

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm100261.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Public Health Support; Division of Planning, Evaluation & Research; National Native Health Research Training Initiative

Announcement Type: New.

Funding Announcement Number: HHS-2017-IHS-DPER-001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates:

Application Deadline Date: October 30, 2016.

Approximate Review Date: November 2-4, 2016.

Earliest Anticipated Start Date: November 15, 2016.

Proof of Non-Profit Status Due Date: October 30, 2016.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support (OPHS), Division of Planning, Evaluation and Research (DPER), is accepting applications for one new cooperative agreement for the National Native Health Research Training Initiative. This initiative will help build capacity and disseminate new and best practices for American Indian and Alaska Native (AI/AN) health research and promote Tribally-driven research activity through a variety of educational and training opportunities. Focus will be on the promotion of health research and related opportunities for AI/AN students, highlighting promising practices and practice-based approaches to improving the health of AI/AN people, and culture-based approaches to reducing health disparities between AI/AN people and the U.S. population. Other areas will focus on resilience and protective factors and their role in AI/AN health outcomes, innovative and culturally-based approaches to improving the health of AI/AN youth, and dissemination of study findings in AI/AN health science research to investigators and providers working in or with Tribal communities as well as Tribal leaders and health officials. Activities will include the planning, coordination, and hosting of research meetings and conferences, webinars, hosting of a Web site/Web page for dissemination of AI/AN health science research information, and other activities to be determined. This IHS activity is authorized under the Snyder Act, codified at 25 U.S.C. 13; the Transfer Act, codified at 42 U.S.C. 2001; the Consolidated Appropriations Act, 2012, Public Law 112-74 and the Continuing Appropriations Resolution, 2013, Public Law 112-175. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The AI/AN populations have long experienced poorer health status compared to other Americans. Although major gains in reducing health disparities were made during the last half of the twentieth century, most gains stopped by the mid-1980s (Trends in Indian Health 1998-99) and a few

diseases, e.g., diabetes, worsened. "All Indian" rates contain marked variation among the "IHS Areas" or regions (Regional Differences in Indian Health 2002-2003); variation by Tribe exists within Areas as well. The Trends and Regional Differences reference can be found on the IHS Web site at <http://www.ihs.gov/dps/publications/>. The daunting task confronting Tribes, research scientists, and health programs is to reduce the disparities among and within areas and Tribes. Factors known to contribute to health status and disparities are complex, and include underlying biology, physiology, and epigenetics, as well as ethnicity, culture, socioeconomic status, gender/sex, age, geographical access to care, and levels of insurance.

Additional factors known to contribute to health status and disparities include:

1. Family, home, and work environments;
2. general or culturally specific health practices;
3. social support systems;
4. lack of access to culturally-appropriate health care; and
5. attitudes and beliefs about health.

Health disparities of AI/ANs may also reflect a lack of in depth research relevant to improving their health status. Many AI/ANs also distrust research for historical reasons. One approach that combats this distrust is to ensure that Tribes are managing partners in training and research that involves them, as for example in community-based participatory research (CBPR) (i.e., a collaborative research process between researchers and community representatives). This approach is especially helpful to design both training relevant to researchers from Tribal communities and research relevant to health needs of the communities. Another approach is increasing the number of AI/AN scientists and growing the intellectual community of researchers working with AIAN health research issues.

DPER has the responsibility of promoting health research to help improve the health status of AI/ANs. The development of AI/AN scientists and scientist-practitioners and enhancing the ability of Tribes to participate in and initiate their own research projects is a key part of improving quality and delivery of health services. Scientific meetings, conferences, and other training opportunities will support AI/AN faculty and student development and promote participatory collaboration between Tribes and the academic community. Such meetings and other

educational approaches will provide opportunities for Tribes and the academic community to learn about resilience and protective factors and their role in AI/AN health outcomes, culture-based prevention, intervention, and treatment modalities, and other research that may help improve health outcomes.

Objectives

A. To increase opportunities for AI/AN scientists and health professionals—Offering development and training opportunities to AI/AN scientists, students, and health professionals and to provide a means for the dissemination of biomedical, clinical, behavioral and health science research that is responsive to the needs of the AI/AN community and the goals of this initiative. The grantee will develop regular (at least annual) conference training and practice sharing opportunities for scientists, students, and health professionals to learn and share findings from scientifically meritorious research projects as well as exploration of methods for further study and evaluation of practice-based projects. The grantee will also support health science education and professional development projects designed to introduce and further develop research skills of AI/AN students, faculty, health professionals, and community members.

B. To enhance Tribal-academic collaborations and improve the ability of Tribes to utilize research findings—Recent CBPR projects suggests that AI/AN communities can work collaboratively with health researchers to further the research needs of AI/ANs. Fully utilizing all cultural and scientific knowledge, strengths, and competencies, such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors affecting health status of AI/ANs and support the development and evaluation of interventions to improve their health status. The grantee will develop training opportunities to inform and educate Tribal leaders and health personnel about health research methods, findings, and best practices in partnering with academic investigators in pursuit of research projects designed to meet the needs and advance the health care of AI/AN communities.

C. To reduce health disparities—Research suggests that enhancing protective factors can be as effective as reducing risk factors in improving health outcomes, particularly among AI/ANs. A better understanding of protective factors among AI/ANs could

be helpful in reducing health disparities. Anecdotal evidence suggests that AI/AN ceremonial and other cultural practices may help to ameliorate major harms and disruptions over the centuries. The grantee will promote health research methods designed to better understand the protective effects of Traditional Indian Medicine, Indigenous Knowledge, Traditional Ecological Knowledge, et al., on AI/AN health. The grantee will also identify and disseminate examples of successful co-delivery of Traditional cultural practices with western biomedical services.

The annual conference will provide critical exposure to health research opportunities for both students and researchers. The applicant must provide opportunities for potential and new AI/AN students to learn the fundamentals of health research, provide exposure to cutting-edge research, and interaction with established AI/AN scientists to explore mentorship and funding opportunities. Mentorship is vital to success in the research field, especially for AI/AN students, and mentorship is often not available at the geographic location where the student is enrolled. Therefore it is paramount that this opportunity occurs at least annually. New scientific research funding opportunities that become available will be explored and wide dissemination of this information will be given to Tribes, Tribal organizations, and Tribal-academic partnerships so they will have the opportunity to apply for this kind of funding.

Purpose

The purpose of this cooperative agreement is to fund a national membership organization of AI/AN scientists and/or researchers and students to further the IHS research program objectives with expanded outreach and education efforts for AI/AN students, faculty, and health professionals. This announcement requests applications to propose activities including, but not limited to, an annual national training opportunity in health research methods and findings of importance to AI/AN people and communities. Other activities may also be considered in coordination with the main annual event. This is an important annual event that will bring together health researchers and key stakeholders to share recent research findings, learn new research methodologies and best practices in service delivery, and learn about human research protections and opportunities for research funding. The annual research training event will be the primary event for AI/AN researchers

and students to present their findings and obtain feedback from other researchers as well as Tribal health professionals. Students also have the opportunity to select and begin working with new mentors. This event will be held by a national membership organization of AI/AN scientists and/or researchers in collaboration with IHS in facilitating a forum designed to improve the health research capacity of AI/AN Tribes and researchers. The organization and continuity of annual national training events is vital to the morale of the health research and larger health professional field working for the benefit of the Tribes and other (including urban) AI/AN people.

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 Mose Herne on (301) 443-1549 or email him at mose.herne@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) 2017 is approximately \$225,000. The award amount is anticipated to be between \$100,000 and \$225,000. The amount of funding available for competing and 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

One award will be issued under this program announcement.

Period of Performance

The project period is for five years and will run consecutively from November 15, 2016 to November 14, 2021.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as a grant. However, 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 the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the award as well as their adherence to the terms and conditions of the cooperative agreements. This includes providing guidance for required reports, development of agendas, tools and other products, and technical assistance with evaluation and overcoming any performance issues encountered. The IHS assigned program official must approve all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to these awards and any supplemental awards prior to the presentation or dissemination of such materials to any party.

IHS staff will provide support for the award as follows:

- i. The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of grantee personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, any training, reports, budget, and evaluation. Collaboration includes agenda setting, analysis, and reporting.
- ii. The IHS assigned program official will work closely with all participating IHS health services/programs, as appropriate, to coordinate award activities.
- iii. The IHS assigned program official will coordinate the following:
 - Discussion and release of any and all special grant conditions upon fulfillment.

- Monthly scheduled conference calls.
- Appropriate dissemination of required reports to each participating program.
- iv. The IHS will, jointly with the awardee, plan and set an agenda for each of the conference(s) mentioned in this announcement that:
 - Shares the training and/or accomplishments.
 - Fosters collaboration amongst the participating program offices, agencies, and/or departments.
 - Increases visibility for the partnership between the awardee and the IHS.
- v. IHS will provide guidance in addressing deliverables and requirements.
- vi. IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned, and new findings.
- vii. IHS will communicate via monthly conference calls, individual or collective site visits, and meetings.
- viii. IHS will provide technical assistance to the entity as requested.
- ix. IHS staff may, at the request of the entity's board, participate on committees and may recommend topics for discussion.

B. Grantee Cooperative Agreement Award Activities

The awardee is responsible for the following:

- i. To succinctly and independently address the requirements for the award.
- ii. To facilitate a forum or forums at which concerns can be heard that are representative of Tribal governments in the area of health research.
- iii. To establish relationships with other national Indian organizations, with professional groups, and with Federal, State, and local entities and universities or medical centers supportive of AI/AN health research programs.
- iv. To improve and expand access for AI/AN Tribal governments to health research programs within HHS.
- v. To disseminate timely health research information to Tribal governments, AI/AN health boards, other national Indian organizations, professional groups, Federal, State, and local entities.
- vi. To reach out to and educate academic and research institutions, and Federal, state and local agencies on the needs and procedures for the conduct of health research in Indian Country, and to promote the academic recognition of the rights of Tribal governments to control their own research and to own their research data.

vii. To establish an appropriate standard of practice for health research concerning AI/AN that addresses the relationship between academic freedom, government procedures, and Tribal rights.

viii. Attendance at regularly scheduled meetings between awardee and the IHS assigned program official, evidenced by meeting minutes which highlight the awardee's specific involvement and participation.

ix. The annual national research conference and other training activities as proposed by the grantee and approved by the program official.

x. Copies of all promotional and educational materials provided to Tribal programs and other projects (electronic form and one hard copy).

xi. Copies of all promotional materials provided to media and other outlets (electronic form and one hard copy).

xii. Copies of all articles published (electronic form and one hard copy).

xiii. Evidence of posting of conference and training-related information on organizational Web site(s).

xiv. Workshops

- The awardee may provide teleconference and/or webinar workshops on health research, subject to approval from the IHS assigned program official.

- The awardee shall conduct workshops and/or presentations including, but not limited to, challenges, potential solutions, and successes in the form of promising practices of health research at one national conference (venue and content of presentations to be agreed upon by the awardee and the IHS assigned program official).

III. Eligibility Information

1. Eligibility

To be eligible for this "New Competition" under this announcement, an applicant must:

- Be 501(c)(3) non-profit entities that are national membership organizations of AI/AN health researchers or scientists.

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

- Demonstrate organizational expertise and successful experience in:
 - Conducting previous national research or scientific conferences.
 - Promoting and supporting AI/AN health research and science education and training.

○ Providing evidence of at least five years of successful experience providing health research and science education and outreach on a national scale.

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 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.

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.

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 not exceed 20 pages).

○ Background information on the organization.

○ Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.

• Letter of Support from organization's Board of Directors.

• 501(c)(3) Certificate.

• 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 (optional).

• Documentation of current Office of Management and Budget (OMB) 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 20 pages and must: be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and printed on one side only of standard size 8½" × 11" paper.

Be sure to succinctly answer all questions listed 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 will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming more familiar with the grantee's activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, only the first 20 pages will be reviewed. The 20-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, 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. The page limitations below are for each narrative and budget submitted.

Part A: Program Information (3 Page Limitation)

Section 1: Needs

Describe your organization's understanding of the needs of this cooperative agreement and how your organization has the experience to provide outreach and education efforts regarding the pertinent changes and updates in health research.

Part B: Program Planning and Evaluation (12 Page Limitation)

Section 1: Program Plans

Describe fully and clearly how the national AI/AN membership organization plans to address the requirements and tasks.

Section 2: Program Evaluation

Describe fully and clearly how your planned outreach and education efforts will impact changes in knowledge and awareness in Tribal health professionals and among AI/AN health researchers and health research students. Describe how your organization will measure/monitor/track these impacts; include existing or planned new data sources.

Part C: Program Report (5 Page Limitation)

Section 1: Identify and describe your organization's significant program activities and achievements over the past five years associated with the goals of this agreement, including improved delivery of quality health research education and the growth of the national community of AI/AN health researchers. 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.

B. Budget Narrative (5 Page Limitation)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59pm, 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. 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.

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.
- 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 needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Robert.Tarwater@ihs.gov. 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.

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 Senior Policy Analyst 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. 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.

- 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 OPHS will notify applicants 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 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 <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 your 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 20 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 70 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (15 Points)

(1) Describe your organization’s understanding of the needs of this cooperative agreement.

(2) Describe the organization’s current operations as related to the spectrum of health research needs and dissemination of health research information and support to Tribes, AI/AN communities, and Tribal colleges and universities among others. Include information regarding technologies currently used (*i.e.*, hardware, software, services, Web sites, etc.), and identify the source(s) of technical support for those technologies (*i.e.*, in-house staff, contractors, vendors, etc.). Include information regarding how long the

applicant has been operating and its length of association/partnerships with Area health boards or other organizations, etc. [historical collaboration].

(3) Describe the organization’s current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, and describe any memorandums of agreement with other national Indian organizations.

(4) Describe the population to be served by the proposed project. Are they hard to reach? Are there barriers? Identify all previous IHS funds received, dates of funding and summaries of the projects’ accomplishments. State how previous funds facilitated education, training and technical assistance nationwide for AI/ANs.

(5) Describe collaborative and supportive efforts with Tribal Epidemiology Centers, NARCH grantees, university centers of AI/AN health research.

(6) Explain the need/reason for your proposed projects by identifying specific gaps or weaknesses in health research training or infrastructure that will be addressed by the proposed projects. Describe the effect of the proposed project on current programs (*i.e.*, Federally-funded, State funded, etc.)

B. Project Objective(s), Work Plan and Approach (40 Points)

(1) Identify the proposed project objective(s) for the project, as applicable, addressing the following:

- Measurable and (if applicable) quantifiable.
- results oriented.
- time-limited.

Example: Issue save the date notices, calls for papers, conference publicity, and registration information. Goals must be clear and concise.

(2) Address the extent to which the proposed projects will provide, improve, or expand health research that address the need(s) of the target population. Submit a work plan in the Appendix that:

- Provides the action steps on a timeline for accomplishing each of the projects’ proposed objective(s).
- Identifies who will perform the action steps.
- Identifies who will supervise the action steps taken.
- Identifies what tangible products will be produced during and at the end of the proposed project objective(s).
- Identifies who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.

- Identifies any training that will take place during the proposed projects and who will be attending the training.

- Identifies evaluation activities proposed in the work plans.

(3) If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

C. Program Evaluation (20 Points)

Each proposed objective requires an evaluation component to assess its progress and ensure its completion. Also, include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- The criteria for determining success of each objective.

- The data to be collected which will determine whether the objective was met.

- Data collection intervals and frequency.

- Who will collect the data and their qualifications.

- How the data will be analyzed.
- How results of evaluation will be used.

(2) For process evaluation, describe:

- How the projects will be monitored and assessed for potential problems and needs for quality improvements.

- Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and their qualifications.

- How ongoing monitoring will be used to improve the project’s performance.

- Products that might be developed and how they might lend themselves to replication by others.

- How the organization will document what is learned throughout the projects’ grant periods.

(3) Describe any evaluation efforts planned after the grant period has ended.

(4) Describe the ultimate benefit to the AI/AN population served by the applicant organization that will be derived from these projects.

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

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

(1) Describe the organizational structure of the applicant.

(2) Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance, as well as other conferences and projects successfully completed.

(3) Describe equipment (*i.e.*, fax machine, phone, computer, etc.) and facility space (*i.e.*, office space) that will be available for use during the proposed projects. Include information about any equipment not currently available and will be purchased through the cooperative agreement.

(4) List key personnel who will work on the projects. Include title used in the work plans. In the Appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed project. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities. If a position is to be filled, indicate that information on the proposed position description.

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

E. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the program costs and justification of expenses for the entire period of the cooperative agreement. The budget and budget justification should be consistent with the tasks identified in the work plans.

(1) Provide a categorical budget for the 12-month budget period requested by the project.

(2) If IDC are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the Appendix. *See Section VI. Award Administration Information, 3. Indirect Costs.*

(3) Provide a narrative justification explaining why each line item is

necessary/relevant to the proposed project. Include sufficient costs and other details to facilitate the determination of cost (*i.e.*, equipment specifications, etc.).

Multi-Year Project Requirements

Projects requiring 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(s) highlighting proposed project staff and their supervisors as well as other key contacts within the organization and key community contacts.
- 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 (80 points) 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 weaknesses and strengths of their application submitted. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF-424) of the application. 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 and policies:

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) http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm. 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 “Grants Note” in the 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 semiannually, 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, 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 period/period of performance.

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 Division of Payment Management, 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/ocr/civilrights/resources/laws/revisedlep.html>. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>; and <http://www.hhs.gov/ocr/civilrights/understanding/index.html>. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/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/ocr/office/about/rgn-hqaddresses.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>.

Applicants will be required to sign the HHS-690 Assurance of Compliance form located at <http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf> and send the original form to: 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 (FAPIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIS) 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 FAPIS

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 FAPIS 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 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: Mr. Robert Tarwater, Director, 5600 Fishers Lane, Mailstop 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/reportfraud/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: Mr. Mose Herne, MPH, MS, IHS Research Director, 5600 Fishers Lane, Mailstop 09E10D, Rockville, Maryland 20857, Telephone: (301) 443-1549, Fax: (301) 443-0114, Email: mose.herne@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Ms. Patience Musikikongo, DGM, Grants Management Specialist, 5600 Fishers Lane, Mailstop 09E70, Rockville, Maryland 20857, Telephone: (301) 443-2059, Fax: (301) 443-9602, Email: Patience.Musikikongo@ihs.gov.

3. Questions on systems matters may be directed to: Mr. Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, Email: 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.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[OMB Control Number 0917-0006]

Request for Public Comment: 30-Day Proposed Information Collection: Application for Participation in the IHS Scholarship Program

AGENCY: Indian Health Service, HHS.