

after this year all appointments to replace members whose terms have expired will be for 3 years.

**David M. Walker,**

*Comptroller General of the United States.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

**Title and Description of Information Collection:** Multi-site Evaluation of the Welfare-to-Work Grants Program—Baseline Forms—NEW—As required by the Balanced Budget Act of 1997, DHHS is planning a four-year project to evaluate the effectiveness of welfare-to-work initiatives undertaken through competitive and formula grants awarded by the US Department of Labor. DHHS' Office of the Assistant Secretary for Planning and Evaluation, in conjunction with DoL and the US Department of Housing and Urban Development (HUD), has designed an evaluation that will involve several rounds of data collection from grantees and grant program participants. The information collection instruments in this request for OMB approval consist of a sample intake form, a contact information form, and a study participation consent form to be used to gather baseline and administrative information on study participants. Respondents: Individuals, State and Local Governments, Businesses or Other For-profit Organizations, Not-for-profit Institutions; Burden Information for the Intake Form—Number of Respondents: 10,000; Number of Responses per Respondent: one; Average Burden per Response: 5 minutes; Total Burden for Intake Form: 830 hours—Burden Information for the Contact Information Form—Number of Respondents: 10,000; Number of Responses per Respondent: one; Average Burden per Response: 5 minutes; Total Burden for Contact Information Form: 830 hours—Burden Information for the Consent Form—

Number of Respondents: 10,000; Number of Responses per Respondent: one; Average Burden per Response: 5 minutes; Total Burden for Consent Form: 830 hours. Total Burden: 2,490 hours. Total Annual Burden: 1,245 hours.

OMB Desk Officer: Allison Eydt

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: February 11, 1999.

**Dennis P. Williams,**

*Deputy Assistant Secretary, Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Notice of Publication of the Executive Summary of the Report, Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity by the National Bioethics Advisory Commission (NBAC)

**SUPPLEMENTARY INFORMATION:** The President established the National Bioethics Advisory Commission (NBAC) on October 3, 1995 by Executive Order 12975 as amended. The functions of NBAC are as follows:

(a) provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

(1) the appropriateness of departmental, agency or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and (2) applications, including the clinical applications, of that research.

(b) identify broad principles to govern the ethical conduct of research, citing

specific projects only as illustrations for such principles.

(c) shall not be responsible for the review and approval of specific projects.

(d) in addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC may also identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council. The members of NBAC are as follows:

Harold T. Shapiro, Ph.D., Chair

Patricia Backlar

Arturo Brito, M.D., Alexander M. Capron, LL.B.

Eric J. Cassell, M.D., M.A.C.P.

R. Alta Charo, J.D.

James F. Childress, Ph.D.

David R. Cox, M.D., Ph.D.

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Laurie M. Flynn

Carol W. Greider, Ph.D.

Steven H. Holtzman

Bernard Lo, M.D.

Lawrence H. Miike, M.D., J.D.

Thomas H. Murray, Ph.D.

Diane Scott-Jones, Ph.D.

### Executive Summary, Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity

In this report, the National Bioethics Advisory Commission (NBAC) considers how ethically acceptable research can be conducted with human subjects who suffer from mental disorders that may affect their decisionmaking capacity; whether, in this context, additional protections are needed; and, if so, what they should be and how they should be implemented.

In addition, this report provides an opportunity for investigators, Institutional Review Board (IRB) members, persons with mental disorders and their families, and the general public to become better informed about the importance of such research and what we believe are the appropriate protections for the human subjects involved.

This report stands in a long line of statements, reports, and recommendations by governmental advisory groups and professional organizations on the ethical requirements of research involving human subjects that have been developed in the United States and elsewhere. Much has changed in the research environment since the National Commission for the Protection of Human Subjects of Biomedical and