

the safety and effectiveness of marketed and investigational devices.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing three to five qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Potential candidates will be required to provide detailed information

concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

All nominations should include: a cover letter; a curriculum vitae or resume that includes the nominee's office address, telephone number, and email address; and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination and is willing to serve as a member of the advisory committee or panel if selected.

The term of office is up to 4 years. FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: February 15, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System Data Access Request

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Neurological Disorders and Stroke (NINDS), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project, obtain a copy of the data collection plans and instruments, or to submit written comments, contact Rebecca L. Frederick, Office of Science Policy and Planning, OSPP, NINDS, NIH, 31 Center Drive, Building 31, Room 8A03, Bethesda, MD 20892; call 301-496-9271; or Email: rebecca.frederick@nih.gov.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Proposed Collection: Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System Data Access Request.

Need and Use of Information Collection: The FITBIR Informatics System Data Access Request form is necessary for "Recipient" Principal

Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from the FITBIR Informatics System for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the FITBIR datasets, as well as to notify interested recipients of updates, corrections or other changes to the database.

Frequency of Response: Once per request.

Affected Public: Individuals.
Type of Respondents: Researchers interested in obtaining access to study data and images from the FITBIR Informatics System for research purposes.

The annual reporting burden is as follows:

Estimated Number of Respondents: approximately 40.

Estimated Number of Responses per Respondent: Once per request.

Average Burden Hours per Response: 95/60.

Estimated Total Annual Burden Hours Requested: 63.

There are two scenarios for completing the form. The first is where the Principal Investigator (PI) completes the entire FITBIR Informatics System Data Access Request form, and the second where the PI has the Research Assistant begin filling out the form and PI provides the final reviews and signs it. The estimated annual burden hours to complete the data request form are listed below.

ESTIMATED ANNUAL BURDEN HOURS

| Form | Number of respondents | Frequency of response | Average time per response (in hours) | Annual hour burden |
|---|-----------------------|-----------------------|--------------------------------------|--------------------|
| FITBIR Informatics System Data Access Request | 40 | 1 | 95/60 | 63 |
| Total | | | | 63 |

Dated: February 13, 2013.

Caroline Lewis,

Executive Officer, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; Comment Request: Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in

the **Federal Register** on November 26, 2012, Vol. 77, No. 227, p. 70451 and allowed 60-days for public comment. Two comments were received in support of this request. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Cognitive Testing of Instrumentation and Materials for Population Assessment of Tobacco and Health (PATH) Study.

Type of Information Collection Request: New. *Need and Use of Information Collection:* The PATH study will establish a population-based framework for monitoring and assessing the behavioral and health impacts of regulatory provisions implemented as part of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) by the Food and Drug Administration

(FDA). NIDA is requesting generic approval from OMB for methodological studies to improve the PATH study instrumentation and data collection procedures. These methodological studies will support ongoing assessment and refinement of the PATH study's design, and highlight ways to improve study implementation, data collection procedures, and techniques for retention and followup. Data collection methods to be used in these methodological studies include: in-person and telephone surveys; web and smartphone/mobile phone surveys; and focus group and individual in-depth qualitative interviews. Biospecimens may also be collected from adults.

Frequency of Response: Annual [As needed on an on-going and concurrent basis]. *Affected Public:* Individuals. *Type of Respondents:* Youth (ages 12-17) and Adults (ages 18+). *Annual Reporting Burden:* See Table 1. The annualized cost to respondents is estimated at: \$371,284. There are no capital, operating or maintenance costs.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY—METHODOLOGICAL STUDIES FOR THE PATH STUDY

| Data collection activity | Type of respondent | Number of respondents | Responses per respondent | Hours per response | Annual hour burden |
|--|--------------------|-----------------------|--------------------------|--------------------|--------------------|
| In-person and telephone surveys | Adults | 5,000 | 1 | 90/60 | 7,500 |
| | Youth | 3,500 | 1 | 90/60 | 5,250 |
| Web and smartphone/mobile phone surveys. | Adults | 5,000 | 1 | 90/60 | 7,500 |
| | Youth | 3,500 | 1 | 90/60 | 5,250 |
| Focus groups and individual in-depth qualitative interviews. | Adults | 1,000 | 1 | 2 | 2,000 |
| | Youth | 1,000 | 1 | 2 | 2,000 |
| Biospecimen collection | Adults | 1,000 | 1 | 15/60 | 250 |