in research as often as others. They generally rejected the notion that they were coerced into participating in research, and stated that they knew their participation would not be revealed to the parole board.

The major complaints of the participants were directed toward the prison system, not the research program. When asked if research in prisons should be stopped, the prisoners interviewed unanimously said no. They urged correction of what they viewed as inequities (e.g., that pay be increased, that authorities be forbidden arbitrarily to withhold permission to participate), but asked that biomedical research programs in prisons be allowed to continue.

As a follow-up to the visit to Jackson, the Commission staff compared the characteristics of the 792 men in the drug-testing pool on November 27, 1975 with a randomly selected control sample of similar size. Data came from a computer print-out of the prison's daily roster. Subjects were disproportionately white; although blacks comprise almost 68% of the nonsubject prison population, they are only about 31% of the subject pool. (Data furnished to the Commission by Dr. William Woodward of the University of Maryland showed a similar inverted racial pattern in the biomedical research program at the Maryland House of Corrections at Jessup.) At Jackson, subjects tended to be older than nonsubjects, to have been in prison much longer (an average of almost two years, compared to one year for nonsubjects), and to have been sentenced to Jackson more times (2.1

times compared to 1.8 times for nonsubjects). There was also a striking over-representation among the subjects of men housed in the prison's two honor blocks.

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In order to observe behavioral programs operating in a prison setting, groups of Commission members visited a unit of the Washington State Penitentiary at Walla Walla and the Michigan Intensive Program Center at Marquette. Neither program is conducted as research, and the Commission is not aware of a behavior modification program in a state or federal prison that is so conducted at present.

The program at Walla Walla utilized a therapeutic community approach, and dealt with the state's most difficult-to-manage prisoners, who were sent to the unit generally because of unacceptable conduct in the regular system. The unit is operated almost entirely by the prisoners themselves, who serve as the therapeutic community, establishing and enforcing rules of conduct. On entering the program, a prisoner is placed in an isolation cell. His only contacts are visits by the director and other prisoners on the unit, who explain the rules to him and urge him to conduct himself in such a way as to be able to join them. When he is willing to conform, he is released from his cell to the open ward. There, the main emphasis becomes retraining in appropriate patterns of social interaction, using such mechanisms as group discussions of current events, recreational programs, and group therapy. Swearing, use of jargon, and fighting are among the numerous forbidden behaviors; violations are punished by a return to the isolation cell, with the group serving as enforcer of the rules and determining when the violator can return to the ward.

The primary purpose of the Walla Walla program is to encourage learning of socially acceptable behavior rather than specifically to prepare the prisoners for return to the outside world or the regular prison system. Most men remain on the unit for long terms. Those who have been released outside the prison are said to have done remarkably well, with recidivism a rare event (follow-up records are apparently not maintained). Return to the regular prison system would be dangerous, since those in the program gain reputations as informers. Interviews with prisoners in the program yielded only the highest praise for it. Prisoners admitted initial resentment of the isolation treatment, but claimed that it was the only way they had ever been made to think seriously about themselves and their behavior, and that it provided the necessary impetus for their behavior change.

The Michigan Intensive Program Center (MIPC) at Marquette is a maximum security facility housing difficult-to-manage prisoners who have been transferred from other facilities in the state. The behavioral program there is based on a six-level token economy. Privileges and comforts increase as a resident earns enough tokens to progress from the lower to the higher levels. Tokens are earned for correct behavior (making the bed, cleaning the cell, attending educational activities, not fighting, etc.) and are awarded at frequent intervals throughout the day. The purpose of the program is to improve the prisoner's behavior sufficiently to enable him to return to the regular prison system and be manageable there.

Interviews with prisoners at the MIPC indicated no enthusiasm for the program. The prisoners seemed to tolerate it grudgingly and submit to the process in order to get back into regular prison life, but with the determination that nothing done

to them in the program was really going to change their behavior. They generally viewed the program as "just another lock-up," no better or worse than the segregation blocks to which they might have been assigned alternatively. Their major objection was the arbitrariness by which the prison system could decide to send them to the MIPC. No figures were available on recidivism, nor was there any other means to document the effectiveness of the program.

Commission members also visited the California Medical Facility at Vacaville, which houses approximately 1400 inmates. Most of the prisoners are referred to Vacaville for medical or psychiatric reasons, and one-fourth of the population is excluded from participation in research for security reasons. Those who wish to volunteer sign a roster at the research office, and selection of subjects is made in numerical order from this list.

Research conducted at Vacaville includes a large program of skin-testing for hypersensitivity, as well as internal administration of experimental drugs. New volunteers begin with a skin-test study before advancing to higher paying pharmaceutical studies.

Other paying prison jobs are available, and at the time of the visit there were unfilled slots for reasons that were unclear but possibly had to do with disparity in pay or difficulty of the work as compared with participation in research. Legal counseling is available from law students who visit the prison weekly. Educational programs range from elementary school through a baccalaureate degree. There is spot censorship of mail. Telephones are available, but the inmates must pay to use them.

The inmates' council reviews all research projects and can veto any protocol. Most of the active protocols have also been reviewed by Institutional Review Boards of outside institutions. Informed consent is obtained in writing, and the prisoner receives a copy of the signed form. Examination of a card file indicated a significant dropout rate from studies; apparently prisoners feel free to withdraw, even though they know that if they do so frequently, their chances of being invited to participate in future studies will be reduced.

Chapter 6. National Minority Conference on Human Experimentation

In order to assure that minority viewpoints would be heard, the Commission contracted with the National Urban Coalition to organize a conference on human experimentation. The conference was held on January 6–8, 1976, at the Sheraton Conference Center, Reston, Virginia. Attended by over 200 representatives, it provided a format for presentations of papers and workshop discussions from which a set of recommendations emerged. The papers and the recommendations relevant to prison research are summarized below.

Joyce Mitchell Cook, Ph.D. Dr. Cook suggests that ethically acceptable research may be assured by a principle of equality (i.e., that researchers not propose experiments which they or members of their family would not participate in). She argues that the term "informed consent" is ambiguous, since it wrongly places the emphasis upon process and information rather than on voluntariness. Dr. Cook adopts the position that volunteering is genuine only if the end to be pursued is one to which the volunteer is devoted. Because of the extraneous motives of prisoners, she concludes that they are volunteers in name only. She recommends that behavioral research be permitted only if it directly benefits the participants and can be conducted on hospital wards rather than in prisons. Dr. Cook concludes that experimentation on prisoners ought to be abolished and that the risks of experimentation should be distributed more equally among members of the free-living world.

Larry I. Palmer, J.D. Mr. Palmer begins with the premise that the ethical problems posed by prison experimentation derive from racial, religious and

nationalist conflicts and that the issues of prisoners and race are merged. He recommends guidelines to encourage scrutiny of: (1) the appropriateness of using prisoners in a particular protocol, (2) the societal priorities associated with the research, and (3) the potential risks and procedures to minimize such risks. He suggests that research involving prisoners might be regulated by state officials, with additional monitoring and scientific evaluation by professionals and some supervision of the consent process. All decisions and consequences regarding experimentation in prisons should be open to public scrutiny. Mr. Palmer sees little justification for a ban on all research in prisons; rather, he advocates a "scrutiny of values," through a statement of the nature, purposes and risks of each protocol in relation to the interests of the prison population.

L. Alex Swan, Ph.D., LL.B. Dr. Swan argues that behavioral research is aimed at quelling dissident prisoners who view their incarceration in political and economic terms. He suggests that such research ought instead to promote "human liberation" by exposing oppressive conditions in prison. He advocates self-determination for prisoners, particularly with regard to the goals of social and behavioral research, and challenges social and behavioral scientists to accept responsibility for the possible misuse of their research findings. Dr. Swan asserts that scientific manipulation of prisoners to conform to the will of the state is unethical, just as it is unethical to use scientific techniques for disciplinary or punitive purposes. He further states that experimentation on the brain to alter behavior violates the inmate's independence and right to free speech, that the prison system is so inherently coercive that informed and voluntary consent is impossible, that labeling of prisoners as aggres-

sive or violent for research purposes is dishonest and repressive, and that civil liberties are endangered by behavior modification techniques in prisons because of the closed nature of such institutions.

Recommendations of Minority Conference workshops on research involving prisoners. Two workshops were devoted to the topic of research involving prisoners. The first of these recommended a moratorium on all nontherapeutic biomedical research in prisons until a comprehensive evaluation of human experimentation has been made. This evaluation should include consideration of the purpose of research involving prisoners, criteria for selection of subjects, assessment of risks, government responsibility for regulating research in prisons, responsibility of professional organizations regarding such research, the role of prisoners in the supervision of the research, the fixing of financial responsibility including compensation for harm resulting from research, and access of prisoners to official bodies outside the prison. The workshop also recommended that behavioral research be redirected from a focus on the individual prisoner to the goal of understanding the nature of prisons and their effects on individual prisoners. Recomendations were not proposed regarding informed consent because of doubts that it is possible to obtain informed consent in our prisons.

The second workshop recommended the establishment of a permanent commission to regulate human experimentation, a ban on biomedical research and psychosurgery in prisons, establishment of a human subjects review committee with prisoner representation, and the provision of technical and legal resources to prisoners who are potential subjects of human experimentation.

Chapter 7. Public Hearing

On January 9, 1976, the Commission conducted a public hearing on the issue of research involving prisoners. Summaries of the presentations that were made to the Commission follow.

Gabe Kaimowitz (Senior Staff Attorney, Michigan Legal Services) suggested that researchers assume that there is informed consent, and that they often fail to use adequate control subjects, particularly in behavioral research. Further, investigators may limit public access to information about prison research projects. He stated that they often use captive populations without considering the availability of community volunteers, and too often apply medical or psychological models inappropriate to economic and social problems. Prisoners are in an inherently coercive environment, and their consent to research is always suspect. Mr. Kaimowitz is not opposed to therapeutic biomedical or behavioral research when the prisoners themselves request its implementation. In such situations a review committee should examine the conditions that caused the prisoners to make such a request.

Matthew L. Myers (National Prison Project of the American Civil Liberties Union Foundation) stated that informed consent is not feasible in the prison environment. Regardless of prison policy concerning participation in research and parole, prisoners may believe that involvement contributes to early release. They may also participate to escape from the routine of prison life or to earn money for necessities. Mr. Myers said that most medical experimentation is conducted in medium or maximum security facilities in which conditions are

oppressive, alternatives are few, and there is a potential for abuse due to the closed, isolated and coercive nature of the prisons.

William R. Martin, M.D. (Director, Addiction Research Center, National Institute on Drug Abuse, DHEW) stated that addiction research is important and necessary both for society and for the prisoners. Limiting such research will retard development of therapy for addicts and will prohibit the evaluation of the addictive properties of new analgesics. Research participation is beneficial to most prisoners, he said, in that it is generally a safe and constructive experience, often improves health, and is a source of pride. Dr. Martin has been unable to identify any other population in which such studies can be done as validly and safely as in prisoners. He feels that prisoner participation may be altruistic, and therefore society should compensate participants for their involvement and for any injuries that may occur. There is empirical evidence that prisoners can and do make informed judgments, and are equally knowledgeable about research programs as other subjects. Practical measures can be taken to minimize the seductiveness of the research setting compared to the prison environment.

Theodore Francis (Occupational Drug Use Program, New York State Office of Drug Abuse Services) urged that biomedical and behavioral research in prisons continue, but that more attention be paid to compensation, the level of health care provided to subjects, and review of behavioral research. Participation of prisoners should be judged an acceptable means of earning money, and inmates should be reimbursed according to discomforts and risks incurred. Money earned should be held in escrow for prisoners until release

or paid to their families. A national board should review all behavior modification research for efficacy, validity, and risks to individuals and to the community. This board would issue public notices in lay language, describing dates and place of the research, as well as the reimbursement provisions.

Michael S. Lottman (Commission on the Mentally Disabled, American Bar Association, and the National Association for Retarded Citizens) urged that special care be given to protecting the rights of mentally disabled prisoners. Thereafter, testifying as an individual, he opposed nontherapeutic biomedical research on prisoners which exposes them to risk of discomfort, pain or incapacity. He stated that the coercive and oppressive nature of penal institutions precludes obtaining voluntary informed consent. Prisoners are not physiologically unique and therefore provide no information which cannot be gained from a free population. Research on prisoners benefits drug companies and researchers, he said. If research is to continue in prisons, particular care should be given to protecting the rights of mentally retarded prisoners, and an independent body should certify that each subject can and has given informed consent. Mr. Lottman is not opposed to therapeutic biomedical research in a prison setting, provided there are proper controls and consent procedures.

Joseph Stetler (President, Pharmaceutical Manufacturers Association) stated that to the best of his knowledge no prisoner has died or been permanently injured from research sponsored by drug companies. He advocated continuation of drug research in prisons provided that: (1) researchers are qualified, (2) facilities are adequate, (3) participation is voluntary and informed, (4) research is monitored, and (5) prisoners are compensated fairly. He stated that prisons

are practical and safe for drug testing, and that discontinuance of such research might delay development of new drugs. He estimated that 85% of all phase 1 drug testing is done on prisoners, and that the rate of compensation could increase substantially and still be insignificant relative to the total cost of new drug development. Prisoner testing of cosmetics or over-the-counter drugs is minimal relative to research involving prescription medications. A 1975 policy statement of PMA on the conduct of clinical research was summarized.

Allan H. Lawson (Executive Director, Prisoners' Rights Council of Pennsylvania) held that prisoners should be permitted to participate in experimentation only if the decision is absolutely voluntary. This is impossible in today's prisons, he said, because of economic pressures, forced idleness and inhuman conditions. In his view, research programs provide an excuse to prison administrators to neglect responsibilities such as housing, medical care and job programs. Because of the reality of economic pressures, the Prisoners' Rights Council would permit some research in prisons provided safeguards are instituted, until other means of earning money are available. However, the Council would ban research which involves exposure to incurable diseases or is otherwise dangerous or unnecessary. Mr. Lawson urged that medical care and compensation be provided for inmates injured during research.

The Reverend Americus Roy (Prisoners Aid Association of Maryland, Inc.) testified against medical experimentation in prisons based on personal experience at the Maryland House of Corrections. Prisoners participate in research, he said, because of economic deprivation and as a temporary escape from inhuman conditions.

Use of prisoners is exploitative of the economically depressed. Risks of research should be widely distributed, especially among those who are likely to benefit.

PART IV. REPORTS TO THE COMMISSION

Chapter 8. Philosophical Perspectives

Papers on the ethical issues involved in research with prisoners were prepared for the Commission by Roy Branson, Ph.D., Cornel Ronald West, M.A., and Marx W. Wartofsky, Ph.D.

Dr. Branson first analyzes the ethical principles underlying the standard arguments for and against research involving prisoners, and, secondly, examines several policy alternatives. He concludes by recommending a moratorium, appealing to the principles of free and informed consent and justice.

In reviewing arguments for experimentation, Dr. Branson cites three justifications generally advanced in support of research involving prisoners: (1) that it contributes to the good of society, of which prisoners are members and therefore recipients of benefits; (2) that it is an appropriate way for prisoners to make reparation; and (3) that prisoners can, in fact, give free and informed consent. A varient of the third argument is that criminal conviction presupposes competence and responsibility; therefore, prisoners must be presumed to have the capacity to volunteer. In fact, advocates of this position point out that prisoners are permitted to choose work in hazardous industries and so should be permitted to choose work as research subjects as well.

Opponents of prison research assume that experimentation is different from other occupations. A person's relationship to his body is not his relationship to his goods. A person's body, in a special and real sense, is

the person. In experimentation risk to bodily integrity is primary to the activity, whereas in other occupations, the risk is secondary.

The two fundamental principles to which opponents of experimentation appeal are free and informed consent and justice. Those citing consent can say that prisoners cannot in principle give free consent because of the inherent nature of prisons as coercive, total institutions. Other opponents appealing to free consent do not go so far. They claim that sufficiently free consent to experimentation cannot in fact be given in American prisons. They cite not only the coercive structure of prisons, but such administrative features as limited alternative to earn money in prisons (none for equivalent rates of pay), and indeterminate release dates with nonobjective or unknown conditions for leaving the prison. Dr. Branson identifies himself with the second position, saying that empirical analyses leave a serious and reasonable doubt that inmates of American prisons can in fact give a sufficiently free consent to experimentation.

Justice is the other principle to which opponents of prisoner experimentation appeal. Injustice can take the form of injury, when a person is wrongfully harmed through exploitation or negligence by others. Injustice can also result from failure to follow the basic requirement of distributive or comparative justice: that like cases are to be treated alike and different cases be treated differently. Since prisoners are in relevant respects equal to free persons, the burdens of risk and harm should be proportional to those of free-living citizens, which would entail a significant reduction in at least phase 1 drug trials. On the other hand, prisoners are unequal to free persons in important respects in that they have been placed in total institutions.

Dr. Branson, citing comparative justice, says the similarities of prisoners to free persons requires that the proportion of experimentation utilizing prisoners should be reduced. The differences between experimentation conducted on prisoners and those conducted on free persons require that prisoner experimentation be stopped, at least until conditions change.

In applying principles to policy alternatives, Dr. Branson sees remuneration as a major and finally insurmountable practical obstacle to prisoner experimentation. The principle of informed consent dictates that in order for prisoners to give consent that is not coerced, they should not be paid more for experimentation than for other prison jobs. But the principle of justice requires that rates of remuneration to prisoners should be equivalent to the rates paid to free volunteers. Schemes relying on committees of prisoners (or prisoners and prison officials) controlling funds created by the difference between the standard amount paid by drug companies and what an individual prisoner received run into practical problems, for the committee itself could manipulate and coerce prisoners.

Dr. Branson's recommendation, therefore, is that the Commission declare a moratorium on prison research and suggest that if and when conditions in American prisons have improved, then research might be resumed in those facilities which can meet the requirements of informed consent and justice. He would not preclude the possibility of offering innovative therapy to an individual inmate in need of treatment, but this, he says, should be distinguished from programs of "therapeutic research" which blur the distinction between individual therapy and experimentation. He suggests, in addition, that the moratorium extend to behavioral research, since new behavioral therapies may

be evaluated first on nonprisoners, but that observational research (noninterventional behavioral research), as well as educational programs, be permitted to continue.

Mr. West advocates a contractual approach to human experimentation which requires full disclosure, written consent and choices that are rational. These requirements reflect the human rights to know, to choose and to be treated fairly He distinguishes between coercion (which involves threats) and bribery (which involves manipulation of incentives). Mr. West considers requests for prisoners to participate in research to be bribery, not coercion; hence, choice is at play. The paucity of alternatives and the conditions of domination within prisons, however, undermine the rational basis for such choice. Mr. West concedes that a certain degree of control over prisoners might be warranted, but only to the extent that basic human rights are not violated. The necessity for such control, he believes, suggests that prisoners are less appropriate subjects for research than are nonprisoners. Therefore, he urges that normal volunteers be recruited, instead; but he cautions against shifting the burden of research to Third World populations.

Mr. West views behavioral research in prisons to be nontherapeutic, inasmuch as the rehabilitative efficacy of behavior modification programs has not been demonstrated. Thus, he would restrict such research according to the same principles he applied for nontherapeutic biomedical research.

Mr. West recommends termination of both nontherapeutic biomedical and "therapeutic" behavioral research involving prisoners until such time as prison reform creates the conditions necessary for their legitimate participation in such research.

Dr. Wartofsky begins his essay on selling the services of one's body for research by discussing the extent to which being a subject is similar to other forms of wage-labor. He examines the nature of that which is being sold (and bought), and the extent to which a person has the right to offer his or her body in exchange for money. His position is that whereas one may not sell one's body, as such, nevertheless one may sell the disposition over the use of one's body for specified purposes, for a specified time and under specified conditions. In other words, while one's life and liberty are inalienable rights (which cannot be separated from one's person and sold), one's services or capacities are commodities which, in our free-market social and economic system, are regularly exchanged for wages.

Dr. Wartofsky then considers the problem of risk-taking. In general, he says, no ethical question arises concerning the risks inherent in dangerous occupations, since the workers are seen as having free choice in undertaking or refusing such jobs, and the risks involved are secondary to the needs of society which the occupations (e.g., coal mining, construction work, chemical manufacturing) are designed to meet. By contrast, the nature of risk in research is such that one is placing one's health or well-being at risk not as a by-product of some other purpose, but as the primary commodity; and it is the intimacy of the relation between one's person and one's well-being which makes the exchange disturbing.

With respect to motivation, Dr. Wartofsky observes, it is generally assumed that placing oneself at risk for monetary gain is for one's own benefit, whereas doing it without tangible reward is more altruistic. However, he points out that one may place oneself at risk for monetary gain and, at the same time, be self-sacrificing (if, for example, the purpose is to support

one's family or otherwise satisfy the needs of others). Whether working for the abstract "good of society" is a higher motive than working for one's family is a question which cannot be settled. Thus, he concludes, motivation should be considered (if at all) only to the extent that the seriousness of the motivation should be commensurate with the degree of risk to be undertaken.

Next, he considers the extent to which prostitution is like wage-labor, involving, as it were, the sale of a disposition over one's body for a certain purpose, at a certain rate and for a certain time. The relevance of the inquiry lies in the fact that what is being bought and sold in prostitution is (just as in participation in research) something which is "so intimate to one's person that there is something disturbing in the notion that it is alienable, as a commodity." In his view, the ethical objections to prostitution, and to being a paid research subject, derive from the translation of relations which are supposed to express fundamental aspects of humanity into an economic exchange. In the paid research context, both the investigator and the subject are reducing an essential human capacity (putting oneself at risk for others) to a commodity; so doing, they may dehumanize each other.

Here, he observes, society is faced with a dilemma: on the one hand, research with human subjects is important for the preservation and well-being of the species; on the other hand, the only means of conducting such research is ethically questionable. He sees three obvious solutions: (1) to stop paying the subjects; (2) to conduct only that research which can be carried out with unpaid volunteers; and (3) to restructure society in order to eliminate the economic need which induces (or coerces) the disadvantaged into making up the largest portion of paid research subjects. All of these "solutions,"

however, are impractical. The pragmatic solution which he recommends, therefore, is to minimize the exploitive elements which "commodify" the situation. An alternative would be to follow the model proposed by Hans Jonas in which the most valuable members of society (rather than the most expendable) undertake the risks, but Dr. Wartofsky considers this also to be impractical. Finally, he proposes that both paid and unpaid research subjects be organized, educated as to their rights, and represented at all levels of review (Institutional Review Boards as well as state and federal commissions). This, he believes, would socialize the interaction, reduce the alienation, and ameliorate the dehumanizing effects of the commodity relationship for both the paid subjects and the researchers.

Chapter 9. Sociological and Behavioral Perspectives

In order to obtain an understanding of the nature of the social structure of a prison and its implications for the prisoner's freedom and competence to make a choice for or against involvement in research, the Commission requested papers by two sociologists: Jackwell Susman, Ph.D., and John Irwin, Ph.D. In addition, Martin Groder, M.D., prepared a paper on behavioral research aimed at rehabilitation of prisoners. These essays are summarized below.

Dr. Susman suggests that a determination regarding prisoners' participation in biomedical or behavioral research depends on understanding their value system and how it deviates from conventional norms. He describes two sets of norms in prison society: (1) the norms which the staff and officials endorse and which support their authority, and (2) the norms of the inmates, which encourage diversity of behavior and subversion of the official system.

It is generally agreed that custody involves profound attacks on the prisoner's self-image through deprivation and control. Inmates cope with the "pains of imprisonment" through various social structures, norms and values. From the sociological literature on prisons and prison life, Dr. Susman identifies two descriptive models of prison society: the "prisoner solidarity" image and the "prisoner diversity" image.

As described by Dr. Susman, the prisoner solidarity image classifies prisoners according to their conformity to or deviation from the inmate code which encourages cohesion and mutual support among prisoners vis-a-vis their captors. Adherence to the inmate code helps protect the average inmate and strengthens

his dignity. A negative aspect of this social structure is the dependence of most prisoners on the few leaders for privileges and protection. The convict leaders are granted special privileges by the administration in return for maintaining order, and thus seem to have little incentive to participate in biomedical and behavioral research. The rest of the inmates may adapt differently to prison life. Some may conform, with varying degrees of intensity to the demands of the inmate code, and might reject biomedical and behavioral research since the code rejects conventional values and cooperation. Others may deviate from the norms of the prisoners' world and participate in research to obtain the goods and services their outcast status denies them. Still others may combine conformity and deviance to maximize their chances of leaving prison emotionally and physically unscathed; their participation in research would depend on a careful analysis of the costs and benefits, in terms of their life in prison and their chances of getting out. Finally, some may conform completely to the official norms and may volunteer for research for both altruistic and pragmatic reasons.

The second model of prison society, the prisoner diversity image, focuses on the inmates' identification with persons or groups outside the prison. In this view, the inmates bring subcultural norms and values with them into prison, and, thus, prison society is diverse. This model describes inmates according to three categories. First is the career criminal or professional thief, who assumes a commitment not to prison life but to criminal lifestyles. His objective is to do his time and get out, not to manipulate the prison environment. He may volunteer for research believing that it will be considered favorably by the parole board, or merely to maximize his comfort until he is released. Second

is the "convict," who is oriented primarily to prison life and seeks status by manipulating the environment, winning special privileges and asserting influence over others. His participation in research is improbable because it might imply cooperation with the staff. The third group of inmates identify with "legitimate" subculture outside the prison. They have no commitment to the values of thieves or convicts and seek status through the means provided by the prison administration. They are usually rejected by the convict and thief subcultures, and might be expected to volunteer for research projects.

Dr. Susman examines the implications of these models of prison society for the requirements of informed consent: competency, knowledge and voluntariness. Rejecting the Kaimowitz court's view of the effects of institutionalization, Dr. Susman believes that prisoners are able to maintain an identity. He suggests that prisoners' autonomy may expand or contract depending on their circumstances, and that at least some prisoners have sufficient autonomy to give informed consent to participate in research. Providing prisoners with knowledge of the risks associated with research may be difficult, but Dr. Susman believes in principle that it can be done satisfactorily. With respect to voluntariness, both images of prison society indicate that prisoners have a great deal of power and influence over how the prison is run. This implies that mechanisms could be developed to insulate research activities from staff and peer pressure. Dr. Susman concludes that prisoners can have the freedom and competence to give informed consent.

Dr. Irwin agrees with Dr. Susman that biomedical research involving prisoners should not be categorically denied, but rather permitted under conditions

that protect against the disparity of bargaining power between prisoners and authorities. Instead of a contract model (which assumes relatively equal bargaining power) Dr. Irwin suggests a "rights model," in which minimal rights are established and guaranteed against abuse of power. He observes that conditions of degradation and coercion vary with the degree of autonomy and isolation under which prisons operate, and he believes that most of the constraints (including arbitrary use of discretionary powers) are, in fact, unnecessary and could be abandoned without interfering with effective operation of the penal system. This, he says, would make the prison environment compatible with conditions necessary for the ethical conduct of research.

Dr. Irwin recommends, therefore, an accreditation process and an ongoing review mechanism, in which prisoners, their families and civil rights groups all participate, with a concomitant reduction of discretionary powers now held by prison authorities. He would also require that drug firms pay at the same rate that they pay nonprisoner participants, but that the difference between those wages and the prevailing prison wages be placed in a fund to increase the wages for the general prison population. He would also eliminate any leakage of information to parole boards about research participation. Finally, he recommends that there be established a review and grievance mechanism independent of the prison system in which prisoners, their families and civil rights organizations would participate. This mechanism would review all decision-making relative to prisoners' rights and perhaps consider, as well, such factors as the adequacy of the health care available to the prisoners.

Dr. Groder, formerly warden-designate of the Federal Correctional Institution at Butner, North Carolina, observes that of all research involving

prisoners, only therapeutic psychosocial research directly addresses "the promise of rehabilitation." Unless society is willing deliberately and intentionally to abandon its commitment to rehabilitation, he argues, research of high quality is essential if services are to be provided to offenders in a safe, effective and humane manner. He believes that offenders, as wards of the state, have a "right to treatment" that will be abridged if correctional research is abolished or stifled through overregulation.

Dr. Groder accepts the likelihood that the Commission will wish to recommend additional regulatory procedures, and suggests the following goals: (1) "wards of the state" should be provided an opportunity to rejoin the social mainstream; (2) the quality of consent should be audited to protect basic rights of volunteers; (3) provision should be made for care, compensation, and possible reversal if a bad effect occurs; and (4) the outcome of all research should be published. Dr. Groder recommends that Congress appoint regional boards with the responsibility of achieving the four goals and ensuring prisoner rights. The boards would approve or disapprove projects, and appeals could be made to the federal court of appeals. The boards should sponsor studies of the correctional process and the impact of research, and make recommendations to Congress regarding pertinent legislation.

Dr. Groder believes, on the basis of his experience, that therapies can be devised to enable prisoners to reenter and remain in the mainstream of society, and he cautions that a ban or limitation on such research will ensure that no correctional innovations will be developed. Therapeutic techniques that become available in nonprison society may also be denied to prisoners, and that would pervert the desire to rehabilitate prisoners as well as infringe upon their right to treatment.

Chapter 10. Legal Perspectives

The Center for Law and Health Sciences, Boston University School of Law, prepared for the Commission an analysis of the law relevant to determining the validity of consent by prisoners to their participation in research. This analysis proceeded on the assumption (consistent with the findings of the Commission) that quality of information and ability to comprehend do not generally constitute problem areas in prison research. The key issues reviewed by the Center are whether consent can be given voluntarily in the prison environment, and whether voluntary consent to treatment (and, by extension, to behavioral programs that might not constitute "treatment") is required. The first of these issues is discussed primarily in the context of nontherapeutic biomedical research, and the second is raised in connection with behavior modification programs.

Motivations of prisoners to participate in nontherapeutic research include financial reward, hope for reduction of sentence, seeking of medical or psychiatric help, relief from tedium, desire for better or more secure living conditions, attraction of risk-taking, altruism, etc. The conditions that give rise to these motivations may constitute duress such as would render a contract voidable and, by analogy, render it difficult if not impossible to uphold a prisoner's "informed consent" to participation in research. It has been argued, but not determined as a matter of law, that incarceration inherently constitutes such coercion (or duress) that nontherapeutic research should not be conducted in prisons. In the absence of such a determination, courts will examine particular prison situation. for evidence of duress in obtaining consent to participation in research.

Thus, as to financial reward, the questions to be asked are whether there are alternative sources of equal income and, more importantly, whether participation in research is the only way prisoners can earn enough money to maintain a minimum standard of living. As to living conditions, the questions would concern the extent of deprivation in the prison, and the contrast between the prison environment and conditions in the research center. These are matters of fact that would be examined in a particular situation to determine whether a consent was voluntary.

Promise of reduction of sentence is now generally thought to be inherently coercive, but, at least with respect to rehabilitative treatment that may be of experimental nature, sentence reductions have been tied to prisoners' consent. Cases involving waiver of rights indicate that even in a coercive situation, rights may be waived if adequate safeguards, e.g., counsel, are provided.

Medical treatment generally constitutes a battery if the patient has not consented to it. Although one jurisdiction has not applied this rule in cases involving prisoners, other jurisdictions have held to the effect that imprisonment does not deprive a person of the capacity to decide whether or not to consent to health care. The latter rule has been applied in cases dealing with physically invasive behavior modification techniques, but there is no holding on the right to withhold consent to noninvasive behavior modification techniques. Whether or not the techniques were experimental does not appear to have been material in any of the holdings. Rather, the courts appear to have taken into account the degree of invasiveness.

State regulations and statutes dealing with experimentation on prisoners cover the entire spectrum, from permission to total bans of such research.

Where any sort of research involving prisoners is permitted, a requirement that informed consent be obtained is explicitly set forth. Where financial or other rewards are explicitly covered, they are generally limited or prohibited. The recently published DHEW proposals related to research on prisoners follow the states that permit such research by accepting the view that prisoners can consent to be subjects so long as adequate safeguards are provided. The proposals published for public comment by DHEW (November 16, 1973) include such safeguards as a required certification by a review committee that there are no undue inducements to participation by prisoners, taking into account the comparability of the earnings otherwise offered; a requirement that no reduction in sentence or parole in return for participation in research be offered unless it is comparable to what is offered in return for other activities; and a provision for accreditation by DHEW of prisons in which research is to be supported or conducted. A subsequent DHEW Notice of Proposed Rulemaking (August 23, 1974) adds a requirement that the review committee also take into account whether living conditions, medical care, etc. would be better for participants than those generally available to prisoners, but deletes the provision for accreditation by DHEW.

The report by the Center for Law and Health Sciences concludes with the following recommendations: that provision for accreditation by DHEW should be made, to ensure that research will not be conducted under such circumstances that participation is the only way for a prisoner to obtain minimally decent living conditions; that the rewards for participation should not be such that they provide the only way for a prisoner to maintain his health and personal hygiene, or induce a person to incur great personal risks; that parole or a

reduction in sentence should never be offered in return for participation in research; that there should be some provision for the protective role of an independent counselor; that full information about the research should be given the prospective participant, and that he should not be asked to waive his rights against anyone for injuries that he might sustain. If these safeguards are adopted, the law generally will recognize the informed consent of a prisoner to participation in research.

Chapter 11. Alternatives and Foreign Practices

Alternatives employed in the United States and foreign countries to the conduct of biomedical research in prisons were examined by the Commission. A paper on alternative populations for conducting phase 1 drug studies was prepared by Dr. John Arnold. Information on two programs using normal volunteers as alternatives to prisoners, one for vaccine testing and one for general physiologic testing, was provided by staff reports. An additional staff report was prepared on the use of prisoners in a research program located in a hospital outside of the prison. Practices in foreign countries related to development and testing of new pharmacologic agents were surveyed and reported to the Commission by Mr. C. Stewart Snoddy and Dr. Marvin E. Jaffe, Clinical Research International, Merck Sharp & Dohme.

The Quincy Research Center, Dr. John Arnold, Director, is an innovative phase 1 drug testing program using cloistered, normal volunteers. It was recently established in Kansas City, Missouri. Dr. Arnold, an investigator with 29 years of experience in drug testing in prisons, highlights some of the practical and ethical problems associated with the use of such a research population, and explains the reasons he now believes that the use of prison inmates as research subjects should be phased out. He identifies limitations imposed by the prison system on the optimal conduct of such studies, and his reasons for believing that the use of nonprisoner volunteers for them is preferable. Cloistering, he says, is necessary to enable the researcher to strictl control the medications received, to intensively monitor subjects for signs of adverse effects, and to identify drug properties with greater confidence. In

contrast with research facilities designed exclusively for the cloistering of free-world volunteers for phase 1 studies, however, prisons are neither built nor operated around the needs of medical research. The prison environment may be poorly controlled, particularly with regard to the presence of contraband drugs that may seriously influence the result of a clinical trial. Further, the dropout rate for his free-world studies has been about 1.5 percent, a lower rate than he experienced in a prison setting.

Dr. Arnold suggests that the behavioral problems associated with cloistering volunteers are the greatest barrier to the development of alternative populations and require sensitivity with regard to volunteer selection, adequate preparation for the experience of complete control of life-style, and physical facilities that are attractive and interesting. The second largest problem is the cost. While lodging and food contribute to this expense, the single largest increment stems from the greater degree of supervision and closer medical control required for volunteers in a nonprison setting.

Despite the problems, Dr. Arnold believes the advantages make the use of nonprisoners preferable. One advantage he cites relates to compensation for injury, which the consent form should address. While an indemnification plan similar to those governing other occupational hazards can be arranged for nonprisoner volunteers, it cannot necessarily be done for prisoners. Rates for the Quincy workman's compensation insurance are based on data that show the risks for participants in phase 1 drug research to be only slightly greater than the occupational risks for office secretaries, one-seventh of those for window washers, and one-ninth of the risks for miners. The problem of rendering

long-term follow-up and extended care, because prisoners are not likely to return to prison for follow-up examinations or medical attention, is also reduced by using a free-living population.

Dr. Arnold believes that three advantages of the free-world volunteer system will eventually lead to its exclusive use: (1) paid stipends can be comparable to wages paid for other services, (2) indemnification can be offered under plans similar to workman's compensation, and (3) volunteers may choose medical research against other forms of limited employment without any special coercive force.

Dr. Arnold described characteristics of the population attracted to his nonprisoner volunteer program, based on the last 150 subjects at the Quincy Research Center. The men were 80% white, 15% black, and 5% other racial background. Age group was 50% age 20-30, 40% age 30-40, and 10% age 40-55. Ninety percent were recently or seasonally unemployed, 8% steadily unemployed, and 2% were college students. Most had completed 8th grade, 60% had completed 12th grade, 2% were college students, and 0.5% were college graduates. Approximately 60% of the subjects were former prisoners; 5 to 10% had been subjects in Dr. Arnold's earlier studies in prisons.

The Clinical Research Center for Vaccine Development (CRCVD) was developed to provide an alternative to the use of prisoners in infectious disease research. It was established in 1974 under a contract with the National Institute of Allergy and Infectious Diseases (NIAID), the primary inpetus being NIAID's desire to develop a dependable source of healthy, adult volunteers that would circumvent many of the problems plaguing its prison-based research and allow

infectious disease research to continue. A contract was awarded to the University of Maryland School of Medicine to demonstrate the feasibility of recruiting adult volunteers from the community for research in which live attenuated vaccines for respiratory viruses and mycoplasma are administered to subjects to test infectious capability, symptoms produced, ability to induce immunity, and contagiosity.

The CRCVD is under the direct supervision of two physician-researchers who conduct the protocols developed by NIAID. They are assisted by two part-time recruiters, a consulting psychologist, and support staff. The facility is part of the University of Maryland School of Medicine complex in Baltimore; its major unit is a self-contained, limited access, air-sealed isolation ward, where volunteers reside for the duration of the study.

Recruiting procedures have focused on attracting young, intelligent and healthy adults, to minimize problems with informed consent and adjustment to the dormitory-like setting of the isolation ward. College students were selected as the free-world population most likely to meet these requirements. Recruiters present information on the program at college campuses; interested students subsequently meet with the recruiters so that a blood sample may be drawn. Those volunteers who pass this initial screening procedure are contacted by the recruiters and offered the opportunity to participate as subjects.

Most of the studies conducted by the CRCVD last between 15 and 30 days. During a two-day acclimation period on the unit, there are intensive educational presentations concerning vaccine development and the upcoming study, preliminary medical and psychological screening procedures are conducted, and

the volunteers become acquainted with the isolation ward environment and staff. The researchers reserve the right to dismiss volunteers prior to inoculation, but thereafter only the subject may choose to withdraw from a study. To supplement the consent form, an examination is administered prior to inoculation, to assess and document the participant's comprehension of the research protocol. Each volunteer must pass this exam before being permitted to participate in a study.

The volunteers earn $20 per day on the isolation ward, based on what the average college student might earn in a summer job. Volunteers who withdraw from the study are paid up to the point they drop out, whether or not a public health quarantine has been imposed, requiring every subject to remain on the ward until completion of the study. The consent forms note that any medical problems that may arise will be treated at the CRCVD's expense.

As of June 1975, 70 volunteers had participated in nine studies, and the subject pool consisted of 547 people. The age range is between 18 and 50. Of the 70 people who have completed studies, there were 4 with less than four years of high school, 30 high school graduates, 19 college undergraduates, 12 college graduates, and 5 with advanced degrees; 84% were white, 7% were former prisoners.

The Normal Volunteer Patient Program of the Clinical Center, National Institutes of Health, was established in 1954 and represents one of the earliest efforts to involve members of the community in experimental studies. Volunteers participate in research designed primarily to measure the parameters

of normal body functions. Most of the subjects are members of certain religious sects which view participation in this program as part of their public service commitment (e.g., Church of the Brethren, Mennonites, Mormons) and college students. While the volunteers in both categories receive little in terms of financial compensation (usually restricted to transportation and living expenses), the student volunteers, who reside at the Clinical Center for up to three months on "career development internships," are offered an opportunity to study with NIH scientists in many of the research laboratories. Hence, the program appeals primarily to students interested in careers in the health sciences and related fields.

Recruitment of many of the volunteers for the program is done by colleges under contract with the NIH. The contractor college or university is responsible for handling all the local recruitment details, transporting the volunteers to and from the Clinical Center, and providing any transportation required for follow-up procedures. In return, the contractor receives a fixed fee for each volunteer (to cover the cost of round trip air fare and ground transportation to and from the airport) plus a certain amount for each day of the volunteers" time and inconvenience.

Prospective participants in the program are advised of its purposes and the restrictions in life-style they may experience during their sojourn at the Clinical Center. Studies in which they are asked to participate include, for example, studies of normal physiology (awake, asleep and during exercise), psychological studies (reaction time, attention), dietary manipulation, studies involving drugs, hormones or tracer doses or radioisotope administered either

orally or by injection, and exposure to viruses or biochemical products derived from viruses or bacteria.

The Eli Lilly Company Research Unit located at Wishard Memorial Hospital, Indianapolis, Indiana, employs prisoner and nonprisoner normal volunteers in phase 1 drug studies. The prisoners come to the hospital unit from Pendleton State Reformatory 30 miles away; most of them have previously participated in pharmaceutical studies in the Lilly unit at the prison. All studies involving the initial administration of an agent to humans, use of radioisotopes, or tests requiring complex monitoring equipment are done at the hospital unit rather than at the prison unit.

Prisoner volunteers, in order to qualify for participation in the Lilly hospital research program, generally must meet the basic work-release requirements: a date set for parole or for a parole hearing, and one year of good behavior. In addition, specific permission from the warden is required. These restrictions are imposed to make escape less likely. Other work-release choices, when available, generally offer better pay and more freedom of movement. A prisoner participates at the hospital only once and returns to the prison afterward. The stay at the hospital may be as long as three months. While at the hospital, prisoners are required to remain on the research ward. They have limited recreation facilities but may have visitors daily. No special security precautions are taken, but escapes from the unit have been rare.

Two hospital wings adjoining the prisoner research unit are used for phase 2 studies in patients and phase 1 studies in nonprisoner normal volunteers. The later are generally men off the streets, chronically unemployed,

who know of the program and request on their own, often repeatedly, to participate in drug studies. Prisoners and nonprisoners usually are not involved in the same protocol, although the types of studies are the same. Nonprisoners are paid $7 a day; the prisoners receive $3 a day (the rate established as the maximum by the prison).

Advantages of the hospital as the setting for research of this type are the availability of excellent emergency care (although no serious adverse reactions requiring it have occurred in 10 years of operation), the ease of access of the investigator to the subjects, and surroundings that are pleasant in comparison with the prison. Disadvantages are the limited number of prisoners who can qualify for the program and the boredom of the research. The main reason men drop out of a study is that they become bored and ask to return to their friends and activities at the prison.

Human studies in pharmaceutical research and development in other countries. The survey* conducted on practices of foreign countries regarding use of prisoners and other groups in the development and testing of new pharmaceutical agents included seven European nations, five English speaking countries, four Latin American nations and Japan. In all the countries surveyed, clinical pharmacology studies (pharmacokinetic and dose-ranging studies) can be conducted in normal subjects. Almost uniformly, these countries do not permit such studies to be conducted in prisoners. In theory, prisoner studies could be done in the United Kingdom, but in practice no such research is conducted in prisoners out-

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* Provided to the Commission by Marvin E. Jaffe, M.D. and C. Stewart Snoddy, Merck Sharp & Dohme Research Laboratories.

side the United States. In most countries volunteers, when used, are students, civil servants (military, police and firemen), and medical and paramedical personnel.

In general, clinical pharmacology studies conducted abroad involve patients with the disease which the drug is intended to treat, rather than normals. The use of patients with other diseases is not uniformly approved, but may be permitted if data relevant to the primary indication can be obtained. The requirement for specific governmental approval (IND or clinical trials certificate) to conduct clinical pharmacology studies in normal subjects or patients also varies among countries. In all the countries surveyed, human pharmacokinetic and pharmacodynamic data are "helpful" to support new drug registration. In about half the countries, such data are mandatory. Only France and Japan require that such data be generated in the indigenous population; other countries accept foreign data.

With the exception of Italy, no country requires long-term (1-3 months) controlled safety studies in volunteers before initiating studies in patients. For registration purposes, however, Belgium, Italy, Canada, and in some cases the United Kingdom require such data. Since prisoners are not used in those countries for such studies, it is assumed that such data often are generated elsewhere. In most countries, longer term studies to determine the safety of a new drug entity are done in the patient population which the drug is intended to treat. This provides a measure of how the drug may be expected to behave in clinical practice under the more usual conditions of use and when combined with the usual concomitant therapies. The subjects of such studies receive the presumed benefits of therapy with the new agent to balance its unknown risks.

Although prisoners have not been subjects in phase 1 drug testing in other countries, they have been subjects of nontherapeutic research. For example, prisoners in a number of countries, including Australia, Canada, Denmark, England, Germany, Greece, Ireland, Mexico, Poland and Japan, have been surveyed to determine the incidence of the XYY chromosome anomaly.

Chapter 12. Survey of Review Procedures, Investigators and Prisoners

Data on research in prisons were presented by the Survey Research Center, University of Michigan, in a preliminary report to the Commission on a study of institutional review procedures, research on human subjects, and informed consent. Data were presented from interviews done in early 1976 with investigators in 41 studies and representatives of review committees in five prisons, with 181 prisoner-subjects in four of these prisons, and with 45 prisoner-non-subjects in two of these prisons. The subjects had all participated in research since July 1, 1974. No individuals or institutions were identified in the report.

The research. As described by principal investigators in the five prisons, their research was predominantly pharmaceutical research, mostly phase 1 testing. In most of the studies, drugs were administered orally and blood and urine samples were analyzed. Very few of the experiments, according to investigators, were intended to benefit subjects, although researchers felt that a medical or psychological benefit might occur in some cases. The research also entailed some medical and psychological risk according to investigators, although they estimated the probability of serious risk to be very low or nonexistent. All investigators reported the existence of procedures for treating subjects who might suffer harmful effects of the research.

Review procedures. The Survey Research Center found that the structure of the review process differed among the five prisons. In some places it included Institutional Review Boards (IRB's) established in compliance with DHEW regulations on protection of human subjects; in others it included review committees

appointed by the state department of corrections, by prison authorities, or by university officials. The review process at some prisons included committees created by drug companies. Biomedical and legal consultants and prisoner representatives played a role in some review procedures. At all prisons, the review was conducted in stages involving different combinations of the above mechanisms. Membership on review committees was reported as being very stable.

While few proposals are rejected in the review process, it was reported that few are approved as submitted. Most frequent changes are in consent procedures, though modifications were also reported in research design. The process was said to work smoothly, at least in part because of long-standing relations between review committees and investigators, and awareness of mutual expectations. Little monitoring of the actual conduct of research was reported, although most members of review committees were said to have visited the prison or research facilities at some time.

The prisoner subjects. The interviews with prisoner subjects revealed them to be generally supportive of biomedical research in prisons. The near concensus of favorable attitude among subjects occurred in all four institutions where prisoners were interviewed. Practically all of these subjects said that the information they received in advance of the experiment was understandable and correct, that the researchers were willing to answer subjects' questions, and that participation was voluntary. About one-third of the subjects indicated that they expected the research would involve some risk. A few subjects nonetheless felt that they had experienced specific difficulties as a result of the

experiments that they did not fully expect. Subjects offered a number of reasons for participating in research, the most prevalent being financial. About 90% of them said that they would be willing to participate in future experiments.

Consent forms. The Survey Research Center's analysis of consent forms provided by investigators indicated that almost all described the purpose of the experiment, and all described the procedures. About 85% mentioned and listed risks. An analysis of the reading ease of consent forms indicated that a large proportion were at a difficult reading level. The difficulty did not appear to be solely attributable to the use of medical and technical terminology; some of the difficulty was related to the complexity of sentence structure and the nature of many of the nontechnical terms that were employed. Reading difficulty appeared to be greater for consent forms associated with projects that investigators estimated to entail relatively higher risks. The explanations provided in the consent forms, however, were supplemented in all cases by oral explanations.

Nonsubject prisoners. Prisoners who have never participated in research projects, or whose participation was not recent, were less favorable, on the average, toward research in prisons than were the current subjects. Differences of opinion about research were more apparent within the group of nonsubjects than within the group of subjects. Some nonsubjects were strongly opposed to research in prisons. Prisoners offered a number of explanations for not participating, including assertions that they had not been asked, that they feared the possibility of serious harmful effects, that they mistrusted research or

researchers, or that they were opposed to the idea of research in general. Some said that they would participate if they were asked and/or if the benefits to themselves were more substantial. Nonsubjects who were interviewed had a slightly lower level of formal education than did the subjects, and the former were less likely to have prison jobs. Furthermore, for those inmates who held jobs, the number of hours worked per week was slightly lower for nonsubjects than for subjects.

Suggestions from respondents. Relatively few prisoners offered suggestions about how studies on human beings might be improved. Increased payment, better facilities (e.g., rooms to be used exclusively for research purposes), more complete explanation of possible harmful effects (e.g., pamphlets or written materials explaining projects), and better treatment (e.g., taking more time with subjects and exercising more care) were among the suggestions of prisoners. Some nonsubject prisoners suggested abolishing the research program.

Principal investigators also offered few suggestions. Some proposed that rules and review procedures be simplified and made less rigid. Others suggested that larger review committees be established, that committee members should have experience in dealing with prisoner volunteers, and that the committee procedure be made less susceptible to the biases of individual members.

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