

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 087569	Hydrocortisone Sodium Succinate for Injection USP, EQ 1 g (base)/Vial.	Do.
ANDA 087584	Potassium Chloride for Injection Concentrate USP	Luitpold Pharmaceuticals, Inc.
ANDA 087601	Aminophylline Injection USP, 25 mg/mL	Hospira, Inc.
ANDA 087956	Vitamin K1 (phytonadione injection emulsion USP), 10 mg/mL.	Do.
ANDA 088279	Meperidine HCl Injection USP, 25 mg/mL	Baxter Healthcare Corp.
ANDA 088280	Meperidine HCl Injection USP, 50 mg/mL	Do.
ANDA 088281	Meperidine HCl Injection USP, 75 mg/mL	Do.
ANDA 088282	Meperidine HCl Injection USP, 100 mg/mL	Do.
ANDA 088326	Lidocaine HCl Injection USP, 1.5%	Hospira, Inc.
ANDA 088331	Lidocaine HCl Injection USP, 2%	Do.
ANDA 088368	Lidocaine HCl Injection USP, 20%	Do.
ANDA 088371	Cyclophosphamide for Injection USP, 100 mg/Vial	Baxter Healthcare Corp.
ANDA 088372	Cyclophosphamide for Injection USP, 200 mg/Vial	Do.
ANDA 088373	Cyclophosphamide for Injection USP, 500 mg/Vial	Do.
ANDA 088374	Cyclophosphamide for Injection USP, 1 g/Vial	Do.
ANDA 089649	Lidocaine HCl and Epinephrine Injection	Hospira, Inc.
ANDA 089703	Prochlorperazine Edisylate Injection USP, EQ 5 mg (base)/mL.	Do.
ANDA 089707	Perphenazine Tablets USP, 2 mg	Ivax Pharmaceuticals Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 090954	Cromolyn Sodium Oral Solution Concentrate, 100 mg/5 mL.	Pack Pharmaceuticals, LLC, 1110 West Lake Cook Rd., suite 152, Buffalo Grove, IL 60089.

¹ This product was an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any metaproterenol sulfate or fluticasone propionate metered-dose inhalers (see 75 FR 19213–19241, April 14, 2010; 71 FR 70870–70873, December 7, 2006).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in table 1 of this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 8, 2011. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 of this document that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 31, 2011.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Division of Epidemiology and Disease Prevention; Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: New.

Funding Opportunity Number: HHS–2011–IHS–EPI–0001.

Catalog of Federal Domestic Assistance Number: 93.231

DATES: *Key Dates:*

Application Deadline Date: July 15, 2011;

≤Review Date: August 16–17, 2011;

Anticipated Start Date: September 16, 2011.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications to establish Tribal Epidemiology Centers serving American Indian/Alaska Native (AI/AN) Tribes and urban Indian communities. This program is managed by the IHS Division of Epidemiology and Disease Prevention (DEDP). This program is authorized under the Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1621m of the

Indian Health Care Improvement Act. To obtain details regarding eligibility, please refer to Section III below.

Background

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1998 as a way to provide public health support to multiple Tribes and urban Indian communities in each of the IHS Areas. The funding opportunity announcement is open to eligible Tribes, Tribal organizations, intertribal consortia, and urban Indian organizations, including currently funded TECs.

TECs are uniquely positioned within Tribes, Tribal and urban Indian organizations to conduct disease surveillance, research, prevention and control of disease, injury, or disability, and to assess the effectiveness of AI/AN public health programs. In addition, they can fill gaps in data needed for Government Performance and Results Act (GPRA) and Healthy People 2020 measures. Some of the existing TECs have already developed innovative strategies to monitor the health status of Tribes and urban Indian communities, including development of Tribal health registries and use of sophisticated record linkage computer software to correct existing state data sets for racial misclassification. TECs work in partnership with IHS DEDP to provide a more accurate national picture of Indian health status.

TECs provide critical support for activities that promote Tribal self-governance and effective management of Tribal and urban Indian health programs. Data generated locally and analyzed by TECs enable Tribes and urban Indian communities to effectively plan and make decisions that best meet the needs of their communities. In addition, TECs can immediately provide feedback to local data systems which will lead to improvements in Indian health data overall.

As more Tribes choose to operate health programs in their communities, TECs ultimately will provide additional public health services such as disease control and prevention programs. Some existing centers provide assistance to Tribal and urban Indian communities in such areas as sexually transmitted disease control and cancer prevention. They also assist Tribes and urban Indian communities to establish baseline data for successfully evaluating intervention and prevention activities through activities such as conducting Behavioral Risk Factor Surveillance Surveys (BRFSS).

The TEC program will continue to enhance the ability of the Indian health system to collect and manage data more effectively and to better understand and develop the link between public health problems and behavior, socioeconomic conditions, and geography. The TEC program will also support Tribal and urban Indian communities by providing technical training in public health practice and prevention-oriented research and by promoting public health career pathways.

Purpose

The purpose of this cooperative agreement program is to fund Tribes,

Tribal and urban Indian organizations, and intertribal consortia to provide epidemiological support for the AI/AN population served by IHS. TEC activities should include, but are not limited to, enhancement of surveillance for disease conditions; research, prevention and control of disease, injury, or disability; assessment of the effectiveness of AI/AN public health programs; epidemiologic analysis, interpretation, and dissemination of surveillance data; investigation of disease outbreaks; development and implementation of epidemiologic studies; development and implementation of disease control and prevention programs; and coordination of activities of other public health authorities in the region. It is the intent of IHS to fund several TECs that will serve Tribes and urban Indian communities in all 12 IHS Administrative Areas.

Each TEC selected for funding will act under a cooperative agreement with the IHS. During funded activities, the TECs may receive Protected Health Information (PHI) for the purpose of preventing or controlling disease, injury or disability, including, but not limited to, reporting of disease, injury, vital events, such as birth or death, and the conduct of public health surveillance, public health investigation, and public health interventions for the Tribal and urban Indian communities that they serve. TECs acting under a cooperative agreement with IHS are public health authorities for which the disclosure of PHI by covered entities is authorized by the Privacy Rule. 45 CFR 164.512(b).

To achieve the purpose of this program, the recipient will be responsible for the activities under item number 1. Recipient Activities and IHS will be responsible for conducting

activities under item number 2. IHS Activities.

II. Award Information

Type of Award: Cooperative Agreement.

Estimated Funds Available:

The total amount identified for FY 2011 is approximately \$4.5 million. Competing and continuation awards issued under this announcement are subject to the availability of funds. In the absence of funding, the agency is under no obligation to fund any awards under this announcement. The program will be awarded for five years with 12 months per budget period. Future year funding levels will be determined based on availability of funds. The average award is approximately \$350,000 to \$1,000,000, depending on the applicant's score and the size of the area covered by the TEC.

Anticipated Number of Awards:

Approximately 12 awards may be issued under this program announcement.

Project Period:

This will be a 5-year project from September 16, 2011 to September 15, 2016.

Funding Information:

As part of an effort to establish TECs throughout the nation, these funds will be used to support activities on an IHS Area basis. Successful applicants must agree to provide services for all AI/AN populations in the respective IHS Area. Collaborative efforts among Tribal, local, State, and Federal health organizations are encouraged.

Funding will be based on scoring levels from the review process. An example is outlined below. Detailed explanations of Review Criteria are described in Section V.

Review Criteria	Total Points	Points Awarded
Introduction, Current Capacity, and Need for Assistance	25
Program Objectives-Recipient Activities	35
Program Evaluation	10
Organizational Capabilities & Qualification	10
Behavioral Risk Factor Surveillance Surveys	15
Budget	5
Total	100

Cooperative Agreements will be funded annually during the project period of five years, contingent on required continuation applications with an approved scope of work. Renewals of cooperative agreements will be based on the following:

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- Satisfactory progress.
- Availability of funds.

- Program priorities of IHS. Programmatic Involvement: IHS will have substantial involvement in all of the TECs (See IHS Activities).

- Recipient Activities:
 - a. Assist and facilitate AI/AN communities, Tribes, Tribal organizations, and urban Indian organizations in identifying Tribal and urban Indian community health status

priorities for building public health capacity at the local level based on epidemiologic data. Assist and facilitate Tribal and urban Indian communities with implementing and conducting disease surveillance, research, prevention and control of disease, injury, or disability, to assess the effectiveness of AI/AN public health programs, monitoring progress toward

meeting each of the health status objectives, developing and implementing epidemiologic studies that have practical application in improving the health status of constituent communities, reporting of notifiable disease conditions to public health authorities and to local Tribes and urban Indian communities in the region, and address emerging public health and epidemiological issues as identified by Tribal and urban Indian community priorities.

b. Develop and disseminate health specific data and Community Health Profiles (CHPs) based on Tribal and urban Indian community health status priorities as follows:

1. Develop CHPs specific for each Tribal and urban Indian community entity served by the TEC. Provide a dissemination plan that includes a project overview, dissemination goals, and health indicators.

2. Develop a regional CHP encompassing all Tribal and urban Indian communities served by the TEC. Provide a dissemination plan that includes a project overview, dissemination goals, and health indicators.

3. Participate in the national TEC CHP Working Group to develop and implement a national CHP.

c. Recipient will need to maintain outbreak response capacity by:

1. Establishing and maintaining relationships with local authorities (Tribal, County, State, etc.) to be able to participate in outbreak response activities on a national or regional scope.

2. Obligating a minimum of one program staff per year to attend IHS training in either the "Outbreak Response Review" or "Epidemiology Ready" course.

3. Explaining how recipient will collaborate and assist in public health emergencies with the IHS, DEDP, State, local, County, Tribal, and other Federal health authorities.

d. Develop a BRFSS project to evaluate health risk behaviors of AI/AN populations served by the TEC, to include, at a minimum, CDC's "core" BRFSS, as follows:

1. Develop a protocol for conducting the BRFSS;

2. Develop a sampling method and recruitment strategy;

3. Meet with the Tribal Health Director, Health Board, and/or the Tribal Council, as appropriate, for review and approval of the BRFSS project;

4. Obtain IRB approval or exempt status;

5. Develop a training protocol for interviewers for the BRFSS;

6. Develop a database to enter data collected from the BRFSS;

7. Develop a dissemination plan that includes a project overview, dissemination goals, targeted audiences, key messages, details of the dissemination plan and how the plan will be evaluated; and

8. Create a separate budget for the BRFSS project.

e. Establish a Data Sharing Agreement (DSA) with the IHS Area Office that delineates:

1. "Routine" activities for which the TEC will have access to de-identified data from IHS Epidemiology Data Mart/ National Data Warehouse (NDW).

2. Activities for which they will need additional permission such as special studies or research involving PHI.

3. Language which outlines compliance with Health Insurance Portability and Accountability Act (HIPAA) and Privacy Act protection.

4. Use of the IHS Epidemiology Data Mart User Tracking System (EDMUTS) by the recipient to track both #1 and #2 above.

5. Use of security measures, including:

- How security measures will be in place for data usage;
- How recipient will be a steward of the data;

- Completion of the IHS/OIT yearly security training and security training required by their respective organization; and

- An annual report on the outcomes of TECs access to IHS data.

f. Participate in national public health priorities and committees, as appropriate, with additional Department of Health and Human Services (HHS) agencies.

g. Explain how recipient will support the IHS Agency's priorities:

1. To renew and strengthen our partnership with Tribes.

2. To bring reform to IHS.

3. To improve the quality of and access to care.

4. To make all our work accountable, transparent, fair and inclusive.

You may access information on IHS priorities via the Internet at the following Web site: <http://www.ihs.gov/PublicAffairs/DirCorner/index.cfm>.

h. Establish an advisory council that can provide overall program direction and guidance. The advisory council should include some members with technical expertise in epidemiology and public health (i.e. state health departments, county health departments, etc.) and representation from the Tribal health and urban Indian health programs served by the TEC.

i. Provide an annual report (no more than 10 pages) at the end of each project year to DEDP.

j. Ensure that TEC staff includes key personnel with appropriate expertise in epidemiology, health sciences, and program management. The TEC must also demonstrate access to specialized expertise such as a doctoral level epidemiologist and/or a biostatistician.

IHS Activities:

a. Provide funded TECs with ongoing consultation and technical assistance to plan, implement, and evaluate each component of the TEC as described under Recipient Activities above. Consultation and technical assistance will include, but not be limited to, the following areas:

1. Interpretation of current scientific literature related to epidemiology, statistics, surveillance, Healthy People 2020 objectives, and other public health issues;

2. Design and implementation of each program component such as surveillance, epidemiologic analysis, outbreak investigation, development of epidemiologic studies, development of disease control programs, and coordination of activities; and

3. Overall operational planning and program management.

b. Coordinate all IHS epidemiologic activities on a national scope including investigation of disease outbreaks and CHPs.

c. Conduct site visits to TECs and/or coordinate TEC visits to IHS to ensure data security; confirm compliance with applicable laws and regulations; assess program activities; and to mutually resolve problems, as needed.

d. Convene an annual TEC meeting for information sharing, problem solving or training.

e. Provide opportunities for training of TEC staff. Examples include: IHS Outbreak Response Review course; Webinars on NDW Technical Assistance; Introduction to SAS; Fellowship opportunities.

III. Eligibility Information

1. Eligibility

AI/AN Tribes, Tribal organizations, and eligible intertribal consortia or urban Indian organizations as defined by 25 U.S.C. 1603(e) may be eligible for a TEC cooperative agreement. Such entities must represent or serve a population of at least 60,000 AI/AN to be eligible as demonstrated by Tribal resolutions or the equivalent documentation from urban Indian clinic directors/Chief Executive Officers (CEOs). Applicants must describe the population of AI/ANs and Tribes that

will be represented. The number of AI/ ANs served must be substantiated by documentation describing IHS user populations, United States Census Bureau data, clinical catchment data, or any method that is scientifically and epidemiologically valid. An intertribal consortium or urban Indian organization is eligible to receive a cooperative agreement if it is incorporated for the primary purpose of improving AI/AN health, and represents the Tribes, AN villages, or urban Indian communities in which it is located. Resolutions from each Tribe, AN village and equivalent documentation from each urban Indian community represented must be included in the application package. Collaborations with IHS Areas, Federal agencies such as the Centers for Disease Control and Prevention (CDC), State, academic institutions or other organizations are encouraged (letters of support and collaboration should be included in the application).

Definitions:

Federally-recognized Indian Tribe means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601, *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. 25 U.S.C. 1603 (d).

Tribal organization means the elected governing body of any Indian Tribe or any legally established organization of Indians which is controlled by one or more such bodies or by a board of directors elected or selected by one or more such bodies or elected by the Indian population to be served by such organization and which includes the maximum participation of Indians in all phases of its activities. 25 U.S.C. 1603(e).

Urban Indian organization means a non-profit corporate body situated in an urban center governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities. 25 U.S.C. 1603(h).

An intertribal consortium or AI/AN organization is eligible to receive a cooperative agreement if it is incorporated for the primary purpose of improving AI/AN health. Collaborations with regional IHS, CDC, State and local health departments, and academic

institutions are encouraged. Proper tribal resolutions or equivalent documentation from urban Indian organizations is required.

2. Cost Sharing or Matching

DEDP does not require matching funds or cost sharing.

3. Other Requirements

(a) If an applicant's budget exceeds the highest stated award amount that is outlined within this announcement (\$1,000,000.00), that application will not be considered for funding.

(b) A letter of intent is required (See section IV(3)).

(c) Tribal Resolution—A resolution of all Indian Tribes served by the project must accompany the application submission. This can be attached to the electronic application. An Indian Tribe that is proposing a project with other Indian Tribes must include resolutions from all Tribes to be served.

Applications by Tribal organizations representing multiple Tribes will not require specific Tribal resolutions if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities. Draft resolutions are acceptable in lieu of an official resolution. However, all official signed Tribal resolutions must be received by the Division of Grants Management (DGM) prior to the beginning of the Objective Review. If official signed resolutions are not received by August 15, 2011, the application will be considered incomplete, ineligible for review, and returned to the applicant without further consideration. Applicants submitting additional documentation after the initial application submission are required to ensure the information was received by the IHS by obtaining documentation confirming delivery (i.e. FedEx tracking, postal return receipt, etc.).

(d) Urban Indian clinic director/CEO equivalent Letter of Support (LoS)—a LoS from the Clinic Director or CEO of all urban Indian clinics served by the TEC must be provided.

(e) Tribal resolutions supportive of the epidemiology cooperative agreement proposal from the Indian Tribe(s) or urban Indian clinic director/CEO equivalent LoS served by the project must accompany the application and the applicant must demonstrate how these documents meet the minimum requirement of 60,000 AI/AN population to be eligible for the cooperative agreement.

(f) Applications with established data sharing agreements (DSAs) or statements acknowledging the

importance of future DSAs from IHS/ Tribal/Urban Indian (I/T/Us) will be given priority in scoring. Likewise, applicants with established DSAs with respective IHS Area Offices will be given priority in scoring. DSAs will be scored within the "Program Objectives" (See Review Criteria in Section II).

(g) Non-profit organizations must provide proof of non-profit status. The applicant must submit a current valid Internal Revenue Service (IRS) tax exemption certificate or a copy of the 501(c)(3) form, as proof of status.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and instructions may be located at <http://www.Grants.gov> or http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_funding.

2. Content and Form Application Submission

Documents for all applications include:

- Application forms:
 - SF-424.
 - SF-424A.
 - SF-424B.
- Table of Contents.
- Program Executive Summary (one page or less).
- Program Narrative (must not exceed 10 single-spaced pages. See Section IV(2)(a)).
- Line-item budget.
- Budget narrative (must be single-spaced).
- Program Objectives(s) to include a spreadsheet with Objective Time-Line, Approach, and Results & Benefits.
- Applicant's organizational capabilities addressing Recipient's Activities.
- Organizational chart.
- Position Descriptions and Biographical sketches for all key personnel.
- Data Sharing Agreements (if applicable).
- Tribal Resolutions or equivalent from urban Indian clinic directors/CEOs.
- Letters of support from collaborating agencies.
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Map of the areas to benefit from the program.
- Disclosure of Lobbying Activities (SF-LLL).
- Documentation of current OMB A-133 required Financial Audit.

Acceptable forms of documentation include:

- E-mail confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Website: <http://harvester.census.gov/fac/dissemin/accessoptions.html?submit=Retrieve+Records>

Policy Requirements: All Federal-wide public policies apply to IHS grantees with exception of the Discrimination policy. See attached link for all public policies. <http://www.acf.hhs.gov/programs/ofis/grants/sf424b.pdf>

Requirements for Program and Budget Narratives

A. Program Narrative: This narrative should be a separate Word document that is no longer than 10 pages, single-spaced (see page limitations for each Part noted below) with consecutively numbered pages. If the narrative exceeds the page limit, only the first 10 pages will be reviewed. There are three parts to the narrative:

Section 1: Program Information—(2 Pages)

- (1) Introduction and organizational capabilities.
- (2) Need for assistance.

(3) User Population.

Section 2: Recipient Activities: Program Planning and Evaluation—(6 Pages)

(1) Program Plans. (2) Program Evaluation. Section 3: Program Report—(2 pages) (1) Describe major accomplishments over the last 24 months. (2) Describe major activities over the last 24 months.

B. Budget Narrative: This narrative must describe the budget requested and match the program plans and evaluation described in the program narrative.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by Friday, July 15, 2011 at 12 a.m. midnight Eastern Time. Any application received after the application deadline will not be accepted for processing, and it will be returned to the applicant(s) without further consideration for funding.

Letters of Intent: A Letter of Intent (LoI) is required from each entity that plans to apply for funding under this announcement. The LoI must be submitted to the Division of Grants Management to the attention of Andrew Diggs by June 10, 2011. Please submit

all letters of intent via fax (301) 443-9602. Your LoI must reference the funding opportunity number, application deadline date, and your eligibility status. The letter must be signed by the authorized organizational official within your entity.

4. Intergovernmental Review

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

5. Funding Restrictions

- Pre-award costs are not allowable for this announcement.
- The available funds are inclusive of direct and appropriate indirect costs.

6. Electronic Submission

Use the <http://www.Grants.gov> Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov website. Electronic copies of the application may not be submitted as attachments to e-mail messages addressed to IHS employees or offices.

Please search for the application package in Grants.gov by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.

After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download your application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the DEDP will notify applicants that the application has been received.

Applicants that do not adhere to the timelines for Central Contractor Registry (CCR) and/or Grants.gov registration and/or request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Technical Challenges:

- If technical challenges arise and assistance is required with the electronic application process, contact the Grants.gov Customer Support via e-mail at support@grants.gov or at (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Paul Gettys, DGM () at (301) 443-5204. Paul.Gettys@ihs.gov

• Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

• Please be sure to contact Mr. Gettys at least ten days prior to the application deadline.

Paper Submission (Waiver Requirements):

Paper applications are not the preferred method for submitting applications. If an applicant needs to submit a paper application instead of submitting electronically via Grants.gov, prior approval must be requested and obtained from the DGM. The waiver request must be documented in writing (e-mails are acceptable), before submitting a paper application. A copy of the written approval must be submitted along with the hardcopy application that is mailed to the DGM. The mailing address for your paper application will be included in your approved waiver request. Paper applications that are submitted without an approved waiver will be returned to the applicant without review or further consideration. Late applications will not be accepted for processing or considered for funding and will be returned to the applicant. Applicants that receive a waiver to submit paper application documents must follow the rules and timelines of this funding announcement. The applicant must seek assistance at least ten days prior to the application deadline.

• If it is determined that a waiver is needed, you must submit a request in writing (e-mails are acceptable) to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Please include a clear justification for the need to deviate from our standard electronic submission process.

• If the waiver is approved, the application should be sent directly to the DGM by the deadline date of July 15, 2011.

• Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov could take up to fifteen working days.

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

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the CCR database. Additionally, all IHS grantees must notify potential first-tier subrecipients

that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee organization. These requirements will ensure use of a universal identifier to enhance the quality of information available to the public. On October 1, 2010 recipients began to report information on subawards, as required by the Federal Funding Accountability and Transparency Act of 2006, as amended (“the Transparency Act”). The DUNS number is a unique nine digit identification number provided by D&B, which uniquely identifies your entity. The DUNS number is site specific; therefore each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, you may access it through the following website <http://fedgov.dnb.com/webform> or to expedite the process, call (866) 705-5711.

Central Contractor Registry (CCR)

Organizations that have not registered with CCR will need to obtain a DUNS number first and then access the CCR online registration through the CCR home page at <https://www.bpn.gov/ccr/default.aspx> (U.S. organizations will also need to provide an Employer Identification Number from the IRS that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour and your CCR registration will take approximately 3–5 business days to process. Registration with the CCR is free of charge. Applicants may register online at <http://www.ccr.gov>. Additional information on implementing the Transparency Act, including the specific requirements for DUNS and CCR, can be found on the IHS Grants Policy website: http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_policy_topics.

V. Application Review Information

Evaluation criteria will be used in reviews of applications. Points will be assigned to each evaluation criterion adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned to the extent that the applicant is able to demonstrate that they met the following criteria.

A. Evaluation Criteria: Program Narrative

(1) Introduction, Current Capacity, and Need for Assistance (25 Points)

a. Describe the applicant’s current public health activities including

whether the applicant has an adequate health department, how long it has been operating, what programs or services are currently provided, and interactions with other public health authorities in the regions (State, local, or Tribal), how long it has been operating, and what programs or services are currently provided. Specifically describe current epidemiologic capacity and history of support for such activities.

b. Provide a physical location of the TEC and area to be served by the proposed program including a map (include the map in the attachments), and specifically describe the office space and how it is going to be paid for.

c. If applicable, identify the past three years of grants relevant to public health and/or epidemiology, including past awarded cooperative agreements from the DEDP, dates of funding, and key project accomplishments (do not include copies of reports).

(2) Program Objective(s) (35 Points)

Approach, Results and Benefits for the entire 5-year funding period by year.

a. State in measurable and realistic terms the objectives and appropriate activities to achieve each objective for the projects as listed in the Recipient Activities.

b. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

c. Include a work-plan for each objective that indicates when the objectives and major activities will be accomplished and who will conduct the activities by each year for the entire five-year period.

(3) Program Evaluation (10 Points)

a. Define the criteria to be used to evaluate activities listed in the work-plan under the Recipient Activities and BRFSS project.

b. Explain the methodology that will be used to determine if the needs identified for the objectives are being met and if the outcomes identified are being achieved.

c. Describe how evaluation findings will be disseminated to stakeholders.

(4) Organization Capabilities and Qualifications (10 Points)

a. Explain the management and administrative structure of the organization including documentation of current certified financial management systems either from the Bureau of Indian Affairs, IHS, or a Certified Public Accountant and an updated organizational chart (include chart in the attachments).

b. Describe the ability of the organization to manage a program of the proposed scope.

c. Provide position descriptions and biographical sketches of key personnel, including those of consultants or contractors in the Appendix. Position descriptions should very clearly describe each position and its duties, indicating desired qualification and experience requirements related to the project. Resumes should indicate that the proposed staff is qualified to carry out the project activities. Applicants with expertise in epidemiology will receive priority.

(5) Behavioral Risk Factor Surveillance System (BRFSS) (15 Points)

a. Describe the BRFSS project specifically for AI/AN populations to evaluate the health risk behaviors to include, at a minimum, CDC’s “core” BRFSS.

b. Identify a statistically representative sample of Tribal and urban communities that will participate in the BRFSS.

c. Describe how the applicant will define and complete the following items as part of their proposal: develop a protocol for conducting the BRFSS; develop a sampling method and recruitment strategy; meet with the Tribal Health Director, Health Board, and Tribal Council for review and approval; submit protocols for IRB review; select and train interviewers for the BRFSS.

d. Describe how to develop a data base to enter data collected on the BRFSS.

e. Provide a dissemination plan that includes a project overview, dissemination goals, targeted audiences, key messages, details of the dissemination plan and evaluation.

f. Complete a separate budget for the BRFSS project.

(6) Budget (5 Points)

a. Provide a categorical budget by line item and by each year for the entire five-year period, including a separate budget for the BRFSS project.

b. Provide a justification by line item in the budget including sufficient cost and other details to facilitate the determination of cost allowability and relevance of these costs to the proposed project. The funds requested should be appropriate and necessary for the scope of the project.

c. If use of consultants or contractors are proposed or anticipated, provide a detailed budget and scope of work that clearly defines the deliverables or outcomes anticipated.

B. Review and Selection Process

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the Objective Review Committee (ORC).

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation. Applicants that receive less than a minimum score and/or are incomplete will be considered to be "Disapproved" and will be informed via e-mail or regular mail by the IHS Program Office of their application's deficiencies. A summary statement outlining the strengths and weaknesses of the application will be provided to each disapproved applicant. The summary statement will be sent to the Authorized Organizational Representative (AOR) that is identified on the face page of the application within 60 days of the completion of the objective review.

Award Date(s): September 16, 2011.

The DEDP will recommend successful applicants for funding based on the results of the objective review.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) will be initiated by DGM and will be mailed via postal mail or e-mailed to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer and is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is the legally binding document and is signed by an authorized grants official within the IHS.

2. Administrative Requirements

Grants are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- 45 CFR, part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments.
- 45 CFR, part 74, Uniform Administrative Requirements for

Awards and Subawards to institutions of Higher Education, Hospitals, Other Non-profit Organizations, and Commercial Organizations.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Title 2: Grants and Agreements, Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB A-87).

- Title 2: Grants and Agreements, Part 230—Cost Principles for Non-Profit Organizations (OMB Circular A-122).

E. 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 obtain a current indirect cost rate agreement 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 covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the indirect cost portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation <http://rates.psc.gov/> and the Department of Interior (National Business Center) <http://www.aqd.nbc.gov/services/ICS.aspx>. If your organization has questions regarding the indirect cost policy, please call (301) 443-5204 to request assistance.

4. Reporting Requirements

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, 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 requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual

responsible for preparation of the reports.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. These reports will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report, (FFR- SF-425), Cash Transaction Reports are due every calendar quarter to the Division of Payment Management, Payment Management Branch, HHS at: <http://www.dpm.gov> Failure to submit timely reports may cause a disruption in timely payments to your organization.

Grantees are responsible and accountable for accurate information being reported on all required reports; the Progress Reports, Financial Status Reports and Federal Financial Report.

C. Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR Part 170.

The Transparency Act requires the Office of Management and Budget to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards.

Effective as of October 1, 2010, IHS implemented new Terms of Award. All New (Type 1) IHS grant and cooperative agreement awards issued on or after October 1, 2010 may be subject to the Transparency Act Subaward and Executive Compensation reporting requirements. Additionally, all IHS Renewal (Type 2) grant and cooperative agreement awards and Competing Revision awards (Competing T-3s) issued on or after October 1, 2010 may also be subject to the following award term. Further guidance on Renewal and Competing Revision awards is expected to be provided as it becomes available.

Please visit the IHS Grants Policy Web site at <https://www.ihs.gov/NonMedical>

Programs/gogp for additional information on award applicability information.

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

VII. Agency Contacts

For program-related information: Selina T. Keryte, Project Officer, Division of Epidemiology & Disease Prevention, Indian Health Service, 5300 Homestead NE, Albuquerque, NM 87110, (505) 248-4132 or Selina.keryte@ihs.gov.

For specific grant-related and business management information: Andrew Diggs, Grants Management Specialist, Division of Grants Management, Indian Health Service, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, (301) 443-2262 or Andrew.diggs@ihs.gov.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: May 31, 2011.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2011-14131 Filed 6-7-11; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the

competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Basic Sciences National Cancer Institute.

Date: July 11, 2011.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

Contact Person: Florence E. Farber, PhD, Executive Secretary, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2205, Bethesda, MD 20892, 301-496-7628, ff6p@nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/bsc/bs/bs.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 31, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-14161 Filed 6-7-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance

with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology, National Cancer Institute.

Date: July 12, 2011.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes Of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

Contact Person: Brian E. Wojcik, PhD, Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, 6116 Executive Boulevard, Room 2201, Bethesda, Md 20892, (301) 496-7628, wojcikb@mail.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.deainfo.nci.nih.gov/advisory/bsc.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 31, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-14158 Filed 6-7-11; 8:45 am]

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