

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

A Guide to the Collection in the
National Reference Center for Bioethics Literature
Kennedy Institute of Ethics
Georgetown University
Washington, D.C.

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

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHS) was established on July 12, 1974, under Title II of Public Law 93-348, the National Research Act, to develop guidelines which should be followed in biomedical and behavioral research involving human subjects and to make recommendations to the Secretary of the Department of Health, Education, and Welfare (DHEW).

The commission was composed of eleven members appointed by the Secretary on December 1, 1974. The Chairman of the Commission, Kenneth, J Ryan, M.D., was selected by the Commission from among its members. Meetings were held approximately once a month and were open to the public except when determined otherwise by the Secretary of HEW. Subject to the specific provision of Title II, Part A, of Public Law 93-348, this Commission was established in accordance with and was governed by the provisions of Public Law 92-463 which set forth standards for the formulation and use of advisory committees. Public Law 94-573 extended the Commission for one year with the same mandate. This extension enabled the Commission to devote additional time and effort to certain duties and to develop some new projects that resulted in a more comprehensive Commission response to its mandate.

In accordance with P.L.93-348, the Commission was given a mandate to investigate and study research involving the living fetus and to recommend whether and under what circumstances such research should be conducted or supported by the DHEW. During the first

year of its monthly meetings this subject dominated other issues. The use of psychosurgery was another issue which the Commission examined and deliberated on during the first two years of its meetings.

The legislative mandate also directed the Commission to make recommendations to Congress regarding the protection of human subjects in research not subject to regulation by DHEW. Classes of research subjects that received the Commission's particular attention included children, prisoners and the institutionalized mentally infirm. The Commission's recommendations on these topics were the product of almost two years of data-gathering and deliberations. Another aspect of this issue pertains to research that is conducted or supported by other federal agencies. In relation to this, the staff compiled an up-to-date survey of the policies and procedures of other federal agencies. Upon completion, this provided a basis for Commission consideration of government-wide protections.

Several other topics of study identified in the Commission's mandate under P.L. 93-348 were the following: disclosure of research information; ethical principles and guidelines (Belmont document); Institutional Review Boards (IRB) and protection of DHEW health care recipients. In addition, the NCPHS was directed to conduct a "special study" of the ethical, social and legal implications for public policy of advances in biomedical and behavioral research and technology. The extension of its Charter gave the Commission the time it required to consider the reports and public opinion polls on these issues. The Commission also supported activities and studies undertaken in particular areas that were encompassed by the special study, especially recombinant DNA research.

Since the Commission's mandate included "any . . . matter pertaining to the protection of human subjects of biomedical and behavioral research" there were other topics to which the Commission turned its attention. These included the problems of confidentiality and privacy, compensation, human experimentation, informed consent, sterilization, swine flu vaccine, and role of assessment of risk/benefit criteria.

CHRONOLOGY

1974	July 12	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHS) established by Public Law 93-348, Section 201(a).
	August 23	Charter of NCPHS approved by Frank Carlucci, Acting Secretary of the Department of Health, Education and Welfare (DHEW).
	December 3-4	First meeting of Commission held at Washington, D.C.
	December 3	Commissioners sworn in by DHEW Secretary Caspar Weinberger.
	December 4	Kenneth John Ryan, M.D., elected by Commission members to serve as Chairman.
1975	January 10-11	Second meeting of commission held at Bethesda, MD.
	February 14-15	Third meeting of Commission held at Bethesda, MD.
	March 14-15	Fourth meeting of Commission held at Bethesda, MD.
	April 11-13	Fifth meeting of Commission held at Bethesda, MD.
	April 25-26	Sixth meeting of Commission held at Bethesda, MD.
	May 9-10	Seventh meeting of Commission held at Bethesda, MD.
	June 27-28	Eighth meeting of Commission held at Bethesda, MD.
	July 25	<i>Research on the Fetus: Report and Recommendations. Appendix</i> , submitted to DHEW, Congress, and the President.
	July 26	Ninth meeting of Commission held at Bethesda, MD.
	September 12-13	Tenth meeting of Commission held at Bethesda, MD.
1975	October 11	Eleventh meeting of Commission held at Waltham, MA.
	November 15	Twelfth meeting of Commission held at Ann Arbor, MI.
	December 13	Thirteenth meeting of Commission held at Bethesda, MD.

1976	January 6-8	National Minority Conference on Human Experimentation, sponsored by Commission, held at Reston, VA.
	January 9-10	Fourteenth meeting of Commission held at Bethesda, MD.
	February 13-16	Fifteenth meeting of Commission held at Belmont Conference House in Elkridge, MD.
	March 12-13	Sixteenth meeting of Commission held at Bethesda, MD.
	April 9-11	Seventeenth meeting of Commission held at Bethesda, MD.
	April 22	Commission's mandate extended by Public Law 94-278 to include a report on disclosure of research information under the Freedom of Information Act.
	May 14-15	Eighteenth meeting of Commission held at Bethesda, MD.
	June 11-13	Nineteenth meeting of Commission held at Bethesda, MD.
	June 23-27	Discussion and working meeting with consultants regarding <i>Special Study</i>
	July 9-10	Twentieth meeting of Commission held at Bethesda, MD.
	August 6-7	Twenty-first meeting of Commission held at Bethesda, MD.
	August 17	Special meeting held at Center for Disease Control in Atlanta, GA to develop consent form for swine flu vaccine.
	September 10-12	Twenty-second meeting of Commission held at Bethesda, MD.
1976	October 1	<i>Research Involving Prisoners: Report and Recommendations. Appendix</i> submitted to DHEW, Congress, and the President.
	October 8-10	Twenty-third meeting of Commission held at Bethesda, MD.
	October 21	Public Law 94-573 extended life of Commission for one year.
	November 13-14	Twenty-fourth meeting of Commission held at San Francisco, CA.
	December	<i>Special Study Scholarly Adjunct</i> submitted to DHEW.

	December 10-11	Twenty-fifth meeting of Commission held at Bethesda, MD.
1977	January 7-8	Twenty-sixth meeting of Commission held at Bethesda, MD.
	February 11-13	Twenty-seventh meeting of Commission held at Bethesda, MD.
	March 11-12	Twenty-eighth meeting of Commission held at Bethesda, MD.
	March 14	<i>Psychosurgery. Report and Recommendations, Appendix</i> submitted to DHEW, Congress, and the President.
	April 5	Public hearings on IRB's held at Bethesda, MD.
	April 8	<i>Disclosure of Research Information Under the Freedom of Information Act: Report and Recommendations</i> submitted to DHEW, Congress, and the President.
	April 8-9	Twenty-ninth meeting of Commission held at Bethesda, MD.
	April 15	Public hearings on IRB's held at Bethesda, MD.
	May 3	Public hearings on IRB's held at Bethesda, MD.
	May 13-14	Thirtieth meeting of Commission held at Bethesda, MD.
1977	June 10-11	Thirty-first meeting of Commission held at Bethesda, MD.
	July 8-9	Thirty-second meeting of Commission held at Chevy Chase, MD.
	August 12-13	Thirty-third meeting of Commission held at Bethesda, MD.
	August 21	Death of Commissioner David Louisdell, whose position was not filled.
	September 6	<i>Research Involving Children: Report and Recommendations and Appendix</i> submitted to DHEW, Congress, and the President.
	September 9-10	Thirty-fourth meeting of Commission held at Bethesda, MD.
	October 14-15	Thirty-fifth meeting of Commission held at Bethesda, MD.
	November 11-12	Thirty-sixth meeting of Commission held at Bethesda, MD.

	November 23	Public Law 95-203 extended life of Commission until September 30, 1978.
	December 9-10	Thirty-seventh meeting of Commission held at Bethesda, MD.
1978	January 13-14	Thirty-eighth meeting of Commission held at Bethesda, MD.
	February 2	<i>Research Involving Those Institutionalized as Mentally Infirm: Report and Recommendations. Appendix</i> submitted to DHEW, Congress, and the President.
	February 10-11	Thirty-ninth meeting of Commission held at Bethesda, MD.
	March 10-11	Fortieth meeting of Commission held at Bethesda, MD.
	April 14-15	Forty-first meeting of Commission held at Bethesda, MD.
	June 9-10	Forty-second meeting of Commission held at Bethesda, MD.
1978	September 1	<i>Institutional Review Boards: Report and Recommendations. Appendix</i> submitted to DHEW, Congress, and the President.
	September 8	Final meeting of Commission held at Bethesda, MD.
	September 30	<i>Ethical Guidelines for the Delivery of Health Services by DHEW: Report and Recommendation, Appendix</i> submitted to DHEW, Congress, and the President.
		<i>Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research: Report and Recommendation. Appendix</i> submitted to DHEW, Congress, and the President.
		<i>Special Study: Implications of Advances in Biomedical and Behavioral Research: Report and Recommendation</i> submitted to DHEW, Congress, and the President.
	October 11	Commission office and staff formally ceased to exist.

Prepared by Laura Shanner, August 1989

INDEX OF SUBJECTS COVERED

Records include drafts of the reports produced by the commission, published articles, printed matter and near-print materials along with copies of papers, technical information, federal regulations, memorandum, contracts, case registers, statistical charts and background materials sent to the commissioners before each meeting. All meetings include tabs of "correspondence" and "news clips" received and/or published during the period preceding the appropriate meeting and contain material pertaining to a variety of subjects, including those of previous meetings. All meeting books also contain a "table of contents" preceding and pertaining to the material in the corresponding file. In addition to the chronological files, there are two subject files containing material arranged alphabetically by subject. The archive has also copies of the published final reports generated by the Commission.

This index does not claim to be at all exhaustive. The multitude of subjects discussed, the variety of types of material and the enormous amount of paper generated during the Commission's existence, rendered the arrangement and compilation of the index difficult, and additional materials on any given subject may be found in other, undetected locations in the collection.

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