2001 Current Fiscal Year Report: National Bioethics Advisory Commission

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2001

3. Committee or Subcommittee	3b. GSA Committee No.
National Bioethics Advisory Commission	1958

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/26/1996		10/03/2001

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes		10/03/2001

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	Yes	Pending

11. Establishment Authority Presidential

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
E.O. 12975	10/03/1995	Continuing	Yes

15. Description of Committee National Policy Issue Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
4	0	0	0	4

Meetings and Dates

Purpose	Start	End
To discuss the draft report on ethical and policy issues in the oversight of human subjects research	10/24/2000	10/25/2000

To discuss the draft chapters of the oversight of human research report and the draft report on international research	12/07/2000 - 12/08/2000
To discuss clinical trials in developing countries for draft report in international research.	01/18/2001 - 01/19/2001
To discuss the various chapters of the draft report on the oversight of research involving human participants	03/15/2001 - 03/16/2001

Number of Committee Meetings Listed: 4

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$75,600.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$75,600.00
18a(3). Personnel Pmts to Federal Staff	$976,766.00	$976,766.00
18a(4). Personnel Pmts to Non-Member Consultants	$1,248,270.00	$1,248,270.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$200,000.00	$200,000.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$625,000.00	$625,000.00
18d. Total	$3,125,636.00	$3,125,636.00
19. Federal Staff Support Years (FTE)	13.00	13.00

20a. How does the Committee accomplish its purpose?

The National Bioethics Advisory Commission advises, consults with, and makes recommendations to the National Science and Technology Council and its Chair, the President, Federal agencies, and other appropriate entities, including the scientific community, professional associations, academic institutions, Congress, and the public on the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations in their relationship to bioethical issues arising from biomedical, clinical and social research. It accomplishes these tasks through the following mechanisms: deliberations at Commission meetings, contracting/ commissioned papers from public, professional, and scientific experts in relevant fields, and through testimony by recognized experts and the public. In addition, opportunities are afforded the public at each meeting to provide comments. In FY 1999, the Commission completed three reports, one of which was in direct response to President Clinton's request. NBAC submitted to the President, through the National Science and Technology Council (NSTC), its report, Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity (2 vol.). The report contained 21 recommendations designed to

enhance protections for human subjects who had mental disorders. The report was referred to the Committee on Science of the NSTC and to Federal agencies for comment. NBAC selected this topic because it was timely, raised critically important questions for the research community, and for patients and families. In July 1999, NBAC submitted its report, Research Involving Human Biological Materials: Ethical Issues and Policy Guidance (Executive Summary and Vol. 1; a second volume for this report containing commissioned papers will be published in FY 2000). NBAC selected this topic because advances in genetic research raised important concerns about the use of genetic (and non-genetic) information, there were disagreements amongst the scientific community about key issues, and because of perceived ambiguity in the Federal regulations. On November 14, 1998, the President asked the Commission to consider the ethical, medical, and legal implications of embryonic stem cell research, including the mingling of human and non-human species. NBAC submitted its report, Ethical Issues in Human Stem Cell Research, to the NSTC on September 7, 1999 (Executive Summary and Vol. 1; a second volume for this report containing commissioned papers, and a third volume containing the written testimony from eleven religious scholars will both be published in FY 2000).

20b. How does the Committee balance its membership?

The President appointed 18 individuals, including the Commission chair, from a pool of knowledgeable non-government experts and community representatives with special qualifications and competence to provide effective

recommendations on a wide range of bioethical issues. At least three members must represent the public and at least one member must be from the following areas of expertise: Philosophy/theology; social/behavioral science; law; medicine/allied health professions; and biological research.

20c. How frequent and relevant are the Committee Meetings?

The original charter stated that meetings may be called up to 10 times a year; the two renewal charters state that there may be up to 12 meetings a year. In order to respond to the very tight deadline for the specific reports requested by the President, the Commission has sometimes met more frequently than expected. The agendae of the meetings are focused on the various aspects of the specific issues being deliberated.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The President established the Commission after a twelve-year absence of any such body. The Commission is to identify broad, overarching principles to govern the ethical conduct of research. There are a considerable number of bioethical issues that impact not only on the ethical conduct of research, but the health and well being of the Nation.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

President Bush has terminated and has implemented a new committee. Waiting for final report

Designated Federal Officer

Eric M. Meslin Executive Director, National Bioethics Advisory Commission

Committee Members	Start	End	Occupation	Member Designation
Backlar, Patricia	07/19/1996	10/03/2001	Research Associate Professor of Bioethics, Portland State University, and Assistant Director, Center for Ethics in Health Care, Oregon Health Sciences University, Portland, Oregon	Special Government Employee (SGE) Member
Brito, Arturo	07/19/1996	10/03/2001	Assistant Professor of Clinical Pediatrics, University of Miami School of Medicine, Miami, Florida	Special Government Employee (SGE) Member
Capron, Alexander	07/19/1996	10/03/2001	Henry W. Bruce Professor of Law and Co-Director, Pacific Center for Health Policy and Ethics, University of Southern California Law Center, Los Angeles, California	Special Government Employee (SGE) Member
Cassell, Eric	07/19/1996	10/03/2001	Clinical Professor of Public Health, Cornell University Medical College, New York, New York	Special Government Employee (SGE) Member
Charo, R.	07/19/1996	10/03/2001	Professor of Law and Medical Ethics, Schools of Law and Medicine, University of Wisconsin, Madison, Wisconsin	Special Government Employee (SGE) Member
Childress, James	07/19/1996	10/03/2001	Kyle Professor of Religious Studies, Professor of Medical Education, University of Virginia, Charlottesville, Virginia	Special Government Employee (SGE) Member

Cox, David	07/19/1996	10/03/2001	Scientific Director, Perlegen Sciences, Santa Clara, California	Special Government Employee (SGE) Member
Dumas, Rhetaugh	09/16/1996	10/03/2001	Vice Provost Emerita, Dean Emerita, and Lucille Cole Professor of Nursing, University of Michigan, Ann Arbor, Michigan	Special Government Employee (SGE) Member
Flynn, Laurie	07/19/1996	10/03/2001	Senior Research and Policy Associate, Dept. of Child & Adolescent Psychiatry, Columbia University College of Physicians & Surgeons, New York, New York	Special Government Employee (SGE) Member
Greider, Carol	10/29/1996	10/03/2001	Professor of Molecular Biology and Genetics, The Johns Hopkins University School of Medicine, Baltimore, Maryland	Special Government Employee (SGE) Member
Holtzman, Steven	07/19/1996	10/03/2001	Chief Business Officer, Millennium Pharmaceuticals Inc., Cambridge, Massachusetts	Special Government Employee (SGE) Member
Kramer, Bette	09/16/1996	10/03/2001	Founding President, Richmond Bioethics Consortium, Richmond, Virginia	Special Government Employee (SGE) Member
Lo, Bernard	07/19/1996	10/03/2001	Director, Program In Medical Ethics, University of California, San Francisco, San Francisco, California	Special Government Employee (SGE) Member
Miike, Lawrence	07/19/1996	10/03/2001	Kaneohe, Hawaii	Special Government Employee (SGE) Member
Murray, Thomas	07/19/1996	10/03/2001	President, The Hastings Center, Garrison, New York	Special Government Employee (SGE) Member

Oldaker, William	09/21/1999	10/03/2001	Oldaker & Harris, LLP, Washington, D.C.	Special Government Employee (SGE) Member
Scott-Jones, Diane	07/19/1996	10/03/2001	Professor, Department of Psychology, Temple University, Philadelphia, Pennsylvania	Special Government Employee (SGE) Member
Shapiro, Harold	07/19/1996	10/03/2001	President, Princeton University, Princeton, New Jersey	Special Government Employee (SGE) Member

Number of Committee Members Listed: 18

Narrative Description

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	☐
Trust in government	☐
Major policy changes	☐
Advance in scientific research	☐
Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☐
Implementation of laws or regulatory requirements	☐
Other	☐

Outcome Comments

What are the cost savings associated with this committee?

	Checked if Applies
None	✓

Unable to Determine ☐
Under $100,000 ☐
$100,000 - $500,000 ☐
$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments

What is the approximate Number of recommendations produced by this committee for the life of the committee?
0

Number of Recommendations Comments

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
%

% of Recommendations Fully Implemented Comments

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
%

% of Recommendations Partially Implemented Comments

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☐ No ☐ Not Applicable ☑

Agency Feedback Comments

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☐
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☐

Action Comments

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☐
Online Agency Web Site	☐
Online Committee Web Site	☐
Online GSA FACA Web Site	☐
Publications	☐
Other	☐

Access Comments