

2011, and October 31, 2011, Pfizer requested that FDA withdraw approval of NDA 21–341 for BEXTRA. In the letter dated October 31, 2011, Pfizer waived any opportunity for a hearing otherwise provided under 21 CFR 314.150 (§ 314.150). In FDA's letter of November 9, 2011, responding to Pfizer's letters dated May 27, 2011, August 8, 2011, and October 31, 2011, the Agency acknowledged Pfizer's request to withdraw approval of BEXTRA under § 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21–341, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 30, 2013.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 2013–18657 Filed 8–1–13; 8:45 am]

**BILLING CODE 4160–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Indian Health Service**

#### **Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education; Cooperative Agreement Program**

*Announcement Type:* Limited New and Competing Continuation  
*Funding Announcement Number:* HHS–2013–IHS–NIHOE–0001  
*Catalog of Federal Domestic Assistance Number:* 93.933

#### **Key Dates**

*Application Deadline Date:* September 6, 2013  
*Review Date:* September 10, 2013  
*Earliest Anticipated Start Date:* September 30, 2013  
*Proof of Non-Profit Status Due Date:* September 6, 2013

### **I. Funding Opportunity Description**

#### *Statutory Authority*

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the National Indian Health Outreach and Education

(NIHOE) I limited competition cooperative agreement program. This award includes the following four components, as described in this announcement: “Line Item 128 Health Education and Outreach funds,” “Health Care Policy Analysis and Review,” “Budget Formulation” and “Tribal Leaders Diabetes Committee” (TLDC). This program is authorized under the Snyder Act, codified at 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

#### *Background*

The NIHOE program carries out health program objectives in the American Indian and Alaska Native (AI/AN) community in the interest of improving Indian health care for all 566 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health program issues and disseminates educational information to all AI/AN Tribes and villages. This program requires that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. This program also requires that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS based on Tribal input through a broad based consumer network.

#### *Purpose*

The purpose of this IHS cooperative agreement is to further IHS's mission and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. This award includes the following four health services components: Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and Tribal Leaders Diabetes Committee (TLDC).

#### *Limited Competition Justification*

Competition for the award included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing education and outreach on a national scale. This limitation ensures that the awardee will

have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between the Department of Health and Human Services (HHS) and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

### **II. Award Information**

#### *Type of Award*

Cooperative Agreement.

#### *Estimated Funds Available*

The total amount of funding identified for the current fiscal year 2013 is approximately \$716,000. Three hundred thousand dollars (\$300,000) is estimated for outreach, education, and support to Tribes who have elected to leave their Tribal Shares with the IHS (this amount could vary based on Tribal Shares assumptions; Line Item 128 Health Education and Outreach funding will be awarded in partial increments based on availability and amount of funding); \$100,000 for the Health Care Policy Analysis and Review; \$16,000 for the Budget Formulation; and \$300,000 associated with providing legislative education, outreach and communications support to the IHS TLDC and to facilitate Tribal consultation on the Special Diabetes Program for Indians (SDPI). All competing and continuation awards

issued under this announcement are subject to the availability of funds. In the absence of funding, 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 comprised of the following four components: Line Item 128 Health Education and Outreach; Health Care Policy Analysis and Review; Budget Formulation; and TLDC.

#### *Project Period*

The project period will run for one year from September 30, 2013 through September 29, 2014.

#### *Cooperative Agreement*

In HHS, a cooperative agreement is administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

#### *Substantial Involvement Description for Cooperative Agreement*

##### A. IHS Programmatic Involvement

1. The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, any training, reports, budget and evaluation. Collaboration includes data analysis, interpretation of findings and reporting.

2. The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the award noted below, as well as their adherence to the terms and conditions of the cooperative agreement. This includes providing guidance for required reports, development of tools, and other products, interpreting program findings and assistance with evaluation and overcoming any slippages encountered.

3. The IHS assigned program official will coordinate review and provide final approval of any deliverables, including printed materials, reports, testimony, and PowerPoint slides, prior to their distribution or dissemination to HHS, Tribes, or the public.

4. The IHS assigned program official will also coordinate the following:

- Discussion and release of any and all special grant conditions upon fulfillment.
  - Monthly scheduled conference calls.
  - Appropriate dissemination of required reports to each participating IHS program.
5. IHS will jointly with the awardee, plan and set an agenda for an annual conference that:
- Shares the outcomes of the outreach and health education training provided.
  - Fosters collaboration amongst the participating IHS program offices.
  - Increases visibility for the partnership between the awardee and IHS.

6. IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned and new findings.

7. IHS staff will review articles concerning the HHS for accuracy and may, if requested by the awardee, provide relevant articles.

8. IHS will communicate via monthly conference calls and meetings, individual or collective (all participating programs) site visits to the awardee.

9. IHS will provide technical assistance to the awardee as requested.

10. IHS staff may, at the request of the entity's board, participate on study groups, attend board meetings, and recommend topics for analysis and discussion.

##### B. Grantee Cooperative Agreement Award Activities

The awardee must obtain written IHS approval of all deliverables produced with award funds, including printed materials, reports, testimony, and PowerPoint slides, prior to their distribution or dissemination to HHS, Tribes, or the public.

The awardee must comply with relevant Office of Management and Budget (OMB) Circular provisions regarding lobbying, any applicable lobbying restrictions provided under other law and any applicable restriction on the use of appropriated funds for lobbying activities.

1. Line Item 128 Health Education and Outreach funding Is Utilized for Outreach, Health Education, and Support to Tribes—Approximately \$300,000 Funding Is Available

The awardee is expected to:

- a. Host an annual conference to disseminate changes and updates on health care information relative to AI/AN.

- b. Host a mid-year consumer conference(s) as appropriate to disseminate changes and updates on health care information relative to AI/AN.

- c. Conduct regional and national meeting coordination as appropriate.

- d. Conduct health care information dissemination as appropriate.

- e. Coordinate planning and technical assistance needs on behalf of Tribes/ Tribal Organizations (T/TO) to IHS.

- f. Convey health care recommendations on behalf of T/TO to IHS.

##### 2. Health Care Policy Analysis and Review

This funding component requires the awardee to provide IHS with research and analysis of the impact of Centers for Medicare and Medicaid Services (CMS) programs on AI/AN beneficiaries and the health care delivery system that serves these beneficiaries. \$100,000 funding is available for analysis of CMS programs that affect AI/AN beneficiaries:

The awardee will produce measurable outcomes to include:

- a. Analytical reports, policy review and recommendation documents—The products will be in the form of written (hard copy and/or electronic files) documents that contain analysis of relevant health care issues to be reported on a monthly or quarterly basis during the IHS and CMS "All Tribes Calls" and face-to-face meetings with hard copies submitted to the Director, Office of Resource, Access and Partnerships (ORAP), IHS.

- b. Educational and informational materials to be disseminated by the awardee and communicated to IHS and Tribal health program staff during monthly and quarterly conferences, the annual consumer conference, meetings and training sessions. This can be in the form of PowerPoint presentations, informational brochures, and/or handout materials.

The IHS will provide guidance and assistance as needed. Copies of all deliverables shall be submitted to the IHS Office of Direct Service and Contracting Tribes (ODSCT) and IHS ORAP.

##### 3. Tribal Budget Consultation—Budget Formulation

The Awardee will provide assistance to IHS, Tribes, the Budget Formulation Workgroup, and to the technical team, by performing the following activities in coordination and support of the IHS Tribal Budget Consultation. Budget consultation is required by the Indian Self-Determination and Education

Assistance Act (ISDEAA), 25 U.S.C. 450j–1(i). Approximately \$16,000 funding is available.

*National Budget Work Session—January 2014*

Meeting Responsibilities (Required)

*Estimated Costs:* The estimated costs for this activity shall not exceed \$6,500. The awardee shall work with IHS/Office of Finance and Accounting (OFA)/Division of Budget Formulation (DBF) closely on this item.

Recordation of Meeting—The Awardee Shall Take Minutes During the Work Session

a. Minutes should be recorded in a clear and concise manner and identify all speakers including presenters and any individuals contributing comments or motions.

b. Minutes will be recorded in an objective manner.

c. Minutes shall include a record of any comments, votes, or recommendations made, as well as notation of any handouts and other materials referenced by speakers, documented by the speaker's name and affiliation.

d. Minutes shall document any written materials that were distributed at the meeting. These materials will be included with the submission of the transcription and the summary page outlining all key topics.

e. Minutes will include information regarding the next meeting, including the date, time and location and a list of topics to be addressed.

f. The minutes must be submitted to IHS/OFA for review and approval within five working days.

Further Instructions

The awardee shall:

a. Package and distribute results of work session to IHS/OFA within five working days, which includes minutes and the final set of agreed upon national budget and health priorities; and

b. Provide final documents needed for IHS budget formulation Web site.

*HHS Tribal Consultation—March 2014*

Preparation and Meeting Responsibilities

*Estimated Costs:* The estimated costs for this activity shall not exceed \$3,000. The awardee shall work with IHS/OFA/DBF closely on this item.

The Tribal testimony is a combined effort that is written and presented by the National Tribal Budget Formulation Workgroup. The testimony is presented to the Secretary of HHS and related staff as part of the Annual National U.S.

Department of Health and Human Services Tribal Budget and Policy Consultation.

Assist the selected Tribal Budget Formulation Workgroup to prepare for the HHS Consultation meeting to:

a. Arrange a workgroup meeting;

b. Prepare testimony, and PowerPoint presentation with talking points, with the content of both based on input from the workgroup and technical team and with the awardee responsible for formatting and design of the products;

c. Submit testimony and draft PowerPoint presentation to IHS for review and approval;

d. Package and distribute final materials, once approval from IHS is obtained; and

e. Deliver final testimony to IHS Budget Formulation prior to the presentation for final printing.

Assist Tribal presenters as needed with rehearsal of the presentation.

Arrange working space for the workgroup to provide final input to the presentation and finalize presentation, if needed—NTE two days.

*Budget Formulation Evaluation/ Planning Meeting—May 2014*

Meeting Responsibilities (Required)

*Estimated Costs:* The estimated costs for this activity shall not exceed \$6,500. The awardee shall work with IHS/OFA/DBF closely on this item.

Recordation of Meeting—The Awardee Shall Take Minutes During the Work Session

a. Minutes should be recorded in a clear and concise manner and identify all speakers including presenters and any individuals contributing comments or motions.

b. Minutes will be recorded in an objective manner.

c. Minutes shall include a record of any comments, votes, or recommendations made, as well as notation of any handouts and other materials referenced by speakers, documented by the speaker's name and affiliation.

d. Minutes shall document any written materials that were distributed at the meeting. These materials will be included with the submission of the transcription and the summary page outlining all key topics.

e. Minutes will include information regarding the next meeting, including the date, time and location and a list of topics to be addressed.

f. The minutes must be submitted to IHS/OFA for review and approval within five working days.

Further Instructions

Package and distribute results of work session:

a. To OFA within five working days; and

b. Provide final documents needed for IHS budget formulation Web site.

*Additionally:*

- All expenses will be itemized.
- If costs exceed the estimated cost for any part of this Scope of Work, approval from IHS/OFA must be granted before any release of funds.
- Preapproval from IHS is required before any subcontract may be awarded at a price above the estimated cost.

4. Facilitate Tribal Consultation on SDPI, Provide Meeting Support for TLDC, and Provide Education, Outreach and Communications Support

A total of \$300,000 is available for tasks associated with facilitating Tribal consultation on the SDPI grant program, providing meeting support for the TLDC and providing education, outreach and communications support on the activities of the TLDC, the SDPI grant program and related diabetes/chronic disease issues.

*Statement of Work*

I. TLDC Tribal Consultation Meetings

a. Arrange TLDC Meetings and Strategic Planning workgroup sessions.

i. Quarterly Face-to-Face TLDC Meetings.

1. Tentative schedule of quarterly meetings will be as follows (subject to change):

- (a) September 2013
- (b) December 2013
- (c) March 2014
- (d) June 2014

2. Location (IHS Area and city) to be determined by TLDC members. Every effort will be made to utilize federal meeting space for TLDC meetings.

ii. TLDC Strategic Planning Workgroups.

1. Schedule conference calls and/or webinars for four workgroups. Schedule of calls will be made in conjunction with TLDC members.

b. Develop TLDC meeting and workgroup session agendas with the Division of Diabetes Treatment Program (DDTP) and TLDC.

i. The draft agenda will be developed in collaboration with the TLDC Tribal co-chair, and DDTP.

ii. The draft agenda will be provided to the TLDC Tribal Chairman and the DDTP Director or assignee.

c. Record and provide minutes of TLDC meetings and workgroup sessions.

i. Minutes will be completed as follows:

1. Minutes will be recorded in a clear and concise manner and identify all speakers including presenters and any individuals contributing comments or motions.

2. Minutes will be recorded in an objective manner.

3. Minutes shall include a record of any comments, votes, or recommendations made, as well as notation of any handouts and other materials referenced by speakers, documented by the speaker's name and affiliation.

4. Minutes shall document any written materials that were distributed at the meeting. These materials will be included with the submission of the transcription and the summary page outlining all key topics.

5. Minutes will include information regarding the next meeting, including the date, time and location and a list of topics to be addressed.

6. The minutes must be submitted to IHS/DDTP for review and approval within five working days.

ii. Provide final minutes and pertinent documents to the DDTP (as determined at each meeting).

d. Coordinate travel planning and travel/per diem reimbursement in accordance with the approved TLDC charter for 12 TLDC members (or their assigned alternate) and five Technical Advisors to attend four quarterly TLDC meetings.

i. Travel planning and reimbursement process will include:

1. Direct communication with TLDC members (and alternates, as necessary) and technical advisors to assist in travel arrangements.

2. Provide logistical information to TLDC members and advisors for meeting location and lodging.

3. Prepare and distribute reimbursement forms with clear instructions in advance of the meeting and serve as the point of contact for communicating any additional travel information that is required.

4. Collect reimbursement forms and provide timely reimbursement of approved participants' expenses within 30 days of the receipt of the claim forms.

5. Report travel reimbursements costs per meeting.

6. Maintain an active TLDC email directory in order to assist the DDTP and the TLDC with broadcasting related meeting, travel and reimbursement information and soliciting related feedback.

7. Include identified DDTP staff on all email correspondence to TLDC members and Technical Advisors.

II. Provide Education, Outreach and Communications Support

a. Communicate with Tribal leaders and Indian organizations about the activities of the TLDC, the SDPI grant program and related diabetes/chronic disease issues.

i. Provide factual information, review and analysis of legislative and policy issues that are relevant to diabetes and related chronic conditions in AI/ANs and on related health care disparities in written and e-file format for the purpose of keeping TLDC membership up-to-date on such information and for sharing with other Tribal leadership, Indian organizations and others.

ii. Coordinate sharing TLDC-approved information with national non-profit organizations such as the Juvenile Diabetes Research Foundation and the American Diabetes Association for strengthening outreach to Tribes and Tribal communities as well as education and outreach to non-Indian communities in the United States about AI/ANs living with diabetes and other chronic diseases.

iii. Support presentation and exhibit costs for DDTP staff and assignees to include a plenary and up to four workshops presentations on diabetes, SDPI and related chronic disease at:

1. National NIHB Public Health Summit and the annual consumer conference; and

2. Other national Tribal health care conferences/meetings such as the NCAI annual conference.

iv. Support exhibit opportunity for SDPI Community-directed and Diabetes Prevention/Health Heart Initiatives grant programs to display programmatic information at the 2013 national NIHB Public Health Summit.

b. Support DDTP collaborative efforts to address issues associated with diabetes and obesity in AI/AN youth including food insecurity, prenatal stressors, depression and adverse childhood events.

i. Provide DDTP with current factual information on the epidemic of diabetes and obesity in AI/AN youth as well as issues related to child wellbeing; and review and analyze legislative and policy issues that are relevant to these topics.

ii. Coordinate several virtual meetings with IHS staff and staff from other agencies, Tribal organizations and relevant non-profit organizations on issues related to current efforts and potential collaborations related to child well-being.

iii. Provide written reports that contain factual analyses of policy issues and summaries of the coordinated

virtual meetings for the purpose of assisting DDTP and the TLDC with communication to Tribes, Tribal leaders, Indian organizations and others about relevant issues pertinent to diabetes, obesity and wellbeing in AI/AN youth.

#### *Eligibility Information*

This is a limited competition announcement.

#### 1. Eligibility

Eligible applicants are 501(c)(3) national Indian organizations that meet the following criteria: Eligible entities must have demonstrated expertise in:

- Representing all Tribal governments and providing a variety of services to Tribes, Area Health Boards, Tribal organizations, and Federal agencies, and playing a major role in focusing attention on Indian health care needs, resulting in improved health outcomes for Tribes.

- Promoting and supporting Indian education, and coordinating efforts to inform AI/AN of Federal decisions that affect Tribal government interests including the improvement of Indian health care.

- Administering national health policy and health programs.

- Maintaining a national AI/AN constituency and clearly supporting critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.

- Supporting improved healthcare in Indian Country.

The national Indian organization must have the infrastructure in place to accomplish the work under the proposed program.

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

#### 2. Cost Sharing or Matching

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

#### 3. Other Requirements

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

Grants Management (DGM) of this decision.

#### *Proof of Non-Profit Status*

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (i.e. FedEx tracking, postal return receipt, etc.).

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

##### *1. Obtaining Application Materials*

The application package and detailed instructions for this announcement can be found at <http://www.Grants.gov> or [https://www.ihs.gov/dgm/index.cfm?module=dsp\\_dgm\\_funding](https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding).

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

##### *2. Content and Form Application Submission*

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF-424, Application for Federal Assistance.
  - SF-424A, Budget Information—Non-Construction Programs.
  - SF-424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must not exceed ten pages for each of the four components pages).
  - Background information on the organization.
  - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Letter of Support from Organization's Board of Directors.
  - 501(c)(3) Certificate.
  - Biographical sketches for all Key Personnel.
  - Contractor/Consultant resumes or qualifications and scope of work.
  - Disclosure of Lobbying Activities (SF-LLL).

- Certification Regarding Lobbying (GG-Lobbying Form).

- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.

- Organizational Chart (optional).
- Documentation of current OMB A-133 required Financial Audit (if applicable).

Acceptable forms of documentation include:

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

- Face sheets from audit reports. These can be found on the FAC Web site: <http://harvester.census.gov/sac/dissemin/accessoptions.html?submit=Go+To+Database>.

##### *Public Policy Requirements*

All Federal-wide public policies apply to IHS grants with exception of the Discrimination policy.

##### *Requirements for Project and Budget Narratives*

*A. Project Narrative:* This narrative should be a separate Word document that is no longer than ten pages per each component pages and must: be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½" × 11" paper.

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

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

Part A: Program Information (2 Page Limitation)

##### Section 1: Needs

Describe how the national Indian organization has the expertise to provide outreach and education efforts on a continuing basis regarding the pertinent changes and updates in health care for each of the four components listed herein.

Part B: Program Planning and Evaluation (6 Page Limitation)

##### Section 1: Program Plans

Describe fully and clearly how the national Indian organization plans to address the NIHOE requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 566 Federally-recognized Tribes for each of the four components described herein. Include proposed timelines as appropriate and applicable.

##### Section 2: Program Evaluation

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal communities. Identify anticipated or expected benefits for the Tribal constituency.

Part C: Program Report (2 Page Limitation)

##### Section 1: Describe Major Accomplishments Over the Last 24 Months

Please identify and describe significant program achievements associated with the delivery of quality health outreach and education services. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

##### Section 2: Describe Major Activities Over the Last 24 Months

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

*B. Budget Narrative:* This narrative must describe the budget requested and match the scope of work described in the project narrative. The budget narrative should not exceed five pages.

##### *3. Submission Dates and Times*

Applications must be submitted electronically through Grants.gov by 12:00 a.m., midnight Eastern Standard Time (EST) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the

application deadline will not be accepted for processing, nor will it be given further consideration for funding. The applicant will be notified by the DGM via email of this decision.

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

If the applicant needs to submit a paper application instead of submitting electronically via Grants.gov, prior approval must be requested and obtained (see Section IV.6 below for additional information). The waiver must be documented in writing (emails are acceptable), *before* submitting a paper application. A copy of the written approval must be submitted along with the hardcopy that is mailed to the DGM. Once the waiver request has been approved, the applicant will receive a confirmation of approval and the mailing address to submit the application. Paper applications that are submitted without a waiver from the Acting Director of DGM will not be reviewed or considered further for funding. The applicant will be notified via email of this decision by the Grants Management Officer of DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EST, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

#### 4. Intergovernmental Review

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

#### 5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

#### 6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the <http://www.Grants.gov> Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the <http://www.Grants.gov> Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

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

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

Please be aware of the following:

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

Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.

- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the ODSCT will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

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

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

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

#### *System for Award Management (SAM)*

Organizations that were not registered with Central Contractor Registration (CCR) and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number

from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge.

Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: [https://www.ihs.gov/dgm/index.cfm?module=dsp\\_dgm\\_policy\\_topics](https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics).

## V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The ten-page narrative allowed per each of the four components page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

### 1. Criteria

#### A. Introduction and Need for Assistance (15 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 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. This could also include HHS agencies that rely on the applicant as the primary gateway organization to AI/AN communities that is capable of providing the dissemination of health information. Include information regarding technologies currently used (i.e., hardware, software, services, Web sites, 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 that deem the applicant as the primary source of health policy information for AI/AN, memorandums of agreement with other Area Indian health boards, etc.

(3) Describe the population to be served by the proposed projects.

(4) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects’ accomplishments. State how previous cooperative agreement funds facilitated education, training and technical assistance nationwide for AI/ANs and relate the progression of health care information delivery and development relative to the current proposed projects. (Copies of reports will not be accepted.)

(5) Describe collaborative and supportive efforts with national, Area and local Indian health boards.

(6) Explain the need/reason for your proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses have been assessed.

(7) If the proposed projects include information technology (i.e., hardware, software, etc.), provide further information regarding measures taken or to be taken that ensure the proposed projects will not create other gaps in services or infrastructure (i.e., negatively or adversely affect IHS interface capability, Government Performance Results Act reporting requirements, contract reporting requirements, Information Technology (IT) compatibility, etc.), if applicable.

(8) Describe the effect of the proposed projects 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 projects on planned/anticipated programs and/or equipment.

(9) Describe how the projects relate to the purpose of the cooperative agreement by addressing the following: Identify how the proposed projects will address outreach and education regarding each of the four components:

Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and TLDC.

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

(1) Identify the proposed objective(s) for each of the four projects, as applicable. Objectives should be:

- Measurable and (if applicable) quantifiable.

- results oriented.
- time-limited.

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

Goals must be clear and concise.

Objectives must be measurable, feasible and attainable for each of the selected projects.

(2) Address how the proposed projects will result in change or improvement in program operations or processes for each proposed project objective for all of the projects. Also address what tangible products, if any, are expected from the projects, (i.e., policy analysis, annual conference, mid-year conferences, summits, etc.).

(3) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a current strategic plan and business plan that includes the expanded services. Include the plan(s) with the application submission.

(4) Submit a work plan in the appendix which includes the following information:

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

5) 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.

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

#### C. Program Evaluation (20 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.

(1) For outcome evaluation, describe:

- What will the criteria 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 will the data be analyzed?
- How will the results be used?

(2) For process evaluation, describe:

- How will each project be monitored and assessed for potential problems and needed quality improvements?

- Who will be responsible for monitoring and managing each project's improvements based on results of ongoing process improvements and their qualifications?

- How will ongoing monitoring be used to improve the projects?

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

- How will the organization document what is learned throughout each of the projects' periods?

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

(4) Describe the ultimate benefit to the AI/AN population that the applicant organization serves that will be derived from these projects.

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

This section outlines 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 projects outlined in the work plan.

(1) Describe the organizational structure of the organization beyond health care activities, if applicable.

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

(3) 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 projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

(4) List key personnel who will work on the projects. Include title used in the work plans. 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 projects. Resumes must indicate that the proposed staff member is qualified to carry out the proposed projects' activities. If a position is to be filled, indicate that information on the proposed position description.

(5) If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to the projects and identify the resources used to fund the remainder of the individual's salary.

#### E. Categorical Budget and Budget Justification (10 Points)

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

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

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

(3) Provide a narrative justification explaining why each 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 (If Applicable)

Projects requiring second, third, fourth, and/or fifth year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

#### Appendix Items

- Work plan, logic model and/or time line for proposed objectives.

- Position descriptions for key staff.

- Resumes of key staff that reflect current duties.

- Consultant or contractor proposed scope of work and letter of commitment (if applicable).

- Current Indirect Cost Agreement.

- Organizational chart(s) highlighting proposed project staff and their supervisors as well as other key contacts within the organization and key community contacts.

- Additional documents to support narrative (i.e. data tables, key news articles, etc.).

#### 2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. Applicants will be notified by DGM, via email, to outline minor missing components (i.e., signature on the SF-424, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation. If an applicant receives less than a minimum score, it will be considered to be "Disapproved" and will be informed via email by the IHS Program Office of their application's deficiencies. A summary statement outlining the strengths and weaknesses of the application will be provided to each disapproved applicant. The summary statement will be sent to the Authorized Organizational Representative (AOR) that is identified on the face page (SF-424), of the application within 30 days of the completion of the Objective Review.

## VI. Award Administration Information

### 1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves

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

#### *Disapproved Applicants*

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

#### *Approved But Unfunded Applicants*

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved," but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2013, the approved application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

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

## 2. Administrative Requirements

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

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- 45 CFR Part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments.

- 45 CFR Part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and other Non-profit Organizations.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- 2 CFR Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).

- 2 CFR Part 230—Cost Principles for Non-Profit Organizations (OMB Circular A-122).

E. Audit Requirements:

- OMB Circular A-133, Audits of States, Local Governments, and Non-profit Organizations.

### 3. Indirect Costs

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

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (National Business Center) [http://www.doi.gov/ibc/services/Indirect\\_Cost\\_Services/index.cfm](http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm). For questions regarding the indirect cost policy, please call (301) 443-5204 to request assistance.

### 4. Reporting Requirements

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

of the grantee organization or the individual responsible for preparation of the reports. Reports must be submitted electronically via GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

#### *A. Progress Reports*

Program progress reports are required semi-annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

#### *B. Financial Reports*

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

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

#### *C. Federal Subaward Reporting System (FSRS)*

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

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

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and

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

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

#### VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Mr. Chris Buchanan, Director, ODSC, 801 Thompson Avenue, Suite 220, Rockville, MD 20852, Telephone: (301) 443-1104, Fax: (301) 443-4666, Email: [Chris.Buchanan@ihs.gov](mailto:Chris.Buchanan@ihs.gov) mailto:

2. Questions on grants management and fiscal matters may be directed to: Mr. Andrew Diggs, DGM, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Telephone: (301) 443-5204, Fax: (301) 443-9602, Email: [Andrew.Diggs@ihs.gov](mailto:Andrew.Diggs@ihs.gov).

3. Questions on systems matters may be directed to: Mr. Paul Gettys, DGM, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: 301-443-2114; or the DGM main line 301-443-5204, Fax: 301-443-9602, Email: [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov).

#### VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, 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: July 26, 2013.

**Yvette Roubideaux,**

*Acting Director, Indian Health Service.*

[FR Doc. 2013-18596 Filed 8-1-13; 8:45 am]

**BILLING CODE 4165-16-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60-Day Comment Request: National Institute of Mental Health Recruitment and Milestone Reporting System

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and For Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed

project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or Email your request, including your address to: [nimhprapubliccomments@mail.nih.gov](mailto:nimhprapubliccomments@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Comment Due Date:* Comments received within 60 days of the date of this publication will receive fullest consideration.

*Proposed Collection:* National Institute of Mental Health Recruitment Milestone Reporting System. 0925-New. National Institute of Mental Health (NIMH), National Institute of Health (NIH).

*Need and Use of Information Collection:* Recruitment Milestone Reporting (RMR) allows NIMH staff to monitor more accurately the recruitment of participants in NIMH-sponsored clinical research studies that plan to enroll 150 or more human subjects in a single study. Clinical studies can have difficulty recruiting, and accurate and timely reporting is the best way to ensure proper use of the grant funds. Investigators develop a recruitment plan that includes tri-yearly milestones for recruitment of the total study population, and for recruitment of racial and ethnic minority participants. Once recruitment is scheduled to begin, investigators report actual progress on recruitment milestones three times per year, by April 1, August 1, and December 1. The primary use of this information is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research. By ensuring timely recruitment into clinical research studies, NIMH can reduce the need to extend timelines or supplement funds in order to complete the research project, and potentially increase efficiency in our funding process.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1519.