

Our estimate of the number of respondents and the total annual responses in table 1, Estimated Annual Reporting Burden, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses are based on initial reports. Followup reports, if any, are not counted as new reports. Based on our experience with adverse event reporting, we assume it takes respondents 0.6 hour to submit a voluntary adverse event report via the SRP, 1 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. We assume it takes respondents 0.6 hour to submit an RFR report, whether the submission is mandatory or voluntary.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910–0284 and 0910–0291. While we do not charge for the use of the ESG, we require respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from \$20 to \$30.

Our estimated burden for the information collection reflects an overall increase of 688,547 hours and a corresponding increase of 1,145,763 responses. We attribute this adjustment to an increase in the number of submissions we have received over the last few years.

Dated: May 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; Tribal Management Grant Program

Announcement Type: New and Competing Continuation.

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

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.228.

Key Dates

Application Deadline Date: July 1, 2019.

Earliest Anticipated Start Date: August 1, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Direct Service and Contracting Tribes (ODSCT), is accepting applications for grants for the Tribal Management Grant (TMG) Program. This program is authorized under: 25 U.S.C. 5322(b)(2) and 25 U.S.C. 5322(e) of the Indian Self-Determination and Education Assistance Act (ISDEAA), Public Law 93–638, as amended. This program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.228.

Background

The TMG Program is a competitive grant program that is capacity building and developmental in nature and has been available for federally recognized Indian Tribes and Tribal Organizations (T/TOs) since shortly after enactment of the ISDEAA in 1975. The TMG Program was established to assist T/TOs to prepare for assuming all or part of existing IHS programs, functions, services, and activities (PFSAs) and further develop and improve Tribal health management capabilities. The TMG Program provides competitive grants to T/TOs to establish goals and performance measures for current health programs; assess current management capacity to determine if new components are appropriate; analyze programs to determine if a T/TO's management is practicable; and develop infrastructure systems to manage or organize PFSAs.

Purpose

The purpose of this IHS grant program is to enhance and develop health management infrastructure and assist T/TOs in assuming all or part of existing IHS PFSAs through a Title I ISDEAA contract and assist established Title I ISDEAA contractors and Title V ISDEAA compactors to further develop and improve management capability. In addition, Tribal Management Grants are available to T/TOs under the authority of 25 U.S.C. 5322(e) for the following: (1) Obtaining technical assistance from providers designated by the Tribe/Tribal Organization (including T/TOs that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary

for contract management, and the development of cost allocation plans for indirect cost rates; and (2) planning, designing, monitoring, and evaluating Federal programs serving T/TOs, including Federal administrative functions.

II. Award Information

Funding Instrument

Grant.

Estimated Funds Available

The total funding identified for fiscal year (FY) 2019 is approximately \$2,465,000. Individual award amounts for the first budget year are anticipated to be between \$50,000 and \$150,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 12–14 awards will be issued under this program announcement.

Period of Performance

The Tribal Management Grant (TMG Project) period of performance vary based on the project type selected. Period of performance could run from 1 to 3 years. Please refer to “Eligible TMG Project Types, Maximum Funding Levels, and Periods of Performance,” for additional details.

III. Eligibility Information

1. Eligibility

“Indian Tribes” and “Tribal Organizations” (T/TOs) as defined by the ISDEAA are eligible to apply for the TMG Program. The definitions for each entity type are outlined below. Only one application per Tribe/Tribal organization is allowed.

- An Indian Tribe as defined by 25 U.S.C. 5304(e). The term “Indian tribe” means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.
- A Tribal organization as defined by 25 U.S.C. 5304(f). The term “tribal organization” means the recognized

governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian tribe, the approval of each such Indian tribe shall be a prerequisite to the letting or making of such contract or grant.

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.

Eligible TMG Project Types, Maximum Funding Levels, and Project Periods: The TMG Program consists of four project types: (1) Feasibility study; (2) planning; (3) evaluation study; and (4) health management structure. Applicants may submit applications for one project type only. An application must state the project type selected. Any application that addresses more than one project type will be considered ineligible and will not be reviewed. The maximum funding levels noted must include both direct and indirect costs. Application budgets may not exceed the maximum funding level or period of performance identified for a project type. Any application with a budget or period of performance that exceeds the maximum funding level or period of performance will be considered ineligible and will not be reviewed. Please refer to Section IV.5, "Funding Restrictions," for further information regarding ineligible project activities.

1. FEASIBILITY STUDY (Maximum funding/project period: \$70,000/12 months).

A feasibility study must include a study of a specific IHS program or segment of a program to determine if Tribal management of the program is possible. The study shall present the planned approach, training, and resources required to assume Tribal management of the program. The study must include the following four components:

- Health needs and health care service assessments that identify existing health care services and delivery systems, program divisibility issues, health status indicators, unmet needs, volume projections, and demand analysis.

- Management analysis of existing management structures, proposed management structures, implementation plans and requirements, and personnel staffing requirements and recruitment barriers.

- Financial analysis of historical trends data, financial projections, and new resource requirements for program management costs and analysis of potential revenues from federal/non-federal sources.

- Decision statement/report that incorporates findings; conclusions; and recommendations; the presentation of the study and recommendations to the Tribal governing body for determination regarding whether Tribal program assumption is desirable or warranted.

2. PLANNING (Maximum funding/project period: \$50,000/12 months).

Planning projects involve data collection to establish goals and performance measures for health programs operation or anticipated PFSA's under a Title I contract. Planning projects will specify the design of health programs and the management systems (including appropriate policies and procedures) to accomplish the health priorities of the T/TO. For example, planning projects could include the development of a Tribe-specific health plan or a strategic health plan, etc. Please note that updated Healthy People information and Healthy People 2020 objectives are available in electronic format at the following website: <http://www.health.gov/healthypeople/publications>. The United States (U.S.) Public Health Service (PHS) encourages applicants submitting strategic health plans to address specific objectives of Healthy People 2020.

3. EVALUATION STUDY (Maximum funding/project period: \$50,000/12 months).

An evaluation study must include a systematic collection, analysis, and interpretation of data for the purpose of determining the value of a program. The extent of the evaluation study could relate to the goals and objectives, policies and procedures, or programs regarding targeted groups. The evaluation study could also be used to determine the effectiveness and efficiency of a T/TO's program operations (*i.e.*, direct services, financial management, personnel, data collection and analysis, third-party billing, etc.), as well as to determine the appropriateness of new components of a T/TO's program operations that will assist efforts to improve Tribal health care delivery systems.

4. HEALTH MANAGEMENT STRUCTURE (Average funding/project period: \$100,000/12 months; maximum

funding/project period: \$300,000/36 months).

The first year maximum funding level is limited to \$150,000 for multi-year projects. The Health Management Structure component allows for implementation of systems to manage or organize PFSA's. Management structures include health department organizations, health boards, and financial management systems, including systems for accounting, personnel, third-party billing, medical records, management information systems, etc. This includes the design, improvement, and correction of management systems that address weaknesses identified through quality control measures, internal control reviews, and audit report findings under required financial audits and ISDEAA requirements.

For the minimum standards for the management systems used by a T/TO when carrying out Self-Determination contracts, please see 25 CFR part 900, Contracts Under the Indian Self-Determination and Education Assistance Act, Subpart F—"Standards for Tribal or Tribal Organization Management Systems," §§ 900.35–900.60. For operational provisions applicable to carrying out Self-Governance compacts, please see 42 CFR part 137, Tribal Self-Governance, Subpart I,—"Operational Provisions," §§ 137.160–137.220.

2. Cost Sharing or Matching

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

3. Other Requirements

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

Additional Required Documentation

A. Tribal Organizations applying for technical assistance and/or training grants must provide written notice that the Tribal Organization is applying upon the request of the Indian Tribe and/or Tribes it intends to serve.

B. Documentation for Priority I participation requires a copy of the **Federal Register** notice or letter from the Bureau of Indian Affairs verifying establishment of recognized Tribal status within the past 5 years. The date on the documentation must reflect that

federal recognition was received during or after March 2014.

C. Documentation for Priority II participation requires a copy of the most current transmittal letter and Attachment A from the Department of Health and Human Services (HHS), Office of Inspector General (OIG), National External Audit Review Center (NEAR). See “Funding Priorities” for more information. If an applicant is unable to provide a copy of the most recent transmittal letter or needs assistance with audit issues; information or technical assistance may be obtained by contacting the IHS Office of Finance and Accounting, Division of Audit by telephone at (301) 443-1270, or toll-free at the NEAR help line at (800) 732-0679 or (816) 426-7720. Recognized Indian Tribes or Tribal Organizations not subject to Single Audit Act requirements must provide a financial statement identifying the federal dollars received in the footnotes. The financial statement must also identify specific weaknesses/recommendations that will be addressed in the TMG proposal and that are related to 25 CFR part 900, subpart F—“Standards for Tribal or Tribal Organization Management Systems.”

D. Documentation of Consortium participation—If an applicant is a member of an eligible intertribal consortium, the Tribe must:

- Identify the consortium.
- Indicate if any of the consortium member Tribes intend to submit a TMG application.
- Demonstrate that the Tribe’s application does not duplicate or overlap any objectives of the consortium’s application.
- Identify all consortium member Tribes.
- Identify if any of the consortium member Tribes intend to submit a TMG application of their own.
- Demonstrate that the consortium’s application does not duplicate or overlap any objectives of other consortium members who may be submitting their own TMG application.

Funding Priorities: The IHS has established the following funding priorities for TMG awards:

- **PRIORITY I**—Any Indian Tribe, or Tribal Organization representing that Indian Tribe, that has received federal recognition (including restored, funded, or unfunded) within the past 5 years, specifically received during or after March 2014, will be considered Priority I.
- **PRIORITY II**—T/TOs submitting a new application or a competing

continuation application for the sole purpose of addressing audit material weaknesses will be considered Priority II.

Priority II participation is only applicable to the Health Management Structure project type. For more information, see “Eligible TMG Project Types, Maximum Funding Levels, and Project Periods,” in Section II.

- **PRIORITY III**—Eligible Direct Service and T/TOs with a Title I ISDEAA contract with the IHS submitting a new application or a competing continuation application will be considered Priority III.

- **PRIORITY IV**—Eligible T/TOs with a Title V ISDEAA compact with the IHS submitting a new application or a competing continuation application will be considered Priority IV.

The funding of approved Priority I applicants will occur before the funding of approved Priority II applicants. Priority II applicants will be funded before approved Priority III applicants. Priority III applicants will be funded before approved Priority IV applicants. Funds will be distributed until depleted.

The following definitions are applicable to the PRIORITY II category:

Audit finding—deficiencies that the auditor is required by 45 CFR 75.516, to report in the schedule of findings and questioned costs.

Material weakness—“Statements on Auditing Standards 115” defines material weakness as a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity’s financial statements will not be prevented, or detected and corrected on a timely basis.

Significant deficiency—“Statements on Auditing Standards 115,” defines significant deficiency as a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

The audit findings are identified in Attachment A of the transmittal letter received from the HHS/OIG/NEAR. Please identify the material weaknesses to be addressed by underlining the item(s) listed in Attachment A.

Tribes and Tribal Organizations not subject to Single Audit Act requirements must provide a financial statement identifying the federal dollars received in the footnotes. The financial statement should also identify specific weaknesses/recommendations that will be addressed in the TMG proposal and that are related to 25 CFR part 900, “Subpart F, “Standards for Tribal and

Tribal Organization Management Systems.”

Note: A decision to award a TMG does not represent a determination from the IHS regarding the T/TO’s eligibility to contract for a specific PFSA under the ISDEAA. An application for a TMG does not constitute a contract proposal.

Tribal Resolution

The DGM must receive an official, signed Tribal resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian T/TO that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and it will not receive IHS funds until it has submitted a signed resolution to the Grants Management Specialist listed in this funding announcement.

Proof of Non-Profit Status

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

V. Application and Submission Information

1. Obtaining Application Materials

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

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

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

- Abstract (one page) summarizing the project.
- Application forms:
 - SF-424, Application for Federal Assistance.
 - SF-424A, Budget Information—Non-Construction Programs.
 - SF-424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 15 pages). See IV.2.A Project Narrative for instructions.

- Background information on the organization.

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

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

- One-page Timeframe Chart.
- Tribal Resolution(s).

- Letters of Support from organization's Board of Directors (if applicable).

- 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).
- Documentation of current Office of Management and Budget (OMB)

Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

- Face sheets from audit reports.

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

Public Policy Requirements

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

Requirements for Project and Budget Narratives

A. *Project Narrative*: This narrative should be a separate document that is no more than 15 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; (4) and be formatted to fit standard letter paper (8-1/2 x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 15-page limit for the narrative does not include the work

plan, standard forms, Tribal resolutions, budget, budget justifications, narratives, and/or other appendix items.

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

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—2 Pages)

Section 1: Needs.

Describe how the T/TO has determined the need to either enhance or develop Tribal management capability to either assume PFSAs or not in the interest of Self-Determination. Note the progression of previous TMG projects/awards if applicable.

Part 2: Program Planning and Evaluation (Limit—11 Pages)

Section 1: Program Plans.

Describe fully and clearly the direction the T/TO plans to take with the selected TMG Project type in addressing their health management infrastructure, including how the T/TO's plans to demonstrate improved health and services to the community or communities it serves. Include proposed timelines.

Section 2: Program Evaluation.

Describe fully and clearly the improvements that will be made by the T/TO that will impact their management capability or prepare them for future improvements to their organization that will allow them to manage their health care system and identify the anticipated or expected benefits for the Tribe.

Part 3: Program Report (Limit—2 Pages)

Section 1: 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 achievements associated with the delivery of quality health services. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

Section 2: Describe major activities over the past five years.

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

B. *Budget Narrative* (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each

line of the budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year 1 or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

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

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

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

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

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.

- The available funds are inclusive of direct and indirect costs.

- Only one grant will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <http://www.Grants.gov> website to submit an application. Find the application by selecting the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the

Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov*. The waiver must: (1) Be documented in writing (emails are acceptable), before submitting an application by some other method, and (2) include clear justification for the need to deviate from the required application submission process.

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

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.

- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>).

- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.

- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

- Applicants must comply with any page limits described in this funding announcement.

- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

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

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B, which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <http://fedgov.dnb.com/webform>, or call (866) 705-5711.

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

System for Award Management (SAM)

Organizations that are not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see SAM.gov for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at <https://www.sam.gov>.

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

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 15-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 possible points. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (20 Points)

(1) Describe the T/TO’s current health operation. Include a list of programs and services that are currently provided (e.g., federally funded, State-funded, etc.), information regarding technologies currently used (e.g., hardware, software, services, etc.), and identify the source(s) of technical support for those technologies (i.e., Tribal staff, Area office IHS, vendor, etc.). Include information regarding whether the T/TO has a health department and/or health board and how long it has been operating.

(2) Describe the population to be served by the proposed project. Include the total number of eligible IHS beneficiaries currently using the services.

(3) Describe the geographic location of the proposed project, including any geographic barriers to health care users in the area to be served.

(4) Identify all TMGs received since FY 2013, dates of funding, and a summary of project accomplishments. State how previous TMG funds facilitated the progression of health development relative to the current proposed project. (Copies of reports will not be accepted.)

(5) Identify the eligible project type and priority group of the applicant.

(6) Explain the need or reason for the proposed TMG project. Identify specific weaknesses and gaps in service or infrastructure that will be addressed by the proposal. Explain how these gaps and weaknesses will be assessed.

(7) If the proposed TMG project includes information technology (i.e., hardware, software, etc.), provide further information regarding measures that have occurred or will occur to ensure the proposed project will not

create other gaps in services or infrastructure (e.g., negatively affect or impact IHS interface capability, Government Performance and Results Act reporting requirements, contract reporting requirements, Information Technology (IT) compatibility, etc.) if applicable.

(8) Describe the effect of the proposed TMG project on current programs (e.g., federally-funded, state-funded, etc.), and if applicable, on current equipment (e.g., hardware, software, services, etc.). Include the effect of the proposed project on planned or anticipated programs and equipment.

(9) Address how the proposed TMG project relates to the purpose of the TMG Program by addressing the appropriate description that follows:

- Identify whether the T/TO is an IHS Title I contractor. Address if the Self-Determination contract is a master contract of several programs or if individual contracts are used for each program. Include information regarding whether or not the T/TO participates in a consortium contract (i.e., more than one Tribe participating in a contract). Address what programs are currently provided through those contracts and how the proposed TMG project will enhance the organization's capacity to manage the contracts currently in place.
- Identify if the T/TO is not an IHS Title I contractor. Address how the proposed TMG project will enhance the organization's management capabilities, what programs and services the organization is currently seeking to contract and an anticipated date for contract.
- Identify if the T/TO is an IHS Title V compactor. Address when the T/TO entered into the compact and how the proposed project will further enhance the organization's management capabilities.

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

(1) The proposed project objectives must be:

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

Example: By installing new third-party billing software, the Tribe proposes to increase the number of claims processed by 15 percent within 12 months.

(2) For each objective address how the proposed TMG project will result in change or improvement in program operations or processes. Also address what tangible products are expected from the project (i.e., policies and procedures manual, health plan, etc.)

(3) Address the extent to which the proposed project will build local capacity to provide, improve, or expand services that address the needs of the target population.

(4) Submit a work plan in the Appendix that includes the following:

- Provide action steps on a timeline for accomplishing the proposed project objectives.
- Identify who will perform the action steps.
- Identify who will supervise the action steps taken.
- Identify tangible products that will be produced during and at the end of the proposed project.
- Identify who will accept and/or approve work products during the duration of the proposed TMG project and at the end of the proposed project.
- Include a description of any training activities proposed. This description will identify the target audience and training personnel.
- Include work plan evaluation activities

(5) If consultants or contractors will be used during the proposed project, please complete the following information in their scope of work. (If consultants or contractors will not be used, please make note in this section):

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

If potential consultants or contractors have already been identified, please include a resume for each consultant or contractor in the Appendix.

(6) Describe updates that will be required for the continued success of the proposed TMG project (i.e., revision of policies/procedures, upgrades, technical support, etc.). Include a timeline of anticipated updates and source of funding to conduct the update and/or maintenance.

C. Program Evaluation (20 Points)

Each proposed objective requires an evaluation activity to assess its progression and ensure completion. This should be included in the work plan.

Describe the proposal's plan to evaluate project processes and outcomes. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- The criteria for determining whether or not each objective was met.
- The data to be collected to determine whether the objective was met.

- Data collection intervals.
- Who will be responsible for collecting the data and their qualifications.

- Data analysis method.

- How the results will be used.

(2) For process evaluation, describe:

- The process for monitoring and assessing potential problems, then identifying quality improvements.
- Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and their qualifications.

• Provide details with regards to the ways ongoing monitoring will be used to improve the project.

- Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.

- How the T/TO will document what is learned throughout the project period.

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

(4) Describe the ultimate benefit to the T/TO that is expected to result from this project. An example would be a T/TO's ability to expand preventive health services because of increased billing and third-party payments.

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

This section outlines the T/TO's capacity to complete the proposal outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for completion of the proposed plan.

(1) Provide the organizational structure of the T/TO.

(2) Provide information regarding plans to obtain management systems if a T/TO does not have an established management system currently in place that complies with 25 CFR part 900, subpart F, "Standards for Tribal or Tribal Organization Management Systems." State if management systems are already in place and how long the systems have been in place.

(3) Describe the ability of the T/TO to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed.

(4) Describe equipment (e.g., fax machine, telephone, computer, etc.) and facility space (i.e., office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased through the grant.

(5) List key project personnel and their titles in the work plan.

(6) Provide the position descriptions and resumes for all key personnel in the Appendix. The included position descriptions should: (1) Clearly describe each position's duties; and (2) indicate desired qualifications and project associated experience. Each resume must include a statement indicating that the proposed key personnel is explicitly qualified to carry out the proposed project activities. If no current candidate for a position exists please provide a statement to that effect in the Appendix.

(7) If an individual is partially funded by this grant, indicate the percentage of his or her time to be allocated to the project and identify the resources used to fund the remainder of that individual's salary.

(8) Address how the T/TO will sustain the proposal created positions after the grant expires. Please indicate if the project requires additional personnel (*i.e.*, IT support, etc.) If no additional personnel is required please indicate that in this section.

E. Categorical Budget and Budget Justification (5 Points)

(1) Provide a categorical budget for each of the 12-month budget periods requested.

(2) If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the Appendix.

(3) Provide a narrative justification explaining why each categorical budget line item is necessary and relevant to the proposed project. Include sufficient cost and other details to facilitate the determination of cost allowability (*e.g.*, equipment specifications, etc.)

Multi-Year Project Requirements

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

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

- Work plan, 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 for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

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

3. Notifications of Disposition

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

A. Award Notices for Funded Applications

The Notice of Award (NoA) is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

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

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

VI. Award Administration Information

1. Administrative Requirements

Grants are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

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

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

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

E. Audit Requirements:

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

2. Indirect Costs

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

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

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of

other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions.

Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required select 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, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

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

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

C. Federal Sub-Award Reporting System (FSRS)

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

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by federal agencies. The Transparency Act also includes a requirement for recipients of federal grants to report information about first-tier sub-awards and executive compensation under federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding

announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the period of performance is made up of more than one budget period) and where: (1) The period of performance start date was October 1, 2010 or after, and (2) the primary awardee will have a \$25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy website at <http://www.ihs.gov/dgm/policytopics/>.

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. The HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/>.

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>; and <http://www.hhs.gov/civil-rights/index.html>. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/civil-rights/for-individuals/disability/index.html>. Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> or call (800) 368-1019 or TDD (800) 537-7697. Also

note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the 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), at <http://www.fapis.gov>, before making any award in excess of the simplified acquisition threshold (currently \$150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

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

Mandatory Disclosure Requirements

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

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

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Mr. Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include "Mandatory Grant Disclosures" in subject line.)

Office: (301) 443-5204.

Fax: (301) 594-0899.

Email: Robert.Tarwater@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201.

URL: <https://oig.hhs.gov/fraud/report-fraud/>. (Include "Mandatory Grant Disclosures" in subject line.)

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

Email: MandatoryGranteeDisclosures@oig.hhs.gov.

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

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Ms. Roselyn Tso, Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop: 08E17, Rockville, MD 20857, Telephone: (301) 443-1104, Email: Roselyn.Tso@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Ms. Vanietta Armstrong, Grants Management Specialist, Indian Health Service, Office of Management Services/

DGM, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-4792, Fax: (301) 594-0899, Email: Vanietta.Armstrong@ihs.gov.

3. Questions on systems matters may be directed to: Mr. Paul Gettys, Grant Systems Coordinator, Indian Health Service, Office of Management Services/ DGM, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov.

VIII. Other Information

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

Michael D. Weahkee,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Cell Biology Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.

Date: June 13-14, 2019.

Time: 8:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John Burch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301-408-9519, burchjb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Panel Name: The Blood-Brain Barrier, Neurovascular Systems and CNS Therapeutics.

Date: June 18, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301-537-9986, macarthurlh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery and Development.

Date: June 24, 2019.

Time: 8:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, ruvinsr@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: June 25-26, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Andrew Maxwell Wolfe, Ph.D., Scientific Review Officer, Center for Scientific Review, NIH, DHHS, 6701 Rockledge Dr., Room 6214, Bethesda, MD 20892, andrew.wolfe@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Immunology and Immunotherapy.

Date: June 25-26, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, sarita.sastry@nih.gov.