

(Category A) device is an innovative device in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the Food and Drug Administration is unsure whether the device type can be safe and effective). A non-experimental/investigational (Category B) device is a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained Food and Drug Administration approval for that device type. The criteria the Food and Drug Administration uses to categorize an investigational device under Category B include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/currently legally marketed device.

(2) Class III devices whose technological characteristics and indication for use are comparable to a Pre-Market Approval (PMA)-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required.

(5) Pre-amendments Class III devices that become the subject of an investigational device exemption after the Food and Drug Administration requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the Food and Drug Administration required the submission of an investigational device exemption.

The following information presents the device number, category (in this case, A), and criterion code.

G960032 A1  
G960055 A  
G960069 A2  
G960125 A1

G960140 A2  
G960143 A2  
G960154 A2  
G960169 A2

The following information presents the device number category (in this case, B), and criterion code.

G940026 B  
G950128 B3  
G960005 B1  
G960022 B2  
G960050 B2  
G960059 B2  
G960077 B3  
G960080 B3  
G960092 B4  
G960114 B4  
G960116 B4  
G960117 B2  
G960120 B1  
G960121 B3  
G960122 B2  
G960123 B1  
G960126 B2  
G960127 B4  
G960128 B1  
G960129 B3  
G960130 B  
G960132 B4  
G960133 B2  
G960135 B1  
G960136 B2  
G960139 B4  
G960141 B  
G960142 B2  
G960148 B  
G960150 B2  
G960151 B4  
G960152 B4  
G960153 B2  
G960155 B1  
G960156 B  
G960157 B  
G960158 B4  
G960159 B  
G960161 B  
G960162 B  
G960165 B  
G960168 B1  
G960170 B4  
G960171 B3  
G960172 B3  
G960173 B  
G960175 B2  
G960176 B1  
G960177 B3  
G960179 B1  
G960180 B4  
G960182 B2  
G960221 B4

**Note:** Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the Food and Drug Administration will agree on the additional criteria to be used. The Food and Drug Administration will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 97-10138 Filed 4-18-97; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Indian Child Protection and Child Abuse Prevention

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice of availability of funds for Competitive Grants for Indian Child Protection and Child Abuse Prevention Demonstration Projects for Mental Health/Social Services for American Indians/Alaska Natives.

**SUMMARY:** The Indian Health Services (IHS) announces that approximately \$900,000 is available for support of competitive grants for approximately five to six projects to Tribal, Urban and non-profit Indian organizations for Demonstration Projects for Indian Child Protection and Child Abuse Prevention for Mental Health/Social Services for American Indians/Alaska Natives. This program is established under the authority of Section 301(a), of the Public Health Service Act, as amended. There will be only one funding cycle during fiscal year (FY) 1997 (see Fund Availability and Period of Support). This program is described at 93.933 in the Catalog of Federal Domestic Assistance. Executive Order 12372 requiring intergovernmental review is not applicable to this program. The Public Health Service (PHS) urges applicants submitting applications to address specific objectives of *Health People 2000*. Such interested applicants may obtain a copy of *Health People 2000* (Full Report; Stock No. 017-001-00474-0) or *Health People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

**SMOKE-FREE WORKPLACE:** The PHS strongly encourages all grant recipients to provide a smokefree workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

**DUE DATE:** An original and two (2) copies of the completed grant application must be submitted, with all required documentation, to the Grants Management Branch, Division of Acquisition and Grants Management, Twinbrook Metro Plaza-Suite 100, 12300 Twinbrook Parkway, Rockville, MD 20852, by close of business MAY 30, 1997.

Applications shall be considered as meeting the deadline if they are either:

(1) Received on or before the deadline with hand carried applications received by close of business 5 p.m.; or (2) postmarked on or before the deadline date and received in time to be reviewed along with all other timely applications. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted as proof of timely mailing. Private metered postmarks will not be accepted as proof of timely mailing. Applications received after the announced closing date will be returned to the applicant and will not be considered for funding.

#### ADDITIONAL DATES:

- A. Application Review Date: June 26–27, 1997
- B. Applicants Notified of Results (approved, approved unfunded, or disapproved): July 15, 1997
- C. Anticipated Start Date: August 1, 1997.

**CONTACTS FOR ASSISTANCE:** For program information, contact Maria E. Stetter-Burns, Training/Administrative Officer, Indian Health Service, Mental Health/Social Services Branch, 5300 Homestead, NE, Albuquerque, New Mexico 87110, (505) 248–4245.

For grant application and business management information, contact M. Kay Carpentier, Grants Management Officer, Grants Management Branch, Division of Acquisition and Grants Management, Indian Health Service, Twinbrook Metro Plaza-Suite 100, 12300 Twinbrook Parkway, Rockville, MD 20852, (301) 443–5204. (The telephone numbers are not toll-free numbers.)

**SUPPLEMENTARY INFORMATION:** This announcement provides information on the general program goal, eligibility and documentation requirements, programmatic activities, funding availability and period of support, and application procedures.

#### General Program Goal

The goal of this project is to establish programs for child protective services, child abuse and family violence treatment. The programs must include a community based and culturally appropriate prevention component which meets *Health People 2000* objectives as they affect American Indians and Alaska Natives.

#### Eligibility and Documentation Requirements

Any federally recognized Indian tribe, Indian tribal organization or non-profit organizations—501 (c)(3) serving primarily American Indians and Alaska Natives is eligible to apply for a

demonstration grant from the IHS under this announcement.

#### Documentation of Support

##### 1. Tribal Resolutions

(a) A resolution of the Indian tribe or Indian Tribal organization supporting this specific project must accompany the application submission.

(b) Applications which propose services which will benefit more than one Indian tribe must include resolutions from all affected tribes to be served.

(c) Applications by tribal organizations will not require resolution(s) if the current tribal resolution(s) under which they operate would encompass the proposed grant activities. A statement of proof or a copy of the current operational resolution must accompany the application.

(d) If a resolution or a statement is not submitted, the application will be considered incomplete and will be returned without consideration.

2. Non-Profit Organizations—Copy of the 501(c)(3) non-profit certificate.

3. Letters of Cooperation/Collaboration/Assistance.

(a) Letters included in the application should be specific to this program.

(b) If other related human services programs are to be involved in the project, letters confirming the nature and extent of their cooperation/collaboration/assistance must be submitted.

#### Programmatic Activities

A grant awarded under this announcement shall support a program to establish innovative demonstration programs for child protective services, child abuse and family violence treatment programs. Treatment programs should include a prevention component, be community based and culturally appropriate to meet *Healthy People 2000* objectives as they affect American Indians and Alaska Natives. Efforts may include, but are not limited to: (1) Establishing child protective service programs; (2) establishing outpatient child abuse and family violence treatment programs; and (3) supporting other innovative and culturally relevant treatment activities, programs, and projects.

#### Fund Availability and Period of Support

In FY 1997, it is anticipated that approximately \$900,000 will be available to support five or six grants. Projects will average \$150,000 each inclusive of direct and indirect costs. Projects may be funded annually for up

to five years depending upon the defined scope of work. Continuation projects will be based upon the availability of appropriations in future years, the continuing need of IHS for the projects, and satisfactory project performance. The anticipated start date will be August 1, 1997.

#### The Indian Child Protection and Child Abuse Prevention Grant Application Kit

An IHS Grant Application Kit, including form PHS 5161–1 (rev. 7/92), may be obtained from the Grants Management Branch, Division of Acquisition and Grants Management, Twinbrook Metro Plaza—Suite 100, 12300 Twinbrook Parkway, Rockville, MD 20852, telephone (301) 443–5204.

#### Factors for Consideration in Preparing the Application

1. Following the outline provided in the announcement will guide the writing of the application and facilitate the reviewers in locating required information.

2. Projects should demonstrate coordination with other agencies and organizations within and without the community who serve the targeted population.

3. Indian cultural aspects should be considered in program design.

#### Grant Application Requirements

All applications must be single-spaced, typewritten, and consecutively numbered pages using black type not smaller than 12 characters per one inch, with conventional one inch border margins, on only one side of standard size 8½ × 11 paper that can be photocopied. The application Narrative (not including the Appendix) must not exceed 10 typed pages. An additional page may be used for each additional year of funding requested. Exclusions from the 10 page limit are the Abstract, Tribal Resolution(s), 501(c)(3) Non-Profit Certification, Documentation or Letters of Support, Standard Forms, Table of Contents, and the Appendix. All applications must include the following in the order presented:

- Tribal Resolution(s), Non-Profit 501(c)(3) Certification and Documentation or Letters of Support.
- Standard Form 424, Application for Federal Assistance.
- Standard Form 424A, Budget Information—Non-Construction Programs (pages 1 and 2).
- Standard Form 424B, Assurances—Non-Construction Programs (front and back).
- Checklist (pages 23–24) NOTE: Each standard form and the checklist is

contained in the PHS Grant Application, Form PHS 5161-1 (OMB #0937-0189; expires 07/31/98).

- A Project Abstract (may not exceed 1 typewritten page) should present a summary view of "who-what-when-where-how-cost" to determine acceptability for review.

- A table of contents to correspond with numbered pages.

- Project Narrative (10 pages).

1. Introduction and Need for Assistance.

2. Project Objective(s), Approach, and Results & Benefits.

3. Project Evaluation.

4. Organizational Capabilities and Qualifications.

5. Budget.

- Appendix to include:

- Resumes of key staff.

- Position Descriptions for key staff.

- Organizational Chart.

- Documentation of current certified financial management systems.

- Copy of current negotiated indirect cost rate agreement.

- A map of the area to benefit from the project, and

- Application Receipt Card, PHS-3038-1 Rev. 5-90.

#### A. Narrative

The narrative section of the application must include the following:

- (1) Justification for need for assistance;
- (2) work plan (including use of appropriate Native healing practices), program objectives, approach, expected results and evaluation process,
- (3) adequacy of management controls, and
- (4) key personnel. The work plan section should be project specific.

These instructions for the preparation of the narrative are to be used in lieu of the instructions on page 19-20 of the PHS 5161-1. 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. The narrative may not exceed TEN single spaced pages in length, excluding attachments, budget, and tribal resolutions/501(c)(3) non-profit certificate/documentation or letters of support (pages must be numbered).

#### 1. Need for Assistance

(a) Describe and define the target population at the project location (e.g. tribal population, number of cases of child abuse reported, number of child abuse cases prosecuted, number of children/families currently in treatment, number of children/families at-risk).

Information sources must be appropriately identified.

(b) Describe the existing resources and services available, including the maintenance of Native healing systems, where appropriate, which are related to the specific program/service the applicant is proposing to provide.

(c) Describe in detail the needs of the target population and what efforts have been made in the past to meet these needs, if any (e.g. number of treatment providers, collaborative efforts with state/county treatment programs, availability of program funding from federal/non-federal sources).

(d) Summarize the applicable federal/national standards, State or tribal laws and regulations, and describe the unmet needs of any applicant's current program in relation to applicable federal/national standards, State or tribal laws and regulations (e.g. Tribal children's codes, state/tribal/federal child abuse reporting, protection of individuals who report suspected child abuse).

#### 2. Work Plan

##### (a) Program Objectives

1. State concisely the objectives of the project.

2. Describe briefly what the project intends to accomplish.

3. Describe how accomplishment of the objectives will be measured (including if replicable).

##### (b) Approach

1. Describe the tasks and resources needed to implement and complete this project.

2. Provide a task time line (milestones) breakdown or chart. Indicate the date that the project will begin to accept clients.

##### (c) Describe the Expected Results

1. Discuss data collection for the project, how it will be obtained, analyzed, and maintained by the project. Data should include, but is not limited to, the number and types of clients served, services provided, client outcomes and satisfaction, and costs associated with the program.

2. Describe how the data collection will support the stated program objectives, and how it will support the program evaluation to determine the impact of the project.

##### (d) Program Evaluation

1. Describe methods for evaluating program activities, effectiveness of interventions, success in achieving objectives, the impact of interventions, acceptance among the targeted

population, and workload accomplishments.

2. Identify who will conduct the evaluation of the projected outcomes and when the evaluation is to be completed.

3. Identify the cost of the evaluation (whether internal or external).

##### (e) Program Continuance

Discuss how the program services will be continued after the grant expires.

##### (f) Experience Sharing

Indicate the project's willingness to share its program experience with IHS Areas, urban programs, tribes and other tribal organizations.

#### 3. Adequacy of Management Controls

(a) Describe where the project will be housed, i.e. facilities and equipment available.

(b) Describe the management controls of the grantee over the directions and acceptability of work to be performed. Discuss personnel and financial systems in use and changes planned for this grant.

(c) Applicant must demonstrate that the organization has adequate systems and expertise to manage Federal funds. Also, include a letter from the accounting firm describing results of the most recent organization-wide audit.

#### 4. Key Personnel

(a) Provide a biographical sketch (qualifications) and position descriptions for the program director and other key personnel as described on page 20-21 of the PHS 5161-1. Identify existing personnel and new program staff to be hired.

(b) Provide an organizational chart and indicate how the project will operate within the organization. Describe how this program will interface with other existing available resources.

(c) List the qualifications and experience of consultants or contractors where their use is anticipated. Identify who will determine if the work of a contractor is acceptable.

#### B. Budget

1. An itemized estimate of costs and justification for the proposed program by line item must be provided on form SF 424A Budget Information Non-Construction Programs.

2. A narrative justification must be submitted for all costs. Indicate needs by listing individual items and quantities necessary. The need for items and quantities should be clearly specified in the narrative justification.

3. Any special start up costs should be indicated.

4. Multi-Year Projects—Projects requiring 2, 3, 4 or 5 years funding must include a brief program narrative and budget for each additional year of funding requested. The applicant may use one additional page to describe the developmental plans for each additional year of the project.

5. Grant funding may not be used to supplant existing public and private resources.

#### C. Assurances

The application shall contain assurance to the Secretary that the applicant will comply with program regulations, 42 CFR part 36, Subpart H.

#### Review Process

Applications meeting eligibility requirements, are complete, responsive, and conform to this program announcement will be reviewed for merit by reviewers appointed by the IHS. The review will be conducted in accordance with PHS review procedures. The review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated and rated on the basis of the evaluation criteria listed below. These criteria are used to evaluate the quality of a proposed project, to assign a numerical score to each application, and to determine the likelihood of its success. Applications scoring below 60 points will not be funded.

#### Evaluation Criteria

Applications will be evaluated against the following criteria and weights:

Weight (per-cent)	Criteria	Description
25 .....	1	Need—The demonstration of identified problems and risks in the target population. Extent of community involvement and commitment.
40 .....	2	Work Plan—The soundness and effectiveness of the applicant's plan for conducting the project, with special emphasis on the objectives and methodology portion of the application.

Weight (per-cent)	Criteria	Description
15 .....	3	Adequacy of Management Controls—The apparent capability of the applicant to successfully conduct the project including both technical and business aspects. The soundness of the applicant's budget in relation to the project work plan and for assuring effective utilization of grant funds. Adequacy of facilities and equipment available within the organization or proposed for purchase under the project.
10 .....	4	Key Personnel—Qualifications and adequacy of the staff.
10 .....	5	Budget—Clarity and accuracy of program costs, and cost justification for the entire grant period.
100 .....	.....	Total Weight.

#### Reporting Requirements

##### A. Progress Report

Program progress reports will be required semiannually. These reports will include a brief description of a comparison of actual accomplishments to the goals established for the period, reasons for slippage and other pertinent information as required. A final report is due 90 days after expiration of the project/budget period.

##### B. Financial Status Report

A semiannual financial status report will be submitted 30 days after the end of the half-year. Final financial status reports are due 90 days after the expiration of the project/budget period. Standard Form 269 (long form) will be used for financial reporting.

#### Grant Administration Requirements

Grants are administered in accordance with the following documents:

A. 45 CFR part 92. Department of Health and Human Services, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, or 45 CFR part 74, Administration of Grants to Non-profit recipients.

B. Public Health Service Grants Policy Statement, and

C. Appropriate Cost Principles: OMB Circular A-87, State and Local Governments, or OMB Circular A-122, Nonprofit Organizations.

#### Results of the Review

Successful applicants are notified through the official Notice of Grant Award (NGA) document. The NGA will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period, and the budget period.

Dated: April 14, 1997.

**Michael H. Trujillo,**

*Assistant Surgeon General, Director.*

[FR Doc. 97-10136 Filed 4-18-97; 8:45 am]

BILLING CODE 4160-16-M

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Office of Inspector General

##### Program Exclusions: March 1997

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of March 1997, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
<b>Program-Related Convictions</b>	
Active Living Center, Inc., Chapel Hill, NC .....	04/15/97