in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aimée Phillippi-Taylor, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl, Rockville, MD 20855, 240–402–0601, *aimee.phillippi-taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry GFI #97 (VICH GL14(R1)) entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Caprines (Revision 1).'' It should be read in conjunction with GFI #90 (VICH GL7), ''Effectiveness of Anthelmintics: General Recommendations,'' which should be referred to for discussion of broad aspects for providing pivotal data to demonstrate product anthelmintic effectiveness. The purpose of this guidance is: (1) to be more specific for certain specific caprine issues not discussed in GFI #90 (VICH GL7); (2) to highlight differences with the GFI #90 (VICH GL7) on effectiveness data recommendations; and (3) to give explanations for disparities with the GFI #90 (VICH GL7). This revision clarifies the definition of adequate infection in individual animals, updates considerations for field studies, and makes additional clarifying changes.

FDA has participated in efforts to enhance international harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; AnimalhealthEurope; FDA—Center for Veterinary Medicine and U.S. Department of Agriculture—Center for Veterinary Biologics; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry and Fisheries; and the Japanese Veterinary Products Association.

There are 10 observers to the VICH Steering Committee: one representative from government and one representative from industry of Australia, New Zealand, Canada, South Africa, and the United Kingdom. The World Organisation for Animal Health is an associate member of the VICH. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Effectiveness of Anthelmintics: Specific Recommendations for Caprines (Revision 1).'' 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 514 have been approved under OMB Control Number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17318 Filed 8–11–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Healthy Lifestyles in Youth Project

Announcement Type: New.

Funding Announcement Number: HHS–2022–IHS–HLY–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.933.

Key Dates

Application Deadline Date: September 15, 2022.

Earliest Anticipated Start Date: September 30, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the Healthy Lifestyles in Youth (HLY) Program. This program is authorized under the Snyder Act, 25 U.S.C. 13; and the Transfer Act, 42 U.S.C. 2001(a). This program is described in the Assistance Listings located at *https://sam.gov/content/home* (formerly known as the CFDA) under 93.933.

Background

This program promotes healthy lifestyles for American Indian and

Alaska Native (AI/AN) youth using the curriculum ''Together Raising Awareness for Indian Life'' (TRAIL) among selected Native Boys and Girls Club sites. Under this cooperative agreement, IHS proposes to enter into a collaborative effort/initiative with an entity that has experience working with Boys and Girls Clubs of America (BGCA), experience working with and implementing the TRAIL curriculum, and overall expertise and experience in addressing and evaluating healthy lifestyle techniques in AI/AN youth. The IHS issued the original funding opportunity announcement for the HLY cooperative agreement in 2003 and the program has been ongoing since that time.

Purpose

The purpose of this program is to support the IHS mission to improve the health of AI/AN youth through health promotion and health education programs. The goal of this IHS cooperative agreement is to address healthy lifestyle development and emphasize nutrition and physical activity for AI/AN children and youth 7 through 11 years of age. To do this, the awardee must meet the following objectives:

- Collaborate with selected Native American Boys and Girls Club sites, via a grant application process;
- Provide health and physical education programs;
- Help youth achieve and maintain healthy lifestyles through participation in fitness programs;
- Help youth acquire a range of physical skills; and
- Help youth develop a sense of teamwork and cooperation.

These early intervention strategies provide evidence based opportunities to reduce and/or halt the increasing trend of obesity and diabetes among youth and young adults. Native Boys and Girls Clubs that develop a health promotion program that includes the TRAIL curriculum may help curtail the effects of unhealthy eating behaviors and lack of physical activity that can lead to obesity, diabetes, and other chronic diseases later in life. The TRAIL curriculum was developed to provide information on good nutrition and to promote physical activity among youth participating in Native American Boys and Girls Clubs. The TRAIL curriculum is a 3-month (12 lessons) program that provides youth with a comprehensive understanding of healthy lifestyles in order to prevent diabetes. Woven throughout the program are self-esteem and prevention activities. Participants draw from Tribal traditions and history to learn about nutrition, healthy food choices, media influences, and the impact of diabetes. The TRAIL curriculum emphasizes the importance of teamwork and community service. Members engage in service projects to improve healthy lifestyles in their communities, including starting community gardens to connect youth to their food source and organizing community-wide physical fitness events.

The overall results show improvement in participant knowledge of diabetes, health, and healthy food choices, as well as improved levels of fitness and physical activity. To date, this cooperative agreement has funded over 95 Native American Boys and Girls Club sites that have established and implemented this curriculum project and have served over 22,144 AI/AN youth. Program test scores each year consistently indicate: (a) increased knowledge about diabetes; (b) increased physical activity; and, (c) increased ability to identify healthier food options (post-intervention scores vs. pre-intervention test scores). Program physical activity logs show participating AI/AN youth collectively perform approximately 20,000 hours of physical activity each year. Boys and Girls Clubs also report annually on the service projects that are carried out by TRAIL participants in their local communities.

Boys and Girl Club sites that are located outside of Tribal communities are not eligible.

The Boys and Girls Club sites selected by the awardee may use IHS grant funds to provide services to eligible IHS beneficiaries only. The awardee will: provide technical consultation; train; monitor; evaluate; and provide funds to support these activities.

Required, Optional, and Allowable Activities

1. Develop a written plan for the planning, implementation, and evaluation of this project to include overseeing at least 98 sites, as agreed upon with the IHS. The local evaluation effort should include local evidence-based practice (EBP) fidelity data and how data will integrate with the National Evaluation Frame. Complete this task within 30 days of the award date and obtain approval by the IHS.

2. Develop selection criteria for additional sites as well as announce, evaluate, and select new sites. Sites must submit documentation verifying that they serve only AI/AN youth from eligible IHS beneficiaries, as a requirement for selection by the awardee. Conduct a start-up planning meeting with new sites within 2 months of each site's initial selection and award.

3. Plan and conduct an orientation and training meeting for new sites within 2 months of selection. Submit agenda, training goals and objectives, and participant list to IHS within 1 month of completion of each orientation session.

4. Update TRAIL curriculum as needed/directed and implement use. Document any specific changes to the curriculum and note expected impacts on implementation, data collection and outcomes.

5. Develop, in consultation with the IHS, the implementation and technical assistance plan for the coordination of the selected Boys and Girls Club sites. Submit criteria to the IHS for approval.

6. Each site will implement the TRAIL program, emphasizing healthy behaviors, such as physical activity and nutrition. Each program plan will also include a parent component describing approaches for involving the families of participants.

7. Each site will implement Physical Activity Strength and Endurance Challenges 3 times, 6 to 8 weeks apart. Physical activity data will be collected and summarized.

8. Awardee will promote and facilitate local, state, and national partnerships for the purpose of establishing or enhancing program support that involves increasing physical activity and good nutrition for the tribally-managed Boys and Girls Club sites. This includes, but is not limited to, establishing other partners such as American Indian-Alaska Native Program Branch (AI–ANPB) of Head Start Programs, Wings of America, United National Indian Tribal Youth, Inc. (UNITY), Tribal colleges, BGCA, Tribal organizations, local community health providers, and other private organizations as appropriate.

9. Awardee will continue to implement current evaluation processes in consultation for the TRAIL project. At a minimum, the evaluation will include:

a. training attendance (gender, age, grade level);

b. pre- and post- tests to assess participant knowledge;

c. monthly activity logs from each site on the physical activity portion of their program. Daily data to be collected includes the date, number of minutes of physical activity, and number of children participating; and

d. information/log on parent and family participation in education and activity programs, community involvement and partnerships.

10. Submit collated and summarized data to the IHS. Work with the IHS in

drafting an evaluation summary at the end of the project period. Submit collated and summarized data and project evaluation summaries to all sites. Provide a minimum of annual reports (feedback) to each site on how their data compare to data (mean, median, and range) from other selected sites.

11. Provide ongoing technical support to the sites for the duration of the initiative. Provide training and technical assistance in all forms, *i.e.,* on-site, on-line, by phone, and mail. The planning, design, and delivery of training and technical assistance will support the local organization's long-term planning and outreach efforts. The training will be customized based on sites' capability and experience. Technical assistance will also be provided on program planning, implementation, evaluation, and data collection. Collaborate with the IHS to provide services to club sites. Maintain records and reports.

12. Provide technical assistance to the sites in developing a written work plan, with measurable goals, objectives and activities that adheres to the terms and conditions of the cooperative agreement.

13. Establish a formal agreement with Native American Boys and Girls Club sites, involving funding assistance and technical support to ensure clubs successfully implement the TRAIL program.

14. Submit to the IHS a written work plan and report describing each site's demographics, information on the number of youth in the eligible age range in the catchment area, the number that attend the Boys and Girls Clubs regularly, and the number served by this project, goals, objectives, activities, partnerships, and proposed outcomes.

15. Provide the IHS written quarterly reports on the evaluation outcomes, activity reports at each site, any parent involvement activities and other participation, description of the community partnerships, and other activities as appropriate. Conduct quarterly conference calls with IHS to review project status.

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for the first budget year, starting in fiscal year (FY) 2022, is approximately $1,250,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

One award will be issued under this program announcement.

Period of Performance

The project period is for 5 years.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as grants. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the entire period of performance. Below is a detailed description of the level of involvement required of the IHS.

Substantial Agency Involvement Description for Cooperative Agreement

(1) Identify a core group of IHS staff to work with the awardee in providing technical assistance and guidance.

(2) Meet with the awardee to review awardee work plan and provide guidance on implementation, program evaluation, and data collection strategy and tools.

(3) Participate in quarterly conference calls. Work with the awardee to display the results of this project by publishing on shared websites as well as in jointly authored publications.

(4) Use the evidence-based program(s), framework(s), and data collection requirement(s) to develop a National Logic Model and Evaluation Plan to collect national program aggregate and local EBP fidelity data.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity an applicant must be an organization with extensive experience developing and managing youth programs, health advocacy and education, and outreach related to AI/AN health care on a national scale.

The program office 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 Division of Grants Management (DGM) will notify the applicant.

The following documentation is required (if applicable):

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.

Tribes 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.

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 25 pages). See Section IV.2.A, Project Narrative for instructions.
- Budget Justification/Narrative (not to exceed 5 pages). See Section IV.2.B, Budget Narrative for instructions.
- Tribal Resolution(s) as described in Section III, Eligibility.
- 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).
- 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 25 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 (8½ 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 application will be considered not responsive and will not be reviewed. The 25-page limit for the project narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget 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—Introduction and Need for Assistance; Part 2—Work Plan; and Part 3—Organizational Capabilities. 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—5 Pages)

Section 1: Needs

Please provide a description of the need for assistance with offering this program. Applicant should demonstrate knowledge of: health concerns for AI/AN youth; health promotion activities in Tribal communities such as BGCA; and working with Tribes and Tribal organizations.

Part 2: Program Planning and Evaluation (Limit—10 Pages)

Section 1: Program Plans

This section should demonstrate the soundness and effectiveness of the proposal. The work plan should be designed to describe how and when the sites will be selected; describe how the sites will be trained on the curriculum and provided technical assistance; and describe how sites will be supported for a physical activity program with the equipment and participant incentives.

Section 2: Program Evaluation

Describe the plan for collecting data, monitoring, and assuring quality and quantity of data and the plan for evaluating and reporting program results.

Part 3: Organizational Capabilities (Limit—10 Pages)

Describe the broader capacity of the organization to complete the project outlined in the work plan, including: (1) identification and bios for key personnel responsible for completing tasks; (2) description of the structure of the organization and chain of responsibility for successful completion of the project outline in the work plan; (3) description of financial and project management capacity, including information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed; (4) description of national experience in providing administrative and support services to Tribal youth organizations, education agencies and other Tribal programs for the benefit of AI/AN children and youth and Tribal communities (indicate experience in national partnerships or national support efforts on behalf of AI/AN communities especially as it pertains to health concerns); (5) description of equipment and space available for use during the proposed project; and (6) description of specialized experience working with Native Boys and Girls Club sites and the TRAIL curriculum program.

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. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the additional pages should highlight the changes from the first year 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 Time 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*), 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* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

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

5. Funding Restrictions

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

6. Electronic Submission Requirements

All applications must be submitted via *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*, 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 *GrantsPolicy@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*. United States (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://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; information for multi-year projects should be included as a separate document. See ''Multi-year Project Requirements'' at the end of this section for more information. 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)

This section should demonstrate knowledge of health concerns and issues regarding AI/AN youth, health promotion activities in Tribal communities, and working with Tribes and Tribal organizations.

B. Work Plan (30 Points)

This section should demonstrate a sound and effective annual work plan that will support accomplishment of deliverables and milestones of the TRAIL project. The work plan should be designed to:

a. Describe how and when the sites will be selected.

b. Describe how the sites will be trained on the curriculum and provided technical assistance.

c. Describe the plan for collecting data, monitoring, and assuring quality and quantity of data.

d. Describe the plan for evaluating and reporting.

e. Describe how sites will be supported for a physical activity program.

C. Organizational Capabilities (40 Points)

This section should outline the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the project outline in the work plan. The section should:

a. Describe the structure of the organization.

b. Describe the ability of the organization to manage the proposed project and include information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed.

c. Describe what equipment (*i.e.,* phone, websites, 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 throughout the agreement.

d. List and provide bios for key personnel who will work on the project. The section should demonstrate knowledge in:

i. Financial and project management.

ii. Nationwide experience in providing administrative and support services to Tribal youth organizations, education agencies and other Tribal programs for the benefit of children and youth.

iii. AI/AN youth and Tribal communities and indicate experience in national partnerships or national support efforts on behalf of AI/AN communities especially as it pertains to health concerns.

iv. Experience working with Tribal Boys and Girls Club sites and the TRAIL curriculum program.

v. Local and national evaluation, including data collection and analysis

D. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the project program costs and justification for expenses for the entire cooperative agreement period. The budget and budget justification should be consistent with the tasks identified in the work plan.

a. Categorical budget (Form SF–424A, Budget Information Non Construction Programs) completed for the first budget period.

b. Narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allow ability.

c. Indication of any special start-up costs.

d. Budget justification should include a description of the planned costs and how they relate to or support the proposed project activities.

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. This narrative should include discussion regarding the meaningful use of program implementation, process, and fidelity data.

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.
- 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 Division of Diabetes Treatment and Prevention 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-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf.*
- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at *https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.*

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. Cost Principles:

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

E. Audit Requirements:

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

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 awardees 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 awardees 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 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 30 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.

C. Data Collection and Reporting

The BGCA defines impact as the contribution a Club makes to the attitudes, skills, values, and behaviors of Club members that enables them to succeed in adulthood. BGCA has designed a model called Formula for Impact—a roadmap for Clubs to help ensure that members achieve BGCA's priority outcomes of Academic Success, Good Character and Citizenship, and Healthy Lifestyles. These priority outcomes are achieved through the

implementation of BGCA's national programs; education and careers, character and leadership, health and life skills, the arts, sports, fitness and recreation, and specialized programs. Through Formula for Impact, BGCA and Clubs are able to use indicators to track and assess their impact, as well as demonstrate it in a consistent and meaningful way. Each Boys & Girls Club is required to complete the Formula for Impact Assessment annually.

The National Youth Outcomes Initiative (NYOI) is an online data management tool that is designed to collect data from Clubs, compile that information, and provides reports on impact back to Clubs and BGCA. The NYOI was developed via the National Commission on Impact's National Outcomes Database and Reporting Tool. One of the priority outcomes tracked through NYOI is Healthy Lifestyles. The indicators measured under this outcome go hand-in-hand with the indicators measured throughout the TRAIL program. In addition, the Good Character and Citizenship indicators support the TRAIL program requirement of participants engaging with their community and community health partners.

Healthy Lifestyles Indicators:

- Regular physical activity (monitored daily)
- Good nutrition (examples provided)
- Avoidance of risky behaviors

Good Character and Citizenship Indicators:

- Contributions to Club and local community
- Positive opportunities
- Building conflict resolution skills

NYOI also measures Club members' engagement in the following physical activities:

- Number of days per week they participate in physical activity during their free time;
- Number of days per week they participate in physical activity during school physical education class;
- Number of days per week they participate in physical activity at the Club;
- Daily fruit and vegetable intake;
- Number of sugar sweetened drinks consumed per day;
- Alcohol, drug, and tobacco use and abuse;
- Sexual activity and condom use;
- Demographic information including gender, age, and grade level of AI/AN youth participants;
- Pre- and Post-tests to assess participant knowledge; and
- Quarterly progress reports to capture program implementation tasks and feedback received from youth participants, family members, and community members.

D. Federal Sub-award Reporting System (FSRS)

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

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for awardees 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/.*

E. 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.*
- HHS funded health and education programs 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/religious-freedom/index.html.*

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

The IHS is required to review and consider any information about the applicant that is in the 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 $10,000,000 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, 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 awardees must disclose in writing, in a timely manner, 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: 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: Ms. Carmen Licavoli Hardin, Acting Director, Indian Health Service, Division of Diabetes Treatment and Prevention, 5600 Fishers Lane, Mail Stop: 08N34A&B, Rockville, MD 20897, *Phone:* 1–844–IHS–DDTP (1–844–447–3387), *Fax:* 301–594–6213, *Email: diabetesprogram@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Donald Gooding, Senior Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* 301–443–2298, *Email: Donald.Gooding@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; or the DGM main line (301) 443–5204, *E-Mail: Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract awardees 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.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

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BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 for Human Genome Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who 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 videocast and can be accessed from *https://www.genome.gov/about-nhgri/Institute-Advisors/National-Advisory-Council-for-Human-Genome-Research.*

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 for Human Genome Research.

Date: September 19–20, 2022.

Closed: September 19, 2022, 9:00 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892.

Open: September 19, 2022, 10:00 a.m. to 6:30 p.m.

Agenda: Report of Institute Director and Institute Staff.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892.

Closed: September 20, 2022, 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892.

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892, (301) 402–0838, *pozzattr@mail.nih.gov.*

Any interested person may file written comments with the committee within 15 days after the meeting by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Additional Health and Safety Guidance: Before attending a meeting at an NIH facility, it is important that visitors review the NIH COVID–19 Safety Plan at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/Pages/default.aspx* and the NIH testing and assessment web page at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/visitor-testing-requirement.aspx* for information about requirements and procedures for entering NIH facilities, especially when COVID–19 community