

**THE
PRESIDENT'S COMMISSION
FOR THE STUDY OF
ETHICAL PROBLEMS IN MEDICINE
AND IN BIOMEDICAL AND
BEHAVIORAL RESEARCH**

A Guide to the Records in the
Bioethics Research Library
Kennedy Institute of Ethics
Georgetown University
Washington, D.C.

CHRONOLOGY

1978, November 9	President's Commission for the Study of Ethical Problems in Medicine and in Biomedical and Behavioral Research established by Public Law 95-622
1979, July	President Carter named eleven original commissioners
September 29	Senate confirmed appointment of Morris B. Abram as Chairman of the Commission
December	Alexander M. Capron appointed Executive Director of Commission
1980, January	Barbara Mishkin appointed Deputy Director of Commission
January 14	Original commissioners sworn in at the White House by Judge David L. Bazelon
January 14-15	First meeting of Commission held at Washington, D.C.
May 16	Frances K. Graham sworn in as commissioner to replace Frederick C. Redlich (resigned, February 1980)
May 16-17	Second meeting of Commission, Washington, D.C.
July 11-12	Third meeting of Commission, Washington, D.C.
September 16	Carolyn A. Williams sworn in as commissioner to replace Patricia A. King (resigned, May 1980)
September 15-16	Fourth meeting of Commission, Washington, D.C.
November 7-8	Fifth meeting of Commission, Washington, D.C.
1981, January 9-10	Sixth meeting of Commission, Washington, D.C.
March 13-14	Seventh meeting of Commission, Washington, D.C.

1981, April 9-10	Eighth meeting of Commission, Miami, Florida
May 8-9	Ninth meeting of Commission, Washington, D.C.
June 4-5	Tenth meeting of Commission, Boston, Massachusetts
July	Publication of <i>Defining Death</i>
July 9-10	Eleventh meeting of Commission, Airlie, Virginia
September 11-12	Twelfth meeting of Commission, Los Angeles, California
September 21-22	Workshop on whistleblowing in biomedical research held in Washington, D.C.
October 22-24	Thirteenth meeting of Commission, Aspen Conference Center, Queenstown, Maryland
November 13-14	Fourteenth meeting of Commission, Washington, D.C.
December	Publication of <i>Protecting Human Subjects</i> (First Biennial Report)
December 11-12	Fifteenth meeting of Commission, Washington, D.C.
1982	Publication of <i>Whistleblowing in Biomedical Research: Proceedings of a Workshop held September 21-22 1981</i>
January 8-9	Sixteenth meeting of Commission, Washington, D.C.
February	New commissioners George R. Dunlop, Daher B.Rahi, Seymour Siegel and Lynda Hare Smith sworn in to replace Mathilde Krim (resigned, October 1981), Frances K. Graham, Donald N. Medearis and Renee C. Fox (terms ended, February 1982)
February 11-12	Seventeenth meeting of Commission, Washington, D.C.

1982, March 12-13	Eighteenth meeting of Commission, Washington, D.C.
April 2-3	Nineteenth meeting of Commission, Atlanta, Georgia
May 14-15	Twentieth meeting of Commission, Washington, D.C.
June	Publication of <i>Compensating for Research Injuries</i>
June 10-11	Twenty-first meeting of Commission, Washington, D.C.
July 9-10	Twenty-second meeting of Commission, Washington, D.C.
August 12	New commissioners H. Thomas Ballantine, Bruce K. Jacobson, John J. Moran and Kay Toma sworn in to replace Mario Garcia-Palmieri, Albert R. Jonsen, Anne A. Scitovsky and Carolyn A. Williams (terms ended, July 1982)
August 12-13	Twenty-third meeting of Commission, Washington, D.C.
September 10-11	Twenty-fourth meeting of Commission, Washington, D.C.
October	Publication of <i>Making Health Care Decisions</i>
October 8-9	Twenty-fifth meeting of Commission, Washington, D.C.
November	Publication of <i>Splicing Life</i>
November 12-13	Twenty-sixth meeting of Commission, Washington, D.C.
December 14-15	Twenty-seventh meeting of Commission, Washington, D.C.
December 20	Termination date of Commission extended from December 31, 1982 to March 31, 1983 by Public Law 97-377
1983, February	Publication of <i>Genetic Screening and Counseling</i>

1983, February 10-11	Twenty-eighth (and last) meeting of Commission, Washington, D.C.
March	Publication of <i>Deciding to Forego life-sustaining Treatment</i> Publication of <i>Securing Access to Health Care</i> Publication of <i>Implementing Human Research Regulations</i> (Second Biennial Report) Publication of <i>Summing Up</i>
March 31	Commission's authority expired and its work ended

CORRESPONDENCE, 1978-83 Box Nos. 1-5

5 containers

Letters received and copies of letters sent, arranged alphabetically by name of correspondent.

SUBJECT FILE. 1969-83 Box Nos. 6-24

19 containers

Correspondence, memoranda, published articles, unpublished papers, printed matter and near-print materials, arranged alphabetically by subject.

MEETING FILES. 1980-83 Box Nos. 25-43

19 containers

A. **Briefing Books, 1980-83** Box Nos. 25-33
9 containers

Copies of papers and background materials sent to the commissioners before each meeting, arranged chronologically by meeting date.

B. **Minutes and miscellaneous materials, 1980-83** Box Nos. 34-36
3 containers

Memoranda, correspondence and other materials pertaining to planning for the meetings, arranged alphabetically by administrative subject, and minutes of the meetings arranged chronologically by meeting date.

C. **Transcripts of Meetings, 1980-83** Box Nos. 37-43
7 containers

Copies of transcripts of some of the meetings of the commission, arranged chronologically by date of the meeting with the "Whistleblowing Workshop" at the end.

REPORT FILES. 1980-83 Box Nos. 44-65

22 containers

Drafts of the reports produced by the commission along with some memoranda, press releases, and correspondence pertaining to their publication, arranged alphabetically by the title of the report.

OVERSIZE MATERIALS

Box Nos. 66-68

3 containers

Camera copy for three of the reports and negatives for one report, arranged alphabetically by the title of the report.

CONTAINER LIST

CORRESPONDENCE. 1978-83

<u>Box No.</u>	<u>Contents</u>
1	A (4 folders) Abram, Morris, correspondence with Alex Capron Annas, George J. B (8 folders) Bai, Koichi Ballantine, H. Thomas C (3 folders) Callahan, Daniel (Hastings Center) Da
2	De - Dy (2 folders) Dunlop, George R. E F (4 folders) Fox, Renee, 1980-82 (3 folders) G (5 folders) Garcia-Palmieri, Mario Gaylin, Willard Graham, Frances Ha - Hu (4 folders)
3	Hamilton, Mari Anne T. I J Jacobson, Bruce K. Jonsen, Albert R. K (3 folders) King, Patricia Krim Mathilde L (5 folders) Levine, Robert J. Ma - Mi (8 folders)
4	Mn - Mu (2 folders) Medearis, Donald N., Jr. Moran, John J. Motulsky, Arno G. N (2 folders) O P (4 folders) Paris, John J.

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4 (cont)	Q R (6 folders) Rahi, Daher B. Roth, Michael D. Sa - Schl
5	Schm - Sw (7 folders) Schweiker, Richard S. Scitovsky, Anne A. Siegel, Seymour Smith, Lynda Hare T (2 folders) Toma, Kay U V W (3 folders) Walker, Charles J. Williams, Carolyn A. X—Y—Z

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6	Abrams, Morris, trip to England, 1981 Access to Health Care, general, 1979-82 (4 folders) Access to Health Care Meetings with Consultants, Sept., 1980 Outlines and plans American Psychological Association Committee for the Protection of Human Subjects, 1980 Annual Report FY 1980 FY 1981 FY 1982 Background information on commission, commissioners, and staff Budget Request FY 1981
7	Budget Request (cont) FY 1982, Testimony in House of Representatives FY 1982, Testimony in Senate Compensation of Subjects Background articles, 1970-81 (4 folders) DES cases and articles

SUBJECT FILE. 1969-83 (cont'd)

<u>Box No.</u>	<u>Contents</u>
7 (cont)	Compensation of Subjects (cont) Comments on drafts of compensation report Draft proposals, 1979-81 Federal response to report, 1982 General, 1979-82 (2 folders)
8	Compensation of Subjects (cont) Reference articles on history of compensation "60 Minutes" broadcast re Swine Flu, 1979 Determination of Death Apparent death Articles by A. M. Capron Articles published at time of report (report not mentioned) Background articles, 1975-82 Background for report, 1980-82 Bibliographies, 1972-80 Cases before 1975 Cases, 1976-82
9	Determination of Death (cont.) Cases, general, 1971-79 Coma study, 1981 Correspondence with Alex Capron, 1976-82 E. E. G./Neurosurgeon availability Federal role Guidelines prepared for PCEMR, 1981 Incidence study, 1971-72, 1980 International aspects, 1979-81 International aspects Argentina Australia Belgium, Canada Czechoslovakia, Denmark
10	International aspects (cont.) Finland, France Great Britain - BBC Panorama Show Germany, Greece Ireland, Israel, Italy New Zealand, Norway Philippines, South Africa Soviet Union Spain

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10 (cont)	Determination of Death (cont) International aspects (cont.) Sweden Switzerland Law review articles, 1975-81 Legislation D.C. Council Hearings, 1981 Draft bill in House of Representatives, 1981-82 General, 1975-81 Model legislation, ABA Model legislation, AMA
11	Determination of Death (cont) Legislation (cont) Model legislation, NCCUSL, 1977-81 Proposed, 1975-82 Proposed, New York, 1977-82 Proposed, Pennsylvania, 1981-82 State legislative consideration, 1982 Uniform law Meeting of May 23, 1980 Missouri hearings, 1981-82 Medical articles Complicating conditions, 1974-81 Criteria, 1972-81 E.E.G., 1969-80 Foreign language, 1972, 1979 General, 1964-79
12	Determination of Death (cont) Medical articles (cont) Incidence and prognosis, 1968-81 Radioisotope, etc., 1973-77 National Conference of Catholic Bishops, 1981-82 Newspaper clippings "Panorama" TV program, 1981 Philosophical perspectives (2 folders) Post-1981 journal articles and correspondence re report Printed matter Religious perspectives (2 folders) Requests for report, 1981-82 Responses from individual states, 1981 Research on brain death

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12 (cont)	Determination of Death (cont) Sociological and historical aspects Time of death Unpublished papers Drugs Commission on Federal Drug Approval Process, 1981
13	FDA role/Regulations on research Regulation Federal Coordinating Council for Science, Engineering and Technology, Ad Hoc Committee for the Protection of Human Research Subjects, 1982 (2 folders) Fetal research Foregoing treatment Correspondence, Meeting with Dr. Koop, 1982 General, 1979-80 (2 folders) Jorgensen, Eric O. (Denmark), Correspondence, 1982 Newborns/abortuses Organizations ABA, Young Lawyers Division, 1981 Association for Freedom to Die (Ohio) Concern for Dying, 1980-82 Press/Public relations, 1982 Research and study areas, 1981 Studies of hospital ethics committees, 1982 "Vignettes," 1981-82
14	Genetic Engineering Agricultural aspects Cline Experiment Commercial aspects Consultants' comments First round, 1980-81 Second round, 1981 Consultants' meetings, March 30-April 4, 1981 Federal agencies activities Initial survey, 1980 Follow-up survey, 1982 General House hearing, Nov. 16-18, 1982 Legal aspects NIH Guidelines (Recombinant DNA Advisory Committee), 1981-82

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15	Genetic Engineering (cont) Office of Technology Assessment Report (Impact on Plants and Animals), 1980 Powledge, Tabitha, study, 1980-81 Religious groups' comments, 1981 Scientific and medical advances using genetic engineering Genetic Screening Informed Consent Correspondence, 1980-82 Doctor-patient relations Education of physicians General - printed matter Health insurance, 1980 Patient package inserts, 1980-82 Patient and physician surveys, 1981
16	Informed Consent (cont) Release of report and press contacts, 1982 Study of public judgment of risk, 1982 IRB's GAO investigation of IRB monitoring Implementation study IRB's and ethics committees in other countries Lay members Legislation, (H.R. 7036, S. 988) Organizational setting for general assurances Workshops, 1981 Legislation Commission testimony on H.R. 5919, April 1982 H.R. 6457, 1982 research legislation Mailings Organ transplantation Philosophical issues in health care policy, abstracts of articles Privacy/Confidentiality General Henry Richardson's work William Winslade's contract William Winslade's paper, "Privacy and Confidentiality in Health Care"
17	Publication of unethical research Publications Editing rules and style sheets Financial

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17 (cont)	Publications (cont) <ul style="list-style-type: none">GraphicsOutside contractorsPrinting and distributionPublicity by GPOStyle samplesTypesetting Research Advisory Group, meeting on Nov. 6, 1980 Research Regulation <ul style="list-style-type: none">AAMC Task Force of Research Fraud, 1982Behavioral research, 1980Biennial report, generalBiomedical researchCapron response to Murray Wax in <u>IRB</u>, 1981Clinical trials, new drug therapiesCongressional oversight hearings on research fraud<ul style="list-style-type: none">Background articlesHouse hearings, April 1981Correspondence<ul style="list-style-type: none">Capron testimonyTestimony of others
18	Research Regulation (cont) <ul style="list-style-type: none">Congressional oversight hearings on national cancer program<ul style="list-style-type: none">Senate, June 1981House, October 1981 (2 folders)Senate, November 1981<ul style="list-style-type: none">Capron statementCapron testimonyCorrespondence & background materialsSchedule & opening remarksTestimony of othersTranscript of Capron remarksFirst Biennial Report<ul style="list-style-type: none">Response & action on report recommendationsResponse to report recommendations
19	Research Regulation (cont.) <ul style="list-style-type: none">First Biennial Report (cont)<ul style="list-style-type: none">Survey of federal agencies policies, 1981

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20	Research Regulation (cont) Food and Drug Administration Disqualifications (cont) Kline, Nathan S. (cont)
21	Research Regulation (cont) FDA Post-marketing surveillance of vaccines, 1979-80 HHS Government-wide debarment regulations, 1980-82 HHS human research regulations Comments by other federal agencies, 1979-80 1979 proposals and revisions HHS policy on fraud and misconduct Documents re meeting with Sec. Schweiker, 1980-81 HHS policy on material failure, 1980-82 International aspects France, 1980 Guidelines in Australia Meeting with National Cancer Institute, January 14, 1982 National Cancer Institute exemption on new drugs, 1980 Particular Cases Boston University oncology Background documents "Boston Globe" articles, 1980-81 FDA investigation IRB minutes, 1978 Memo of Judith P. Swazey, 1979 NCI investigation, 1980-81
22	Research Regulation (cont) Particular Cases (cont) Straus v. Polackwich et al. (81-1406-N) Kennedy, Samuel Ian T. Violation of DNA guidelines, 1980 Kline, Nathan, FDA debarment, 1981 Levin, Harvey M., M.D., disqualified by FDA, 1982 M.D. Anderson Hospital FDA inspection of, 1981 NCI site visit report, 1981

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23	Research Regulation (cont) Particular Cases (cont) Straus, Marc, N.Y. Medical College (cont.) NIH withdrawal of funds UCLA Bone marrow, 1980-81 Cline, Martin J., NIH report, 1981 University of Kansas (2 folders) Yale University, Felig & Soman, 1980 Social Experiments, IRB waivers, 1982 (3 folders)
24	Research Regulation (cont) Task Force on NCI-FDA Investigational New Drugs General, 1981 Report, Vols. I & II, 1982 (2 folders) Testimony on research bill, H.R. 5919, April 1982 "Therapeutic Research" in <u>IRB</u> , Capron/Levine comments U. Cal. IRB meeting, May 21-22, 1981 Unnecessary Treatment Whistleblowing Workshop Comments on report, 1981 Contracts for participants, discussants, 1981 Notes, 1981 Organization, 1981 Participants and attendees, 1981 Published proceedings, 1982

MEETING FILES. 1980-83

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A. Briefing Books. 1980-83 (cont'd)

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27	Meeting #6 (cont) Day 1, January 9, 1981, Tabs F-S (3 folders) Day 2, January 10, 1981 (3 folders) Meeting #7, March 13-14, 1981 Availability (5 folders)
28	Meeting #7, March 13-14, 1981 (cont) Confidentiality (2 folders) Meeting #8, April 9-10, 1981 (3 folders) Meeting #9, May 8-9, 1981 (4 folders) Meeting #10 Day 1, June 4, 1981 (2 folders)
29	Meeting #10 (cont) Day 2, June 5, 1981 (3 folders) Meeting #11, July 9-10, 1981 (2 folders) Meeting #12 Day 1, September 11, 1981 (3 folders) Day 2, September 12, 1981 (2 folders) Meeting #13, October 22-24, 1981 Tabs A-E
30	Meeting #13, October 22-24, 1981 (cont) Tabs F-X (3 folders) Meeting #14, November 13-14, 1981 (5 folders) Meeting #15, December 11-12, 1981 (3 folders)
31	Meeting #16, January 8-9, 1982 (3 folders) Meeting #17, February 12-13, 1982 (3 folders) Meeting #18, March 12-13, 1982 (4 folders) Meeting #19, April 2-3, 1982 Tabs A-D

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A. Briefing Books. 1980-83 (cont'd)

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33	Meeting #23, August 12-13, 1982 (4 folders) Meeting #24, September 10-11, 1982 (5 folders) Meeting #28, February 11, 1983 (2 folders)

B. Minutes & miscellaneous materials

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35	Minutes of meetings (cont) Meeting #7, March 13-14, 1981 Meeting #8, April 9-10, 1981 Meeting #9, May 8-9, 1981 Meeting #10, June 4-5, 1981 (2 folders) Meeting #11, July 9-10-11, 1981 Meeting #12, September 9-10-11, 1981 Meeting #13, October 22-24, 1981 Meeting #14, November 13-14, 1981 Meeting #15, December 11-12, 1981 Meeting #16, January 8-9, 1982

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B. Minutes & miscellaneous materials (contd.)

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C. Transcripts of Meetings

37	Meeting #2 Day 1, May 16, 1980, McCarthy's testimony Day 2, May 17, 1980 Meeting #3, Day 2, July 12, 1980 Meeting #4 Day 1, September 15, 1980 Day 2, September 16, 1980 Meeting #5, Day 1, November 7, 1980
38	Meeting #8, Days 1 & 2, April 9-10, 1981 Meeting #10, Day 2, June 5, 1981 Meeting #11, Day 2, July 10, 1981
39	Meeting #14, Day 2, November 14, 1981 Meeting #16, Day 2, January 9, 1982 Meeting #18, Days 1 & 2, March 12-13, 1982
40	Meeting #19, Days 1 & 2, April 2-3, 1982
41	Meeting #21, Day 2, June 11, 1982 Meeting #22, Day 2, July 10, 1982 Meeting #23, Day 1, August 12, 1982 Meeting #24, Day 2, September 11, 1982
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C. Transcripts of Meetings (contd.)

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45	<i>Compensating for Research Injuries (cont)</i> Camera copy (cont) Appendices M-U (5 folders) Commissioner's comments Drafts (5 folders) Press release Printing and distribution
46	<i>Deciding to Forego Life-sustaining Treatment</i> Drafts (7 folders) <i>Defining Death</i> Artwork Draft of November 1980 (4 folders)
47	<i>Defining Death (cont)</i> Draft of November 1980 (2 folders) Comments on November 1980 draft A. R. Jonsen revisions, November 1980 Notes & comments on drafts, 1980-81 Drafts Appendices Appendix F. Guidelines, 1981 May 1981 (4 folders)

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49	<i>Defining Death</i> (cont) Final draft, July 1981 Press <i>Implementing Human Research Regulations</i> (2d Biennial Report) Background materials (3 folders) Comments on draft Drafts December 1982, post meeting revisions
50	<i>Implementing Human Research Regulations</i> (2d Biennial Report) (cont) Drafts (cont) March 1983 (3 folders) Final typed copy Notes from September 1982 meeting Notes from December 1982 meeting Notes and miscellaneous materials Outlines, plans <i>IRB Guidebook</i> Comments and requests for revision Contents (hand-outs) Design, production, etc. Document Design Center
51	<i>IRB Guidebook</i> (cont) Drafts, 1981-82 (4 folders) Editing by Terry Savage Editorial board General Mailing lists (distribution) Memos to OPRR & FDA Plans, outline, etc. PRIM&R contract and correspondence
52	<i>IRB Guidebook</i> (cont) PRIM&R contract and correspondence (cont) PRIM&R letters to authors Thank you letters to contributors

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54	<i>Making Health Care Decisions (cont)</i> Drafts (cont) Addendum Final revisions Master copy Page proofs (2 folders) Graphics <i>Protecting Human Subjects</i> (1st Biennial Report) Comments by A.G. Motulsky, 1981 Comments on draft, Nov.-Dec. 1981 Drafts, December 1981 Graphics Tables, data, background information <i>Screening and Counseling for Genetic Conditions</i> Comments on draft, April-May 1982 Drafts Outline and drafts, February 1982 May-June 1982
55	<i>Screening and Counseling for Genetic Conditions (cont)</i> Outline and drafts, February 1982 (cont) September-October 1982 (3 folders) October 1982 revisions (5 folders) November 1982 (3 folders)
56	<i>Screening and Counseling for Genetic Conditions (cont)</i> Outline and drafts, February 1982 (cont) November 1982 (3 folders) December 1982 January 1983 (3 folders) February 1983 (2 folders) Final draft (2 folders)

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58	<i>Securing Access to Health Care</i> (cont) Drafts, Chapters 1-3 (10 folders)
59	<i>Securing Access to Health Care</i> (cont) Drafts Chapters 3-4 (9 folders) Ballantine's statement & Abrams' reply (2 folders) Commission's process Figures & tables (2 folders) September 1982 meeting copy (4 folders)
60	<i>Securing Access to Health Care</i> (cont) Drafts (cont) November 1982 meeting copy (4 folders) November 1982, notes & revisions December 1982 meeting copy (3 folders) December 1982 meeting copy with revisions (4 folders)
61	<i>Securing Access to Health Care</i> (cont) Drafts (cont) December 1982 meeting copy with revisions January 1983 (4 folders) Memos to commissioners and notes from meetings, September 1982 - January 1983 Page proofs (8 folders)
62	<i>Splicing Life</i> Drafts, March 1981 June 1981 (2 folders) Introduction, Chapters 1-3 (8 folders)
63	<i>Splicing Life</i> (cont) Drafts (cont) Chapters 3-4 & appendices (5 folders)

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64	<i>Splicing Life</i> (cont) Edited copy Final typed copy Pre-publication copies (3 folders) Page proofs <i>Summing Up</i> Draft, January 1983 (2 folders)
65	<i>Summing Up</i> (cont) Drafts January 1983 revisions (4 folders) March 1983 (4 folders) Final typed copy Page proofs

OVERSIZE MATERIAL

66	Camera Copy <i>Making Health Care Decisions</i> <i>Screening and Counseling for Genetic</i> Conditions Negatives for <i>Securing Access to Health Care</i>
67	Camera copy <i>Protecting Human Subjects</i>
68	Camera copy <i>Whistleblowing in Biomedical Research</i>