Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Telephone: (301) 443–5204, Fax: (301) 594–0899, Email: *Pallop.Chareonvootitam@ihs.gov*.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Telephone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, Email: *Paul.Gettys@ ihs.gov*.

VIII. Other Information

The U.S. Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, the Pro-Children Act of 1994, (Pub. L. 103–227), 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.

Michael D. Weahkee,

RADM, Assistant Surgeon General, U.S. Public Health Service, Principal Deputy Director, Indian Health Service.

[FR Doc. 2019–08414 Filed 4–25–19; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Urban Indian Health Programs; Urban Indian Education and Research Program

Announcement Type: New or Competing Continuation.

Funding Announcement Number: HHS–2019–IHS–UIHP3–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.193.

Key Dates

Application Deadline Date: August 15, 2019.

Earliest Anticipated Start Date: September 15, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Urban Indian Health Programs (OUIHP), is accepting applications for a cooperative agreement for the Urban

Indian Education and Research Organization Program. This program is authorized under: The Snyder Act, 25 U.S.C. 13, and Section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a). This program is described in the Assistance Listings located at *https:// beta.sam.gov* (formerly known as Catalog of Federal Domestic Assistance) under 93.193.

Background

The OUIHP oversees the implementation of the Indian Health Care Improvement Act (IHCIA) provisions for making health care services more accessible to Urban Indians. Pursuant to those authorities, the IHS enters into contracts and grants with Urban Indian Organizations (UIOs) for the provision of health care and referral services for Urban Indians residing in urban centers. This program provides services and education for UIOs that include the following Five Core Projects: (1) Public policy; (2) research and data; (3) training and technical assistance; (4) education, public relations, and marketing; and (5) payment system reform/monitoring regulations.

Purpose

The purpose of this IHS announcement is to fund a National Urban Indian Organization to act as an education and research partner for OUIHP and UIOs funded under the IHCIA.

Limited Competition Justification

Competition for the one award included in this announcement is limited to national organizations with at least ten years of experience providing national awareness, visibility, advocacy, education and outreach related to urban Indian health care on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between IHS and UIOs on a broad scale; (2) a national perspective on the needs of urban Indian communities that will ensure the information developed and disseminated through the projects is appropriate and useful and addresses the most pressing needs of urban Indian communities; and (3) established relationships with UIOs that will foster open and honest participation by urban Indian communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing urban Indians

nationwide. Organizations with less experience will lack the established relationships with UIOs throughout the country that will facilitate participation and the open and honest exchange of information between UIOs and the IHS. With the limited funds available for these Five Core Projects, the IHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of urban Indian communities throughout the country, and come from a source that urban Indians recognize and trust.

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 January 23, 2015 (Policy), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at *https://www.hhs.gov/grants/ contracts/contract-policies-regulations/ efficient-spending/index.html ?language=es.*

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 website, (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 Shannon Beyale at 301–945–3657 or email at *Shannon.Beyale@ihs.gov.*

II. Award Information

Funding Instrument

Cooperative Agreement.

Estimated Funds Available

The total funding identified for fiscal year (FY) 2019 is approximately $1,050,000. Award amount for the first budget year is anticipated to be $1,050,000. The funding available for competing and subsequent continuation awards issued under this announcement is 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 period of performance is for three years.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency (IHS) is anticipated 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 the IHS.

Substantial Involvement Description for Cooperative Agreement

In addition to the usual monitoring and technical assistance provided under the cooperative agreement, the IHS OUIHP responsibilities shall include:

(1) Assurance of the availability of services from experienced OUIHP staff to participate in the planning and development of all phases of this cooperative agreement;

(2) Participation in, including the planning of, any meetings conducted as part of the Five Core Projects;

(3) Assistance in establishing federal interagency contacts necessary for the successful completion of tasks and activities identified in the approved scope of work;

(4) Identification of organizations with whom the awardee will be asked to develop cooperative and collaborative relationships;

(5) Assisting the awardee to establish, review, and update priorities for the Five Core Projects conducted under this cooperative agreement; and

(6) Assisting the awardee in determining issues to be addressed during the project period, sequence in which they will be addressed, what approaches and strategies will be used to address them, and how relevant information will be transmitted to specified target audiences and used to enhance core project activities and advance the program.

III. Eligibility Information

1. Eligibility

To be eligible for this New and Competing Continuation FY 2019 Funding Opportunity, applicants must be national organizations with at least ten years of experience providing national awareness, visibility, advocacy, education and outreach related to urban Indian health care on a national scale. See Limited Competition Justification section above.

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 letter of support from organization's board of directors, 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

Applications with budget requests that exceed the highest dollar amount outlined under the Award Information, Estimated Funds Available section, or exceed the Period of Performance outlined under the Award Information, Period of Performance section will be considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit a copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are hosted on *http://www.Grants.gov.*

Please direct questions regarding the application process 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:

• 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.

• Project Narrative (not to exceed 20 pages). See IV.2.A Project Narrative for instructions.

○ Background information on the organization.

○ Proposed scope of work objectives, and activities that provide a description of what the applicant plans to accomplish.

• Budget Justification and Narrative (not to exceed 5 pages). See IV.2.B Budget Narrative for instructions.

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

• 501(c)(3) Certificate.

• Biographical sketches for all Key Personnel (not to exceed one page each).

• Contractor/Consultant proposed scope of work and letter of commitment (not to exceed one page each, if applicable).

• Disclosure of Lobbying Activities (SF–LLL).

• Certification Regarding Lobbying (GG-Lobbying Form).

• Copy of current Negotiated Indirect Cost (IDC) rate agreement (required in order to receive IDC).

• Organizational chart.

• 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. Applicants can find these on the FAC website: *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All federal public policies apply to IHS grants and cooperative agreements with the exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate document that is no more than 20 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 20-page limit for the narrative does not include the standard forms, line item budgets, budget justifications and narratives, and/or other appendix items.

There are four parts to the project narrative: Part 1—Statement of Need; Part 2—Program Information/Proposed Approach; Part 3—Organizational Capacity and Staffing/Administration; and Part 4—Performance Measurement Plan and Evaluation. See below for additional details about what must be included in the narrative.

*Part 1: Statement of Need—*Corresponds to Criteria, Section V.1.A.

This section should help reviewers understand the UIOs that will be served

by the proposed project. Summarize the overall need for assistance: (1) The target population and its unmet health needs; and (2) sociocultural determinants of health and health disparities impacting the urban Indian population or communities served and unmet. Demographic data should be used and cited whenever possible to support the information provided.

Part 2: Program Information/Proposed Approach—Corresponds to Criteria, Section V.1.B.

Describe the purpose of the proposed project, including a clear statement of goals and objectives. Clearly state how proposed activities address the needs detailed in the statement of need. You are required to address all Five Core Projects in your project narrative. Address each project with a corresponding time frame.

Part 3: Organizational Capacity and Staffing/Administration—Corresponds to Criteria, Section V.1.C.

Describe your organizational capacity for all Five Core Projects and experience working with UIOs. Outline current staff and future positions for the five program components.

Part 4: Performance Measurement Plan an Evaluation—Corresponds to Criteria, Section V.1.D.

Describe efforts to collect and report project data that will support and demonstrate grant activities for all Five Core Projects. Awardee will be required to collect and report data pertaining to activities, processes, and outcomes. Also describe the plan to evaluate program activities. Describe in the evaluation plan the expected results and any identified metrics to support program effectiveness. Incorporate questions related to outcomes and processes, including documentation of lessons learned.

B. Budget and Budget Narrative—Corresponds to Criteria, Section V.1.E.

Provide a budget narrative that explains the amounts requested for each line of the budget. The budget narrative should specifically describe how each item will support the achievement of all five proposed projects. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative. The conference budget and budget narrative will not count as part of the 5-page budget and budget narrative. Please include a line item amount for the conference in the budget and budget narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*). 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.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

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

5. Funding Restrictions

• Pre-award costs are not allowed.
• The available funds are inclusive of direct and indirect costs.
• Only one cooperative agreement will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the *http://www.Grants.gov* website to submit an application. Find the application by selecting the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM. 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 an application by some other method, and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

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, please contact *Grants.gov* Customer Support (see contact information at *https://www.grants.gov*).
• Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
• 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 20 working days.
• Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
• Applicants must comply with any page limits described in this funding announcement.
• After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

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

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 that 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 the request service through *http://fedgov.dnb.com/webform,* or call (866) 705–5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS recipients 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 are 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). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics website: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 20-page project narrative and 5-page budget and budget 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 project 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 possible points.

Note: Additional documentation requested as attachments do not count towards the narratives' page limits, *e.g.* position descriptions, timelines, biographical sketches, etc.

1. Criteria

A. Statement of Need (25 Points)

(1) Describe and document the target population and its unmet needs.

(2) Based on the information and/or data currently available, document the need to implement, sustain, and improve health care services offered to urban Indians.

(3) Based on available data, describe the service gaps and other problems related to the needs of urban Indians. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are epidemiologic data such as Tribal Epidemiology Centers or IHS Area Offices, state data from state needs assessments, and/or national data from the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health or from the National Center for Health Statistics/Centers for Disease Control, and census data. This list is not exhaustive. Applicants may submit other valid data, as appropriate for the applicant's programs.

B. Program Information/Proposed Approach (30 Points)

Describe the purpose of the proposed project, including a clear statement of goals and objectives. Provide a work plan for the first year of the project period that details expected key activities, accomplishments, and includes responsible staff for each of the Five Core Projects. The project narrative is required to address all Five Core Projects of the program, see below:

(1) *Public Policy:* Summarize the public policy opportunities and challenges of UIOs in the implementation of the various laws. Describe efforts to increase awareness and actively seek support for the health care needs of urban Indians. Describe efforts to engage Urban Indian Organization Leaders' participation in policy workgroups, national advisory committees, Urban Confers, budget formulation, and listening sessions.

(2) *Research and Data:* Describe the need to collect and analyze health disparities data, morbidity and mortality data, and urban IHS cost data in order to reduce urban Indian health disparities and identify, improve, evaluate, and document UIOs' efforts

through practice-based and evidence-based best practices. Describe efforts to solidify partnerships with UIOs, tribal and urban epidemiology centers, and other data and research partners to improve and increase research and data on urban Indian issues.

(3) *Training and Technical Assistance:* Describe the need for UIOs' training and technical assistance to support new and continuing executive directors and chief executive officers, board of directors and program staff (clinical staff, administration, business office, health information technology, integrated behavioral health, etc.).

(i) Further describe the need for training and technical assistance to support Urban Indian Organization administration in orienting new Urban Indian Organization Leaders and Board of Directors, grant writing, and credentialing and privileging. Describe the need for technical assistance and training for UIOs to effectively engage in the IHS Urban Confer process. Describe the need for UIOs to attract and retain skilled, culturally competent health service providers.

(4) *Education, Public Relations, and Marketing:* Summarize the need to market the UIOs through development of national, regional, and local marketing strategies and campaigns.

(i) Describe efforts to increase awareness of health care needs of urban Indians. Describe efforts to engage UIOs to participate in national health campaigns. Describe the need for enhanced communication among local private and non-profit health care entities. Summarize the need to enhance communication, interaction, and coordination on policy and health care reform activities by initiating and maintaining partnerships and collaborative relationships with other UIOs, national Indian organizations, key state and local health entities, and education and public safety networks. Describe efforts to strengthen the capacity of UIOs to work as a community to improve knowledge sharing.

(5) *Payment System Reform/Monitoring Regulations:* Describe services to be provided, *e.g.,* billing, health information technology, regulations, etc. Describe efforts to support UIOs' efforts to diversify funding and increase third party reimbursement to ensure UIOs' sustainability. Describe technical assistance, training, and tools to be provided on billing and coding best practices, and negotiating with private health insurers and health plans. Describe efforts to establish and enhance third party billing for UIOs that

have limited or no third party billing capabilities. Describe the need to understand, document and analyze current and new federal regulations impacting UIOs for reimbursement. Describe services to be provided to UIOs on regulations. Describe types of regulatory activities needed to support efforts to lessen the impact on UIOs financial and operational systems.

C. Organizational Capacity and Staffing/Administrationm (15 Points)

(1) Describe the management capability of the National Urban Indian Organization and other participating organizations in administering similar projects.

(2) Identify staff to maintain open and consistent communication with the IHS program official on any financial or programmatic barriers to meeting the requirements of the award.

(3) Identify the department(s) and/or division(s) that will administer all Five Core Projects. Include a description of these department(s) and/or division(s), their functions, and their placement within the National Urban Indian Organization and their direct link to management.

(4) Discuss the National Urban Indian Organization's experience and capacity to provide culturally appropriate and competent services to UIOs and specific populations of focus.

(5) Describe the resources available for the proposed project (*e.g.,* facilities, equipment, information technology systems, and financial management systems).

(6) Identify other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to all Five Core Projects.

(7) Describe how project continuity will be maintained if there is a change in the operational environment (*e.g.,* staff turnover, change in project leadership, etc.) to ensure project stability over the life of the grant.

(8) Provide a list of staff positions for the project and other key personnel, showing the role of each and their level of effort and qualifications for all Five Core Projects. Key personnel include the Chief Executive Officer or Executive Director, Chief Financial Officer, Deputy Director, and Information Officer.

(9) Demonstrate successful project implementation for the level of effort budgeted for the project staff and other key staff.

(10) Include position descriptions as attachments to the application for all key personnel. Position descriptions should not exceed one page each.

(11) For individuals who are currently on staff, include a biographical sketch with their name for each individual that will be listed as the project staff and other key positions. Describe the experience of identified staff in all Five Core Projects. Include each biographical sketch as attachments to the project proposal/application. Biographical sketches should not exceed one page per staff member. Do not include any of the following:

(a) Personally Identifiable Information (social security number and date and place or birth);

(b) Resumes; or

(c) Curriculum Vitae.

D. Performance Measurement Plan and Evaluation (20 Points)

Describe plans to monitor activities under all Five Core Projects, demonstrate progress towards program outcomes, and inform future program decisions over the 3-year project period. Describe how issues will be addressed during the project period, the sequence in which they will be addressed, what approaches and strategies will be used to address them, and how relevant information will be transmitted to specified target audiences and used to enhance project activities and advance the program.

1. Describe proposed data collection efforts (performance measures and associated data) and how you will use the data to answer evaluation questions. This should include (data collection method, data source, data measurement tool, identified staff for data management, and data collection timeline).

2. Identify key program partners and describe how they will participate in the implementation of the evaluation plan (*e.g.,* Tribal Epidemiology Centers, universities, etc.).

3. Describe how evaluating findings will be used at the applicant level. Discuss how data collected (*e.g.,* performance measurement data) will be used and shared by the key program partners.

4. Discuss any barriers or challenges expected for implementing the plan, collecting data (*e.g.,* responding to performance measures), and reporting on evaluation results. Describe how these potential barriers would be overcome. In addition, applicants may also describe other measures to be developed or additional data sources and data collection methods that applicant will use.

E. Budget and Budget Narrative (10 Points)

1. Include a line item budget for all Five Core Projects including expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for Budget year one only.

2. Provide a categorized budget for all Five Core Projects. If it is anticipated that there will be travel costs to cover the cost of staff and Urban Indian Organization Leaders' attendance at national advisory committees and workgroups, the applicant should ensure the associated travel costs are included in the categorized budget for public policy.

3. Ensure that the budget and budget narrative are aligned with the project narrative. Questions to address include: What resources are needed to successfully carry out and manage the Five Core Projects? What other resources are available from the organization? Will new staff be recruited? Will outside contractors/consultants be required?

4. Include the total cost for any outside contractors/consultants broken down by activity within each core project.

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

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

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

• Work plan or logic model, with time line, for proposed goals and objectives.

• Position descriptions for key staff (not to exceed one page each).

• Biographical sketches for key staff (not to exceed one page each).

• Consultant or contractor proposed scope of work and letter of commitment (if applicable).

• Current Indirect Cost Rate Agreement.

• Organizational chart.

• Additional documents to support narrative (*e.g.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened 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. Incomplete applications and applications that are not responsive to the administrative thresholds will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS OUIHP within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The Notice of Award (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. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for one year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed 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 the IHS.

VI. Award Administration Information

1. 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.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. 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 agreement 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 agreement 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" in Section VII or the main DGM office at (301) 443–5204.

3. 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 quarterly, 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 period of performance.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at *https://pms.psc.gov.* The applicant is also requested to upload a copy of the FFR (SF–425) into our grants management system, GrantSolutions. Failure to submit timely reports may result in adverse award actions blocking access to funds.

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 website, (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.

The 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 period of performance is made up of more than one budget period) and where: (1) The period of performance 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 website 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. The 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 (OCR) 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 OCR for more information about obligations and prohibitions under federal civil rights laws at *https://www.hhs.gov/ocr/about-us/contact-us/index.html* or call (800) 368–1019 or TDD (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 *https://minority health.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 IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following website: *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), at *http:// www.fapiis.gov,* 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. The 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.

G. 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: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant Disclosures'' in subject line).

Office: (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: *https://oig.hhs.gov/fraud/ report-fraud/,* (Include ''Mandatory Grant Disclosures'' in subject line).

Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or

Email: MandatoryGrantee Disclosures@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: Shannon Beyale, Health Information Specialist, Office of Urban Indian Health Programs, 5600 Fishers Lane, Mail Stop: 08E65D, Rockville, MD 20857, Phone: (301) 945–3657, Fax: (301) 443–8446, Email: *Shannon.Beyale@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Donald Gooding, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2298, Fax: (301) 594–0899, Email: *Donald.Gooding@ihs.gov.*

3. Questions on systems matters may be directed to: 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) 594–0899, Email: *Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all grant, 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.

Michael D. Weahkee,

RADM, Assistant Surgeon General, U.S. Public Health Service, Principal Deputy Director, Indian Health Service.

[FR Doc. 2019–08413 Filed 4–25–19; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of changes to the *NIH Guidelines.*

SUMMARY: This notice sets forth final changes to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) to streamline oversight for human gene transfer clinical research protocols and reduce duplicative reporting requirements already captured within the existing regulatory framework, as initially outlined by the NIH Office of Science Policy (OSP) in a **Federal Register** notice issued on August 17, 2018. Following the solicitation of public comment on its original proposal, the NIH is amending the *NIH Guidelines* to: (A) Delete the NIH protocol registration submission and reporting requirements under Appendix M of the *NIH Guidelines,* and (B) modify the roles and responsibilities of entities that involve human gene transfer and the Recombinant DNA Advisory Committee (RAC).

DATES: Changes outlined in this notice will be effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional background information about these changes, please contact the NIH by email at *SciencePolicy@od.nih.gov,* or telephone at 301–496–9838. You may also contact Jessica Tucker, Ph.D., Director of the Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy, Office of Science Policy, NIH, at 301–451–4431 or *Jessica.Tucker@nih.gov.*

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice issued on August 17, 2018 (83 FR 41082), the NIH proposed a series of actions to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline oversight of human gene transfer research (HGT), and to focus the *NIH Guidelines* more specifically on biosafety issues associated with research involving recombinant or synthetic nucleic acid molecules. The field of HGT has recently experienced a series of advances that has resulted in the translation of research into clinical practice, including Food and Drug Administration (FDA) approvals for licensed products. Additionally, oversight mechanisms for ensuring HGT is appropriately assessed for safety risks have sufficiently evolved to keep pace with new discoveries in this field. At this time, there is duplication in submitting protocols, annual reports, amendments, and serious adverse events for HGT protocols to both the

NIH and the FDA that does not exist for other areas of clinical research. It is an opportune time to make changes to the *NIH Guidelines* to make oversight of HGT commensurate with oversight afforded to other areas of clinical research, given the robust infrastructure in place to oversee this type of research.

After careful consideration of public comments, the NIH is amending the *NIH Guidelines* in the following areas:

1. Elimination of HGT protocol submission and reporting requirements to the NIH, and individual HGT protocol review by the Recombinant DNA Advisory Committee (RAC).

2. Modification of roles and responsibilities of investigators, institutions, Institutional Biosafety Committees (IBCs), the RAC, and the NIH to be consistent with these goals including:

a. Modification of roles of IBCs in reviewing HGT to be consistent with review of other covered research.

b. Elimination of roles of the RAC in HGT and biosafety.

The proposed changes outlined above will require amendment of multiple portions of the *NIH Guidelines* (see section below on "Amendments to the *NIH Guidelines*"). Following deletions, sections and appendices will be relabeled to proceed consecutively throughout the *NIH Guidelines.* Language in the "Amendments to the *NIH Guidelines*" section below includes updated references to relabeled section and appendix names, where relevant. Sections of the *NIH Guidelines* also will be amended to include several minor additional changes to provide non-substantive clarifications or for consistency.

Overview of Comments Received in Response to NIH's Proposal To Amend the *NIH Guidelines* (83 FR 41082)

The NIH received 43 comments (available at *https://osp.od.nih.gov/wp-content/uploads/Aug162018_AllComments_r508.pdf*) in response to its proposal to amend the *NIH Guidelines,* posted in the **Federal Register** on August 17, 2018, including from individuals from the general public, academic institutions, and industry; and professional or membership organizations representing the biosafety, gene therapy, biotechnology, patient advocacy, academic, medical, and Institutional Review Board (IRB) communities. Few comments received in response to the **Federal Register** notice (83 FR 41082) (hereafter referred to as the August 17, 2018 FRN) reflected views entirely supportive of or in opposition to the proposal, but instead indicated support