

This Arrangement is not intended to create any obligation under international or other laws.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective government agencies, have signed this Arrangement.

SIGNED in the of Spanish and English languages.

Signed on behalf of FDA:



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6/26/2012
Date

Signed on behalf of SS:



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6/18/2012
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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Indian Health Services

[HHS-2012-IHS-HLY-0001]

Healthy Lifestyles in Youth Project; Proposed Single Source Cooperative Agreement With National Congress of American Indians

Application Due Date: August 16, 2012.

Review Date: August 21, 2012.

Earliest Start Date: September 1, 2012.

I. Funding Opportunity Description

The Indian Health Service (IHS) proposes a single source competing continuation cooperative agreement with the National Congress of American Indians (NCAI) for the purpose of continued implementation of the Healthy Lifestyles in Youth Project in selected Native American Boys and Girls Clubs of America. This program promotes healthy lifestyles among American Indian and Alaska Native (AI/

AN) youth using the curriculum "Together Raising Awareness for Indian Life" (TRAIL) among selected Boys and Girls Club sites.

This program is authorized under the authority of the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001; and the Public Health Service Act, as amended, 42 U.S.C. 241(a). Under this cooperative agreement, IHS proposes to enter into a collaborative effort/initiative with NCAI, because of their unique experience partnering with the IHS and Boys and Girls Clubs of America in successfully establishing this program, as well as, their overall expertise and experience in addressing and evaluating healthy lifestyle techniques in AI/AN youth. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

The focus of the project continues to be on addressing healthy lifestyle development, emphasizing nutrition and physical activity for AI/AN children and youth 6 through 17 years of age. The long term goal is to prevent or delay the onset of obesity and related diseases such as type 2 diabetes. NCAI will continue partnering work with selected

Tribal Boys and Girls Club sites to: (a) Provide health and physical education programs; (b) help youth achieve and maintain healthy lifestyles through participation in fitness programs; (c) help youth to acquire a range of physical skills; and (d) help youth develop a sense of teamwork and cooperation.

These early intervention strategies provide evidence based opportunities to reduce and/or halt the increasing trend of obesity and diabetes among youth and young adults. Clubs that develop a health promotion program that includes the TRAIL curriculum may help curtail the effects of unhealthy eating behaviors and lack of physical activity that can lead to obesity, diabetes, and other chronic diseases later in life. The T.R.A.I.L. curriculum was developed to provide information on good nutrition and to promote physical activity among youth participating in Tribal Boys and Girls Clubs. T.R.A.I.L. is a three-month (12 lessons) program that provides youth with a comprehensive understanding of healthy lifestyles in order to prevent diabetes. Woven throughout the program are self-esteem and prevention activities. Participants

draw from tribal traditions and history to learn about nutrition, healthy food choices, media influences, and the impact of diabetes. Clubs also implement the Nike Let Me Play and SPARK physical activity programs to foster Club-wide participation in fun activities and games for 60 minutes every day. T.R.A.I.L. emphasizes the importance of teamwork and community service. Members engage in service projects to improve healthy lifestyles in their communities, including starting community gardens to connect youth to their food source and organizing community-wide physical fitness events.

This work will continue to support the IHS mission to improve the health of AI/AN youth through health promotion and health education programs. This work also represents a significant collaborative endeavor which is supportive of the IHS Director's Healthy Weight for Life Initiative and the First Lady's Let's Move Indian Country Initiative.

Since the inception of the program in 2003, T.R.A.I.L. has been implemented at 79 AI/AN Boys and Girls Club of America (BGCA) sites located in 17 states. There are currently 35 sites in 15 states participating in the program.

The overall results show improvement in participant knowledge of diabetes, health, and healthy food choices, as well as, improved fitness and level of physical activity. To support this project, NCAI will select and assist 50 Native American Boys and Girls Club sites to establish and implement this curriculum project. Boys and Girl Club sites that are located outside of Tribal communities will not be considered by the grantee. The Boys and Girls Club sites selected by the grantee may use IHS grant funds to provide services to members of Federally-recognized Tribes only. The grantee will be expected to: provide technical consultation; train; monitor; evaluate; as well as provide funds to support these activities.

II. Award Information

Type of Award: Single Source Competing Continuation Cooperative Agreement.

Estimated Funds Available: The IHS intends to commit \$1,000,000 each year.

Anticipated Number of Awards: One award will be granted from this announcement.

Project Period: The project period will be for five years and will run consecutively from September 1, 2012 to August 31, 2017. The average award amount will be \$1,000,000 annually. Competing and continuation awards

issued under this announcement are subject to the availability of funds. In the absence of funding, IHS is under no obligation to make awards under this announcement.

A. IHS Cooperative Agreement Activities

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

2. Meet with the grantee to review grantee work plan and provide guidance on implementation and data collection tools.

3. Participate in quarterly conference calls. Work with the grantee to showcase the results of this project by publishing on shared Web sites as well as in jointly authored publications.

B. Grantee Cooperative Agreement Award Activities

1. Develop a written plan for the planning, implementation, and evaluation of this project to include selection of at least 50 sites as agreed upon with the IHS. This task will be completed within 30 days from award and approved by the IHS.

2. Develop selection criteria for new sites, announce, evaluate, and select sites. Sites must submit documentation verifying they serve only AI/AN youth from Federally recognized Tribes as a requirement for selection by the grantee. A start-up planning meeting with new sites will be conducted within 2 months of each site's initial selection and award.

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

4. Update T.R.A.I.L. curriculum and implement use.

5. Develop, in consultation with the IHS, the implementation and technical assistance plan for the coordination of the 50 sites (35 existing and 15 new). Submit criteria to the IHS for approval. Grantee will continue work with sites to develop and report measurements for assessment of physical activity and nutrition behaviors among club participants.

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

7. Each site will implement a 6-minute walk test three times, six to eight weeks apart. Physical activity data will be collected and summarized.

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

9. Grantee will continue to implement current evaluation processes in consultation for the T.R.A.I.L. project. At a minimum, the evaluation will include:

(a) Training attendance (gender, age, grade level); and
(b) Pre- and post- tests to assess participant knowledge.

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

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

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

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

11. Provide technical consultation to the sites in developing a written work plan, with measurable goals, objectives, and activities.

12. Establish a formal agreement with Tribal Boys and Girls Club sites which involves minimal fiscal assistance but substantial technical support to make sure clubs successfully implement the T.R.A.I.L. program.

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

14. Provide IHS written quarterly reports on the evaluation outcomes, activity reports at each site, any parent involvement activities and other participation, description of the community partnerships, and other activities as appropriate. Quarterly reports shall coincide with dates for IHS quarterly reports to HHS and shall highlight work supporting Healthy Weight for Life and Let's Move Indian Country.

15. Conduct quarterly conference calls with IHS to review project status.

C. Continuation of Ongoing and Prior Activity as a Cooperative Agreement

All of the identified activities are continuation activities associated with the previous cooperative agreement. This collaboration for the implementation of the T.R.A.I.L. program at selected sites, along with the evaluation process and reporting are deemed very successful and supportive of ongoing Agency and Administration activities and initiatives. This agreement is proposed for the purpose of continuation of these activities.

III. Justification for Single Source Award

NCAI is identified as the single source for the award, based on their successful record of performance with this project, their unique relationship and work in developing and maintaining: (1) Relationships with the Boys and Girls Clubs organization and staff, (2) being able to successfully implement the T.R.A.I.L. program curriculum, (3) the project web site information, and (4) the project data and evaluation systems.

The award is for a continuation of activities identified. These activities, the collaboration with the network of Native American Boys and Girls Clubs, and the evaluation process have been effectively undertaken by NCAI for the past 8 years. The process, as well as, the outcomes have been deemed very successful and clearly supportive of Agency initiatives for youth (including Healthy Weight for Life), as well as the Administration's Let's Move Indian Country initiative.

The grantee has documented success in (1) Recruiting and working with sites, (2) developing and implementing the T.R.A.I.L. curriculum at the sites, (3) implementing a method for collecting data from the sites, (4) fostering collaboration between sites and their communities, and (5) collecting and reporting data that demonstrates participant increases in health and food choice knowledge and increases in participant physical activity and level of fitness. Some of the data for the current 3 year cooperative agreement (2008–2011) and 1 year extension (2012) are as follows:

Year One Data (2008–2009)

# of AI/AN Children Participating in Training	1691 (811 males/880 females).
Age Range of Children Participating	ages 4–14 (67% were 8–10 year olds).
# of Children Participating in the Walk Challenges	668 (542/81% showed improvement).
Hours of Physical Activity	19,688.

Program test scores indicate: (a) Increased knowledge about diabetes, (b) increased physical activity, and (c) increased ability to identify healthier food options (increase in post test scores vs. pre test scores).

Year Two Data (2009–2010)

# of AI/AN Children Participating in Training	1673 (767 males/906 females).
Age Range of Children Participating	ages 4–14 (72% were 8–10 year olds).
# of Children Participating in the Walk Challenges	654 (438/67% showed improvement in level of physical activity).
Hours of Physical Activity	14,527.

Program test scores indicate: (a) Increased knowledge about diabetes, (b) increased physical activity, and (c) increased ability to identify healthier food options (increase in post test scores vs. pre test scores).

Year Three Data (2010–2011)

# of AI/AN Children Participating in Training	1762 (839 males/923 females).
Age Range of Children Participating	Ages 4–14 (average age was 8.5).
# of Children Participating in the Walk Challenges	509 (360/71% showed improvement in level of physical activity).
Hours of Physical Activity	12,150.

Program test scores indicate: (a) Increased knowledge about diabetes, (b) increased physical activity, and (c) increased ability to identify healthier food options (increase in post test scores vs. pre test scores).

The T.R.A.I.L. curriculum was developed by the grantee as a part of the initial agreement. The requested update to the curriculum and subsequent implementation will be more efficiently and cost effectively performed as the grantee is very familiar with the existing curriculum and the implementation.

The grantee uses a sub-contractor (First Pic) to develop and implement the evaluation and reporting process for individual sites and for analysis and reporting of aggregated data. This unique and program specific evaluation system has been beneficial to sites and to IHS. All of the tools for using this

system have been made available via the Native American Boys and Girls Clubs Web site—www.naclubs.org/trailCurrent information about health and fitness activities is available at—http://www.naclubs.org/media/pdf/Club_Notes_2012V1.pdf.

The grantee (NCAI) has been effective, timely, and cooperative, and has

consistently achieved or exceeded requirements of the previous agreement. NCAI and First Pic are uniquely qualified to continue to receive the award and provide the identified program activities based on their history with this project and project sites, their evaluation system, their knowledge of the curriculum, and their documented performance achievements with the sites under the previous agreement.

All HHS and IHS policies, regulations, grants management and programmatic reporting requirements from the prior funding segment remain in effect under this renewal announcement unless otherwise stated or modified in the terms and conditions of the new Notice of Award.

Agency Contacts

1. Questions on the programmatic issues may be directed to: Lorraine Valdez, MPA, BSN, RN, Acting Director, IHS Division of Diabetes Treatment and Prevention, 5300 Homestead Road NE., Albuquerque, NM 87110, 505-248-4182, s.lorraine.valdez@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. Andrew Diggs, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, 301-443-2262, Andrew.diggs@ihs.gov.

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: June 27, 2012.

Yvette Roubideaux,
Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research

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 Clinical Center, the 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.

Proposed Collection

Title: The Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research.

Type of Information Collection Request: Extension; 0925-0602.

Need and Use of Information

Collection: The information collected will allow continued assessment of the value of the training provided by the Office of Clinical Research Training and Medical Education (OCRTME) at the NIH Clinical Center and the extent to which this training promotes (a) Patient safety; (b) research productivity and independence; and (c) future career development within clinical, translational, and academic research settings. The information received from respondents is presented to, evaluated by, and incorporated into the ongoing operational improvement efforts of the Director of the Office of Clinical Research Training and Education, and the Clinical Center Director. This information will enable the ongoing operational improvement efforts of the OCRTME and its commitment to providing clinical research training and medical education of the highest quality to each trainee.

Frequency of Response: Annually.

Affected Public: Former clinical research trainees at the NIH Clinical Center.

Type of Respondents: MD's, MD trainees, and students.

The annual reporting burden is as follows:

Estimated Number of Respondents: 825; **Estimated Number of Responses per Respondent:** 1; **Average Burden Hours per Response:** 0.35; and **Estimated Total Annual Burden Hours Requested:** 289.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Doctoral Level	625	1	0.35	219
Students	100	1	0.35	35
Other	100	1	0.35	35
Total				289

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact:

Contact: Robert M. Lembo, MD.

Address: 10 Center Drive/1N252C, Bethesda, MD 20892-1352.

Telephone: 301-496-2636.

Fax: 301-435-5275.

Email: robert.lembo@nih.gov.