

adding to the challenges of pediatric device development. There currently exists a great need for medical devices designed specifically with children in mind. Such needs include the original development of pediatric medical devices, as well as the specific adaptation of existing adult devices for children. Thus, as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress passed the Pediatric Medical Device Safety and Improvement Act of 2007. Section 305 of FDAAA requires the Secretary of Health and Human Services to provide demonstration grants or contracts to nonprofit consortia to promote pediatric device development.

#### B. Research Objectives

The goal of FDA's Pediatric Device Consortia Grant Program is to promote pediatric device development by providing grants to nonprofit consortia. The consortia will facilitate the development, production, and distribution of pediatric medical devices by: (1) Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers; (2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing; (3) connecting innovators and physicians to existing Federal and non-Federal resources; (4) assessing the scientific and medical merit of proposed pediatric device projects; and (5) providing assistance and advice as needed on business development, personnel training, prototype development, post-marketing needs, and other activities.

#### C. Eligibility Information

The grants are available to any domestic, public or private, nonprofit entity (including State and local units of government). Federal agencies that are not part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. Organizations that engage in lobbying activities, as described in section 501(c)(4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

## II. Award Information/Funds Available

#### A. Award Amount

Approximately \$2.5 million will fund two to four new awards. Grants will be

awarded up to \$1,500,000 in total cost (direct costs plus indirect costs) per year.

#### B. Length of Support

Grants will be awarded on a competitive basis for up to 2 years.

### III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement when posted and located at <http://grants.nih.gov/grants/guide/index.html>. (The FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**). Persons interested in applying for a grant may obtain an application at <http://grants.nih.gov/grants/funding/phs398/phs398.html>. For all paper application submissions, the following steps are required:

- *Step 1:* Obtain a Dun and Bradstreet (DUNS) Number.
- *Step 2:* Register With Central Contractor Registration.

Steps 1 and 2, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). After you have followed these steps, submit paper applications to: Division of Acquisition Support and Grants, Office of Acquisition & Grant Services, 5630 Fishers Lane, rm. 2128, Rockville, MD 20857, 301-827-7175.

Dated: January 13, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; The Atherosclerosis Risk in Communities Study (ARIC)

*Summary:* Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below.

This proposed information collection was previously published in the **Federal Register** on October 12, 2010, page 62544, and allowed 60 days for public comment. No comments were received. 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:* The Atherosclerosis Risk in Communities Study (ARIC). *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925-0281). *Need and Use of Information Collection:* ARIC will conduct a clinical examination of the cohort over a 24-month period (May 2011 to April 2013). In addition, this project involves biennial follow-up by telephone of participants in the ARIC study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. *Frequency of Response:* The participants will be contacted bi-annually for follow-up. A subset of the cohort may choose to volunteer for the clinical examination; these individually will be contacted once in a 3 year period. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 12,673; *Estimated Number of Responses per Respondent:* 2.7; *Average Burden Hours per Response:* 0.5916; and *Estimated Total Annual Burden Hours Requested:* 20,434. The annualized cost to respondents is estimated at \$355,882, assuming respondent's time at the rate of \$17.00 per hour and physician time at the rate of \$75.00 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

## ESTIMATES OF HOUR BURDEN

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Participants .....	10,933	3	0.6165	20,220.6
Physician (or coroner) (for CHD) .....	420	1	0.1667	70
Physician (for heart failure) .....	920	1	0.0833	76.6
Participants' next of kin .....	400	1	0.1667	66.7
Totals .....	12,673	.....	.....	20,433.9 or 20,434

(Note: reported and calculated numbers differ slightly due to rounding.)

**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: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Hanyu Ni, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number (301) 435-0448 or E-mail your request, including your address to: *nihanyu@nhlbi.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.

**Suzanne Freeman,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

**Michael Lauer,**

*Director, DCVS, National Institutes of Health.*

[FR Doc. 2011-1038 Filed 1-18-11; 8:45 am]

**BILLING CODE 4141-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

**Date:** February 17, 2011.

**Time:** 8:30 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

**Contact Person:** Thomas A. Tatham, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, *tathamt@mail.nih.gov*.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases

Special Emphasis Panel; Lactation and Diabetes Ancillary Studies.

**Date:** February 18, 2011.

**Time:** 1 p.m. to 2 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Carol J. Goter-Robinson, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7791, *goterrobinsnc@extra.niddk.nih.gov*.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; LRP Reviews.

**Date:** March 7, 2011.

**Time:** 2 p.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** D. G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, *pateldg@niddk.nih.gov*.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Coordinating and Bioinformatics Unit for the MMPC and DCC (U24).

**Date:** March 7, 2011.

**Time:** 2 p.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Najma Begum, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, *begumn@niddk.nih.gov*.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Centers for Diabetes Translation Research.

**Date:** March 14-16, 2011.

**Time:** 3 p.m. to 5 p.m.