

10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Mary Thanh Hai, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2134, Silver Spring, MD 20993-0002, 301-796-2310, Mary.ThanhHai@fda.hhs.gov.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993-0002, 301-796-5259, Jill.Adleberg@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials.” The final guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and

industry associations from around the world (refer to <https://www.ich.org/>).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In April 2019, the ICH Assembly endorsed the draft guideline entitled “E19 Optimisation of Safety Data Collection” and agreed that the guideline should be made available for public comment. The guideline is the product of the Efficacy Expert Working Group of the ICH. In the **Federal Register** of June 27, 2019 (84 FR 30730), FDA published a notice announcing the availability of the draft guidance. The notice gave interested persons an opportunity to submit comments by September 25, 2019.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in September 2022.

The final guidance provides recommendations regarding appropriate use of a selective approach to safety data collection in some late-stage pre- or post-marketing studies of drugs where the safety profile, with respect to commonly occurring adverse events, is well understood and documented. The final guidance is intended to advance important clinical research questions through the conduct of clinical investigations that collect relevant patient data, which will enable an adequate benefit-risk assessment of the drug for its intended use, while reducing the burden to patients from unnecessary tests that may yield limited additional information.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the current

thinking of FDA on “E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338. FDA’s guidance entitled “E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)” (available at <https://www.fda.gov/media/93884/download>) have been approved under OMB control number 0910-0843.

III. Electronic Access

Persons with access to the internet may obtain the final guidance at <https://www.regulations.gov>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: November 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-26433 Filed 12-5-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program

Announcement Type: New.

Funding Announcement Number: HHS-2023-IHS-TMD-0001.

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

Key Dates

Application Deadline Date: March 6, 2023.

Earliest Anticipated Start Date: April 20, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants for the Tribal Management Grant (TMG) Program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Self-Determination and Education Assistance Act (ISDEAA), Public Law 93–638, as amended, 25 U.S.C. 5322(b)(2) and 25 U.S.C. 5322(e). This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as the CFDA) 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 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 T/TOs (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.

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) 2023 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 14–16 awards will be issued under this program announcement.

Period of Performance

The TMG Project period of performance varies based on the project type selected. Period of performance is from 1 to 3 years. Please see the next section for additional details.

Eligible TMG Project Types, Maximum Funding Levels, and Periods of Performance

The TMG Program consists of four project types:

1. Feasibility study.
2. Planning.
3. Evaluation study.
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, new resource requirements for program management costs, and analysis of potential revenues from Federal/non-Federal sources.

• Decision statement/report that incorporates findings (sustainability, etc.), conclusions, and recommendations. The study and recommendations report is to be presented 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 PFSAs 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 <https://www.healthypeople.gov/2020/topics-objectives>. The United States (U.S.) Public Health Service 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 impact 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 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 PFSAs. 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 ISDEAA, 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.

III. Eligibility Information

1. Eligibility

"Indian Tribes" and "Tribal Organizations", as defined by the Indian Health Care Improvement Act (IHCA), are eligible to apply for the TMG Program. The definitions for each entity type are outlined below. To be eligible for this funding opportunity for "New Applicants Only," an applicant cannot

be an existing TMG awardee under this program.

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). 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. 1603(26). The term "Tribal organization" has the meaning given the term in section 4 of the ISDEAA (25 U.S.C. 5304(l)): "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. Applicant shall submit Tribal Resolutions from the Tribes to be served.

Please note that Tribes prohibited from contracting pursuant to the ISDEAA are not eligible for the TMG program. See section 424(a) of the Consolidated Appropriations Act, 2014, Public Law 113–76, as amended by section 428 of the Consolidated Appropriations Act, 2018, Public Law 115–141, and section 1201 of the Consolidated Appropriations Act, 2021, Public Law 116–260.

The Division of Grants Management (DGM) will notify any applicants deemed ineligible.

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 nonprofit status, etc.

2. Cost Sharing or Matching

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

3. Other Requirements

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

Additional Required Documentation Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any Tribe or Tribal organization selected for funding. An applicant 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 application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Applicants organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

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

Additional Required Documentation for Specific TMG Project Types

A. Federally recognized Indian Tribes applying for technical assistance and/or training grants must provide a Tribal Resolution; or a designated Tribal Organization applying on behalf of the Indian Tribe and/or Tribes it intends to serve must also provide a Tribal Resolution.

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 2016.

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 T/TOs 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:

1. Identify the consortium.
2. Demonstrate that the Tribe’s application does not duplicate or overlap any objectives of the consortium’s application.
3. Identify all consortium member Tribes.
4. Identify if any of the consortium member Tribes intend to submit a TMG application of their own.
5. 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 2016, will be considered Priority I.
- **PRIORITY II**—Indian Tribes and Tribal Organizations 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.

Indian 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.

IV. Application and Submission Information

Grants.gov uses a Workspace model for accepting applications. The Workspace consists of several online forms and three forms in which to upload documents—Project Narrative, Budget Narrative, and Other Documents. Give your files brief descriptive names. The filenames are key in finding specific documents during the objective review and in processing awards. Upload all requested and optional documents individually, rather than combining them into a package. Creating a package creates confusion when trying to find specific documents. Such confusion can contribute to delays in processing awards, and could lead to lower scores during the objective review.

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to DGM@ihs.gov.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Application forms:
 1. SF-424, Application for Federal Assistance.
 2. SF-424A, Budget Information—Non-Construction Programs.
 3. SF-424B, Assurances—Non-Construction Programs.
 4. Project Abstract Summary form.
- Project Narrative (not to exceed 15 pages). See Section IV.2.A, Project Narrative for instructions.
- Budget Justification and Narrative (not to exceed 5 pages). See Section IV.2.B, Budget Narrative for instructions.
- One-page Timeframe Chart.
- Tribal Resolution(s) as described in Section III, Eligibility.
- 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), if applicant conducts reportable lobbying.

- Certification Regarding Lobbying (GG-Lobbying Form).

- Copy of current Negotiated Indirect Cost (IDC) rate 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:

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

2. Face sheets from audit reports. Applicants can find these on the FAC website at <https://facdissem.census.gov/>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

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 (applicants may use 10 point font for tables); (3) be single-spaced; and (4) be formatted to fit standard letter paper (8-1/2 x 11 inches). Do not combine this document with any others.

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 overall page limit, the reviewers will be directed to ignore any content beyond the page limit. The 15-page limit for the narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items. Page limits for each section within the project narrative are guidelines, not hard limits.

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 PFSA 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 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 5 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.

B. Budget Narrative (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs) for the first year of the project. The applicant can submit with the budget narrative a more detailed spreadsheet than is provided by the SF-424A (the spreadsheet will not be considered part of the budget narrative). 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. Do NOT use the

budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through [Grants.gov](https://www.Grants.gov) by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. [Grants.gov](https://www.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](https://www.Grants.gov) Customer Support (see contact information at <https://www.Grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), Deputy Director, DGM, by telephone at (301) 443-2114. Please be sure to contact Mr. Gettys at least 10 days prior to the application deadline. Please do not contact the DGM until you have received a [Grants.gov](https://www.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 may be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via [Grants.gov](https://www.Grants.gov). Please use the <https://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 you cannot submit an application through [Grants.gov](https://www.Grants.gov), you must request a waiver prior to the application due date. This contact must be initiated prior to the application due date or your waiver request will be denied. Prior approval must be requested and obtained from Mr. Paul Gettys, Deputy Director, DGM. You must send a written waiver request to DGM@ihs.gov with a copy to Paul.Gettys@ihs.gov. The waiver request must be documented in writing (emails

are acceptable) before submitting an application by some other method, and must include clear justification for the need to deviate from the required application submission process.

If the DGM approves your waiver request, you will receive a confirmation of approval email containing submission instructions. You must include a copy of the written approval with the application submitted to the DGM. Applications that do not include a copy of the signed waiver from the Deputy 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. Eastern Time 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 <https://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, you will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify you that the application has been received.

System for Award Management (SAM)

Organizations that are not registered with SAM must access the SAM online registration through the SAM home page at <https://sam.gov>. Organizations in the U.S. 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://sam.gov>.

Unique Entity Identifier

Your *SAM.gov* registration now includes a Unique Entity Identifier (UEI), generated by *SAM.gov*, which replaces the DUNS number obtained from Dun and Bradstreet. *SAM.gov* registration no longer requires a DUNS number.

Check your organization's *SAM.gov* registration as soon as you decide to apply for this program. If your *SAM.gov* registration is expired, you will not be able to submit an application. It can take several weeks to renew it or resolve any issues with your registration, so do not wait.

Check your *Grants.gov* registration. Registration and role assignments in *Grants.gov* are self-serve functions. One user for your organization will have the authority to approve role assignments, and these must be approved for active users in order to ensure someone in your organization has the necessary access to submit an application.

The Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), requires all HHS awardees to report information on sub-awards. Accordingly, all IHS awardees must notify potential first-tier sub-awardees that no entity may receive a first-tier sub-award unless the entity has provided its UEI number to the prime awardee 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.

Additional information on implementing the Transparency Act, including the specific requirements for SAM, are available on the DGM Grants Management, Policy Topics web page at <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of

activities. The project 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 fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation 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:

a. 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.

b. 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.

c. 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:

- a. measureable and (if applicable) quantifiable;
- b. results-oriented;
- c. 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 Other Attachments that includes the following:

- a. Provide action steps on a timeline for accomplishing the proposed project objectives.
- b. Identify who will perform the action steps.
- c. Identify who will supervise the action steps taken.
- d. Identify tangible products that will be produced during and at the end of the proposed project.
- e. 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.
- f. Include a description of any training activities proposed. This description will identify the target audience and training personnel.
- g. 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):

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

If potential consultants or contractors have already been identified, please upload a resume for each consultant or contractor in the Other Attachments in *Grants.gov*.

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 (such as a logic model) 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. Process evaluation relates to the work plan and activities of the project.

1. For outcome evaluation, describe:

- a. The criteria for determining whether each objective was met.
- b. The data to be collected to determine whether the objective was met.
- c. Data collection intervals.

d. Who will be responsible for collecting the data and their qualifications.

- e. Data analysis method.
 - f. How the results will be used.
2. For process evaluation, describe:
- a. The process for monitoring and assessing potential problems, then identifying quality improvements.
 - b. Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and their qualifications.
 - c. Provide details with regards to the ways ongoing monitoring will be used to improve the project.
 - d. Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.
 - e. 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) that 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 as

Other Attachments in *Grants.gov*. 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 Other Attachments.

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 are required, please indicate that in this section.

E. Categorical Budget and Budget Justification (5 Points)

1. Provide a categorical budget for the first budget period.

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 Other Attachments.

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.).

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, logic model, and/or timeline 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 Rate 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 Objective Review Committee (ORC)

based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, period of performance limit) will not be referred to the ORC and will not be funded. The program office will notify the applicant 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 Office of Direct Service and Contracting Tribes 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 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 award, the terms and conditions of the award, the effective date of the award, the budget period, and period of performance. 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 1 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

Awards issued under this announcement are subject to, and 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, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented

during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-sec75-372.pdf>.

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrps107.pdf>.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75 subpart E, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75-subpartE.pdf>.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, Audit Requirements, located at 45 CFR part 75 subpart F, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75-subpartF.pdf>.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

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

provided to the DGM. Per 45 CFR 75.414(f) Indirect (F&A) costs,

any non-Federal entity (NFE) [*i.e.*, applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs.

Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or write to DGM@ihs.gov.

3. Reporting Requirements

The awardee 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 the imposition of special award provisions and/or 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 awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must 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 use the form under the Recipient User section of <https://www.grantsolutions.gov/home/getting-started-request-a-user-account/>. Download the Recipient User Account Request Form, fill it out completely, and submit it as described on the web page and in the form.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). 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 Reports are due 90 days after the end of each budget period, and a final report is due 90 days after the end of the period of performance.

Awardees are responsible and accountable for reporting accurate information on all required reports: the Progress Reports and the Federal Financial Report.

Failure to submit timely reports may result in adverse award actions blocking access to funds.

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 threshold met for any specific reporting period.

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

D. Non-Discrimination Legal Requirements for Awardees of Federal Financial Assistance

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>.

- Health and education programs funded by the HHS must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/conscience-protections/index.html>.

www.hhs.gov/conscience/religious-freedom/index.html.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov/fapiis/#/home> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10 million 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, the IHS must require an NFE 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.

All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS OIG 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: Marsha Brookins, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-4750, Fax: (301) 594-0899, email: DGM@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 part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Terri Schmidt, Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop: 08E17, Rockville, MD 20857, Phone: (301) 443-1104, email: terri.schmidt@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Sheila A.L. Miller, Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (240) 535-9308, email: sheila.miller@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Deputy Director, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114, 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.

P. Benjamin Smith,

Deputy Director, Indian Health Service.

[FR Doc. 2022-26480 Filed 12-5-22; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: National Advisory Council on Aging.

Date: January 18-19, 2023.

Closed: January 18, 2023, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Open: January 19, 2023, 10:00 a.m. to 2:00 p.m.

Agenda: Call to order and report from the Director; Discussion of future meeting dates; Consideration of minutes of last meeting; Reports from Task Force on Minority Aging Research, Working Group on Program; Council Speaker; Program Highlights.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Closed: January 19, 2023, 2:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kenneth Santora, Director, Office of Extramural Activities, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496-9322, ksantora@nih.gov.

Information is also available on the Institute's/Center's home page: www.nia.nih.gov/about/naca, where an