

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 6, 2008, 1 p.m. to 5:30 p.m. EST March 7, 2008, 9 a.m. to 12 p.m. EST.

Place: Parklawn Building (and via audio conference call), Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, March 6 from 1 p.m. to 5:30 p.m. (EST) and Friday, March 7 from 9 a.m. to 12 p.m. (EST). The public can join the meeting via audio conference call by dialing 1-888-455-3612 on March 6 & 7 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the March meeting will include, but are not limited to: a report from the ACCV Futures II Workgroup, updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics Evaluation and Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Michelle Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: mherzog@hrsa.gov. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or

telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the ACCV should contact Michelle Herzog, DVIC, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-6593 or e-mail: mherzog@hrsa.gov.

Dated: February 7, 2008.

Alexandra Hutterer,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E8-2737 Filed 2-12-08; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Demonstration Project for Healthy Lifestyles in Youth

Announcement Type: New.

Funding Opportunity Number: HHS-2008-IHS-HLY-0001

Catalog of Federal Domestic Assistance Number: 93.933

Key Dates: Application Deadline Date: April 18, 2008.

Review Date: May 2, 2008.

Earliest Anticipated Start Date: May 16, 2008.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces a cooperative agreement, HHS-2008-IHS-HLY-0001 for Tribes or Tribal organizations to promote healthy lifestyles among American Indian and Alaska Native (AI/AN) youth using the curriculum "Together Raising Awareness for Indian Life" (TRAIL) among selected Boys and Girls Club sites. This program is authorized under the authority of the Snyder Act, 25 U.S.C. 13; section 301 of the Public Health Service Act, as amended; and the Indian Health Care Improvement Act, 25 U.S.C. 1652 and 1621(b). This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA).

Under this grant opportunity, IHS proposes to enter into a collaborative effort/initiative with an eligible Tribal entity that has experience in addressing healthy lifestyle techniques in AI/AN youth. The purpose of the initiative is to address healthy lifestyle development with a focus on nutrition and physical

activity for children and youth 6 through 17 years of age. The eligible Tribal entity will work with Tribal Boys and Girls Club sites to provide health and physical education by helping youth: Achieve and maintain healthy lifestyles through fitness programs; acquire a range of physical skills; and develop a sense of teamwork and cooperation. These early intervention opportunities may reduce and/or halt the increasing trend of obesity and diabetes among youth and young adults. Clubs that develop a health promotion program that includes the TRAIL curriculum may curtail the effects of unhealthy eating behaviors and lack of physical activity that can lead to obesity, diabetes, and other chronic diseases later in life.

The TRAIL curriculum was developed to provide information on good nutrition and promoting physical activity among adolescents participating in Tribal Boys and Girls Clubs. This work will support the IHS mission to improve the health of AI/AN youth through health promotion and health education programs. Boys and Girls Club sites that are located outside of Tribal communities will not be considered by the grantee.

TRAIL was piloted at 40 AI/AN Boys and Girls Club of America (BGCA) sites located in 19 states where the overall results showed improvement in participant knowledge. For all eligible applicants that want to obtain additional information regarding the TRAIL curriculum, contact the IHS program official (see section VII).

To support this project, the awarded grantee will select and assist 35 AI/AN Boys and Girls Club sites to establish and implement this curriculum project. The selected sites must serve 100% Federally-recognized AI/AN youth. The Boys and Girls Club sites selected by the grantee must not support State-recognized or non-natives using IHS grant funds. The grantee will be expected to: Provide technical consultation; train; monitor; evaluate; as well as provide funds to support these activities.

II. Award Information

Type of Award: Cooperative Agreement.

Estimated Funds Available: The IHS intends to commit approximately \$1,000,000 each year. Total project period is three years in duration. The award that is issued under this announcement is subject to availability of funds.

Anticipated Number of Awards: One award will be issued under this announcement.

Project Period: May 16, 2008—May 15, 2011 (three year project period).

Award Amount: \$1,000,000 per year for three years and all future support is subject to the availability of funds.

Programmatic Involvement:

It is expected that the grantee will:

1. Develop a written plan for the planning, implementation, and evaluation of this project to include selection of at least 35 demonstration sites as agreed upon with the IHS. The selected sites must serve 100% Federally recognized AI/AN youth. The Boys and Girls Club sites selected by the grantee must not support State-recognized Tribes or non-natives using IHS grant funds. This task will be completed within 30 days from award and approved by the IHS. A start-up planning meeting will be conducted within 3 months of the initial (first year) award.

(a) Develop selection criteria, announce, evaluate, and select sites. Sites must submit documentation verifying they serve only AI/AN youth from Federally recognized Tribes as a requirement for selection by the grantee.

(b) Develop, in consultation with the IHS, the implementation of the TRAIL curriculum, and technical assistance plan for the coordination of the 35 sites. Submit criteria to the IHS for approval. Grantee will work with sites to develop measurements to assess physical activity and nutrition behaviors among club participants.

(c) Each site will implement the TRAIL program, emphasizing healthy behaviors such as physical activity and nutrition. Each program plan will also include a parent component describing approaches for involving the families of participants.

(d) Each site will implement a 6-minute walk test three times, six to eight weeks apart. Physical activity data will be collected and summarized.

2. Promote and facilitate local, state, and national partnerships for the purpose of establishing or enhancing program support that involves increasing physical activity and good nutrition for the Tribally-managed Boys and Girls Club sites. This includes but is not limited to establishing other partners such as American Indian-Alaska Native Program Branch (AI-ANPB) of Head Start Programs, Wings of America, United National Indian Tribal Youth, Inc. (UNITY), Tribal colleges, BGCA, Tribal organizations, local community health providers and other private organizations as appropriate.

3. Implement evaluation processes in consultation with the IHS on an agreed upon evaluation plan for the TRAIL

project. At a minimum, the evaluation will include:

(a) Training attendance (gender, age, grade level); and

(b) Pre- and post-tests to assess participant knowledge. Submit summarized data to the IHS.

4. Collect, collate, and submit monthly activity logs from each site on the physical activity portion of their program. Daily data to be collected includes the date, number of minutes of physical activity, and number of children participating. Submit collated and summarized data to the IHS.

5. Work with the IHS in drafting an evaluation summary at the end of the project period for publication.

6. Provide ongoing technical support to the sites for the duration of the initiative. The planning, design and delivery of training and technical assistance will support the local organization's long-term planning and outreach efforts. The training will be customized based on sites' capability and experience. Technical assistance will also be provided on program planning and implementation.

(a) Plan and facilitate an orientation and training meeting for the sites within 60 days of selection. Submit agenda, training goals and objectives, and participant list to IHS within 30 days of completion.

(b) Provide technical consultation to the sites in developing a written work plan, with measurable goals, objectives and activities. Each site will include activities for the individual child and family, community involvement and an identifiable community health partner.

(c) Establish a formal agreement with Tribal Boys and Girls Club sites which involves minimal fiscal assistance but substantial technical support to make sure clubs successfully implement the TRAIL project.

(d) Conduct on-site technical assistance visits to each of the selected sites. Visits will be initiated within 30 days of selection.

(e) Submit to the IHS a written work plan and report describing each site's demographics, information on the number of youth in the eligible age range in the catchment area, the number that attend the Boys and Girls Clubs regularly, and the number served by this project, demonstrated need, community assessment data, goals, objectives, activities, partnerships, and proposed outcomes within 60 days of site selection.

(f) Provide training and technical assistance in all forms, i.e., on-site, on-line, by phone, and mail. Collaborate with IHS to provide services to club sites. Maintain records and reports.

(g) Provide IHS written quarterly reports on the evaluation outcomes, activity reports at each site, any parent involvement activities and other participation, description of the community partnerships, and other activities as appropriate.

(h) Conduct quarterly conference calls with IHS to review project status.

(i) Provide quarterly reports (feedback) to each site on how their data compare to data (mean, median, and range) from other selected sites.

IHS will:

1. Identify a core group of IHS staff to work with the grantee in providing technical assistance and guidance.

2. Meet with the grantee to review grantee work plan and provide guidance on implementation and data collection tools. The IHS will be able to share information on lessons learned from implementing the curriculum with the pilot sites.

3. Participate in quarterly conference calls. Work with the grantee to showcase the results of this project by publishing on shared websites as well as in jointly authored publications.

III. Eligibility Information

1. Federally recognized Tribes,
2. Tribal organizations, and
3. Non-profit Urban Indian organizations.

Applicant must provide proof of Federal recognition status.

Cost Sharing or Matching—This program does not require matching funds or cost sharing.

IV. Application and Submission Information

1. Applicant package may be found in Grants.gov (<http://www.grants.gov>) or at: http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp Web sites.

Information regarding the electronic application process may be directed to Michelle G. Bulls, at (301) 443-6290. Detailed application instructions for this announcement are downloadable from Grants.gov. Please see section VII for agency contacts regarding programmatic and/or business-related questions.

2. Content and Form of Application Submission:

- Be single spaced.
- Be typewritten.
- Have consecutively numbered pages.
- Use black type not smaller than 12 characters per one inch.
- Contain a narrative that does not exceed 15 typed pages that includes the other submission requirements below. The 15 page narrative does not include the work plan, standard forms, table of

contents, budget, budget justifications, narratives, and/or other appendix items.

- Contain two letters of support that demonstrate past working experiences in promoting the health and well-being of AI/AN youth at a national level.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants.

3. *Submission Dates and Times:*

The application must be submitted electronically through Grants.gov by April 18, 2008 by 12 midnight Eastern Standard Time (EST). If technical challenges arise and you are unable to successfully complete the 9 electronic application process, you must contact Michelle G. Bulls, Grants Policy Staff 15 days prior to the application deadline and advise of the difficulties that you are experiencing. You must obtain prior approval, in writing (e-mails are acceptable), from Ms. Bulls allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies must be sent to the appropriate grants contact that is listed in section IV. 1 above. Applications not submitted through Grants.gov, without an approved waiver, may be returned without review or consideration. Telecommunication for the hearing impaired is available at 301-443-6394. A late application will be returned without review or consideration.

4. *Intergovernmental Review:*

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. *Funding Restrictions:*

A. Pre-award costs are allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR Part 92, all pre-award costs are incurred at the recipient's risk. The awarding office is under no obligation to reimburse such costs if for any reason applicant does not receive an award or if the award to the recipient is less than anticipated.

B. The available funds are inclusive of direct and applicable indirect costs.

C. Only one grant will be awarded.

6. *Other Submission Requirements:*

Electronic Submission—You must submit through Grants.gov. However, should any technical challenges arise regarding the submission, please contact Grants.gov Customer Support at 1-800-518-4726 or support@grants.gov. The Contact Center hours of operation are Monday-Friday from 7 a.m. to 9 p.m. EST. If you require additional assistance, please call (301) 443-6290 and identify the need for assistance regarding your Grants.gov application. Your call will be transferred to the appropriate grants staff member. You

must seek assistance at least 15 days prior to the application deadline. If you do not adhere to the timelines for Central Contractor Registry (CCR), Grants.gov registration and request timely assistance with technical issues, paper application submission may not be granted.

To submit an application electronically, please use the <http://www.Grants.gov> Web site. Download a copy of the application package on the Grants.gov Web site, complete it offline and then uploaded and submit to application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to IHS.

Please be reminded of the following:

- Under the new IHS application submission requirements, paper applications are not the preferred method. However, if there are technical problems submitting the application online, you should contact directly Grants.gov Customer Support at: <http://www.grants.gov/CustomerSupport>.

- Upon contacting Grants.gov, obtain a Grants.gov tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver request from Grants Policy Staff (GPS) must be obtained. If you are still unable to successfully submit the application online, please contact Michelle G. Bulls, GPS, at (301) 443-6290 at least 15 days prior to the application deadline to advise her of the difficulties experienced.

- If it is determined that a formal waiver is necessary, you must submit a request, in writing (emails are acceptable), to Michelle.Bulls@ihs.gov providing a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded from Grants.gov, and sent directly to the Division of Grants Operations, 801 Thompson Avenue, TMP 360, Rockville, MD 20852 by April 18, 2008.

- Upon entering the Grants.gov Web site, there is information available that outlines the requirements regarding electronic submission of application and hours of operation. We strongly encourage that applicants do not wait until the deadline date to begin the application process as the registration process for CCR and Grants.gov could take up to 15 working days.

- To use Grants.gov, applicants must have a Dun and Bradstreet (DUNS) Number and be registered in the CCR. You should allow a minimum of 10 working days to complete CCR registration. See below on how to apply.

- You must submit all documents electronically, including all information typically included on the SF-424 and all necessary assurances and certifications.

- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS.

- You must comply with any page limitation requirements described in the program announcement.

- After the application is submitted electronically, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The Division of Grants Operations (DGO) will retrieve applications from Grants.gov. The DGO will notify applicants that their application has been received.

- You may access the electronic application for this program on <http://www.Grants.gov>.

- You may search for the downloadable application package using either the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.

- To receive an application package, you must provide the Funding Opportunity Number: HHS-2008-IHS-HLY-0001.

E-mail applications will not be accepted under this announcement.

DUNS Number

Applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

Applications submitted electronically must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1-888-227-2423. Please review and complete the CCR Registration Worksheet located on <http://www.grants.gov>.

More detailed information regarding these registration processes can be found at <http://www.grants.gov>.

V. Application Review Information

1. The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The narrative should include the first year of activities; information for multi-year projects should be included as an appendix (see D. Categorical Budget and Budget Justification at the end of this section for more information). The narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of your organization. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully.

A. Understanding of the Need and Necessary Capacity (30 points)

Applicant should demonstrate knowledge in:

- (1) Health concerns of AI/AN youth.
- (2) Health promotion activities in Tribal communities such as BGCA.
- (3) Working with Tribes and Tribal organizations.

B. Work Plan (20 points)

This section should demonstrate the soundness and effectiveness of the applicant's proposal. The annual work plan should reflect deliverables and milestones of the TRAIL project. The work plan should be designed to:

- (1) Describe how and when the sites will be selected.
- (2) Describe how the sites will be trained on the curriculum and provided technical assistance.
- (3) Describe the plan for collecting data, monitoring, and assuring quality and quantity of data.
- (4) Describe the plan for evaluating and reporting.
- (5) Describe how sites will be supported for a physical activity program with equipment and participant incentives.

Organizational Capabilities and Qualifications (40 points)

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the project outline in the work plan.

- (1) Describe the structure of the organization.
- (2) Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and

financial assistance as well as other grants and projects successfully completed.

- (3) Describe what equipment (i.e., phone, Web sites, etc.) and facility space (i.e., office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased throughout the agreement.

- (4) List key personnel who will work on the project.

a. Identify existing personnel and new program staff to be hired or contracted.

b. In the appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties indicating desired qualifications experience, requirements related to the proposed project and how they will be supervised. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities and who will determine if the work of a contractor is acceptable.

c. Note who will be writing the progress reports.

d. If a position is to be filled, indicate that information on the proposed position description.

e. If the project requires additional personnel beyond those covered by the cooperative agreement funds, (i.e., IT support, volunteers, interviewers, etc.), note these and address how these positions will be filled and, if funds are required, the source of these funds.

f. If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual's salary.

Applicant should demonstrate knowledge in:

- (1) Financial and project management.
- (2) Nationwide experience in providing administrative and support services to Tribal youth organizations, education agencies and other Tribal programs for the benefit of children and youth.

(3) AI/AN youth and Tribal communities. Indicate experience in national partnerships or national support efforts on behalf of AI/AN communities especially as it pertains to health concerns.

(4) Applicant should have at least two years of specialized experience working with Tribal Boys and Girls Club sites and the TRAIL curriculum program.

Categorical Budget and Budget Justification (10 points)

This section should provide a clear estimate of the project program costs and justification for expenses for the

entire cooperative agreement period. The budget and budget justification should be consistent with the tasks identified in the work plan.

(1) Categorical budget (Form SF 424A, Budget Information Non-Construction Programs) completing each of the budget periods requested.

(2) Narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allowability.

(3) Indication of any special start-up costs.

(4) Budget justification should include a brief program narrative for the second and third years.

(5) If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.

2. Review and Selection Process

In addition to the above criteria/requirements, the application will be considered according to the following:

A. *The submission deadline:* April 18, 2008. The application submitted in advance of or by the deadline and verified by the postmark will undergo a preliminary review to determine that:

- (1) The applicant is eligible in accordance with this announcement.
- (2) The application is not a duplication of a previously funded project.

(3) The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the reviewers to undertake an in-depth evaluation; otherwise, it may be returned.

3. Anticipated Award Dates

Anticipated Award Date: May 16, 2008.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) will be initiated by the DGO and will be mailed via postal mail. The NoA will be signed by the Grants Management Officer and this is the authorizing document for which funds are dispersed. The NoA is the legal binding document, will serve as the official notification of the cooperative agreement award and will reflect the amount of Federal funds awarded for the purpose of the cooperative agreement, the terms and conditions of the award, the effective date of the award, and the budget/project period.

2. Administrative Requirements

Grants are administered in accordance with the following documents:

- This Program Announcement.
- 45 CFR part 74, "Uniform Administrative Requirements for Awards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations."
- Grants Policy Guidance: HHS Grants Policy Statement, January 2007.
- "Non-profit Organizations" (title 2, part 230).
- Audit Requirements: OMB Circular A-133, "Audits of States, Local Governments, and Non-profit Organizations."

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the Division of Grants Operations at the time of the award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate is provided to the DGO.

If you have questions regarding the indirect cost policy, please contact the DGO at (301) 443-5204.

4. Reporting

A. Progress Report. Program progress reports are required semiannually. These reports will include a brief comparison of actual accomplishments to the goals established for the period, reasons for slippage (if applicable), and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Status Report. Semi-annual financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget period. Standard Form 269 (long form) will be used for financial reporting.

C. Reports. Grantee is responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due semi-annually. Financial Status Reports (SF-269) are due 90 days after each budget period and the final SF-269 must be verified on how the value was derived. Grantee must submit reports in a reasonable period of time.

Failure to submit required reports within the time allowed may result in suspension or termination of an active agreement, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the organization or the individual responsible for preparation of the reports.

5. Telecommunication for the hearing impaired is available at: TTY 301-443-6394.

VII. Agency Contacts

For program-related information (including TRAIL curriculum): Leeanna Travis, Indian Health Service, 1700 Cerrillos Rd., Santa Fe, New Mexico 87505, (505) 946-9541 or Leeanna.travis@ihs.gov.

For specific grant-related and business management information: Norma Jean Dunne, Grants Management Specialist, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, 301-443-5204 or normajeane.dunne@ihs.gov.

Dated: January 31, 2008.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 08-626 Filed 2-12-08; 8:45 am]

BILLING CODE 4165-16-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health/National Institute of Environmental Health Sciences; Proposed Collection; Comment Request

The Parkinson's, Genes and Environment (PAGE) Study II

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 Environmental Health Sciences (NIEHS), 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.

Proposed Collection: Title: The Parkinson's, Genes and Environment

(PAGE) Study II. **Type of Information Collection Request:** NEW. **Need and Use of Information Collection:** We propose a large case-control study to evaluate roles of environmental exposures, genes, and gene-environment interactions in the etiology of late-onset sporadic Parkinson's disease (PD). This project, the Parkinson's, Genes and Environment Study II (PAGE II), will be developed based on the infrastructure that was set up for the ongoing PAGE I project. PAGE I was designed to prospectively evaluate diet and lifestyle exposures in relation to PD risk. In PAGE I, we expect to recruit approximately 1,200 incident PD cases and 2,800 controls from the NIH-AARP Diet and Health (DH) cohort. The dietary and lifestyle data were collected as part of the NIH-AARP DH baseline surveys in the mid-1990s by investigators from the National Institute of Cancer. The cases in PAGE I were PD cases who reported a physician diagnosed PD during the 10 year follow-up of NIH-AARP DH cohort and controls were appropriately selected by frequency matching from participants without PD in the same cohort. As part of PAGE I, we are confirming PD diagnoses for self-identified PD cases by contacting their neurologists and reviewing medical records and are collecting saliva samples for genetic testing from both cases and appropriately selected controls. As the NIH-AARP DH study was designed to examine dietary and lifestyle exposures important in the etiology of cancer, many environmental exposures key to PD research were not collected. Examples include pesticide use, occupational history, history of infections, and use of statins. Therefore the primary aim of the PAGE II project is to retrospectively collect these important environmental exposures from PD cases and appropriately selected controls. Cases and controls identified from PAGE I will be re-contacted and interviewed for data collection in PAGE II. Assuming a 70% response rate from cases and controls, we expect to obtain this information from approximately 850 PD cases and 1960 controls. This data collection, together with the dietary and lifestyle data and genetic samples obtained in PAGE I, will make the PAGE study one of the largest and most comprehensive studies to date to examine environmental and genetic causes of PD. **Frequency of Response:** One 90 minute long telephone interview. **Affected Public: Individuals.** **Type of Respondents:** We will enroll men and women who participated in the PAGE I study. The annual reporting burden is as