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Information Collection Request Title: Positive Adolescent Futures (PAF) Study

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Positive Adolescent Futures (PAF) Study will provide information about program design, implementation, and impacts through a rigorous assessment of program impacts and implementation of two programs designed to support expectant and parenting teens. These programs are located in Houston, Texas and throughout the state of California. This revised information collection request includes the 24-month follow-

up survey instrument related to the impact study. The data collected from this instrument in the two study sites will provide a detailed understanding of program impacts about two years after youth are enrolled in the study and first have access to the programming offered by each site.

Need and Proposed Use of the Information: The data will serve two main purposes. First, the data will be used to determine program effectiveness by comparing outcomes on repeat pregnancies, sexual risk behaviors, health and well-being, and parenting behaviors between treatment (program) and control youth. Second, the data will be used to understand whether the programs are more effective for some youth than others. The findings from these analyses of program impacts will

be of interest to the general public, to policymakers, and to organizations interested in supporting expectant and parenting teens.

Likely Respondents: The 24-month follow-up survey data will be collected through a web-based survey or through telephone interviews with study participants; *i.e.* adolescents randomly assigned to a program for expectant and parenting teens being tested for program effectiveness, or to a control group. The mode of survey administration will primarily be based on the preference of the study participants. The survey will be completed by 1,515 respondents across the two study sites. Clearance is requested for three years.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
24-month follow-up survey of impact study participants	505	1	.5	252.5
Total	252.5

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

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

Announcement Type: Competing Continuation

Funding Announcement Number: HHS-2016-IHS-EPI-0001

Catalog of Federal Domestic Assistance Number: 93.231

Key Dates

Application Deadline Date: June 21, 2016

Review Date: July 11-15, 2016

Earliest Anticipated Start Date:

September 15, 2016

Signed Tribal Resolutions Due Date: June 21, 2016

Proof of Non-Profit Status Due Date: June 21, 2016

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for 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 by the Indian Health Care Improvement Act (IHCA), as amended, 25 U.S.C. 1621m, the Snyder Act, 25 U.S.C. 13, and described in the Catalog of Federal Domestic Assistance (CFDA) under 93.231.

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, Indian 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 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 (BRFS).

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 is to strengthen public health capacity and to fund Tribes, Tribal and urban Indian organizations, and intertribal consortia in identifying relevant health status indicators and priorities using sound epidemiologic principles. Work-plans submitted in response to this announcement must incorporate the grantee's desired objectives and demonstrate at minimum, four of the seven TEC core functional areas as outlined in the Indian Health Care Improvement Act (IHCIA) at 25 U.S.C. 1621m(b). Below is a list of the seven core functions of the TECs:

(1) Collect data relating to, and monitor progress made toward meeting, each of the health status objectives of the Service, the Indian Tribes, Tribal organizations, and urban Indian organizations in the service area;

(2) Evaluate existing delivery systems, data systems, and other systems that impact the improvement of Indian health;

(3) Assist Indian Tribes, Tribal organizations, and urban Indian organizations in identifying highest-priority health status objectives and the services needed to achieve those

objectives, based on epidemiological data;

(4) Make recommendations for the targeting of services needed by the populations served;

(5) Make recommendations to improve health care delivery systems for Indians and urban Indians;

(6) Provide requested technical assistance to Indian Tribes, Tribal organizations, and urban Indian organizations in the development of local health service priorities and incidence and prevalence rates of disease and other illness in the community; and

(7) Provide disease surveillance and assist Indian Tribes, Tribal organizations, and urban Indian communities to promote public health.

As grantees develop their desired objectives addressing a minimum of four of the core functions as outlined in IHCIA, grantees may include but are not limited to the following activities: 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 sufficient TECs to 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 letter B. Grantee Cooperative Agreement Award Activities. Program Office will be responsible for activities under letter A. IHS Programmatic Involvement.

Pre-Conference Grant Requirements

The awardee is required to comply with the "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications," dated December 16, 2013 ("Policy"), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at <http://www.hhs.gov/grants/contracts/contract-policies-regulations/conference-spending/>.

The awardee is required to:

Provide a separate detailed budget justification and narrative for each conference anticipated. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, (8) Other (explain in detail and cost breakdown). For additional questions, please contact Selina Keryte, Program Officer at 301-443-7064 or email her at selina.keryte@ihs.gov.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2016 is approximately \$4.4 million. Individual award amounts are anticipated to be between \$350,000 and \$1,000,000 annually. The amount of funding available for the competing continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 12 awards will be issued under this program announcement.

Project Period

The project period is for five years and will run consecutively from September 30, 2016 to September 29, 2021.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement

in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and each grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) Provide funded TECs with ongoing consultation and technical assistance to plan, implement, and evaluate each component as described under Recipient Activities. Consultation and technical assistance may include, but not be limited to, the following areas:

(a) Interpretation of current scientific literature related to epidemiology, statistics, surveillance, Healthy People 2020 and 2030 objectives, and other public health issues;

(b) 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

(c) Overall operational planning and program management.

(2) Coordinate all IHS epidemiologic activities on a national scope including development and management of disease surveillance systems, generation of related reports, and investigation of disease outbreaks.

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

(4) Participate in annual TEC meeting for information sharing, problem solving, or training.

(5) Provide training in the use of data from the Epidemiology Data Mart (EDM) for purposes of creating reports for disease surveillance, epidemiologic analysis, and epidemiologic studies. Training can be provided online, or at the request of the grantee onsite.

(6) Coordinate opportunities for training of TEC staff where applicable. Examples include IHS Outbreak Response Review course, webinars on the Epi Data Mart and data use, technical assistance, use of statistical software, and fellowship opportunities.

B. Grantee Cooperative Agreement Award Activities

(1) Collect data relating to, and monitor progress made toward meeting,

each of the health status objectives of the service, the Indian Tribes, Tribal organizations, and urban Indian organizations in the Service area.

(a) Establish culturally appropriate community health assessments to allow Tribal and urban Indian leaders to make informed decisions, prioritize health problems, and develop, implement, and evaluate community health improvement plans. Examples of the health reports could include stakeholder health assessments, profile data or any other data reports.

(b) Establish a Data Sharing Agreement (DSA) with the IHS Area Office to facilitate access to IHS electronic health record data that facilitates:

1. "Routine" activities for which the TEC will have access to de-identified data from IHS EDM.

2. Activities for which TECs will need additional permission for access and use of IHS data, such as special studies or research involving personal identifiers.

3. Complies with the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Act, and related practices to ensure sufficient stewardship of shared data.

4. Training requirements that must be met for initial and continued data access, such as periodic privacy and security procedures training.

5. For TECs that receive EDM data, annual reporting on data use, number and types of data products produced (e.g., reports, publications, presentations), and impacts of EDM data use and products on established health status objectives is required.

(2) Evaluate existing delivery systems, data systems, and other systems that impact the improvement of Indian health.

(a) Evaluations can address but are not limited to availability of health care resources, impacts of the Affordable Care Act, access to care, quality of care, health impact assessment, patient satisfaction, and the availability and capacity of providers.

(3) Assist Indian Tribes, Tribal organizations, and urban Indian organizations in identifying highest-priority health status objectives and the services needed to achieve those objectives, based on epidemiological data.

(9a) Develop relevant Community Health Profiles (CHPs) for Tribal and urban Indian communities served by the TEC within the geographical area of responsibility.

1. Establish CHPs specific for each Tribal or urban Indian community entirely served by the TECs.

2. Establish a regional CHP encompassing all the Tribal, and/or urban Indian communities served by the TEC.

3. Provide a plan that includes a project overview, specific health indicators, and means of dissemination for both Tribe-specific and regional CHPs.

(b) Participate in local, regional and national committees that address public health priorities and, as appropriate, with other Federal agencies.

(c) Establish and maintain 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 (e.g., from state health departments or county health departments) and representation from the Tribal health and urban Indian health programs within the TECs regional area.

(4) Make recommendations for the targeting of services needed by the populations served.

(a) Translate available data and/or results of analyses on disease incidence/prevalence and determined risk factors into useful products, messaging, and outreach to effectively guide stakeholders' interventions addressing public health priorities.

(5) Make recommendations to improve health care delivery systems for Indians and urban Indians.

(6) Provide technical assistance to Indian Tribes, Tribal organizations, and urban Indian organizations in the development of local health service priorities and incidence and prevalence rates of disease and other illness in the community.

(a) Provide culturally appropriate training based on the needs of Indian Tribes, Tribal organizations, and urban Indian organization served. Topics may include but are not limited to program evaluation, data analysis, data quality, survey design and administration, program planning, community health assessment, and outbreak response.

(b) Establish an outbreak response capacity.

1. Explain how the TEC will establish and maintain relationships with other public health authorities (e.g., Tribal, county, state) in order to facilitate collaborative outbreak response activities at the local or on a national or regional level.

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

3. Explain how the TEC will collaborate and assist in public health

emergencies with the IHS, DEDP, State, local, county, Tribal and other Federal authorities.

(7) Provide disease surveillance and assist Indian Tribes, Tribal organizations, and urban Indian organizations to promote public health.

(a) Enhance or develop disease surveillance systems. Surveillance systems can address infectious and chronic diseases, record linkage studies to improve existing surveillance systems, suicide data tracking, regional health registries, influenza surveillance, among others.

(b) Develop and implement at least one Tribal and/or urban Indian BRFS survey to evaluate health risk behaviors of AI/AN populations served by the TECs, to include at minimum:

1. Protocol development that includes interview trainings, sampling method and recruitment strategy;

2. Database development to house data collected from the BRFS;

3. A dissemination plan that includes a project overview, dissemination goals, targeted audiences, key messages, and project evaluation;

4. Collaboration with the Tribal health director, health board, and/or the Tribal council, as appropriate, for review and approval of the BRFS project;

5. Obtain institutional review board (IRB) review(s) and approval(s) as needed to facilitate implementation.

In addition to the seven TEC core functional areas as outlined in the IHGIA, the grantee must also address the following activities in the work plan.

(1) Describe existing TEC staff capabilities or hiring plans for the 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.

(2) Explain how recipient will support the Agency's priorities:

(a) To renew and strengthen our partnerships with Tribes and urban Indians;

(b) To improve IHS;

(c) To improve the quality of and access to care; and

(d) To make all work accountable, transparent, fair and inclusive.

You may access information of IHS priorities via the Internet at the following <https://www.ihs.gov/aboutihs/index.cfm/overview/>.

III. Eligibility Information

1. Eligibility

To be eligible for this competing continuation announcement an applicant must be one of the following:

Definitions

Indian Tribe—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(14).

Tribal Organization—Tribal organization means the elected governing body of any Indian Tribe or any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community 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(26), 25 U.S.C. 450b(1).

Urban Indian organization—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 described in section 1653(a) of the IHGIA. 25 U.S.C. 1603(29).

Intertribal consortium—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 and representative of the Indian Tribes or urban Indian communities residing in the area in which the intertribal consortium is located. 25 U.S.C. 1621m (d)(2).

Current Tribal Epidemiology Center grantees are eligible to apply for competing continuation funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities grant in order to receive funding under this announcement.

All applicants must represent or serve a population of at least 60,000 AI/AN to be eligible, as demonstrated by Tribal resolutions, blanket Tribal resolutions or Letter of Support (LoS) from urban Indian clinic directors and/or 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. Resolutions from each Tribe, AN village and LoS from each urban Indian community represented must be included in the application package. Collaborations with IHS Areas, Federal agencies such as the CDC, State, academic institutions or other organizations are encouraged (letters of support and collaboration should be included in the application).

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount (\$1,000,000) outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution

An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include Tribal resolutions from all affected Tribes to be served. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities. TECs that have an existing resolution(s) or blanket resolution in place that supports authority to apply for funding opportunity announcement on behalf of the members will not be required to submit a new resolution(s), if the resolution(s) from the prior cycle is still active.

Urban Indian organization(s) that is proposing a project affecting another urban Indian organizations or urban Indian clinics must include LoS signed by the Urban Indian clinic director and/

or CEO. An urban epidemiology center that has existing LoS documents from the Urban Indian clinic director and/or CEO in place granting authority to apply for the funding opportunity announcement on behalf of the urban Tribal members will not be required obtain additional LoS documents.

Please include a copy of the new or active Tribal resolution(s), blanket resolutions, or LoS in the application. The applicant must demonstrate how these documents meet the minimum requirement of 60,000 AI/AN population to be eligible for the cooperative agreement.

An official signed Tribal resolution, Tribal blanket resolution, or LoS for the urban Indian organization must be received by the DGM prior to a Notice of Award being issued to any applicant selected for funding. However, if an official signed Tribal resolution, Tribal blanket resolution, or LoS cannot be submitted with the electronic application submission prior to the official application deadline date, a draft Tribal resolution, Tribal blanket resolution, or LoS for urban Indian organization must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution, Tribal blanket resolution, or LoS is not in lieu of the required signed resolution, but is acceptable until a signed resolution or LoS is received. If an official signed Tribal resolution, Tribal blanket resolution, or LoS is not received by DGM when funding decisions are made, then a Notice of Award will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the grants management specialist listed in this funding announcement.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.*, FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at <http://www.Grants.gov> or <http://www.ihs.gov/dgm/funding/>.

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
 - SF-424, Application for Federal Assistance.
 - SF-424A, Budget Information—Non-Construction Programs.
 - SF-424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must be single spaced and not exceed 10 pages).
 - Background information on the organization.
 - Proposed scope of work that includes grantees' desired objectives, a minimum of four of the seven core functions of the TEC as outlined in the IHClA, and provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Tribal resolution, Tribal blanket resolution, or LoS from urban Indian clinic directors/CEOs.
- 501(c)(3) Certificate (if applicable).
- Position descriptions and biographical sketches for all key personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF-LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Organizational Chart.
- Map of the areas to benefit from the program.
- Data Sharing Agreements (if applicable).
- Letters of support from collaborating agencies.
- Documentation of current Office of Management and Budget (OMB) Audit as required by 45 CFR part 75, subpart

F or other required Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 - Face sheets from audit reports.
- These can be found on the FAC Web site: <http://harvester.census.gov/sac/dissemin/accessoptions.html?submit=Go+To+Database>.

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is no longer than 10 pages and must: Be single-spaced, be typewritten, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½" x 11" paper.

Be sure to succinctly address and answer all questions listed under the narrative and place them under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they shall not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this cooperative agreement award. If the narrative exceeds the page limit, only the first 10 pages will be reviewed. The 10 page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

Part A: Program Information (3 Pages)

Section 1: Introduction and Need for Assistance

Must include the applicant's background information, a description of epidemiological service, epidemiologic capacity and history of support for such activities. Applicants need to include current public health activities, what program services are currently being provided, and

interactions with other public health authorities in the region (State, local, or Tribal).

Section 2: Organizational Capabilities

The applicant must describe staff capabilities or hiring plans for the key personnel with appropriate expertise in epidemiology, health sciences, and program management. The applicant must also demonstrate access to specialized expertise such as a doctoral level epidemiologist and/or a biostatistician. Applicants must include an organizational chart, and provide position descriptions and biographical sketches of key personnel including consultants or contractors. The position description should clearly describe each position and its duties. Resume should indicate that proposed staff is qualified to carry out the project activities.

Section 3: User Population

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.

Part B: Program Planning and Evaluation (5 Pages)

Section 1: Program Plans

Applicant must include a work-plan that describes program goals, objectives, activities, timeline, and responsible person for carrying out the objectives/activities. The applicant must include at least a minimum of four of the seven core functions of the IHCLA and other activities listed under the Grantee Cooperative Agreement Award Activities.

Section 2: Program Evaluation

Applicant must define the criteria to be used to evaluate activities listed in the work-plan under the Grantee Cooperative Agreement Award Activities. They must 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 and describe how evaluation findings will be disseminated to stakeholders.

Part C: Program Report (2 Pages)

Section 1: Describe major accomplishments over the last 24 months.

Sample: Please identify and describe significant program achievements associated with the delivery of quality health services. Provide a comparison of the actual accomplishments to the goals established for the project period, or if

applicable, provide justification for the lack of progress.

Section 2: Describe major activities over the last 24 months.

Sample: Please identify and summarize recent major health related project activities of the work done during the project period.

B. Budget Narrative: This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals, objectives, and activities as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The page limitation should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to 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 Mr. Paul Gettys (Paul.Gettys@ihs.gov), DGM Grant Systems Coordinator, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to

Robert.Tarwater@ihs.gov. Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

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

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please 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 completed application via the <http://www.Grants.gov> Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or <http://www.Grants.gov> registration or that fail to request timely assistance with technical issues will not be considered

for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- 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.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to GrantsPolicy@ihs.gov with a copy to Robert.Tarwater@ihs.gov. Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the DEDP will notify the applicant that the application has been received.
- Email 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 SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each 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, please access it through <http://fedgov.dnb.com/webform>, or to expedite the process, call (866) 705-5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2-5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3-5 business days to process. Registration with the SAM is free of charge. Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: <http://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

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 10 page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "Multi-year Project Requirements" at the end of this section for more information. The narrative

section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 Points)

a. Describe the applicant's current public health activities including programs or services currently provided, interactions with other public health authorities in the regions (State, local, or Tribal) and how long it has been operating. 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. Describe the applicant's user population. The applicant must demonstrate AI/ANs will be served and 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 data.

B. Project Objectives, Work Plan, and Approach (45 Points)

a. State in measurable and realistic terms the objectives and appropriate activities to achieve each objective for the projects as listed in the Substantial Involvement Description for Cooperative Agreement, B. Grantee Cooperative Agreement Award Activities. The work-plan needs to include the grantees desired objectives and must demonstrate a minimum of four of the seven TEC core functional areas as outlined IHCIA.

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.

C. Program Evaluation (10 Points)

a. Define the criteria to be used to evaluate activities listed in the work-

plan under the Substantial Involvement Description for Cooperative Agreement, B. Grantee Cooperative Agreement Award Activities.

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.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

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

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.

d. Applicant must at least have two epidemiologists as part of the proposal.

E. Categorical Budget and Budget Justification (5 Points)

a. The five points for Categorical Budget only applies to Year 1. Provide a line item budget and budget narrative for Year 1.

b. Provide a justification by line item in the budget including sufficient cost and other details to facilitate the determination of cost allowance 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.

d. If applicable, if the applicant will be hosting a conference, the applicant must include a separate detailed budget justification and narrative for the conference. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual,

(5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, (8) Other (explain in detail and cost breakdown).

e. Applicant is encouraged to submit a line item budget and budget narrative by category for years 2–5 as an appendix to show the five-year plan of the proposal.

Multi-Year Project Requirements

Projects requiring a second, third, fourth, and/or fifth year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.*, data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.*, budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (<https://www.grantsolutions.gov>). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects 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.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65 and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be “Approved”, but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2016 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements 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*:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. *Grants Policy*:

- HHS Grants Policy Statement, Revised 01/07.

D. *Cost Principles*:

- Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75, subpart E.

E. *Audit Requirements*:

- Uniform Administrative Requirements for HHS Awards, "Audit Requirements," located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC 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 IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) <https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-Tribes>. For questions regarding the indirect cost policy, please call the grants management specialist listed under "Agency Contacts" or the main DGM office at (301) 443-5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. 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. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date 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. For TECs that receive EDM data, annual reporting on data use, number and types of products produced (e.g., reports, publications, presentations), and impacts of EDM data use and products on established health status objectives is required.

B. Financial Reports

Federal Financial Report FFR (SF-425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: <http://www.dpm.psc.gov>. It is recommended that the applicant also send a copy of the FFR (SF-425) report to the grants management specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

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

C. Post Conference Grant Reporting

The following requirements were enacted in Section 3003 of the Consolidated Continuing Appropriations Act, 2013, and Section 119 of the Continuing Appropriations

Act, 2014; *Office of Management and Budget Memorandum M-12-12*: All HHS/IHS awards containing grants funds allocated for conferences will be required to complete a mandatory post award report for all conferences. Specifically: The total amount of funds provided in this award/cooperative agreement that were spent for "Conference X", must be reported in final detailed actual costs *within 15 days of the completion of the conference*. Cost categories to address should be: (1) *Contract/Planner*, (2) *Meeting Space/Venue*, (3) *Registration Web site*, (4) *Audio Visual*, (5) *Speakers Fees*, (6) *Non-Federal Attendee Travel*, (7) *Registration Fees*, (8) *Other*.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB 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 sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: <http://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must

administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/>.

The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>; and <http://www.hhs.gov/civil-rights/index.html>. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/civil-rights/for-individuals/disability/index.html>. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under Federal civil rights laws at <http://www.hhs.gov/civil-rights/for-individuals/disability/index.html> or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the Indian Health Service.

Recipients will be required to sign the HHS-690 Assurance of Compliance form which can be obtained from the following Web site: <http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf>, and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently \$150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop 09E70, Rockville, Maryland 20857 (Include "Mandatory Grant Disclosures" in subject line). Ofc: (301) 443-5204; Fax: (301) 594-0899; Email: Robert.Tarwater@ihs.gov. AND U.S. Department of Health and Human

Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201. URL: <http://oig.hhs.gov/fraud/report-fraud/index.asp> (Include "Mandatory Grant Disclosures" in subject line). Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Selina T. Keryte, MPH, Project Officer, Office of Public Health Support, Division of Epidemiology & Disease Prevention, Indian Health Service, 5600 Fishers Lane, Mailstop 09E10D, Rockville, MD 20857. Phone: (301) 443-7064 or Selina.keryte@ihs.gov.

2. *Questions on grants management and fiscal matters may be directed to:* John Hoffman, Senior Grants Management Specialist, IHS Division of Grants Management, 5600 Fishers Lane, Mailstop 09E70, Rockville, MD 20857. Phone: (301) 443-2116; Email: John.Hoffman@ihs.gov.

3. *Questions on systems matters may be directed to:* Paul Gettys, Grant Systems Coordinator, IHS Division of Grants Management, 5600 Fishers Lane, Mailstop 09E70, Rockville, MD 20857. Phone: (301) 443-2114; or the DGM main line 301-443-5204; Fax: (301) 594-0899; E-Mail: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement 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: April 8, 2016.

Elizabeth A. Fowler,
Deputy Director for Management Operations
Indian Health Service.

[FR Doc. 2016-09012 Filed 4-18-16; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of the CB1/iNOS Series of Compounds as a Therapeutic To Treat System Sclerosis, Scleroderma, and Other Skin Fibrotic Diseases in Humans

AGENCY: National Institutes of Diabetes and Digestive and Kidney Diseases, Public Health Service, PHS, National Institutes of Health.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the following inventions embodied in the following patent applications, entitled "CB1 receptor mediating compounds":

1. U.S. Provisional Patent Application No.: 61/991,333, HHS Ref. No.: E-140-2014/0-US-01, Filed: May 09, 2014
2. PCT Application No.: PCT/US2015/029946, HHS Ref. No.: E-140-2014/0-PCT-02, Filed: May 08, 2015
3. U.S. Provisional Patent Application No.: 61/725,949, HHS Ref. No.: E-282-2012/0-US-01, Filed: November 13, 2012
4. PCT Application No.: PCT/US2013/069686, HHS Ref. No.: E-282-2012/0-PCT-02, Filed: November 12, 2013
5. U.S. Patent Application No.: 14/442,383, HHS Ref. No.: E-282-2012/0-US-03, Filed: May 12, 2015
6. Canadian Patent Application No.: 2889697, HHS Ref. No.: E-282-2012/0-CA-04, Filed: April 27, 2015
7. European Patent Application No.: 13802153.0, HHS Ref. No.: E-282-2012/0-EP-05, Filed: June 01, 2015
8. Indian Patent Application No.: 3733/DELNP/2015, HHS Ref. No.: E-282-2012/0-IN-06, Filed: May 01, 2015
9. Japanese Patent Application No.: 2015-542015, HHS Ref. No.: E-282-2012/0-JP-07, Filed: May 11, 2015
10. Chinese Patent Application No.: 201380069389.9, HHS Ref. No.: E-282-2012/0-CN-08, Filed: July 3, 2015
11. US Provisional Application No.: 62/171,179, HHS Ref. No.: E-282-2012/1-US-01, Filed: June 04, 2015

to Vital Spark Inc., ("Vital Spark"), a company incorporated under the laws of Delaware and having an office in

Jerusalem, Israel. The patent rights in these inventions have been assigned to the United States of America. This license may be worldwide. The field of use may be limited to the use of the Licensed Patent Rights to "develop the CB1/iNOS series of compounds as a therapeutic to treat systemic sclerosis, scleroderma, and other skin fibrotic diseases."

DATES: Only written comments and/or applications for a license which are received by the Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases on or before May 4, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty Tong, Ph.D., Sr. Licensing and Patenting Manager, Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892, Email: betty.tong@nih.gov. A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology, and its corresponding patent applications, is directed to methods of treating fibrosis, obesity and associated diseases such as type 2 diabetes by administering an agent that reduces appetite, body weight, hepatic steatosis, and insulin resistance. This technology may be useful as a means for treating various fibrotic diseases and metabolic syndromes without serious adverse neuropsychiatric side effects.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the Technology Advancement Office receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released

under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 13, 2016.

Anna Amar,
Acting Deputy Director, Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2016-08985 Filed 4-18-16; 8:45 am]

BILLING CODE 4140-01-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; PAR-13-228: Biomarkers for Diabetes and Kidney Diseases using Biosamples from the NIDDK Repository (R01).

Date: June 1, 2016.

Time: 11:00 a.m. to 1:00 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, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, ROOM 7349, 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-KUH Fellowship Review.

Date: June 3, 2016.

Time: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard,