

SIGNATURES OF RESPONSIBLE PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE
UNITED STATES FOOD AND DRUG ADMINISTRATION

_____ Date _____
Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE
INTERNATIONAL ANESTHESIA RESEARCH SOCIETY

_____ Date _____
Robert N. Sladen, M.D.
Chair, IARS Board of Trustees
International Anesthesia Research Society

*FDA/IAR SmartTots PPP
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

National Institutes of Health

**Submission for OMB Review;
Comment Request; Interactive Diet and
Activity Tracking in AARP (iDATA):
Biomarker Based Validation Study
(NCI)**

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), 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 March 14, 2011 (76 FR 13647) and allowed 60-days for public comment. There were no public comments in response to the notice. 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: Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker Based Validation Study. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The AARP-based study is one component of a multi-center biomarker validation study project involving two other large cohorts in the United States. The iDATA study involves large cohorts and provides the necessary sample size to evaluate the measurement error structure of the diet and physical activity assessment

instruments and the heterogeneity of the measurement error structure across multiple and diverse study populations. The iDATA study will include 1,500 participants from the NIH-AARP Diet and Health Study and current AARP membership. The data collection instruments adhere to The Public Health Service Act, which provides authority to the Risk Factor Monitoring and Methods Branch in the Division of Cancer Control and Population Sciences and the Division of Cancer Epidemiology and Genetics. Both divisions work to reduce cancer in the U.S. population by establishing and supporting programs for the detection, diagnosis, prevention

and treatment of cancer; and by collecting, identifying, analyzing and disseminating information on cancer research, diagnosis, prevention and treatment. Dietary and physical activity data will be gathered using the instruments as detailed below. In addition, biospecimen and clinic data will be also gathered. *Frequency of Response:* Monthly. *Affected Public:* Individuals. *Type of Respondents:* U.S. adults (persons aged 50–74). The annual reporting burden is provided for each study component as shown in the table below. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Study component	Instrument	Number of respondents	Frequency of response	Average time per response (Minutes/Hour)	Annual burden hours
Type of Respondents for All Instruments: Adult Participants, 50–74 Years of Age					
Screening	Pre-Screening Telephone Interview (Attachment 1).	1,334	1	15/60 (.25)	334
	Clinic Eligibility Screening Interview (Attachment 3).	742	1	10/60 (.167)	124
Clinical Components.	NHANES III Anthropometry (Attachment 13).	742	3	10/60 (.167)	371
	Resting Metabolic rate—Main (Attachment 7).	742	1	30/60 (.50)	371
	Resting Metabolic Rate—Sub-sample (Attachment 7).	34	1	30/60 (.50)	17
	Fasting Blood Protocol and Form (Attachment 5).	742	2	10/60 (.167)	247
	Fitness test Protocol and Form (Attachment 10).	742	1	15/60 (.25)	186
	Physical Activity Readiness Questionnaires—PAR-Q or PARmed-X (Attachments 11A–11B).	742	1	5/60 (.083)	62
	Doubly Labelled Water—Main (Attachment 6).	742	1	40/60 (.667)	495
	Doubly Labelled Water—Sub-sample (Attachment 6).	34	1	40/60 (.667)	23
Dietary Questionnaires.	Automated Self-Administered 24-hour Dietary Recall (ASA24) (Attachment 32).	742	6	30/60 (.50)	2,227
	4-Day Food Record (Attachment 17).	742	2	60/60 (1.0)	1,485
	Diet History Questionnaire (DHQ*Web-II) (Attachment 33).	742	2	45/60 (.75)	1,114
	7-Day Food Checklist (Attachment 16).	742	2	60/60 (1.0)	1,485
Physical Activity Questionnaires.	Activities Completed over Time in 24 Hours (ACT24) (Attachment 34).	742	6	30/60 (.50)	2,227
	Community Healthy Activities Model Program for Seniors (CHAMPS) (Attachment 19).	742	2	15/60 (.25)	371
	Harvard Lifestyle Validation Study Physical Activity Questionnaire (Attachment 18).	742	2	10/60 (.167)	247
	Sedentary Behaviors Questionnaire (Attachment 21).	742	2	20/60 (.33)	495
	Stanford physical activity Survey (Attachment 22).	742	2	8/60 (.133)	198
	NIH-AARP physical activity questions (Attachment 20).	742	2	10/60 (.167)	247
Home Collections	24 Hour Urine Collection Log (Attachment 14).	742	2	60/60 (1.0)	1,485

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Study component	Instrument	Number of respondents	Frequency of response	Average time per response (Minutes/Hour)	Annual burden hours
	Saliva Protocol and Form (Attachment 15).	742	3	10/60 (.167)	371
	Heart Rate Monitor Log (Attachment 8).	34	1	35/60 (.583)	20
	Physical Activity Monitor Log (Accelerometer/Inclinometer) (Attachment 12).	742	2	35/60 (.583)	866
Total	15,060

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the *Attention:* NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Heather Bowles, Risk Factor Monitoring and Methods Branch, Division of Cancer Control and Population Sciences, National Cancer Institute, 6130 Executive Blvd. MSC 7344, Bethesda, MD 20892-7335 or call non-toll-free number 301-496-7344 or e-mail your request, including your address to: *bowleshr@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: May 9, 2011.
Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.
 [FR Doc. 2011-11824 Filed 5-12-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Advisory Neurological Disorders and Stroke Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council, Clinical Trials Subcommittee.
Date: May 25, 2011.
Closed: 6:30 p.m. to 8 p.m.
Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Open: 8 p.m. to 8:30 p.m.
Agenda: To discuss clinical trials policy.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Petra Kaufmann, MD, Director, Office of Clinical Research—NINDS, National Institutes of Health, Neuroscience Center—Room 2216, 6001 Executive Blvd., Bethesda, MD 20892, 301-496-9135, *Kaufmanp2@ninds.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review funding cycle.

Name of Committee: National Advisory Neurological Disorders and Stroke Council, Basic and Preclinical Programs Subcommittee.

Date: May 26, 2011.
Open: 8 a.m. to 9 a.m.
Agenda: To discuss basic and preclinical programs policy.
Place: National Institutes of Health, Building 31, C Wing, Conference Room 10, Bethesda, MD 20892.
Closed: 9 a.m. to 9:30 a.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, Conference Room 10, Bethesda, MD 20892.
Contact Person: Walter Joseph Koroshetz, MD, Deputy Director, NINDS, Building 31, Room 8A52, 31 Center Drive, MSC 2540, 301-496-3167, *Koroshetzw@ninds.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review funding cycle.

Name of Committee: National Advisory Neurological Disorders and Stroke Council Training, Career Development, and Special Programs Subcommittee.

Date: May 26, 2011.
Open: 9:30 a.m. to 10:30 a.m.
Agenda: To discuss the training plan of the institute.

Place: National Institutes of Health, Building 31, C Wing, Conference Room 10, Bethesda, MD 20892.

Contact Person: Stephen J. Korn, PhD, Training and Special Programs Officer, National Institute of Neurological Disorders and Stroke, National Institutes of Health,