

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 I 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 I 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 extramural 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 I 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.

* 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.)

