

projectors. Although these LIPs emit laser light from extended sources and their uncollimated beams do not present the same hazards as other lasers, they are laser products that present risks and must undergo classification in accordance with § 1040.10(c).

Under § 1040.10(c), FDA recognizes four major hazard classes (I to IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). Under this classification procedure, higher laser classes correspond to more powerful lasers and the potential to pose serious danger if used improperly.

As demonstration laser products, LIPs cannot exceed class IIIa (which is comparable to IEC class 3R) emissions limits as specified in § 1040.11(c) unless granted a variance by FDA under § 1010.4. Many LIPs and applications for LIPs will exceed the class IIIa limits and therefore require a variance to exceed those emission limits.

This guidance document describes FDA's intent with regard to the application of certain aspects of the performance standard requirements in § 1040.11(c) for LIPs. The IEC standards used to evaluate lamps are applicable to characterizing ocular hazards in LIPs, because a laser retinal hazard is related to the radiance of the laser source and the radiant emission levels produced by LIPs are comparable to conventional lamps. Because the radiant emission levels produced by LIPs can scientifically be characterized by an alternative IEC standard, FDA does not intend to consider whether LIP manufacturers that conform to these standards under the situations described in this guidance also comply with §§ 1040.10(c) and 1040.11(c).

II. Significance of Guidance

The guidance represents the Agency's current thinking on the classifications and requirements for LIPs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy

of "Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400056 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 1002, 1010, and 1040 are approved under OMB control number 0910–0025.

The labeling referenced in section (IV)(c)(ii) of the guidance does not constitute a "collection of information" under the PRA because the labeling is a "public disclosure of information supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03209 Filed 2–17–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Negotiation Cooperative Agreement

Announcement Type: New—Limited Competition.

Funding Announcement Number: HHS–2015–IHS–TSGN–0001.

Catalog of Federal Domestic Assistance Number: 93.444.

Key Dates

Application Deadline Date: June 3, 2015.

Review Date: June 10, 2015.

Earliest Anticipated Start Date: July 1, 2015.

Signed Tribal Resolutions Due Date: June 10, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting limited competition Negotiation Cooperative Agreement applications for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 458aaa–2(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA), available at <https://www.cfda.gov/>, under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the government-to-government relationship between the United States and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP is one of three ways that Tribes can choose to obtain health care from the Federal Government for their members. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual PSFAs that the IHS would otherwise provide (referred to as Title I Self-Determination Contracting), or (3) compact with the IHS to assume control over healthcare PSFAs that the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances. Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs to the needs of their communities.

The TSGP is a Tribally-driven initiative and strong Tribal/Federal partnerships are essential for program success. The IHS established the OTSG to implement Tribal Self-Governance authorities. The OTSG: (1) Serves as the primary liaison and advocate for Tribes participating in the TSGP, (2) develops,

directs, and implements Tribal Self-Governance policies and procedures, (3) provides information and technical assistance to Self-Governance Tribes, and 4) advises the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director, who has the authority to negotiate Self-Governance Compacts and Funding Agreements. A Tribe should contact the respective ALN to begin the Self-Governance planning process or, if currently an existing Self-Governance Tribe, discuss methods to expand current PSFAs. The ALN shall provide an overview of the TSGP negotiations process and will provide technical assistance as the Tribe prepares to participate in the TSGP.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray costs related to preparing for and conducting TSGP negotiations. TSGP negotiations are a dynamic, evolving, and Tribally-driven process that requires careful planning and preparation by both Tribal and Federal parties, including the sharing of precise, up-to-date information. The design of the negotiations process: (1) Enables a Tribe to set its own priorities when assuming responsibility for IHS PSFAs, (2) observes the government-to-government relationship between the United States and each Tribe, and (3) involves the active participation of both Tribal and IHS representatives, including the OTSG. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of their current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans.

The negotiations process has four major stages, including: (1) Planning, (2) pre-negotiations, (3) negotiations, and (4) post-negotiations. Title V of the ISDEAA requires that a Tribe or Tribal organization complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal government planning and organizational preparation relating to the administration of health care programs. During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. A draft Compact, Funding Agreement, and funding tables are developed, typically by the Tribe, and distributed to both the Tribal and

Federal negotiation teams. These draft documents are used as the basis for pre- and final negotiations. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, Funding Agreement, and Tribal shares. At final negotiations, Tribal and Federal negotiation teams come together to determine and agree upon the terms and provisions of the Tribe's Compact and Funding Agreement.

The Tribal negotiation team must include a Tribal leader from the governing body. This representative may be a Tribal leader or a designee, like the Tribal Health Director. The Tribal negotiation team may also include technical and program staff, legal counsel, and other consultants. The Federal negotiations team is led by the ALN and generally includes an OTSG Program Analyst and a member of the Office of the General Counsel. It may also include other IHS staff and subject matter experts as needed. The ALN is the only member of the Federal negotiation team with delegated authority to negotiate on behalf of the IHS Director.

Negotiations provide an opportunity for the Tribal and Federal negotiation teams to work together in good faith to enhance each self-governance agreement. Negotiations are not an allocation process; they provide an opportunity to mutually review and discuss budget and program issues. As issues arise, both negotiation teams work through the issues to reach agreement on the final documents. After the negotiations are complete, the Compact and Funding Agreement are signed by the authorizing Tribal official and submitted to the ALN who then reviews the final package to ensure each document accurately reflects what was negotiated. Once the ALN completes this review, the final package is submitted to the OTSG to be prepared for the IHS Director's signature. After the Compact and Funding Agreement have been signed by both parties, they become legally binding and enforceable agreements. The negotiating Tribe then becomes a "Self-Governance Tribe," and a participant in the TSGP.

A Negotiation Cooperative Agreement is not a prerequisite to enter the TSGP. A Tribe may use other resources to develop and negotiate its Compact and Funding Agreement. Tribes that receive a Negotiation Cooperative Agreement are not obligated to participate in Title V and may choose to delay or decline participation or expansion in the TSGP.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria. See 25 U.S.C. 458aaa-2(e); 42 CFR 137.24-26; see also 42 CFR 137.10.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for fiscal year (FY) 2015 is approximately \$240,000. Individual award amounts are anticipated to be \$48,000. The amount of funding available for competing 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 five awards will be issued under this program announcement.

Project Period

The project period is for 12 months and runs from July 1, 2015 to June 30, 2016.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for the TSGP Negotiation Cooperative Agreement

A. IHS Programmatic Involvement

(1) Provide descriptions of PSFAs and associated funding at all organizational levels (Service Unit, Area, and Headquarters), including funding formulas and methodologies related to determining Tribal shares.

(2) Meet with Negotiation Cooperative Agreement recipient to provide program information and discuss methods currently used to manage and deliver health care.

(3) Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

(4) Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

B. Grantee Negotiation Cooperative Agreement Award Activities

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and Funding Agreement. Prepare and discuss each PSFA in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(2) Identify Tribal shares associated with the PSFAs that will be included in the Funding Agreement.

(3) Develop the terms and conditions that will be set forth in both the Compact and Funding Agreement to submit to the ALN prior to negotiations.

III. Eligibility Information

I.

1. Eligibility

To be eligible for this Limited Competition Negotiation Cooperative Agreement under this announcement, an applicant must:

A. Be an "Indian Tribe" as defined in 25 U.S.C. 450b(e); a "Tribal Organization" as defined in 25 U.S.C. 450b(l); or an "Inter-Tribal Consortium" as defined at 42 CFR 137.10. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity. *See Consolidated Appropriations Act, 2014, Pub. L. 113-76.* By statute, the Native Village of Eyak, Eastern Aleutian Tribes, and the Council for Athabaskan Tribal Governments have also been deemed Alaska Native regional health entities and therefore are eligible to apply. Those Alaska Tribes not represented by a Self-Governance Tribal consortium Funding Agreement within their area may still be considered to participate in the TSGP.

B. Submit a Tribal resolution from the appropriate governing body of each Indian Tribe to be served by the ISDEAA Compact authorizing the submission of the Negotiation Cooperative Agreement application. Tribal consortia applying for a TSGP Negotiation Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application. Applications by Tribal organizations will not require a specific Tribal

resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

Draft Tribal resolutions are acceptable in lieu of an official signed resolution and must be submitted along with the electronic application submission prior to the official application deadline date or prior to the start of the Objective Review Committee (ORC) date. However, an official signed Tribal resolution must be received by the DGM prior to the beginning of the Objective Review. If an official signed resolution is not received by the Review Date listed under the Key Dates section on page one of this announcement, the application will be considered incomplete and ineligible for review or further consideration.

Mail the official signed resolution to the DGM, Attn: Mr. John Hoffman, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852. Applicants submitting Tribal resolutions after or aside from the required online electronic application submission must ensure that the information is received by the IHS/DGM. It is highly recommended that the documentation be sent by a delivery method that includes delivery confirmation and tracking. Please contact Mr. Hoffman by telephone at (301) 443-5204 prior to the review date regarding submission questions.

C. Demonstrate, for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three years prior to participation in Self-Governance, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance Funding Agreements with any Federal agency. *See 25 U.S.C. 458aaa-2; 42 CFR 137.15-23.*

For Tribes or Tribal organizations that expended \$750,000 or more (\$500,000 for FYs ending after December 31, 2003) in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse.

For Tribes or Tribal organizations that expended less than \$750,000 (\$500,000 for FYs ending after December 31, 2003) in Federal awards, the Tribe or Tribal organization must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. *See 42 CFR 137.21-23.*

Meeting the eligibility criteria for a Negotiation Cooperative Agreement does not mean that a Tribe or Tribal organization is eligible for participation in the IHS TSGP under Title V of the

ISDEAA. *See 25 U.S.C. 458aaa-2; 42 CFR 137.15-23.* For additional information on eligibility for the IHS TSGP, please visit the Eligibility and Funding page on the OTSG Web site, located at: <http://www.ihs.gov/SelfGovernance>.

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

2. Cost Sharing or Matching

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

3. Other Requirements

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

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 https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding.

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

2. Content and Form Application Submission

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
 - SF-424, Application for Federal Assistance.
 - SF-424A, Budget Information—Non-Construction Programs.
 - SF-424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must be single spaced and not exceed ten pages).
 - Background information on the Tribe or Tribal organization.

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

- Tribal Resolution(s).
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Organizational Chart (optional).

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 ten pages and must: be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8¹/₂ xsp0;2" x 11" paper.

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

There are three parts to the narrative, including: (1) Part A—Program Information; (2) Part B—Program Planning and Evaluation; and (3) Part C—Program Report. See below for additional details about what must be included in the narrative.

Part A: Program Information (4 page limitation)

Section 1: Needs

Introduction and Need for Assistance

Demonstrate that the Tribe has conducted previous self-governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the knowledge and expertise to assume or expand PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

Part B: Program Planning and Evaluation (4 page limitation)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measurable terms the objectives and appropriate activities to achieve the following Cooperative Agreement Recipient Award Activities: (a) Determine the PSFAs that will be negotiated into the Tribe's Compact and Funding Agreement. Prepare and discuss each PSFA in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(b) Identify Tribal shares associated with the PSFAs that will be included in the Funding Agreement.

(c) Develop the terms and conditions that will be set forth in both the Compact and Funding Agreement to submit to the ALN prior to negotiations.

Describe fully and clearly how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health services to the community and incorporate the proposed timelines for negotiations.

Organizational Capabilities, Key Personnel and Qualifications

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

Section 2: Program Evaluation

Describe fully and clearly the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected

benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

Part C: Program Report (2 page limitation)

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

Please identify and describe significant health related accomplishments associated with the delivery of quality health services. This section should highlight major program achievements over the last 24 months.

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

Please provide an overview of significant program activities associated with the delivery of quality health services over the last 24 months. This section should address significant program activities including those related to the accomplishments listed in the previous section.

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

3. Submission Dates and Times

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

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to support@grants.gov or at (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys, DGM (Paul.Gettys@ihs.gov), DGM Grants Systems Coordinator, by telephone at (301) 443-2114. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Once the waiver request has been approved, the applicant will receive a confirmation of approval Email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Acting 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., EST, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

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

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant per grant cycle. Tribes cannot apply for both the Planning Cooperative and the Negotiation Cooperative Agreement within the same grant cycle.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the <http://www.Grants.gov> Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the <http://www.Grants.gov> Web site. Electronic

copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

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

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

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.

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

- Email applications will not be accepted under this announcement.

Unique Entity Identifier (UEI) Numbering System

All IHS applicants and grantee organizations are required to obtain a UEI number and maintain an active registration in the SAM database. The UEI number is a unique 9-digit identification number provided to each entity. The UEI number is site specific; therefore, each distinct performance site may be assigned a UEI number. Obtaining a UEI number is easy, and there is no charge. To obtain a UEI number, please contact Mr. Paul Gettys at (301) 443-2114.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its UEI 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 (CCR) and have not registered with SAM will need to obtain a UEI 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 UEI and SAM, can be found on the IHS

Grants Management, Grants Policy Web site: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

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 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 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 points)

Demonstrate that the Tribe has conducted previous self-governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the knowledge and expertise to assume or expand PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

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

State in measurable terms the objectives and appropriate activities to achieve the following Cooperative Agreement Recipient Award Activities:

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and Funding Agreement. Prepare and discuss each PSFA in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(2) Identify Tribal shares associated with the PSFAs that will be included in the Funding Agreement.

(3) Develop the terms and conditions that will be set forth in both the Compact and Funding Agreement to submit to the ALN prior to negotiations. Clearly describe how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health care services to the community and incorporate the proposed timelines for negotiations.

C. Program Evaluation (25 points)

Describe fully the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

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

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

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 OTSG to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The

applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.*, budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

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

VI. Award Administration Information

1. Award Notices

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

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval (60 points), and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The OTSG will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved", but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2015, then the approved but unfunded application may be re-considered by the OTSG for possible funding. The applicant will also receive

an Executive Summary Statement from the OTSG within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the Project Director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

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

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- 45 CFR part 75, Uniform Administrative Requirements Cost Principles, and Audit Requirements for HHS Awards.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- 45 CFR part 75, subpart E—Cost Principles

E. Audit Requirements:

- 45 CFR part 75, subpart F—Audit Requirements

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required

reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Reports must be submitted electronically via 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 semi-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, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

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

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

C. Federal Subaward Reporting System (FSRS)

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

The Transparency Act requires the 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 subawards 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 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 subaward obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

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

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Jeremy Marshall, Program Officer, Office of Tribal Self-Governance, 801 Thompson Avenue, Suite 240, Rockville, MD 20852.

Phone: (301) 443–7821.

Fax: (301) 443–1050.

Email: Jeremy.Marshall@ihs.gov.

Web site: www.ihs.gov/selfgovernance.

2. Questions on grants management and fiscal matters may be directed to: John Hoffman, Grants Management Specialist, Division of Grants Management, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852.

Phone: (301) 443–5204.

Fax: (301) 443–9602.

Email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852.

Phone: (301) 443–2114; or the DGM main line (301) 443–5204.

Fax: (301) 443–9602.

E-Mail: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 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: February 10, 2015.

Robert G. McSwain,

Deputy Director, Indian Health Service.

[FR Doc. 2015-03235 Filed 2-17-15; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: March 6, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Camilla E. Day, Ph.D., Scientific Review Officer, CIDR, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892, 301-402-8837, camilla.day@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: February 10, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-03212 Filed 2-17-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Effectiveness of Treatment, Prevention, and Services Interventions (R01/R01 Collaborative).

Date: March 4, 2015.

Time: 11:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301-451-2356, gavinevanskm@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Pilot Effectiveness Studies and Services Research Grants (R34).

Date: March 4, 2015.

Time: 1:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-1225, aschulte@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Gut-Microbiome-Brain Interactions and Mental Health (R21/R33).

Date: March 11, 2015.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive BLVD, Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-9734, millerda@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Fellowships and Dissertation Grants.

Date: March 11, 2015.

Time: 11:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892-9606, 301-443-9699, bursteinme@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Dimensional Approaches to Research Classification in Psychiatric Disorders (RDoC).

Date: March 13, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 11, 2015.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-03218 Filed 2-17-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as