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 I 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.*)

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., 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 whole.

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-BEING OF 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;
The racial composition of the staff is reasonably concordant with that of the prisoners; 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 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 participation 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).

(B) ALL RESEARCH INVOLVING PRISONERS SHOULD BE REVIEWED BY AT LEAST ONE HUMAN SUBJECTS REVIEW COMMITTEE OR INSTITUTIONAL REVIEW BOARD COMPRISED OF MEN AND WOMEN OF DIVERSE RACIAL AND CULTURAL BACKGROUNDS THAT INCLUDES AMONG ITS MEMBERS PRISONERS OR PRISONER ADVOCATES AND SUCH OTHER PERSONS AS COMMUNITY REPRESENTATIVES, CLERGY, BEHAVIORAL SCIENTISTS AND MEDICAL PERSONNEL NOT ASSOCIATED WITH THE CONDUCT OF THE RESEARCH OR THE PENAL INSTITUTION; 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, PROCEDURES FOR THE SELECTION OF SUBJECTS, AND PROVISIONS FOR PROVIDING COMPENSATION FOR RESEARCH-RELATED INJURY.

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 appropriate 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.**