

Report and
Recommendations

Research Involving Prisoners

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

1976

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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

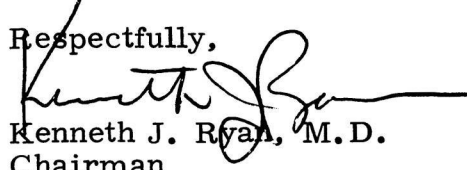
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The Honorable Carl Albert
Speaker of the House of Representatives
Washington, D.C. 20515

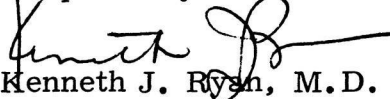
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October 1, 1976

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


Dear Mr. Secretary:

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Kenneth J. Ryan, M.D.
Chairman

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

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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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