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A Guide to the Archival Collection of

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

July, 2013

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Joseph and Rose Kennedy Institute of Ethics

Georgetown University Washington, D.C.

The Archival Collection of the *National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research, 1974-1978* maintained by the Bioethics Research Library, Georgetown University spans from the years 1974 to 1978 and contains 13.76 linear feet of materials. The archive encompasses 43 meetings held between 1974 and 1978 and includes briefing books, subject files, and transcripts from these meetings. The Executive's Branch of the Department of Health, Education, and Welfare established the group in 1974 and it is considered one of the first modern bioethics commissions.

This finding aide has been produced to answer frequently asked questions about the *National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research* and provides researchers a base by which to begin their exploration of the Commission. It includes a background of the Commission, a chronology of the Commission, and an index of the materials broken down by subject type, archival box location, and format.

A permanent link to this guide has been created and will be maintained on Digital Georgetown.

<https://repository.library.georgetown.edu/handle/10822/708752>

The original guide to the collection of materials of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the Bioethics Research Library, Joseph and Rose Kennedy Institute of Ethics was prepared by Ariella Barrett in August, 1989.

This updated and expanded guide to the collection of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the Bioethics Research Library, Joseph and Rose Kennedy Institute of Ethics was prepared by Laura Ruth Barry and Charles N. Norton in August 2012.

**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 Service Reward Act of 1974", 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.

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 the Department of Health, Education, and Welfare. 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 Public Law 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 Department of Health, Education, and Welfare. 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 the Department of Health, Education, and Welfare. 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. An additional aspect examined by the Commission was 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 the Commission's consideration of government-wide protections.

Several other topics of study identified in the Commission's mandate under Public Law 93-348 were the following: disclosure of research information; ethical principles and guidelines (Belmont document); Institutional Review Boards and protection of the Department of Health, Education, and Welfare health care recipients. In addition, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 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 also turned its attention. Other areas examined by the Commission included the problems of confidentiality and privacy, compensation, human experimentation, informed consent, sterilization, the swine flu vaccine and role of assessment of risk/benefit criteria.

In September 1978 the Commission publishes three reports, including the Belmont Report, which draws a close to the Commissions' publications. In total twelve studies and reports would be published. The Belmont Report(occasionally referred to as the Belmont Document in the collected materials) is widely considered to be the defining document produced by the Commission. Its recommendations would go on to form the basis of many Federal regulations concerned with the protection of human subjects.

The Commissions' Charter officially expired in October of 1978 with the dismissal of staff and closure of the office.

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Chronology

1974	July 12	The 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	The NCPHS Charter is approved by Frank Carlucci, Acting Secretary of the Department of Health, Education and Welfare (DHEW).
	December 3-4	The First meeting of the NCPHS held in Washington, D.C. Commissioners sworn in by DHEW Secretary Caspar Weinberger.
	December 4	Kenneth John Ryan, M.D., is elected by NCPHS members to serve as chairman.
1975	January 10-11	Second meeting of the NCPHS held in Bethesda, Maryland.
	February 14-15	Third meeting of the NCPHS held in Bethesda, Maryland.
	March 14-15	Fourth meeting of the NCPHS held in Bethesda, Maryland.
	April 11-13	Fifth meeting of the NCPHS held in Bethesda, Maryland.
	April 25-26	Sixth meeting of the NCPHS held in Bethesda, Maryland.
	May 9-10	Seventh meeting of the NCPHS held in Bethesda, Maryland.
	June 26-27	Eighth meeting of the NCPHS held in Bethesda, Maryland.
	July 25	Research on the Fetus: Report and Recommendations, with Appendix , submitted to DHEW, Congress, and the President.
	July 26	Ninth meeting of the NCPHS held in Bethesda, Maryland.
	September 12-13	Tenth meeting of the NCPHS held in Bethesda, Maryland.
	October 11	Eleventh meeting of the NCPHS held in Bethesda, Maryland.
	November 15	Twelfth meeting of the NCPHS held in Bethesda, Maryland.
	December 13	Thirteenth meeting of the NCPHS held in Bethesda, Maryland.

1976	January 6-8	National Minority Conference on Human Experimentation, sponsored by NCPHS, held in Reston, VA.
	January 9-10	Fourteenth meeting of the NCPHS held in Bethesda, Maryland.
	February 13-16	Fifteenth meeting of the NCPHS held at Belmont Conference House in Elkridge, Maryland.
	March 12-13	Sixteen meeting of the NCPHS held in Bethesda, Maryland.
	April 9-11	Seventeenth meeting of the NCPHS held in Bethesda, Maryland.
	April 22	The Commission's mandate is 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 Sixteen meeting of the NCPHS held in Bethesda, Maryland.
	June 11-13	Nineteenth Sixteen meeting of the NCPHS held in Bethesda, Maryland.
	June 23-27	Discussion and working meeting with consultants regarding <i>Special Study</i>
	July 9-10	Twentieth meeting of the NCPHS held in Bethesda, Maryland.
	August 6-7	Twenty-first meeting of the NCPHS held in Bethesda, Maryland.
	August 17	Special meeting held at Center for Disease Control in Atlanta, Georgia to develop consent form for swine flu vaccine.
	September 10-12	Twenty-second meeting of the NCPHS held in Bethesda, Maryland.
	October 1	Research Involving Prisoners: Report and Recommendations, with Appendix submitted to DHEW, Congress, and the President.
	October 8-11	Twenty-third meeting of the NCPHS held in Bethesda, Maryland.
	October 21	Public Law 94-573 added a year to the NCPHS original Charter.
	November 13-14	Twenty-fourth meeting of the NCPHS held in Bethesda, Maryland.
	December	Special Study Scholarly Adjunct submitted to DHEW.
	December 10-11	Twenty-fifth meeting of the NCPHS held in Bethesda, Maryland.

1977	January 7-8	Twenty-sixth meeting of the NCPHS held in Bethesda, Maryland.
	February 11-13	Twenty-seventh meeting of the NCPHS held in Bethesda, Maryland.
	March 11-12	Twenty-eighth meeting of the NCPHS held in Bethesda, Maryland.
	March 14	Psychosurgery: Report and Recommendations, with Appendix submitted to DHEW, Congress, and the President.
	April 5	Public hearings on institutional review boards held in Bethesda, Maryland.
	April 8	Disclosure of Research Information under the Freedom of Information Act: Report and Recommendations submitted to DHEW, Congress, and the President.
	April 8-9	Twenty-ninth meeting of the NCPHS held in Bethesda, Maryland.
	April 15	Public hearings on institutional review boards held in Bethesda, Maryland.
	May 3	Public hearings on institutional review boards held in Bethesda, Maryland.
	May 13-14	Thirtieth meeting of the NCPHS held in Bethesda, Maryland.
	June 10-11	Thirty-first meeting of the NCPHS held in Bethesda, Maryland.
	July 8-9	Thirty-second meeting of the NCPHS held in Chevy Chase, Maryland.
	August 21	Thirty-third meeting of the NCPHS held in Bethesda, Maryland.
	September 6	Research Involving Children: Report and Recommendations, with Appendix submitted to DHEW, Congress, and the President.
	September 9-10	Thirty-fourth meeting of the NCPHS held in Bethesda, Maryland.
	October 14-15	Thirty-fifth meeting of the NCPHS held in Bethesda, Maryland.
	November 11-12	Thirty-Sixth meeting of the NCPHS held in Bethesda, Maryland.
	November 23	Public Law 95-203 added a year to the NCPHS Charter until September 30, 1978.
	December 9-10	Thirty-seventh meeting of the NCPHS held in Bethesda, Maryland.

1978	January 13-14	Thirty-eighth meeting of the NCPHS held in Bethesda, Maryland.
	February 2	Research Involving Those Institutionalized as Mentally Infirm: Report and Recommendations, with Appendix submitted to DHEW, Congress, and the President.
	February 10-11	Thirty-ninth meeting of the NCPHS held in Bethesda, Maryland.
	March 10-11	Fortieth meeting of the NCPHS held in Bethesda, Maryland.
	April 14-15	Forty-first meeting of the NCPHS held in Bethesda, Maryland.
	June 9-10	Forty-second meeting of the NCPHS held in Bethesda, Maryland.
	September 1	Institutional Review Boards: Report and Recommendations, with Appendix submitted to DHEW, Congress, and the President.
	September 8	Final meeting of the NCPHS held in Bethesda, Maryland.
	September 30	Ethical Guidelines for the Delivery of Health Services by DHEW: Report and Recommendation, with Appendix submitted to DHEW, Congress, and the President.
		Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research: Report and Recommendation, with Appendix submitted to DHEW, Congress, and the President.
		Special Study: Implications of Advances in Biomedical and Behavioral Research: Report and Recommendations submitted to DHEW, Congress, and the President.
	October 11	The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research authority expires. Staff is dismissed and the office is closed.

Original Chronology prepared by Laura Shanner, August 1989.

Chronology was updated and expanded by Charles N. Norton, July 2012.

Index of Subjects Covered

The archive of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research owned by the Bioethics Research Library encompasses 43 Meetings from 1974-1978. **The list of subjects and their corresponding Meeting Numbers and Box Numbers is on the reverse of this aid.** The archives include briefing books, subject files, and transcripts from these meetings. When accessing information on a subject in the collection the information will either be in one of these formats. These formats are defined below:

Briefing Books (Boxes 1-21): Background materials sent to the commissioners before each meeting. These materials, in folders separated by tabs (loose leaf), include but are not limited to:

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|--------------------------------|----------------------|
| ○ Table of Contents | ○ Memorandum |
| ○ Lists of Participants | ○ Contracts |
| ○ <i>Curriculum Vitae</i> (CV) | ○ Statistical Charts |
| ○ Drafts of the Reports | ○ Published Articles |
| ○ Correspondence | ○ Case Registers |
| ○ Federal Regulations | ○ News Clippings |

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.

Subject Files (Boxes 22-23): Similar to the briefing books but instead include background material for the commission unrelated to a particular meeting. Information provided in like formats to the briefing books.

Transcripts (Boxes 24-33): Bound copies of the proceedings of that specific meeting.

Each box contains multiple subjects so it will be necessary to evaluate the primary documents in the boxes themselves for specific subject information.

The multitude of subjects discussed, the variety of types of material, and the enormous amount of paper generated during the Commission’s existence means that this index does not claim to be exhaustive. Additional materials on any given subject may be found in other, unindexed locations in the collection.

Copies of the final reports published by the Commission can be furnished upon request.

Tip:

After you have chosen a specific box you may want to investigate the contents of the box by format (briefing books, subject files, or transcript, etc.) This may be helpful by identifying specific materials you wish to explore.

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