

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
SOP maintenance	3,295	1	3,295	1	3,295
Total					135,095

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

### C. Costs Associated With Electronic Submission

There are no capital costs or operating and maintenance costs associated with the transition from paper to electronic submissions. To create an SPL file and submit it to FDA, a registrant would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's ESG.

Registrants (and most individuals) have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and Internet are usually available at public facilities, e.g., a community library; or they may request a waiver from submitting the information electronically. Software is necessary to create a "document." The SPL file or "document" may be created internally by a business with experience with SPL, or a business may use a user-friendly software (XForms)<sup>3</sup> available at no cost for industry use. In addition to the software, FDA also provides technical assistance, and other resources, code sets and codes, and data standards regarding SPL files.<sup>4</sup>

Once the SPL file is created, the registrant would upload the file through the ESG. A digital certificate is needed to use the ESG. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents. However, a small fee of up to \$20.00 is charged for the digital certificate and the registrant may need to renew the certificate not less than annually. FDA is not calculating this small fee as cost of doing business because it is less than or equal to the biannual courier costs the registrant incurs for paper submissions.

<sup>3</sup> See <http://www.fda.gov/oc/datacouncil/xforms.html>.

<sup>4</sup> See <http://www.fda.gov/oc/datacouncil/spl.html>.

Dated: December 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

**[Funding Announcement Number: HHS-2009-IHS-NIHB-0001]**

#### Office of Tribal Program; Announcement Type: Competing Continuation

Catalog of Federal Domestic Assistance Numbers (s): 93.933

*Key Dates:* Application Deadline Date: January 9, 2009

*Review Date:* January 16, 2009

*Results Notification:* January 21, 2009

*Earliest Anticipated Start Date:* February 1, 2009

#### I. Funding Opportunity Description

**Authority:** The Indian Health Service (IHS) announces that a Single Source cooperative agreement is open for receipt of an application from the National Indian Health Board. This program is authorized under Public Health Service Act, 42 U.S.C. 301. This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA). Purpose: The Office of Tribal Programs (OTP) has designated funds for the Single Source National Indian Health Board (NIHB) to further health program objectives in the American Indian/Alaska Native (AI/AN) community with outreach and education efforts in the interest of improving Indian health care. The NIHB is the only national Indian organization with expertise on the variety of issues related to the provision of health care to Indian people.

The NIHB represents all 562-Federally recognized tribes: including Tribal governments operating their own health care delivery systems through self-determination agreements with the IHS and tribes that continue to receive health care directly from the IHS. The NIHB is governed by twelve elected Tribal Government Officials who represent each of the twelve IHS Areas and the HHS regions where Federally

recognized Tribes exist. The NIHB is the only national organization with an expertise in health policy and health programs, and the only national organization with the designated authority to represent all AI/AN tribes and villages. The NIHB has a national constituency and clearly supports critical services and activities within the IHS mission of quality health care for AI/AN people. The NIHB provides policy analysis and development, program assessment and development, regional and national meeting coordination, consultation and health care advocacy to IHS and HHS based on tribal input through a broad based consumer network. Furthermore, the NIHB also provides planning and technical assistance to Tribes, Area Health Boards, and other Tribal organizations through the cooperative agreement with the IHS.

#### II. Award Information

*Type of Award:* Cooperative Agreement. A cooperative agreement will be awarded as the OTP staff will have substantial programmatic involvement with the recipient in carrying out the project as noted in the following delineated roles of involvement to further IHS' health program objectives in the AI/AN community with outreach and education efforts in the interest of improving Indian health care.

#### Cooperative Agreement—Involvement of Parties

This project is a cooperative agreement between the IHS and the NIHB.

Selected entity is responsible for the following:

1. To provide technical advice in the area of health care policy analysis and program development on which IHS needs to take action;
2. To provide consultation that is representative of all Tribal governments in the area of health care policy analysis and program development;
3. To assure that health care advocacy is based on Tribal input through a broad based consumer network involving the Area Indian Health Boards or Health

Board Representatives from each of the twelve IHS areas;

4. To provide an opportunity for Tribal Government officials to share their concerns, challenges, and recommendations for improving health care delivery through the IHS in forums designed to provide training, technical assistance, and appropriate policy discussions; and

5. To provide periodic dissemination of health care information, including publication of a newsletter.

#### **Programmatic Involvement of the IHS Staff**

1. IHS staff will review articles concerning the Agency for accuracy and may, as requested by the NIHB, provide relevant articles.

2. IHS staff will have input over the hiring of key personnel as defined by regulation or provision in the cooperative agreement.

3. IHS will provide technical assistance to the NIHB as requested and attend and participate in all the NIHB meetings.

4. IHS staff may, at the request of the NIHB, participate on study groups and may recommend topics for analysis and discussion.

*Estimated Funds Available:* The estimated total amount that is available to support the two year program is \$1,616,374. Fiscal year (FY) 2009 is estimated at: \$808,187, which may vary, based on Tribal shares assumptions; \$100,000 associated with providing legislative education, outreach and communications support to the IHS Tribal Leaders Diabetes Committee and to facilitate Tribal consultation on Special Diabetes Program for Indians; \$150,000 to support the IHS Just Move-It health promotion and disease prevention initiative with Tribes; \$250,000 to support the IHS Behavioral Health program in its suicide prevention and methamphetamine initiative. The second year (FY) 2010 award will be issued for an estimated total award of \$808,187. Non-competing continuation awards for the remainder of the project are also subject to the availability of funds.

The estimated total amount that is available to support the two year program is \$1,616,374 and is subject to the availability of funds. Fiscal year (FY) 2009 is estimated at \$808,187 total costs which may vary based on tribal shares assumption. The second year (FY) 2010 award will be issued for an estimated total of \$808,187 total costs. Non-competing continuation awards for the remainder of the project are also subject to the availability of funds.

*Anticipated Number of Awards:* One Single Source award will be issued to the NIHB Program.

*Project Period:* Twenty-Three months. The initial budget period will cover 11 months commencing on February 1, 2009 through December 31, 2009 and the second budget period will run from January 1, 2010 through December 31, 2010.

*Award Amount:* Estimated \$808,187, per year as described above.

#### **III. Eligibility Information**

1. Eligibility is limited to the NIHB based on the single source justification provided under Section I. Funding Opportunity Description.

2. This is a Single Source announcement. The funding level noted includes both direct and indirect costs. Applicant's budget may not exceed the maximum funding level described above per budget period.

3. Proof of non-profit status required: 501c(3) Non-Profit certification.

4. Cost Sharing or Matching—The NIHB Program does not require matching funds or cost sharing.

5. Other Requirements—

- If the application budget exceeds the stated dollar amount that is outlined within this announcement, it will not be considered for funding.

- Please refer to section IV., Item 6, "Funding Restrictions," for further information regarding ineligible activities.

#### **IV. Application and Submission Information**

1. Application package may be found on the Grants.gov Web site: <http://www.grants.gov> or at: [http://www.ihs.gov/NonMedicalPrograms/gogp/gogp\\_funding.asp](http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp). Detailed application instructions for this announcement are downloadable from the Grants.gov Web site.

2. *IHS Contacts:*

##### *Programmatic Concerns*

Mr. Ronald B. Demaray, Acting Director, Office of Tribal Programs, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852. Contact Information: (301) 443-1104 (Telephone) (301) 443-4666 (Fax) and E-Mail Address: [Ronald.Demaray@IHS.GOV](mailto:Ronald.Demaray@IHS.GOV).

##### *Business Concerns*

Ms. Sylvia Ryan, Grants Management Specialist, Division of Grants Operations, Indian Health Service, 801 Thompson Avenue, IMP 360, Rockville, Maryland 20852. Contact Information: (301) 443-5204 (Telephone), (301) 443-9602 (Fax), and E-Mail Address: [Sylvia.Ryan@IHS.GOV](mailto:Sylvia.Ryan@IHS.GOV).

**Note:** The Division of Grants Operations is the official receipt point for grant applications (electronic and paper).

#### *Grants.gov Agency Contact*

Information regarding the electronic grants.gov process, issues, and waivers waiving the electronic process may be obtained from the following person:

Ms. Michelle G. Bulls, Chief Grants Management Officer, Director, Division of Grants Policy, Indian Health Service, 801 Thompson Avenue, TMP 625, Rockville, Maryland 20852. Contact information: (301) 443-6528 (Telephone) and E-Mail Address: [Michelle.Bulls@IHS.GOV](mailto:Michelle.Bulls@IHS.GOV).

*Paper Applications (only allowed under approved waivers):* NIHB must obtain prior approval to submit a paper application. Please use the following link to obtain the necessary forms for paper submissions:

#### *Forms*

- SF-424 Application for Federal Assistance [POFI].
- SF-424A Budget Information/Non-construction Programs [PDF].
- PHS 5161 Form [PDF]; Certification forms (see pages 17-19 of the PHS 5161) checklist pages (see pages 25-26).
- SF-424B Non-construction Programs [PDF].
- Disclosure of Lobbying Activities Form [PDF].
- Certification Regarding Lobbying.
- Debarment Certification (Primary).
- Drug-free Certification.
- Environmental Tobacco Smoke.
- Maintenance of Effort Certification.

Please mail the original application and two copies to: The Division of Grants Operations; 801 Thompson Avenue, TMP 360; Rockville, Maryland 20852. Please send it to the attention of the grants management contact that is listed above.

3. *Content and Form of Narrative Submission:*

- Abstract (one page) summarizing the project.
- Introduction and Need for Assistance.
- Project Objective(s), Approach and Results and Benefits.
- Project Evaluation.
- Organizational Capabilities and Qualifications.
- Be typewritten and single spaced.
- Use black type not smaller than 12 characters per one inch.
- Margins must not be less than one inch.
- Have consecutively numbered pages.
- Contain a narrative that does not exceed 14 typed pages that includes the other submission requirements below.

The 14-page narrative does not include the abstract, the work plan, standard forms, 501 c(3) Non-Profit Statement, table of contents, budget, budget justifications, multi-year narratives, multi-year budget, multi-year budget justification, and/or other appendix items.

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

4. *Submission Dates and Times:* The application must be submitted electronically through Grants.gov by 12:00 midnight Eastern Standard Time (EST) on Friday, January 9, 2009. NOTE: The application package is posted in Adobe vs. PureEdge Forms. In addition, Grants.gov currently utilizes a Microsoft Office Word 2003 software version. Entities utilizing other than Microsoft Office Word 2003 software version must make arrangements to accommodate this situation. If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant must contact Michelle G. Bulls, Division of Grants Policy, fifteen days prior to the application deadline and inform her of the difficulties that the organization is experiencing. The grantee must obtain prior approval, in writing (e-mail requests are acceptable), allowing the paper submission. If submission of a paper application is requested and approved, the manually signed original and two copies of the application must be sent to the appropriate grants person listed in Section IV.2. above. Unsigned paper applications will not be accepted and will be returned to the applicant. Applications not submitted through Grants.gov, without an approved waiver, will be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the applicant, and will not be considered for funding.

5. *Intergovernmental Review:* Executive Order 12372 requiring intergovernmental review is not applicable to this program.

6. *Funding Restrictions:* Pre-award costs are allowable. In accordance with 45 CFR Part 74 all pre-award costs are incurred at the recipient's risk. The awarding office is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated.

- Only one Single Source cooperative agreement will be awarded.
- IHS will not acknowledge receipt of the application.

- An unsigned paper application is not acceptable; therefore, it will not be reviewed and will be returned.

7. *Other Submission Requirements:*

*Electronic Submission*—The preferred method for receipt of applications is electronic submission through Grants.gov. However, should any technical challenges arise regarding the submission, please contact Grants.gov Customer Support at 1-800-518-4726 or [support@grants.gov](mailto:support@grants.gov). The Contact Center hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. EST. If you require additional assistance please call (301) 443-6290 and identify the need for assistance regarding your Grants.gov application. Your call will be transferred to the appropriate grants staff member. The applicant must seek assistance at least fifteen days prior to the application deadline. An applicant that does not adhere to the timelines for Central Contractor Registry (CCR) and/or Grants.gov registration and/or requesting timely assistance with technical issues will not be a candidate for receiving a waiver approval to submit a paper application.

To submit an application electronically, please use the <http://www.Grants.gov> apply site. Download a copy of the application package from the Grants.gov Web site, complete it offline and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to IHS.

*Please be reminded of the following:*

- The preferred application receipt process is Grants.gov. The paper process is not the preferred method. However, if you have technical problems submitting your application on-line, please contact directly Grants.gov Customer Support at: <http://www.grants.gov/CustomerSupport>.

- 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.

- If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (e-mails are acceptable), to [Michelle.Bulls@ihs.gov](mailto:Michelle.Bulls@ihs.gov) that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of the waiver approval, a hard-copy application package must be downloaded by the applicant from Grants.gov, completed, manually signed, and sent directly to the Division of Grants Operations (DGO), 801 Thompson Avenue, TMP 360; Rockville, MD 20852 by the due date, Friday, January 9, 2009.

- Upon entering the Grants.gov site, there is information available that outlines the requirements to the applicant regarding electronic submission of an application through Grants.gov, as well as the hours of operation. Applicants are strongly encouraged to not wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov could take up to fifteen working days.

- To use Grants.gov, an applicant, must have a Data Universal Numbering System (DTJNS) Number that is also registered in the CCR allowing a minimum often days working days to complete CCR registration.

- All documents must be submitted electronically, including all relevant information on the SF-424 and all necessary assurances and certifications.

- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS such as Memorandum of Agreements (MOAs) with Area Local Health Boards as well as national affiliations with organizations, e.g., National Congress of American Indians (NCAI), etc.

- The application must comply with the 14-page limitation requirements described in the program announcement.

- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The IHS DGO will retrieve your application from Grants.gov. The DGO will not notify applicants that the application has been received.

- You may access the electronic application package which includes the synopsis for this program on: <http://www.Grants.gov> or the full announcement on: [http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp\\_funding](http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_funding).

- You may search for the downloadable application package utilizing Grants.gov FIND to search for the CFDA number 93.933.

- The applicant must provide the Funding Opportunity Number: HHS-2009-IHS-NIHB-0001.

E-mail applications will not be accepted under this announcement.

#### DUNS Number

Applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities.

Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access Dun and Bradstreet at the following Web site: <http://www.dunandbradstreet.com> or call 1-866-705-5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

Applicants must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the telephone number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1-888-227-2423. Please review and complete the CCR Registration Worksheet located at <http://www.grants.gov/CCRRegister>.

More detailed information regarding these registration processes can be found at <http://www.grants.gov>.

#### V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 14-page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "MULTI-YEAR PROJECT REQUIREMENTS" at the end of this section for more information.

##### 1. Narrative

- A. Abstract—one page summary.
- B. Criteria

##### Introduction and Need for Assistance (20 points)

(1) Describe the organization's current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include authorized delegation of authority, *i.e.*, memorandum of agreement from a national organization representative of all AI/ANs (such as NCAI) authorizing entity to act in the health care advocacy role for all AI/AN communities. Include what programs and services are currently provided (*i.e.*, Federally funded, State funded, etc.), any memorandums of agreement with other National, Area or Local Indian Health Board organizations, HHS agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information, information regarding technologies currently used (*i.e.*,

hardware, software, services, etc.), and identify the source(s) of technical support for those technologies (*i.e.*, in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with Area Health Boards, etc. [historical collaboration].

(2) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, memorandums of agreement with other National Indian organizations such as NCAI that deem the applicant as the primary source of information for AI/AN, memorandums of agreement with other Area Indian Health Boards, etc.

(3) Describe the population to be served by the proposed project. Include a description of the number of Tribes who currently benefit from the technical assistance provided by the applicant.

(4) Describe the geographic location of the proposed project including any geographic barriers experienced by the recipients of the technical assistance to the health care information provided.

(5) Identify all previous IRS Single Source cooperative agreement awards received including dates of funding and summaries of the project's accomplishments. State how previous IHS Single Source cooperative agreement funds facilitated education, training, and technical assistance nation-wide and relate the progression of health care information delivery and development relative to the current proposed project. (Copies of reports will not be accepted.)

(6) Describe collaborative and supportive efforts with National, Area and Local Indian Health Boards.

(7) Describe budget consultation efforts undertaken on behalf of Tribes, Tribal organizations and urban organization and the benefits and outcomes derived as a result of these consultations. What changed for the AI/AN community?

(8) Explain the reason for your proposed project by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed project. Explain how these gaps/weaknesses were discovered. If the proposed project includes information technology (*i.e.*, hardware, software, etc.), provide further information regarding measures taken or to be taken that ensure the proposed project will not create other gaps in services or infrastructure (*i.e.*, IHS interface capability, GPRA reporting requirements, contract reporting

requirements, Information Technology (IT) compatibility, etc.), if applicable.

(9) Describe the effect of the proposed project on current programs (*i.e.*, Federally-funded, State funded, etc.) and, if applicable, on current equipment (*i.e.*, hardware, software, services, etc.). Include the effect of the proposed project on planned/anticipated programs and/or equipment.

(10) Describe how the project relates to the purpose of the cooperative agreement by addressing the following: Identify how the proposed project will address NIHB education, budget consultation, health data dissemination, training, and technical assistance.

##### Project Objective(s), Workplan and Consultants (40 points)

A. Identify the proposed project objective(s) addressing the following:

- Measurable and (if applicable) quantifiable.
- Results oriented.
- Time-limited.

*Example:* Issue four quarterly newsletters, provide NIHB alerts and quantify number of contacts with Tribes annually.

B. Address how the proposed project will result in change or improvement in program operations or processes for each proposed project objective. Also address what tangible products, if any, are expected from the project, (*i.e.* legislative analysis, policy analysis, Annual Conference, Summits, etc.)

C. Address the extent to which the proposed project will build the organization's capacity to provide, improve, or expand services that address the need(s) of the target population. Include a strategic plan and business plan currently in place that are being used. Include the plan(s) with the application submission.

D. Submit a workplan in the appendix which includes the following information:

- Provide the action steps on a timeline for accomplishing the proposed project objective(s).
- Identify who will perform the action steps.
- Identify who will supervise the action steps taken.
- Identify what tangible products will be produced during and the end of the proposed project objective(s).
- Identify who will accept and/or approve work products during the duration of the proposed project and at the end of the proposed project.
- Include any training that will take place during the proposed project and who will be attending the training.
- Include evaluation activities planned.

E. If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):

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

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

F. Describe what updates will be required for the continued success of the proposed project. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

#### **Project Evaluation (15 points)**

Each proposed objective requires an evaluation component to assess its progression and ensure its completion. Also, include the evaluation activities in the work-plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work-plan and activities of the project.

A. For outcome evaluation, describe:

- What the criteria will be for determining success of each objective.
- What data will be collected to determine whether the objective was met.

- At what intervals will data be collected.
- Who will collect the data and their qualifications.
- How the data will be analyzed.
- How the results will be used.

B. For process evaluation, describe:

- How the project will be monitored and assessed for potential problems and needed quality improvements.

- Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and their qualifications.
- How ongoing monitoring will be used to improve the project.
- Any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.
- How the project will document what is learned throughout the project period.

C. Describe any evaluation efforts that are planned to occur after the grant period ends.

D. Describe the ultimate benefit for the AL/AN that will be derived from this project.

#### **Organizational Capabilities and Qualifications (15 points)**

A. Describe the organizational structure of the organization beyond health care activities, if applicable.

B. Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other cooperative agreements/grants and projects successfully completed.

C. Describe what equipment (*i.e.*, fax machine, phone, computer, etc.) and facility space (*i.e.*, office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

D. List key personnel who will work on the project. Include title used in the work-plan. In the appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed project. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities. If a position is to be filled, indicate that information on the proposed position description.

#### **Categorical Budget and Budget Justification (10 points)**

A. Provide a categorical budget for each of the 12-month budget periods requested.

B. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.

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

#### **Multi-Year Project Requirements**

For additional years of funding, the applicant must include a narrative for each additional year's project objectives, evaluation components, work plan, categorical budget, and budget justification. The same weights and criteria as noted in Section V. Application Review Information that is used to evaluate the first year of a multi-year project will be applied when evaluating the second year of the multi-year application. A weak second year submission could negatively impact the overall score of the application.

#### **Appendix Items**

- A. Work plan for proposed objectives.
- B. Position descriptions for key staff.
- C. Resumes of key staff that reflect current duties.
- D. Consultant proposed scope of work (if applicable).
- E. Indirect Cost Rate Agreement, if applicable.
- F. Organizational chart.
- G. Multi-Year Project Requirements noted above.

H. Application Checklist.

#### **2. Review and Selection Process**

In addition to the above criteria/requirements, applications are considered according to the following:

A. Application Submission (*Application Deadline*: Friday, January 9, 2009). The application received in advance of or by the deadline and verified by the tracking number will undergo a preliminary review to determine that:

- The applicant and proposed project is eligible in accordance with this Single Source cooperative agreement announcement;
- The application builds upon previously funded project(s); and
- The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise the application may be returned.

B. Objective Review of Application—

The objective review of the cooperative agreement is scheduled for Friday, January 16, 2009. The application will be screened to ensure that eligibility requirements are complete, responsive, and conform to this Single Source cooperative agreement program announcement. The application will be reviewed for merit by the Ad Hoc Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on the application. The technical review will be conducted in accordance with the [HS Objective Review Guidelines]. The technical review process ensures objectivity is maintained on the Single Source cooperative agreement application. The application will be evaluated and rated on the basis of the evaluation criteria listed in Section V.1. The criteria will be used to evaluate the quality of a proposed project, determine the likelihood of success and to assign a numerical score to the application. The application must score 60 points or above by the ORC to be considered for funding. The DGO will conduct a cost analysis on the proposal and provide additional recommendations. The program official accepts the DGO

recommendations when considering or recommending funding. The program official forwards the final recommendations and documentation to the Acting Director, Office of Tribal Programs (OTP), for final review and approval.

3. Anticipated Announcement and Award Dates. The IHS anticipates the earliest award start date will be February 1, 2009.

## VI. Award Administration Information

### 1. Award Notices

The Notice of Award (NoA) will be initiated by the DGO and will be mailed via postal mail to the recipient. The NoA will be signed by the Grants Management Officer and is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the cooperative agreement award and will reflect the amount of Federal funds awarded for the purpose of the cooperative agreement and the involvement of each party's responsibilities: Recipient's and IHS, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is the legally binding document. The applicant will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted.

ORC Results Notification: Wednesday, January 23, 2009.

The Acting Director, OTP, or program official, will notify the contact person identified on the proposal of the results of the objective review in writing via postal mail. If the application is declared ineligible, the applicant will receive written notification of the ineligibility determination. The ineligibility notification will include information regarding the rationale for the ineligibility decision citing specific information from the application and/or this Single Source cooperative agreement program announcement. If the application is disapproved for a low score, the applicant will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted. Any other correspondence announcing to the Applicant's Project Director that an application was recommended for approval is not an authorization to begin performance. Pre-award costs are allowable charges under this cooperative agreement as noted in Part IV. Application and Submission Information, Item 6. Funding Restrictions.

### 2. Administrative and National Policy Requirements

Cooperative Agreements are administered in accordance with the following authorities and regulations:

- This single source cooperative agreement program announcement.
- Public Health Service Act Section 301.
- 45 CFR Part 74, "Administration of Grants to Non-Profit Recipients."
- Department of Health and Human Services, Grants Policy Statement, January 2007.
- Appropriate Cost Principles: OMB Circular A-122, "Non-profit Organizations."
- OMB Circular A-133, "Audits of States, Local Governments and Non-Profit Organizations."
- Healthy People 2010—The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Program Announcement is related to one or more of the priority areas. A copy of "Healthy People 2010" is available at: <http://www.healthypeople.gov>.

### 3. Indirect Costs

This section applies to all grant recipients that request indirect cost in their application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate refers to the rate covering the applicable activities during the award budget period. If the current rate is not on file with the awarding office, the award shall include funds for reimbursement of indirect costs. However, the indirect cost portion will remain restricted until the current rate is provided to the DGO.

Questions regarding the indirect cost policy may be addressed to the grants management staff at either 301-443-6290 or 301-443-5204.

If it is determined by the Division of Cost Allocation (DCA) that it is not feasible for the organization to develop a rate in order to charge the costs as direct costs, the organization must have an accounting system that identifies and segregates costs and assigns them commensurate with the benefits provided to each grant-supported project and the entity's other activities.

### 4. Reporting

A. Progress Report. Program progress reports are required quarterly. Quarterly program progress reports must be submitted within 30 days at the end of each quarter. These reports will include a brief comparison of actual accomplishments to the goals established for the period, reasons for slippage (if applicable), and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Status Reports. Financial status reports are required quarterly. Quarterly financial status reports must be submitted within 30 days at the end of each quarter. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

C. Reports. The recipient is responsible and accountable for accurate reporting of the Progress Narrative Reports and Financial Status Reports. Final Financial Status Reports (SF-269) must be verified from the grantee records on how the value was derived. Final reports (narrative and financial) are due within 90 days after each budget period. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

## VII. Agency Contact(s)

Interested parties may obtain programmatic information from the person listed under Programmatic Concerns under section IV of this program announcement. Grant-related and business management information may be obtained from the Grants Management Specialist listed under section IV of this program announcement. Grants.gov concerns submission and waiver requests may be addressed by Ms. Michelle Bulls, Division of Grants Policy. Contact information is noted under section IV of this program announcement. Please note

that the telephone numbers provided are not toll-free.

**VIII. Other Information**

*Application Checklist:* The following application checklist is included to assist the applicant in proposal preparation and follow-up. Applicant is

highly encouraged to employ this checklist for their benefit and to submit it as part of their proposal as an attachment in Grants.gov to allow for verification of receipt. This checklist will be utilized by the DGO during their initial screening for eligibility and will

be utilized by the OTP during their programmatic review for content of the application to ensure required items requested are submitted and the application is eligible for further review via the ORC. This checklist is available upon request from the OTP office.

**FY 2009 IHS COOPERATIVE AGREEMENT APPLICATION CHECKLIST**

Applicant Name: .....  
 Application Tracking Number: .....  
 Signed Paper Submission: .....  
 Electronic Submission: .....  
 Waiver Obtained: .....  
 Project Type: .....

Item	Applicant	Grants	Program
1. IHS FY 2009 Checklist .....	.....	.....	.....
2. Eligibility: National Indian Health Board Organization .....	.....	.....	.....
3. 501c(3) Non-Profit Certification .....	.....	.....	.....
4. SF 424 Application for Federal Assistance .....	.....	.....	.....
5. SF 424A Budget—Non-Construction .....	.....	.....	.....
6. SF 424B Assurances—Non-Construction .....	.....	.....	.....
7. Disclosure of Lobbying Activities .....	.....	.....	.....
8. Certification Regarding Lobbying .....	.....	.....	.....
9. Debarment Certification (Primary) .....	.....	.....	.....
10. Drug-free Certification .....	.....	.....	.....
11. Environmental Tobacco Smoke .....	.....	.....	.....
12. Maintenance of Effort Certification .....	.....	.....	.....
13. Abstract .....	.....	.....	.....
14. Project Narrative (14 pages maximum) .....	.....	.....	.....
a. Introduction and Need for Assistance .....	.....	.....	.....
b. Project Objective(s), Work-plan & Consultants .....	.....	.....	.....
c. Project Evaluation .....	.....	.....	.....
d. Organizational Capabilities & Qualifications .....	.....	.....	.....
e. Categorical Budget and Budget Justification .....	.....	.....	.....
15. APPENDIX ITEMS:			
a. Work-plan for proposed objectives .....	.....	.....	.....
b. Multi-year Summaries and Budget Justifications .....	.....	.....	.....
c. Position Descriptions for Key Staff .....	.....	.....	.....
d. Resumes of Key Staff that reflect current duties .....	.....	.....	.....
e. Consultant proposed scope of work (if applicable) .....	.....	.....	.....
f. Memorandums of Agreements .....	.....	.....	.....
g. Indirect Cost Rate Agreement, if applicable .....	.....	.....	.....
h. Organizational chart .....	.....	.....	.....

Applicant Signature/Date: .....  
 IHS Grants Management Signature/Date: .....  
 IHS Program Office Signature/Date: .....

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

Dated: 12/29/08  
**Robert G. McSwain,**  
*Director, Indian Head Service.*  
 [FR Doc. E8-31468 Filed 1-7-09; 8:45 am]  
**BILLING CODE 4160-16-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Environmental Health Sciences; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following meeting.

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

*Name of Committee:* National Institute of Environmental Health Sciences Special