

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Michael Brent, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0647, [michael.brent@fda.hhs.gov](mailto:michael.brent@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of March 27, 2018, FDA published a notice of availability with a 60-day comment period to request comments on draft GFI #255 entitled “Elemental Impurities in Animal Drug Products—Questions and Answers.”

This level 1 draft guidance is being issued consistent with FDA’s good

guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Elemental Impurities in Animal Drug Products—Questions and Answers”, providing recommendations to sponsors regarding the control of elemental impurities in animal drug products, including all dosage forms and routes of administration. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The Agency received two requests for an extension of the comment period for the draft guidance. The requestors indicated they needed more time to complete development of comments to submit in response to the draft guidance.

FDA has considered the requests and is reopening the comment period for the draft guidance for 60 days, until October 15, 2018. The Agency believes that a 60-day reopening of the comment period allows adequate time for interested persons to submit comments to ensure that the Agency can consider the comments on this draft guidance before it begins work on the final version of the guidance.

**II. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: August 9, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

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

*Announcement Type:* Competing Supplement

*Funding Announcement Number:* HHS-2018-IHS-EPI-0002

*Catalog of Federal Domestic Assistance Number:* 93.231

**Key Dates**

*Application Deadline Date:* September 12, 2018

*Review Date:* September 14–18, 2018

*Earliest Anticipated Start Date:* September 30, 2018

**I. Funding Opportunity Description**

*Statutory Authority*

The Indian Health Service (IHS) Office of Public Health Support, Division of Epidemiology and Disease Prevention (DEDP), is accepting applications for a cooperative agreement for competitive supplemental funds to enhance activities in the Epidemiology Program for American Indian/Alaska Native (AI/AN) Tribes and Urban Indian communities.

This program is authorized under: Section 317(k)(2) of the Public Health Service Act [42 U.S.C. 247(b)(k)(2), as amended]. Funding for this award will be provided by: The Centers for Disease Control and Prevention’s (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). The authorities will be exercised by CDC and through an Intra-Departmental Delegation of Authority (IDDA) with IHS to create a supplemental funding opportunity for Tribal Epidemiology Centers. The administration will be carried out through an Intra-agency Agreement (IAA) between CDC and IHS. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.231.

*Background*

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1998 as a way to provide public health support to multiple Tribes and Urban Indian communities in each of the IHS Areas. Only current TEC grantees serving Arizona Indian Tribes or Urban Indian communities with confirmed cases of Rocky Mountain spotted fever (RMSF) between 2003–2017 are eligible to apply for the competing supplemental funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the TEC program.

Positioned uniquely within Tribes and Tribal or Urban Organizations, TECs are able to conduct disease surveillance, research, prevention and control of disease, injury, or disability. This allows them to assess the effectiveness of AI/AN public health programs. In addition, they can fill gaps in data needed for the relevant Government Performance and Results Act and Healthy People 2020 measures. Some of the existing TECs have already

developed innovative strategies to monitor the health status of Tribes and Urban Indian communities, including development of Tribal health registries and use of sophisticated record linkage computer software to correct existing state data sets for racial misclassification. Tribal Epidemiology Centers work in partnership with IHS DEDP to provide a more accurate national picture of Indian health status. To further the goals of the partnership, a new CDC funding opportunity will be made available to TECs to implement cancer projects in Indian Country, designed to help decrease these disparities and lessen the burden of cancer in this population. For administrative purposes, this new funding opportunity will be packaged with the existing IHS cooperative agreements.

RMSF is a life-threatening tickborne disease. RMSF has been an emerging threat to Tribal communities in Arizona since 2003, with more than 388 cases and 23 deaths—a case fatality rate 15 times higher than the national rate.

Epidemics in Arizona Tribal communities are driven by large populations of brown dog ticks and free-roaming dog populations, and thus require control of the animal and vector population. Effective control strategies have been identified through evidence-based research with Tribal, Federal, state, and private partners in an innovative project called the RMSF Rodeo. This project demonstrated that integrated pest management techniques including use of tick preventives on dogs, environmental pesticide and community education could effectively reduce the number of ticks on dogs, in the environment, and more importantly, reduced the incidence of RMSF in Tribal communities. Cases in the project area were reduced by 43%. While these effective techniques have been identified and successfully implemented, they require fundamental infrastructure in vector control and animal control, which are often lacking in Tribal communities.

Many of the impacted Tribal communities are small (fewer than 15,000 residents), rural communities where resources for vector and animal control may not be available. Consolidation of resources by region can ensure prudent use of funds where individual positions cannot be supported. Tribal Epidemiology Centers have a unique appreciation and understanding of these factors and ensure that health priorities and program interventions are culturally competent, appropriate, and locally minded. Tribal Epidemiology Centers

provide technical assistance by way of program management, epidemiologic support and project design. These resources are often provided to one or more Tribal nations in the region and can serve as a regional support for area Tribes.

For the purpose of this Notice of Funding Opportunity (NOFO), technical assistance to support prevention of RMSF should be locally tailored and evidence-based. Recommended prevention practices could focus on material resources for vector control, environmental cleanup or animal control, training and staff development relating to RMSF prevention, or developing educational materials to educate the public and providers about issues relating to RMSF. All assistance with educational materials needs to ensure those that are used are culturally appropriate and locally-minded. Awardees are expected to provide support for applicant-identified outcomes from the following: Improve RMSF prevention practices to support the health of targeted Tribal communities at risk for RMSF, disseminate lessons learned on proven interventions of RMSF, and create sustainable RMSF prevention programs.

#### *Purpose*

The purpose of this IHS cooperative agreement is to build capacity for RMSF prevention in Arizona's Tribes. RMSF prevention is a multidisciplinary problem, requiring technical resources across public health, veterinary, clinical medicine, vector control, environmental health and sanitation. This NOFO will support Tribes, through the technical assistance and trainings of regional TECs, in providing training for staff, purchasing equipment, building facilities, developing communications materials, and establishing partnerships that will sustain RMSF prevention in the long term.

#### *Limited Competition Justification*

The IHS enters into cooperative agreements with TECs under the authority of Section 214(a)(1) of the Indian Health Care Improvement Act, Public Law 94-437, as amended by Public Law 102-573. Tribal Epidemiology Centers carry out a list of functions specified in statute. These functions include data collection and analysis; evaluation of existing delivery systems, data systems, and other systems that impact the improvement of Indian health; making recommendations for the targeting of services; and provision of requested technical assistance to Indian Tribes, Tribal organizations, and Urban Indian

organizations [25 U.S.C. 1621m(b)]. Other organizations do not have the capacity to provide this support. With respect to access to information, TECs are treated as public health authorities for the purpose of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191). Unlike their counterparts, they have no (or little) funding from their jurisdictional governments to perform these public functions.

The limited-eligibility NOFO will allow direct support of RMSF prevention to TECs serving Arizona Indian Tribes and Urban Indian Organizations with confirmed cases of RMSF between 2003–2017. Utilization of TECs allows for the consolidation of regional resources across Tribal boundaries. TECs already possess technical expertise in program management, community-based interventions and educational tool development. Tribal Epidemiology Centers must have demonstrated their ability to methodically and effectively reach Tribal members and efficiently work with AI/AN populations on their public health capacity building. Selected organizations that have previous experience working effectively with Tribal governments will help ensure that interventions and infrastructure are culturally appropriate and locally minded.

## **II. Award Information**

### *Type of Award*

Cooperative Agreement.

### *Estimated Funds Available*

The total amount of funding identified for the current fiscal year (FY) 2018 is approximately \$300,000. Individual award amounts are anticipated to be between \$100,000 and \$300,000. 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*

Approximately two awards will be issued under this program announcement.

### *Period of Performance*

The period of performance is for three years and will run consecutively from September 30, 2018 to September 29, 2021.

### Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency (CDC) 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 the CDC and the grantee. The CDC per the Memorandum of Understanding (MOU) between the IHS and the CDC, 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 and CDC Programmatic Involvement

(1) IHS will compete funds for TEC's using a NOFO. The IHS will be responsible for convening an Objective Review Committee (ORC) and selecting eligible applicants as detailed above.

(2) The IHS and the CDC will be involved with ongoing consultation and technical assistance to plan, implement, and evaluate each component as described under Recipient Activities. Consultation and technical assistance may include, but not be limited to, the following areas:

- (i) Interpretation of current scientific literature related to epidemiology, statistics, surveillance, and other public health issues relating to RMSF;
- (ii) Technical assistance on the design and implementation of each program component such as surveillance, epidemiologic analysis, outbreak investigation, development of epidemiologic studies, development of disease control programs, coordination of activities, and training of study staff;
- (iii) Participating in the presentation of results in publications, if applicable; and

(iv) Technical assistance on overall operational planning and program management.

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

##### B. Grantee Cooperative Agreement Award Activities

(1) Build Tribal capacity to provide animal control, vector control or environmental cleanup, by providing

technical assistance to the Tribe and/or Urban Indian Organization (UIO) in the purchase or rental of equipment, hiring of staff and training of staff in safe and effective vector control, animal control, and environmental cleanup practices.

(2) Assist Tribes with conducting evidence-based RMSF prevention activities in communities at risk. Rocky Mountain spotted fever prevention activities can include (but are not limited to) cleanup of solid waste in and around homes, spay and neuter activities, and tick prevention campaigns.

(3) Provide assistance to Tribes to conduct community education about RMSF, including the signs and symptoms, prevention, importance of early treatment and confirmatory testing.

### III. Eligibility Information

#### 1. Eligibility

Only current Arizona TEC grantees serving Tribes with previously reported cases of RMSF are eligible to apply for the competing supplemental funding under this announcement. They must demonstrate that they have complied with previous terms and conditions of the TEC program.

Rocky Mountain spotted fever is a life-threatening tickborne disease. An ongoing epidemic of RMSF affects Tribal lands in Arizona with more than 388 cases and 23 deaths since 2003—a case fatality rate 15 times higher than that national rate. All deaths from locally acquired RMSF in Arizona have occurred among Native peoples. Six Tribes in the Arizona area have experienced epidemic rates of RMSF transmitted by this tick vector. Only Arizona TECs serving Tribes with previously reported cases of RMSF will be eligible to apply for this cooperative agreement. To avoid redundancy for funded activities, applicants must disclose any other federal funds from the current FY that have been received or applied specifically for RMSF prevention.

#### No Supplanting of Funds

The applicant must certify that: (1) The TEC RMSF Competing Supplemental Funds, if awarded, will not supplant expenditures from other Federal, State, or local sources or funds independently generated by the grantee; and (2) the TEC RMSF Competing Supplemental Funds, if awarded, will not supplant any leverage related to this grant, if any (that is, the grantee must have pursued and secured leverage to the fullest extent possible in order to ensure that expenditures from other

Federal, State, or local sources or funds independently generated by the grantee are not supplanted).

**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 and documents required.

#### 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, the IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

### IV. Application and Submission Information

#### 1. Obtaining Application Materials

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

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

#### 2. Content and Form Application Submission

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF-424, Application for Federal Assistance.
  - SF-424A, Budget Information—Non-Construction Programs.
  - SF-424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single-spaced and not exceed 5 pages).
- Project Narrative (must be single-spaced and not exceed 10 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.
- Letters of Support from organization's Board of Directors.

- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor or 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 website: <https://harvester.census.gov/facdissem/Main.aspx>.

*Public Policy Requirements:* All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

#### Requirements for Project and Budget Narratives

*A. Project Narrative:* This narrative should be a separate Word document that is no longer than 10 pages and must: Be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 points, and be printed on one side only of standard size 8½" x 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 ORC in becoming familiar with the applicant's activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, only the first 10 pages will be reviewed. The 10-page limit for the narrative does not include the work plan, standard forms, 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 Limit

##### *Section 1: Needs.*

Describe applicant's current health program activities relating to RMSF prevention, including elements of vector control, animal control and solid waste cleanup, how long each element has been operating, what programs or services are currently being provided and identify any current partnerships supporting current Tribal programs. Describe the TEC's administrative infrastructure to support the assumption of program goals and accomplishments.

#### Part B: Program Planning and Evaluation 5 Page Limit

##### *Section 1: Program Plans.*

Fully and clearly describe the TEC's plans to demonstrate improved health and services to the community it serves. Include proposed timelines for negotiations and deliverables. Please note any partnerships you plan to utilize as part of program implementation. Please discuss any prioritization of RMSF prevention elements or justification for not addressing any of the key RMSF prevention tenets (animal control, vector control, education, or environmental cleanup).

##### *Section 2: Program Evaluation.*

Describe fully and clearly the improvements that will be made by the TEC to RMSF and identify the anticipated or expected benefits for Tribal communities they serve. Describe the outcomes that you plan to achieve within the funding period and how you plan to collect outcome and performance measures.

#### Part C: Program Report 2 Page Limit

Describe your organization's significant program activities and accomplishments over the past five years associated with the goals of this announcement.

Please identify and describe significant program activities and achievements associated with RMSF. 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 Limit

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

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email at [support@grants.gov](mailto:support@grants.gov) or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys ([Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov)), Grant Systems Coordinator, DGM, by telephone at (301) 443–2114 or (301) 443–5204. Please 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 or cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

#### 6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the <http://www.Grants.gov> website to submit an application electronically and select the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the Package tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

#### Waiver Request

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below

for additional information). A written waiver request must be sent to [GrantsPolicy@ihs.gov](mailto:GrantsPolicy@ihs.gov) with a copy to [Robert.Tarwater@ihs.gov](mailto: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 Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. 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](mailto:Grants.gov) Support directly at: [support@grants.gov](mailto: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](http://www.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](http://www.Grants.gov) as the registration process for SAM and [Grants.gov](http://www.Grants.gov) could take up to 15 working days.

- Please use the optional attachment feature in [Grants.gov](http://www.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](http://www.Grants.gov) that contains a [Grants.gov](http://www.Grants.gov) tracking number. The DGM will download the application from [Grants.gov](http://www.Grants.gov) and provide necessary copies to the appropriate agency officials. Neither the DGM nor the Division of Epidemiology and Disease Prevention will notify the applicant that the application has been received.

- Email applications will not be accepted under this announcement.

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

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, 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 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 website: <http://www.ihs.gov/dgm/policytopics/>.

## V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 10 page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

### 1. Criteria

A. Introduction and Need for Assistance (10 Points)

- Background and problem statement. Provide concise summary of RMSF in Tribal communities served by the TEC. Include information about:

- Impacted Tribal communities. (1 point)

- Number of RMSF cases in Tribal communities. (1 point)

- Tribal Epidemiology Center jurisdiction (which of the impacted Tribal communities are served by the TEC). (1 point)

- Evidence of previous work with Tribal populations. (2 points)

- Evidence of gaps in current Tribal RMSF response. (5 points)

B. Project Objective(s), Work Plan and Approach (25 Points)

- Clearly identify the objectives of the program to be fulfilled by the TEC. At least two objectives should be able to be completed within the program period (indicate these two objectives in bold). (10 points)

- Outline approach for achieving above listed objectives in work plan or

logic model. Outline overarching activities, short-term and long term-outcomes. Make note of proposed timelines and partners who will be involved in each activity. (15 points)

#### C. Program Evaluation (30 Points)

- Clearly identify plans for program evaluation to ensure that objectives of the program are met at the conclusion of the funding period. (10 points)
- Include SMART (Specific, measurable, achievable, realistic and time-bound) evaluation criteria. (10 points)
- Evaluation should minimally include summaries of activities in each of the key RMSF prevention tenants (animal control, vector control, education, or environmental cleanup). (10 points)

#### D. Organizational Capabilities, Key Personnel and Qualifications (30 Points)

- Include an organizational capacity statement which demonstrates the ability to execute program strategies within the program period. (10 points)
- Project management and staffing plan. Detail that the organization has the current staffing and expertise to address each of the program activities. If current capacity does not exist please describe the actions that the TEC will take to fulfill this gap within a specified timeline. (10 points)
- Demonstrate Tribal willingness to work with TEC on RMSF prevention efforts. (5 points)
- Demonstrate that the TEC has previous successful experience providing technical or programmatic support to Tribal communities. (5 points)

#### E. Categorical Budget and Budget Justification (5 Points)

- Provide a detailed budget and accompanying narrative to explain the activities being considered and how they are related to proposed program objectives. (5 points)

#### Multi-Year Project Requirements

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

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

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.

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

- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

#### 2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, regarding 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 or project period.

#### Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. 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 retained by DGM for a period of one year. If additional funding becomes available during the course of FY 2018 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) <https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443–5204.

### 4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

#### A. Progress Reports

Program progress reports are required annually, within 30 days after the

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

#### D. Compliance With Executive Order 13166 Implementation of Services

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

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

The HHS Office for Civil Rights (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://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his or 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.

#### E. 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: 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](mailto:Robert.Tarwater@ihs.gov).

#### AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <http://oig.hhs.gov/fraud/report-fraud/index.asp>.

(Include "Mandatory Grant Disclosures" in subject line)  
Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or

Email: [MandatoryGranteeDisclosures@oig.hhs.gov](mailto: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 and 376 and 31 U.S.C. 3321).

#### VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Lisa C. Neel, Public Health Advisor, Office of Public Health Support, Division of Epidemiology & Disease Prevention, Indian Health Service, 5600 Fishers Lane, Mailstop: 09E17B, Rockville, MD 20857, Phone: (301) 443-4305, EMail: [Lisa.Neel@ihs.gov](mailto:Lisa.Neel@ihs.gov).

2. Questions on grants management and fiscal matters may be directed to: John Hoffman, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2116, Fax: (301) 594-0899, Email: [John.Hoffman@ihs.gov](mailto:John.Hoffman@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](mailto:Paul.Gettys@ihs.gov).

#### VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement

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

Dated: August 9, 2018.

**Michael D. Weahkee,**

*Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.*

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BILLING CODE 4165-16-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

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

*Announcement Type:* Competing Supplement

*Funding Announcement Number:* HHS-2018-IHS-EPI-0001

*Catalog of Federal Domestic Assistance Number:* 93.231

#### Key Dates

*Application Deadline Date:* September 12, 2018

*Review Date:* September 14-18, 2018

*Earliest Anticipated Start Date:* September 30, 2018

#### I. Funding Opportunity Description

##### *Statutory Authority*

The Indian Health Service (IHS) Office of Public Health Support, Division of Epidemiology and Disease Prevention (DEDP), is accepting applications for cooperative agreement for competitive supplemental funds to enhance activities in the Epidemiology Program for American Indian/Alaska Native (AI/AN) Tribes and Urban Indian communities. This program is authorized under: Section 317(k)(2) of the Public Health Service Act (42 U.S.C. Section 247b(k)), as amended. Funding for this award will be provided by: The Centers for Disease Control and Prevention's (CDC) National Center for Chronic Disease Prevention and Health Promotion. The authorities will be exercised by CDC and through an Intra-Departmental Delegation of Authority