

workshop entitled "Pediatric Clinical Investigator Training." The purpose of this workshop is to provide investigators with training and expertise in designing and conducting clinical trials in pediatric patients that will lead to appropriate labeling. The training course is intended to provide investigators with a clear understanding of some of the challenges of studying products in the pediatric population when the data are intended to be used to support product labeling, an overview of extrapolation as it relates to the pediatric population, a familiarity with FDA processes and timelines that are specific to pediatric product development, and an overview of ethically appropriate methods related to the design of clinical trials in the pediatric population.

**DATES:** The public workshop will be held on September 22, 2014, from 8 a.m. to 5:30 p.m.

**ADDRESSES:** The public workshop will be held at the Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. The hotel's telephone number is 301-897-9400.

**FOR FURTHER INFORMATION CONTACT:** Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8646, FAX: 301-847-8640, email: [terrie.crescenzi@fda.hhs.gov](mailto:terrie.crescenzi@fda.hhs.gov); or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8659, FAX: 301-847-8640, [elizabeth.sanford@fda.hhs.gov](mailto:elizabeth.sanford@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In July 2012, the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) made permanent the pediatric initiatives, Best Pharmaceuticals for Children Act and Pediatric Research Equity Act, which have stimulated pediatric research over the past 15 years. Though much progress has been made, pediatric trials for the purpose of developing product use parameters and information are still performed much less frequently than adult trials. As such, current standards for trials are much more oriented to adult scientific, ethical, and clinical processes. This situation is due, in part, to the fact that pediatric trials have a number of unique attributes and requirements, which must be met if the data are to be accepted or used by FDA.

The development of safe and effective products in the pediatric population presents many challenges. These

challenges include trial design, appropriate endpoints, extrapolation of data from adults, and ethical issues. It is extremely important that pediatric researchers recognize and understand the challenges and differences between the standards for adult trials and pediatric trials. Researchers are responsible for ensuring the safe and ethical treatment of pediatric patients and obtaining adequate and reliable data to support regulatory decisions. There is a critical need for further pediatric research on medical products to obtain additional data, which will help ensure that these products are safe and effective in the pediatric population. We are able to obtain data and information in older children; however, the challenge of obtaining data from non-verbal children and neonates is much more difficult. This need reinforces our responsibility to educate clinical investigators to assure that children are only enrolled in research that is scientifically necessary, ethically sound, and designed to meet the challenges of review by FDA.

**II. Participation in the Public Workshop**

*A. Registration*

There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online by sending an email to [OPT@fda.hhs.gov](mailto:OPT@fda.hhs.gov) before September 8, 2014, and include the following information: Name, title, affiliation, email address, and telephone number. For those without Internet access, please contact Terrie L. Crescenzi or Betsy Sanford (see **FOR FURTHER INFORMATION CONTACT**) to register. In the event that a minimum number of participants have not registered, the workshop will be postponed. Registered participants will be notified of any change. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

Registration information, the agenda and additional background materials can be found at <http://www.fda.gov/NewsEvents/MeetingsConferences/Workshops/ucm392506.htm>.

If you need special accommodations due to a disability, please contact Betsy Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

*B. Videotaping*

The workshop will be videotaped and available on the Internet at <http://wcms.fda.gov/FDAgov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm?ssSourceSiteId=null&SSContributor=true>, approximately 30 days after the workshop.

Dated: April 23, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

[Funding Opportunity Number: HHS-2014-IHS-INMED-0001; CFDA Number: 93.970]

**Funding Opportunity: American Indians Into Medicine**

*Announcement Type:* New and Competing Continuation.

**Key Dates**

*Application Deadline:* June 13, 2014.

*Review Date:* June 25, 2014.

*Earliest Anticipated Start Date:*

September 1, 2014.

*Proof of Non-Profit Status Due Date:*

June 13, 2014.

**I. Funding Opportunity Description**

*Statutory Authority*

The Indian Health Service (IHS) is accepting competitive grant applications for the Indians into Medicine Program (INMED). This program is authorized under the authority of 25 U.S.C. 1616g, Indian Health Care Improvement Act, Public Law 94-437, as amended (IHCA). This program is described in the Catalog of Federal Domestic Assistance under 93.970.

*Background*

The IHS, an agency within the Department of Health and Human Services (HHS), is responsible for providing Federal health services to American Indians and Alaska Natives (AI/AN). The mission of the IHS is to raise the physical, mental, social, and spiritual health of AI/AN. The IHCA authorizes the IHS to administer programs that are designed to attract and recruit qualified individuals into health professions needed at IHS facilities. The programs administered are designed to encourage AI/AN to enter health professions and to ensure the availability of health professionals to serve AI/AN populations.

### Purpose

The purpose of the Indians into Medicine Program (INMED) is to augment the number of Indian health professionals serving Indians by encouraging Indians to enter the health professions and removing the multiple barriers to their entrance into practice serving Indians.

## II. Award Information

### Type of Awards

Grant.

### Estimated Funds Available

The total amount of funding identified for fiscal year (FY) 2014 is approximately \$397,360. Individual award amounts are anticipated to be between \$170,000 and \$195,000. The amount of funding available for both competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

### Anticipated Number of Awards

Approximately two awards will be issued under this program announcement.

### Project Period

The project period will be for five years and will run consecutively from September 1, 2014 to August 31, 2019.

## III. Eligibility Information

### 1. Eligible Applicants

Public and nonprofit private colleges and universities with medical and other allied health programs accredited by an accrediting agency recognized by the U.S. Secretary of Education are eligible to apply for the grants. Public and nonprofit private colleges that operate nursing programs are not eligible under this announcement since the IHS currently funds the nursing recruitment grant program.

The existing INMED grant program at the University of North Dakota has as its target population Indian Tribes primarily within the States of North Dakota, South Dakota, Nebraska, Wyoming, and Montana. A college or university applying under this announcement must propose to conduct its program among Indian Tribes in states not currently served by the University of North Dakota INMED program.

### 2. Cost Sharing/Matching

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

### 3. Other Requirements

**Required Affiliations**—The grant applicant must submit official documentation indicating a Tribe's cooperation with and support of the program within the schools on its reservation and its willingness to have a Tribal representative serve on the program advisory board. Documentation must be in the form prescribed by the Tribe's governing body, i.e., letter of support or Tribal resolution. Documentation must be submitted from every Tribe represented on the program advisory board.

If application budgets exceed the stated dollar amount that is 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.

## IV. Application and Submission Information

### 1. Obtaining Application Materials

The application package and instructions may be located at [www.Grants.gov](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 Mr. Paul Gettys at (301) 443-5204 or [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov).

### 2. Content and Form of Application Submission

The application 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.
  - SF424A, 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 be single spaced and not exceed ten 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.
- Tribal Resolution or Tribal Letter of Support (if applicable).
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF-LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Organizational Chart.
- Documentation of current Office of Management and Budget (OMB) audit (if applicable), as required by 2 CFR 200.501.

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/dissem/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 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 will be

reviewed. The 10-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.

Part A: Program Information (3 page limitation)

#### Section 1: Needs

a. State specific objectives of the project, and the extent to which they are measurable and quantifiable, significant to the needs of Indian people, logical, complete, and consistent with the purpose of 25 U.S.C. 1616g.

b. Describe briefly what the project intends to accomplish. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

c. Provide a project specific work plan (milestone chart) which lists each objective, the tasks to be conducted in order to reach the objective, and the timeframe needed to accomplish each task. Timeframes should be projected in a realistic manner to assure that the scope of work can be completed within each 12-month budget period.

d. In the case of proposed projects for identification of Indians with a potential for education or training in the health professions, include a method for assessing the potential of interested Indians for undertaking necessary education or training in such health professions.

e. State clearly the criteria by which the project's progress will be evaluated and by which the success of the project will be determined.

f. Explain the methodology that will be used to determine if the needs, goals, and objectives identified and discussed in the application are being met and if the results and benefits identified are being achieved.

g. Identify who will perform the evaluation and when.

#### Part B: Program Planning and Evaluation (5 page limitation)

##### Section 1: Program Plans

a. Provide an organizational chart and describe the administrative, managerial and organizational arrangements and the facilities and resources to be utilized to conduct the proposed project (include in appendix).

b. Provide the name and qualifications of the project director or other individuals responsible for the conduct of the project; the qualifications of the principal staff carrying out the project; and a description of the manner in which the applicant's staff is or will be organized and supervised to carry out

the proposed project. Include biographical sketches of key personnel (or job descriptions if the position is vacant) (include in appendix).

c. Describe any prior experience in administering similar projects.

d. Discuss the commitment of the organization, i.e., although not required, the level of non-Federal support. List the intended financial participation, if any, of the applicant in the proposed project specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space, materials or facilities or other contributions.

e. The IHCA requires that applicants agree to provide a program which:

(A) provides outreach and recruitment for health professions to Indian communities including elementary, secondary and community colleges located on Indian reservations which will be served by the program,

(B) incorporates a program advisory board comprised of representatives from the tribes and communities which will be served by the program,

(C) provides summer preparatory programs for Indian students who need enrichment in the subjects of math and science in order to pursue training in the health professions,

(D) provides tutoring, counseling and support to students who are enrolled in a health career program of study at the respective college or university, and

(E) to the maximum extent feasible, employs qualified Indians in the program.

Describe the college's or university's ability to meet this requirement.

##### Section 2: Program Evaluation

a. Describe the current and proposed participation of Indians (if any) in your organization.

b. Identify the target Indian population to be served by your proposed project and the relationship of your organization to that population.

c. Describe the methodology to be used to access the target population.

d. Identify affiliation agreements with Tribal community colleges, the IHS, university affiliated programs, and other appropriate entities to enhance the education of Indian students.

e. Identify existing university tutoring, counseling and student support services.

#### Part C: Program Report (5 page limitation)

a. Provide data and supporting documentation to substantiate need for recruitment.

b. Indicate the number of potential Indian students to be contacted and

recruited as well as potential cost per student recruited. Those projects that have the potential to serve a greater number of Indians will be given first consideration.

c. Describe methodology to locate and recruit students with educational potential in a variety of health care fields. Primary recruitment efforts must be in the field of medicine with secondary efforts in other allied health fields such as pharmacy, dentistry, medical technology, x-ray technology, etc. The field of nursing is excluded since the IHS does fund the IHS Nursing Recruitment grant program.

#### B. Budget Narrative

This narrative must describe the budget requested and match the scope of work described the project narrative. The page limitation should not exceed five pages.

##### 1. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 12 a.m., midnight Eastern Daylight Time (EDT) 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 Mr. Paul Gettys, DGM ([Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov)) at (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically via Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see Section 4 below for additional information). A waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application and (2) include a clear justification for the need to deviate from the required electronic grants submission process. Written waiver

request can be sent to [GrantsPolicy@ihs.gov](mailto:GrantsPolicy@ihs.gov) with a copy to [Tammy.Bagley@ihs.gov](mailto:Tammy.Bagley@ihs.gov). 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 copy of the signed waiver from the Acting Director of the 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 the DGM. Paper applications must be received by the DGM no later than 5 p.m., EDT, 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.*

## 2. Intergovernmental Review

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

## 3. Funding Restrictions

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

## 4. 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, the applicant 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 the 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 Office of Public Health Support (OPHS) 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 each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through <http://fedgov.dnb.com/webform>, or to expedite the process, call (866) 705-5711.

All HHS grant 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 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 10-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 70 points is required for funding. Points are assigned as follows:

#### 1. Evaluation Criteria

##### *Project Narrative (30 points)*

a. State specific objectives of the project, and the extent to which they are measurable and quantifiable, significant to the needs of Indian people, logical, complete, and consistent with the purpose of 25 U.S.C. 1616g.

b. Describe briefly what the project intends to accomplish. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

c. Provide a project specific work plan (milestone chart) which lists each objective, the tasks to be conducted in order to reach the objective, and the time frame needed to accomplish each task. Time frames should be projected in a realistic manner to assure that the scope of work can be completed within each 12-month budget period.

d. In the case of proposed projects for identification of Indians with a potential for education or training in the health professions, include a method for assessing the potential of interested Indians for undertaking necessary education or training in such health professions.

e. State clearly the criteria by which the project's progress will be evaluated and by which the success of the project will be determined.

f. Explain the methodology that will be used to determine if the needs, goals, and objectives identified and discussed in the application are being met and if the results and benefits identified are being achieved.

g. Identify who will perform the evaluation and when.

##### *Program Planning (20 points)*

a. Provide an organizational chart and describe the administrative, managerial and organizational arrangements and the facilities and resources to be utilized to conduct the proposed project (include in appendix).

b. Provide the name and qualifications of the project director or other individuals responsible for the conduct of the project; the qualifications of the principal staff carrying out the

project; and a description of the manner in which the applicant's staff is or will be organized and supervised to carry out the proposed project. Include biographical sketches of key personnel (or job descriptions if the position is vacant) (include in appendix).

c. Describe any prior experience in administering similar projects.

d. Discuss the commitment of the organization, i.e., although not required, the level of non-Federal support. List the intended financial participation, if any, of the applicant in the proposed project specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space, materials or facilities or other contributions.

e. Describe the ability to provide outreach and recruitment for health professions to Indian communities including, but not limited to, elementary and secondary schools and community colleges located on Indian reservations which will be served by the program.

f. Describe the organization's plan to incorporate a program advisory board comprised of representatives from the Tribes and communities which will be served by the program.

g. To the maximum extent feasible, employ qualified Indians in the program.

##### *Program Evaluation (20 points)*

a. Describe the current and proposed participation of Indians (if any) in your organization.

b. Identify the target Indian population to be served by your proposed project and the relationship of your organization to that population.

c. Describe the methodology to be used to access the target population.

d. Identify existing university tutoring, counseling and student support services.

##### *Progress Report (20 points)*

a. Provide data and supporting documentation to substantiate need for recruitment.

b. Indicate the number of potential Indian students to be contacted and recruited as well as potential cost per student recruited. Those projects that have the potential to serve a greater number of Indians will be given first consideration.

c. Describe methodology to locate and recruit students with educational potential in a variety of health care fields. Primary recruitment efforts must be in the field of medicine with secondary efforts in other allied health fields such as pharmacy, dentistry, medical technology, x-ray technology,

etc. The field of nursing is excluded since the IHS does fund the IHS nursing recruitment grant program.

##### *Program Budget (10 points)*

a. Clearly define the budget. Provide a justification and detailed breakdown of the funding by category for the first year of the project. Information on the project director and project staff should include salaries and percentage of time assigned to the grant. List equipment purchases necessary to conduct the project.

b. The available funding level of \$195,000 is inclusive of both direct and indirect costs or 8 percent of total direct costs. Because this project is for a training grant, the HHS policy limiting reimbursement of indirect cost to the lesser of the applicant's actual indirect costs or 8 percent of total direct costs (exclusive of tuition and related fees and expenditures for equipment) is applicable. This limitation applies to all institutions of higher education.

c. The applicant may include as a direct cost student support costs related to tutoring, counseling, and support for students enrolled in a health career program of study at the respective college or university. Tuition and stipends for regular sessions are not allowable costs of the grant; however, students recruited through the INMED program may apply for funding from the IHS Scholarship Programs.

d. Provide budgetary information for summer preparatory programs for Indian students, who need enrichment in the subjects of math and science in order to pursue training in the health professions.

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

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 in an appendix.

##### **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.
- Tribal Resolution(s)/Letters of Support.
- 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 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

### 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, 70, 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 2014, 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.

### 1. Administrative Requirements

Grants 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:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, "Cost Principles," located at 2 CFR part 200, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, "Audit Requirements," located at 2 CFR part 200, subpart F.

### 2. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires

applicants to obtain a current indirect cost 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 indirect cost portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) [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.

### 3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. 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 and 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: Jackie Santiago, Office of Public Health Support, 801 Thompson Avenue, TMP Suite 450, Rockville, Maryland 20852, Telephone: (301) 443-2486, Fax: (301) 443-4815, Email: [Jackie.Santiago@ihs.gov](mailto:Jackie.Santiago@ihs.gov).
2. Questions on grants management and fiscal matters may be directed to: Andrew Diggs, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852, Phone: (301) 443-2262, Email: [Andrew.Diggs@ihs.gov](mailto:Andrew.Diggs@ihs.gov).
3. Questions on systems matters may be directed to: Paul Gettys, 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, E-Mail: [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov).

#### VIII. Other Information

The Public Health Service strongly encourages all grantees 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: April 17, 2014.

**Yvette Roubideaux,**

*Acting Director, Indian Health Service.*

[FR Doc. 2014-09607 Filed 4-28-14; 8:45 am]

**BILLING CODE 4165-16-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

*Date:* May 29, 2014.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Washington DC, Dupont Circle; 1143 New Hampshire Avenue NW., Washington, DC 20037.

*Contact Person:* Kathryn M Koeller, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301-435-2681, [koellerk@csr.nih.gov](mailto:koellerk@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Chronic Dysfunction and Integrative Neurodegeneration Study Section.

*Date:* May 29-30, 2014.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301-435-1785, [kondratyevad@csr.nih.gov](mailto:kondratyevad@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; BD2K Data Discovery Index Coordination Consortium Panel.

*Date:* May 30, 2014.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Vonda K Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301-435-1789, [smithvo@csr.nih.gov](mailto:smithvo@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 22, 2014.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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