dose evaluation, safety, and tolerance studies that ordinarily initiate a clinical drug development program. Thus, FDA believes that, typically, the duration of dosing would be limited (e.g., 7 days). The agency is, however, interested in soliciting comment from the public on the appropriate duration of dosing for such exploratory studies.

The amount and type of preclinical information necessary to support an exploratory study will depend on the planned nature and extent of human exposure relative to the toxicity (or lack thereof) at the planned dose. Thus, this guidance emphasizes the concept that limited investigations in humans can be initiated with more limited preclinical support because such studies present fewer potential risks than do traditional phase 1 studies that look for dose-limiting toxicities. The studies discussed here ordinarily do not have therapeutic intent. They are designed to evaluate whether a particular candidate should be entered into a drug development program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on exploratory IND studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance has been approved under OMB control number 0910–0014 and expires on January 31, 2006.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7485 Filed 4–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Injury Prevention Program Announcement Type: New

Funding Opportunity Number: HHS–2005–IHS–IPP–0001.

CFDA Number: 93.284.

Key Dates:

Application Deadline: May 20, 2005.

Application Review: June 27–28, 2005.

Anticipated Award Start Date: September 1, 2005.

Application Notification: September 30, 2005.

I. Funding Opportunity Description

Legislative Authority

The Indian Health Service (IHS) announces competitive cooperative agreement applications for Injury Prevention Program for American Indians and Alaska Natives (AI/AN):

(A) Part I Basic Five-year projects (minimum population required 2,500)

(B) Part I Advanced Five-year projects (minimum population required 2,500)

Part I Advanced applicants include Tribes and organizations who are current recipients of the 2000–2005 IHS Injury Prevention Cooperative Agreements (applies only to 2000–2005 Tribal Injury Prevention Cooperative Agreement recipients).

(C) Part II Intervention Three-year projects (no population requirement)

These cooperative agreements are established under the authority of section 301(a), Public Health Service Act, as amended. This program is described at 93.284 in the Catalog of Federal Domestic Assistance, the Indian Health Care Improvement Act, U.S.C. 1602 (b)(17); and Urbans (25 U.S.C. 1652).

II. Award Information

Type of Instrument: Cooperative Agreement (CA)

A cooperative agreement will have substantial oversight to ensure best practices and high quality performance in sustaining capacity of the Injury Prevention projects. The estimated amount of funds available is $1.475 million for Fiscal Year 2005 to fund up to approximately 33 awards.

Types of Cooperative Agreement (CA) covered under this announcement:

Part I—Basic: Approximately 47% of funds are available to fund up to 14 new awards for the Basic Injury Prevention Program. Individual awards will range from $25,000 up to $50,000.

Part I—Advanced: Approximately 46% of funds are available to fund up to 9 Injury Prevention Program considered ''experienced'' in Injury Prevention. Part I Advanced applicants are Tribes and organizations who are current recipients of the 2000–2005 IHS Injury Prevention Cooperative Agreements (applies only to 2000–2005 Tribal Injury Prevention Cooperative Agreement recipients). Individual awards will range from $25,000 up to $75,000.

Part II—Intervention: Approximately 7% of funds are available to fund up to 10 awards to implement proven or promising injury intervention projects that are based on addressing local injury problems. Individual awards will be $10,000. Injury Prevention applicants may apply for new funding under Part I Basic or Part I Advanced or Part II—Intervention, but only one award will be funded to each applicant. A separate application is required for each type of project.

Project Period: The Cooperative Agreement (CA) will be a 12-month budget period within a project year:

- Part I—Basic—5 years beginning on or about Sept 1, 2005.
- Part I—Advanced—5 years beginning on or about Sept 1, 2005.
- Part II—Intervention—3 years beginning on or about Sept 1, 2005.

Future continuation awards within the project period will be based on satisfactory performance, availability of funding, and continuing needs of the Indian Health Service.

Estimated Range of Awards: $10,000 to $75,000.

Substantial Involvement Description for Cooperative Agreement Activities for Part I

The cooperative agreement Part I awardee (Tribe or Tribal/urban/non-profit Indian organization) will be responsible for activities listed under A. IHS will be responsible for activities listed under B. A contractor will be hired to assist in the oversight in the Part I CA projects. Oversight includes assurances to promote best practices and high quality performance in

sustaining the Injury Prevention programs. The contractor will be responsible in reporting to the IHS Injury Prevention Manager on the progress and issues of the cooperative agreement awardee.

A. Cooperative Agreement Awardee Activities for Part I Projects

(1) When possible, to locate the Injury Prevention Program in the recipient's urban organization, Tribal health department or community-based program to enhance opportunities for the injury prevention program to collaborate with other Tribal public health or community programs.

(2) Provide a full-time Injury Prevention coordinator who has the authority, responsibility, and expertise to conduct and manage the Tribal-level, multi-Tribal, urban, or non-profit injury prevention program. Coordinator must be solely dedicated to injury prevention. Positions can not be part-time or split duties.

(3) Review secondary injury and health data (*i.e.,* Trends in Indian Health 2000–2001, etc.) to assist to define the magnitude of the injury problem within the target American Indian/Alaska Native population, including those at greatest risk and the specific causes of injury.

(4) Develop an action plan based on data and prioritized for the prevention and control of injuries. This would include specific process and impact objectives and action steps to accomplish each.

(5) Implement community-based projects to reduce injuries and gain visibility and acceptance in the communities for the injury control program.

(6) Evaluate the effect of these projects.

(7) The program coordinator or director will budget for and attend a start-up orientation meeting with other new Injury Prevention program coordinators, IHS Injury Prevention Program staff, and IHS consultants. An annual regional project coordinator/IHS project officer meeting will be held for each subsequent year of the project cycle, and should be budgeted.

(8) The injury prevention program coordinator director will collaborate with the IHS Injury Prevention Specialists (Area and/or District).

B. Indian Health Service's Cooperative Agreement Activities for Part I Projects

(1) An identified IHS Injury Prevention Specialist (Area or District) will serve as project officer for the injury prevention project and will be responsible at the local level in providing technical assistance and consultation to the recipient on program planning, injury data collection (*i.e.,* safety belt use surveys, etc.) and analysis to assist in evaluation of program interventions. Technical assistance also includes assistance in program implementation, marketing, reporting, and evaluation.

(2) IHS contractor will be responsible for technical assistance oversight, monitoring reporting of projects, conference calls, a newsletter, and site visits. The IHS contractor serves as a liaison to the IHS Injury Prevention Manager and the Injury Prevention Cooperative Agreement Awardee.

(3) IHS and the Contractor will coordinate an annual training workshop for the Injury Prevention project coordinators and their IHS project officers to share lessons learned, successes, and new state-of-the-art strategies to reducing injuries in Indian communities.

Substantial Involvement for Activities for Cooperative Agreement for Part II

Part II Intervention—The Part II Intervention projects funds are to develop, implement, and evaluate proven or promising injury prevention intervention programs. These types of interventions are those that have been tested and accepted widely to prevent injury morbidity and mortality. Projects include, but are not limited to, programs designed to reduce alcohol-related injuries, *i.e.,* supporting initiatives to reduce drinking and driving, etc. Other projects include seat belt promotion campaigns, pedestrian safety, child passenger safety, smoke alarm distribution programs, domestic violence programs, suicide prevention, youth violence prevention, elder fall prevention, home safety, drowning prevention and Emergency Medical Services for Children (EMSC) projects. Police salaries, police weapon supplies, uniforms, safety-bulletproofed vests are unallowable costs for this funding. Purchases must be aligned with the completion of the goals and objectives of the project (Equipment to support DWI initiatives are acceptable purchase, *i.e.,* breath analyzer testing equipment, etc.). Purchases will be scrutinized on how they relate to project's objectives.

Part II Intervention—Cooperative Agreement Activities—In conducting activities to achieve the purpose of this program under Part II, the recipient will be responsible for the activities listed under A, and the IHS will be responsible for activities listed under B.

A. Part II Intervention—Cooperative Agreement Awardee Activities

Provide the Injury Prevention awardee with the authority, responsibility, and expertise to conduct and manage the injury intervention project. The Injury Prevention Intervention awardee must collaborate with the Tribe(s), IHS Area and/or District Injury Prevention Specialists in planning and designing the intervention project. Develop a plan based on local data and utilizes proven or promising intervention strategies to reduce injuries. Implement and evaluate the injury prevention intervention project that promotes visibility and acceptance by the community.

B. Indian Health Service's Cooperative Agreement Activities for Part II Intervention Projects

IHS Area or District Injury Prevention Specialists will provide technical assistance and consultation to the recipient on program planning, data collection (*i.e.,* safety belt surveys, child safety seat surveys, etc.) and analysis to effectively evaluate interventions initiatives. Technical assistance also includes program implementation and reports. This goal is to promote high quality performance and success in completing the project. Contact will be through conference calls and site visits.

III. Eligibility Information

1. Eligible Applicants

The AI/AN applicant must be one of the following:

A. A federally recognized Indian Tribe; or
B. A Tribally sanctioned non-profit Tribal organization; or
C. A non-profit national or area Indian health board; or
D. Consortium of two or more of those Tribes, Tribal organizations, or health boards
E. Urban Indian Organizations (Urbans—25 U.S.C. 1652)
F. Non-profit Tribal organizations on or near a Federally-recognized Indian Tribe community

Part I Basic and Part I Advanced Injury Prevention Cooperative Agreement applicants must serve a minimum population size of 2,500 American Indian/Alaska Native people. IHS user population data is the only acceptable population source for this cooperative agreement application. There is no requirement for minimum population size for Part II—Intervention applicants.

2. Cost Sharing or Matching

Not applicable.

IV. Application and Submission Information

1. Address to Request Application Package

Division of Grants Operation, Indian Health Service, 801 Thompson Ave, Suite 100, Rockville, Maryland 20852. (301) 443–5204.

The entire application kit is available at: *www.ihs.gov/MedicalPrograms/InjuryPrevention/index.cfm.*

2. Content and Form for paper Application Submission

- An original and two copies of the completed application
- Be doubled-spaced
- Be typewritten
- Have consecutively numbered pages
- Use black type not smaller than 12 characters per one inch
- Have one-inch border margins
- Printed on one side only of standard size 8½″ × 11″ paper that can be photocopied
- Not be tabbed, glued, or placed in a plastic holder

The application narrative (not including the abstract, workplan, Tribal resolutions, letters of support, standard forms, table of contents, budget, budget justification, multi-year budget, multi-year budget justification, appendix items) must not exceed 15 typed pages.

A. Abstract
B. Background, Need for Assistance, Capacity Building
C. Goals & Objectives
D. Methods and Staffing
E. Evaluation
F. Collaboration
G. Budget and Accompanying Justification
H. Appendix

For paper application submission, the following documents in the order presented.

Application Receipt Record, Checklist, General Information Page, Standard Forms Certifications, and Disclosure of Lobbying Activities documents will be available in the appendix of application kit.

- Application Receipt Record, IHS–815 A (Rev.2/04)
- Narrative
- Tribal Resolution (final signed or draft unsigned)
- Standard Form 424, Application for Federal Assistance
- Standard Form 424A, Budget Information-Non-Construction Programs (pages 1–2)
- Standard Form 424B, Assurances—Non-Construction Programs (front and back). The application shall contain assurances to the Secretary that the applicant will comply with program regulations, 42 CFR Part 136 Subpart H.
- Certifications (pages 25–26)
- PHS 5161 checklist (pages 25–26)
- Disclosure of Lobbying Activities
- Table of Contents with corresponding numbered pages
- Categorical Budget and Budget Justification
- Multi-year Objectives and work plans with multi-year Categorical Budgets and Multi-year Budget justifications. (Not part of the 15 page narrative)
- Appendix items

3. Submission Dates and Times

Applications are due by close of business May 20, 2005, 5 PM Eastern Time. 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 postmarked on or before the deadline date at: Indian Health Service, Division of Grants Operation, Attention Lois Hodge, 801 Thompson Avenue, Suite 120, Rockville, MD 20852. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Applicants are cautioned that express/overnight mail services do not always deliver as agreed. IHS cannot accommodate transmission of applications by fax or e-mail.

Applications which do not meet the criteria above will be considered late. Late applications will be returned to the applicant and will not be considered for funding. Extension of deadlines: IHS may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. Determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

Acknowledgment of Receipt: Acknowledgment of receipt of applications will be via the Application Receipt Card, IHS 815–1A (Rev, 2/04).

Electronic Transmission—You may submit your application to us in either electronic or paper format. To submit an application electronically, please use the *http://www.Grants.gov* apply site. If you use Grants.gov, you will be able to download a copy of the application package, complete it offline and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to us.

Please note the following if you plan to submit your application electronically via Grants.gov:

- Electronic submission is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the deadline date to begin the application process through Grants.gov.
- To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete CCR registration. See Section 6 on how to apply.
- You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.
- You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in the program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The Indian Health Service will retrieve your application from Grants.gov.
- You may access the electronic application for this program on *http://www.Grants.gov.*
- You must search for the downloadable application package by CFDA number. Email applications will not be accepted under this announcement.

4. Intergovernmental Review—Executive Order 12372 Requiring Intergovernmental Review is not Applicable to This Program

5. Funding Restrictions

- Maximum Award is $50,000 for Part I Basic per year (5 years)
- Maximum Award is $75,000 for Part I Advanced per year (5 years)
- Maximum Award is $10,000 for Part II Intervention per year (3 years)

Ineligible Project Activities

- Federal Housing Projects that are requesting funds for repairs or construction (Repairs or construction items are the responsibility of the local housing authority)
- Bureau of Indian Affairs' school playground equipment
- Bureau of Indian Affairs' Law Enforcement supplies involving

purchase of uniforms, weapons or construction and repairs of detention centers

- Projects related to water, sanitation and waste management
- Projects that include design and planning of construction of facilities

Other Limitations

An applicant may not be awarded a Part I Basic or Part I Advanced CA for any of the following reasons:

1. Current awardee is not progressing in a satisfactory manner; or

2. Did not comply with program progress and financial reporting requirements.

Delinquent Federal Debts. No Award shall be made to an applicant who has an outstanding delinquent Federal debt until either:

1. The delinquent account is paid in full, or

2. A negotiated repayment schedule is established and at least one payment is received.

A Tribe, Tribal organization, urban Indian, or nonprofit organization is eligible to apply for one or both of those types of awards, but only one Cooperative Agreement will be funded. If an applicant chooses to submit dual proposals, the cover letter should rank the proposals in the order that the applicant would like them to be funded. For example, if an applicant submits a Part I Basic and Part II Intervention (and all scored well during the review process), IHS will need to know how to determine which application to fund.

Pre-award costs are not allowable charges under this program grant.

6. Other Submission Requirements

Beginning October 1, 2003, applicants are required to have a DUN and Bradstreet (DUNS) number to apply for a cooperative agreement from the Federal Government. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal *(www.grants.gov).* A DUNS number will be required for every application for a new or renewal/continuation of an award submitted on or after October 1, 2003. Please ensure that your organization has a DUNS number. The DUNS number is a nine-digit identification number which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge.

To obtain a DUNS number, access www.dunandbradstreet.com at *http://www.dunandbradstreet.com* or call 1–866–705–5711. Internet application for a DUNS number can take up to 30 days to process. Interested parties may wish to obtain one by phone to expedite the process. The following information is needed when requesting a DUNS number:

- Organization name
- Organization address
- Organization telephone number
- Name of CEO, Executive, President, etc.
- Legal structure of the organization
- Year organization started
- Primary business (activity) line
- Total number of employees

Electronic Submission: The IHS will accept complete applications in electronic format submitted through the *www.grants.gov* Web site only.

An interim electronic website is available for those who want to submit electronically at *www.grants.gov*. E-mail applications will not be accepted under announcement. Evidence of Tribal/Urban/Tribal organizations and Non-profit organizations must submit:

1. Copies of their 501(C) (3) Certificate (required).

2. A signed and dated resolution from the Tribal/Urban/Tribal organization's governing Board of Directors of the non-profit organization (required).

3. Letters of support from the AI/AN community served (required).

4. Letter of support from IHS Area and/or District Injury Prevention Specialist (required).

5. Letters of support from the Tribal chairperson/president, the Tribal council, or the Tribal health director in support of the application (required).

Evidence of Proof of non-profit status of Tribal organization on or near a Federally recognized Tribe:

(a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of the tax-exempt organization described in the IRS Code.

(b) A copy of a currently valid IRS tax exemption certificate.

(c) A statement from a State or Tribal taxing body, State attorney general, or other appropriate State or Tribal Official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.

(d) A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

(e) Any of the items in the subparagraphs immediately above for a State, Tribe or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Evidence of (Urban) Support

A signed and dated resolution from the governing Board of Directors for the Injury Prevention program and a letter from the Chairman of the Board (Required).

1. A letter of commitment showing in-kind (dollar) participation, if applicable.

2. If applicant is unable to obtain a signed letter in time to meet the deadline, they should submit a draft of the letter in the appendix. A final signed letter from the board will be required prior to award if applicant is selected for a cooperative agreement.

3. Letters of support from within the community served.

Evidence of (Tribal) Support:

Examples of Tribal support include but are not limited to resolutions. Signed and dated resolution(s) for the Tribal Injury Prevention Program from the Indian Tribe or Tribes served by the project (Required). If applicant is unable to obtain a signed resolution in time to meet the deadline, they should submit a final draft of the resolution and state the date the proposed final resolution will be obtained. A signed resolution from the Tribe will be required prior to award if the Tribe is selected for a cooperative agreement. For the Navajo Nation, a signed Tribal resolution (by the Tribal council) is required unless a local governing body, such as incorporated 501(1) (3) Chapter House or township will be acceptable for the intent to participate. A final signed resolution from the Navajo Nation council or official governing body of the 501(1) (3) Chapter House or township will be required prior to award if selected for a Cooperative Agreement. Applications that propose projects affecting more than one Indian Tribe: Applications involving more than one Tribe must include a resolution from all affected Tribes to be served. A statement of proof or a copy of the current operational resolution must accompany the application. If a resolution or a statement is not submitted, the application will be considered incomplete and will be returned without consideration. Other supporting documents:

- A description of Tribal in-kind contributions for the injury prevention program (office space, administrative support, telephone service, employee fringe benefits, etc., or any other contribution to the proposed program).
- Letters of Support/Collaboration from potential project collaborators or partners. Support from potential partners such as the police department, Tribal health department, health boards,

Tribal council, local schools, community groups, the Indian Health Service, State agencies, and others are important for a program to be successful.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application (Part I Basic, Part I Advanced, Part II Intervention). Total weights are assigned to each major section noted in parentheses. Weights are further identified per item under each specific criteria. Total possible points per application is 100.

1. Criteria

Application narrative instructions, and application standards (evaluation criteria) and weights in parentheses.

Multi-Year Program Requirement—Part I Basic is a five-year project. Applicants must include a detailed program narrative, itemized categorical budget, and a detailed budget justification for the first year activities. An outline of program objectives, time line, and a budget summary should be included for each subsequent year (Year 2–Year 5).

Part I Basic: Part I Basic awards are for new applicants seeking to build their local capacity to establish an injury prevention program.

Abstract—A one page summary of the five-year proposed program request. Include information on applicant, purpose of request, problem or need to be met, objectives to be achieved through the funding, proposed activities and total amount of request of program.

Program Narrative—Introduction, Need and Capacity (Total 30 Points)

1. A statement of the injury problem. Describe the extent of the injury problem in the community or target area. (3)

2. A description of the geographic location of the proposed program. (2)

3. A description of organizational structure (chart) and staff (resumes and position descriptions) who will be managing of the injury prevention program. (10)

4. A description of the Tribe's or Tribal organization's support for the proposed injury prevention program. (5)

5. A description of the population to be served by the proposed program. Provide documentation that the target population is at least 2,500 people. (IHS User population is the ONLY acceptable source). (5)

6. A description of how the proposed program will build capacity to plan, develop, implement and evaluate an injury prevention program. (5)

Program Goals and Objectives (Total 10 Points)

1. Goals and objectives that are clear and concise.(4)

2. Feasible and attainable to accomplish during the 5 year project period (3)

3. Are specific, time-framed, measurable and realistic. (3)

Methods and Staffing (Total 30 Points)

The application will be evaluated on the extent to which the applicant provides:

1. A detailed description of proposed activities that are likely to achieve each objective and overall program goals, and which includes designation of responsibility for each action undertaken. (10)

2. A reasonable and complete time line for implementing all objectives and activities with the responsible person listed for each task. (2)

3. A description of the roles of the Tribal involvement, organization, or agency and evidence of coordination, supervision, and degree of commitment (*e.g.,* time in-kind, financial) of staff, organizations, and agencies involved in activities. (4)

4. The extent to which proposed interventions are either proven or promising to be effective and based on a documented need in the target communities. (2)

5. Resumes of existing staff, detailed position descriptions and duties included for projected staff. (2)

6. Job description of proposed Injury Prevention Coordinator. Job description to include work experience in injury prevention, or training in injury prevention and working with partners or coalitions in the local community. (10)

Evaluation (Total 10 Points)

1. Describe type of evaluation methods that will be utilized to evaluate the goals and objectives. This includes but is not limited to how the progress of the proposed program objective(s) will be tracked (*i.e.,* reports, training, car seat distributions, seat belt surveys, etc.). (4)

2. Describe how program will be evaluated to show process, effectiveness, and impact. This includes but is not limited to what data will be collected to evaluate the success of the proposed project objectives. (4)

3. Document staff availability, expertise, experience, and capacity to perform the evaluation. (2)

Collaboration (Total 10 Points)

Describe the extent to which relationships between the program, the Tribe or urban community, the Indian Health Service and other organizations will relate to the program or conduct related activities. This includes the scope to which an advisory committee or partners' roles are clear and appropriate.

Categorical Budget and Budget Justification (Total 10 Points)

Provide a detailed and justification of budget for the first 12-month budget periods. A budget summary should be included for each subsequent year (Year 2—Year 5).

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

2. Provide a narrative justification explaining why each line item is necessary/relevant to the proposed project. Include sufficient cost and other details to facilitate the determination of cost allowability (*i.e.,* equipment specifications, etc.). (6)

3. Include travel expenses for annual workshop (required participation) at a major city location to be determined by IHS (Washington DC, Albuquerque, Denver, etc.). Include airfare, per diem, mileage, etc. (2)

Appendix Items

- Work plan for proposed 5-year objectives and activities in a time line format with persons responsible
- Position descriptions for key staff
- Resumes of IP Coordinator and key staff
- Current Indirect Cost Agreement
- Organizational chart
- Resolutions
- Letters of support
- Injury Prevention training certificate verification (see page 33)
- Documentation specifically related to injury prevention
- Application Receipt Card, IHS 815–1A (Rev. 2/04)

Part I Advanced: Part I Advanced applicants are Tribes and organizations who are current recipients of the 2000–2005 IHS Injury Prevention Cooperative Agreements (applies only to 2000–2005 Tribal Injury Prevention Cooperative Agreement recipients).

Abstract—A one page summary of the five-year proposed project request. Include information on applicant, purpose of request, problem or need to be met, objectives to be achieved through the funding, proposed activities and total amount of request of project.

Program Narrative—Introduction, Need and Capacity (Total 40 Points)

1. Describe the need for the existing injury prevention program in the community. (2)

2. Describe your accomplishments as a recipient of the 2000–2005 Indian Health Service Injury Prevention Cooperative Agreement. Accomplishments must show documentation of meeting program goals and objectives, compliance in reporting (quarterly progress and financial reporting), coalition building, training, Injury Prevention coordinator (FTE) continuity, sustaining Tribal capacity building and securing Tribal support. (20)

3. Describe and show documentation of successes at reducing injury risk factors (such as increase child passenger safety restraints or seat belt use; smoke alarm installation, safe home interventions, etc.) or any positive changes in the target population. Provide supporting data to demonstrate process, impact or outcome. (5)

4. Describe the applicant's partnership with Tribal, IHS, community groups, law enforcement, and others in implementing injury prevention policy or programs to reduce injuries. (3)

5. Describe how the proposed program will build the local capacity to provide, improve, and expand services that address the injury problem of the target population. This includes but not limited to sustaining capacity in strategic planning, developing, implementing and evaluating an injury prevention program. (8)

6. Describe and provide documentation of the target population (2,500 people to be served by the proposed program and geographic location of the proposed program. (IHS User population is the ONLY acceptable source). (2)

Program Goals and Objectives (Total 10 Points)

1. Goals and objectives that are relevant to the purpose of the proposal. (4)

2. Feasible to accomplish during the 5 year project period. (3)

3. Are specific, time-framed, measurable and realistic. (3)

Methods and Staffing (Total 20 Points)

The application will be evaluated on the extent to which the applicant provides:

1. A detailed description of proposed activities that are likely to achieve each objective and overall program goals, and which includes designation of responsibility for each action undertaken. (7)

2. A reasonable and complete time line for implementing all objectives and activities with the person(s) responsible listed for each activity. (2)

3. A description of the roles of Tribal involvement, organization, or agency and evidence of coordination, supervision, and degree of commitment (*e.g.*, time, in-kind, financial) of staff, organizations, and agencies involved in activities. (2)

4. Description of how proposed interventions are either proven or promising to be effective and based on a documented need in the target communities. (2)

5. The extent to which resumes are included for existing staff, and detailed position descriptions and duties are included for projected staff. (2)

6. Description of the proposed staff's work or training experiences in injury prevention. (5)

Evaluation (Total 10 Points)

Describe how it will be determined if the proposed project's objectives were achieved and how proposed evaluation measures will measure success in implementing injury prevention programs.

1. Describe type of evaluation methods that will be utilized to evaluate the goals and objectives. This includes but is not limited to how the program's progress will be tracked (*i.e.,* reports, training, number of car seat distributions, conducting seat belt surveys, etc.). (2)

2. Describe how the program will be evaluated to show program process, effectiveness, and impact. This includes but is not limited to what data will be collected to evaluate the success of the proposed program objectives. (2)

3. Describe the potential data sources for evaluation purposes and methods to evaluate the data sources. (2)

4. Documents staff availability, expertise, experience, and capacity to perform the evaluation. (2)

5. Includes a feasible plan for reporting evaluation results and using evaluation information for programmatic decisions. (2)

Collaboration (Total 10 Points)

Describe the extent to which relationships between the programs, the Tribe or urban community, the Indian Health Service and other organizations will relate to the program or conduct related activities. This includes the scope to which an advisory committee or partners' roles are clear and appropriate. Letters of support should be provided in the Appendix.

Categorical Budget and Budget Justification (Total 10 Points)

Provide a categorical budget for each of the 12-month budget periods requested. A budget summary should be included for each subsequent year (Year 2–Year 5).

1. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the current rate agreement in the appendix. (3)

2. Provide a narrative justification explaining why each line item is necessary/relevant to the proposed project. Include sufficient cost and other details to facilitate the determination of cost allowability (*i.e.,* equipment specifications, etc.). (5)

3. Include travel expenses for annual workshop (required participation) at a major city location to be determined by IHS (Washington, DC, Albuquerque, Denver, etc.). Include airfare, per diem, mileage, etc. (2)

Appendix Items

- Work plan/time line for 5 year objectives
- Position descriptions for key staff
- Resume of IP Coordinator and key staff
- Current Indirect Cost Agreement
- Organizational chart
- Resolutions
- Letter of support
- IP training certificate verification (see page 33)
- Documentation specifically related to injury prevention
- Application Receipt Card, IHS 815–1A (Rev. 2/04)

Part II—Intervention:

Abstract—A one page summary of the three-year proposed project request. Include information on applicant, purpose of request, problem or need to be met, objectives to be achieved through the funding, proposed activities and total amount of request of project.

Criteria Rating

Program Narrative—Introduction, Need and Capacity (Total 30 Points)

1. Describe the injury problem in the community or target area. (5)

2. Describe geographic location of the proposed project. (5)

3. Describe the Tribe's/Tribal organization's support for the proposed project. (5)

4. Describe the population to be served by the proposed project (no minimum population requirement). (5)

5. Describe how the proposed project will support capacity to plan, develop, implement and evaluate an injury prevention program. (10)

Goals and Objectives (Total 15 Points)

1. Goals and objectives that are relevant to the purpose of the proposal. (5)

2. Feasible to accomplish during the 3-year project period. (5)

3. Are specific, time-framed, measurable and realistic. (5)

Methods (Total 25 Points)

1. A detailed description of proposed activities that are likely to achieve each goal and objective, and which includes designation of responsibility for each action undertaken. (15)

2. A reasonable and complete schedule for implementing all activities. (2)

3. A description of the roles of Tribal involvement, organization, or agency and evidence of coordination, supervision, and degree of commitment (*e.g.*, time, in-kind, financial) of staff, organizations, and agencies involved in activities. (3)

4. The extent to which proposed interventions are either proven or promising to be effective and based on a documented need in the target communities. (5)

Evaluation (Total 10 Points)

1. Describe type of evaluation methods that will be utilized to evaluate the goals and objectives. This includes but is not limited to how the progress of the proposed project objective (s) will be tracked (*i.e.*, reports, training, car seat distributions, seat belt surveys, etc.). (5)

2. Describe how project will be evaluated to show program process, effectiveness, and impact. This includes but is not limited to what data will be collected to evaluate the success of the proposed program objectives. (5)

Collaboration (Total 10 Points)

Describe the extent to which relationships between the programs, the Tribe or urban community, the Indian Health Service and other organizations will relate to the project or conduct related activities. This includes the scope to which an advisory committee or partners' roles are clear and appropriate.

Categorical Budget and Budget Justification (Total 10 Points)

Multi-Year Project Requirement

Three-year intervention projects must include a program narrative, categorical budget, and budget justification for each year of funding requested.

1. Provide a categorical budget for each of the 12-month budget periods requested. (3)

2. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the current rate agreement in the appendix. (3)

3. Provide a narrative justification consistent with stated objectives and planned project activities. Include cost and other details to facilitate the determination of cost allowability (*i.e.*, equipment specifications, etc.). (4)

Appendix Items

- Work plan for proposed objectives
- Indirect Cost Agreement
- Organizational chart
- Resolutions
- Letter of support
- Application Receipt Card, IHS 815–1A (Rev. 2/04)

2. Review and Selection Process

Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed by an Objective Review Committee (ORC) in accordance with IHS Objective review procedures. The objective review process ensures a nationwide competition for limited funding. The ORC will be comprised of federal and non-federal individuals with appropriate expertise. The ORC will review each application against established criteria. Based on the evaluation criteria, the reviewer will assign a numerical score to each application, which will be used in making the final decision. Approved applications scoring less than 60 points will not be considered for funding.

3. Anticipated Announcement and Award Dates

Successful applicants can expect notification no later that September 30, 2005. A notice of award signed by the Grants Management Officer will be mailed to the authorized representative. IHS will mail notification to the authorized representative of unsuccessful applicants.

VI. Award Administration Information

1. Award Notices

Proposed Start Date: September 1, 2005. Grants Management will not award a grant without an approved application in conformance with regulatory and policy requirements which describes the purpose and scope of the project to be funded. When the application is approved for funding, the Grants Management Office will prepare a Notice of Grant Award (NGA) with special terms and conditions binding upon the award and refer to all general terms applicable to the award. The NGA will serve as the official notification of the grant award and will state the amount of Federal funds awarded.

2. Administrative and National Policy Requirements

- 45 CFR Part 92, ''Department of Health and Human Services, Uniform Administrative Requirements for State and Local Governments Including Indian Tribes,'' or 45 CFR Part 74, ''Administrative Requirements for Non-Profit Recipients''
- Appropriate Cost Principles: OMB Circular A–87, ''State and Local Governments, ''or OMB Circular A–122, ''Non-Profit Organizations''
- OMB Circular A–133, ''Audits of States, Local Governments, and Non-Profit Organizations'''

3. Reporting Requirements

Part I Basic and Advanced

Program Narrative Progress Reports and Financial Status Reports (FSR) are due 30 days after the end of each three-month period (quarter) of the project period. The final quarterly report for both are due 90 days after the expiration of the project period. Standard Form (SF) 269 Financial Status Report (Long Form) is recommended for use in financial reporting.

Part II Intervention

Program Narrative Progress Reports and the Financial Status Reports (FSR) are due 30 days after the end of each six-month period (semi-annual report) of the project period. The final semi-annual reports for both are due 90 days after the project period. Standard Form (SF) 269 Financial Status Report (Long Form) is recommended for use in financial reporting.

VII. Agency Contacts

For Grants administrative and business questions, contract Ms. Patricia Spotted Horse, Grants Management Specialist, Division of Grants Operation, Indian Health Service, 801 Thompson, Suite 120, Rockville, Maryland 20852, telephone (301) 443–5204. Programmatic technical assistance regarding the Injury Prevention Cooperative Agreement Program contact Ms. Nancy Bill, IHS, Injury Prevention Program Manager, telephone (301) 443–0105.

VIII. Other Background Information

Indian Health Service Injury Prevention Program is the lead federal agency in the development and implementation of American Indian and Alaska Native injury prevention programs. IHS is directed to develop, implement, and evaluate injury prevention programs that would be

successful in reducing American Indian and Alaskan Native morbidity and mortality related to injuries. The purpose of the IHS Cooperative Agreement funding is to promote the capacity of Tribes and Tribal/urban/non-profit Indian organizations to build and sustain their own community-based injury prevention programs.

Injury Prevention Training Opportunities

The Indian Health Service offers three short courses in injury prevention training. The courses are designed specifically for community-based practitioners to learn the basics of preventing injuries specific to American Indian/Alaska Native communities. The three short courses are: (1) Introduction to Injury Prevention; (2) Intermediate Injury Prevention; and (3) Advanced Injury Prevention. Each of these courses are approximately one week in length.

Indian Health Service Injury Prevention Program offers a one-year Fellowship training with two separate training tracks: (1) Epidemiology and (2) Program Development. For more information on the IHS Injury Prevention training courses, contact an IHS Area Injury Prevention Specialist at the IHS Injury Prevention website: *http://www.ihs.gov/MedicalPrograms/InjuryPrevention/index.cfm.*

United Tribes Technical College at Bismarck, North Dakota is the only college that offers a degree in injury prevention. Courses including online courses are available. Contact Mr. Dennis Renville, Director, Injury Prevention Department, United Tribes Technical College at (701) 255–3285 ext. 374. Or e-mail: *drenville@uttc.edu* Web site: *http://www.uttc.edu/injuryprevention.*

The Public Health Service (PHS) strongly encourages all contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. 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 IHS mission to protect and advance the physical and mental health of the American Indian/Alaska Native people.

Dated: April 6, 2005.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 05–7459 Filed 4–13–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Health Promotion and Disease Prevention

Funding Opportunity Number: HHS–2005–IHS–0001.

Announcement Type: New.

CFDA Number: 93.193 and 93.284.

Key Dates:

Application Deadline: June 1, 2005.

Application Review: July 15, 2005.

Application Notification: August 31, 2005.

Earliest Anticipated Start Date: October 1, 2005.

I. Funding Opportunity Description

The Indian Health Service (IHS), announces the availability of Fiscal Year (FY) 2005 grants to implement the IHS Health Promotion/Disease Prevention (HP/DP) Initiative to create healthier American Indian/Alaska Native (AI/AN) communities through innovative and effective community, school, clinic, and work site health promotion and chronic disease prevention programs.

The IHS HP/DP Initiative is focusing on enhancing and expanding health promotion and chronic disease prevention to reduce health disparities among AI/AN populations. The plan is fully integrated with the Department of Health and Human Services (HHS) Initiative such as *Healthy People 2010* and Steps to a HealthierUS *http://www.healthierus.gov/.*

The initiative focuses on cardiovascular disease, diabetes, cancer, obesity, and unintentional injury prevention and intervention efforts in AI/AN communities. Focus efforts include enhancing and maintaining personal and behavioral factors that support healthy lifestyles such as making healthier food choices, avoiding the use of tobacco, alcohol, and other harmful substances, being physically active, and demonstrating other positive behaviors to achieve and maintain good health.

Major focus areas include preventing and controlling obesity by developing and implementing science-based nutrition and physical activity interventions (*i.e.,* increased consumption of fruits and vegetables, reduced consumption of foods that are high in fat, increased breastfeeding, reduced television time, and increased opportunities for physical activity). Other focus areas include preventing consumption of alcohol and tobacco use among youth, reducing unintentional injury, increasing accessibility to tobacco cessation programs, and reducing exposure to second-hand smoke.

The purpose of this initiative is to enable American Indian/Alaska Native (AI/AN) communities to enhance and expand health promotion and reduce chronic disease by: increasing physical activity; avoiding the use of tobacco, alcohol, and other unhealthy addictive substances; and improving nutrition to support healthier AI/AN communities through innovative and effective community, school, clinic and work site health promotion and chronic disease prevention programs.

The initiative encourages Tribal applicants to fully engage their local schools, communities, health care providers, health centers, faith-based/spiritual communities, senior centers, youth programs, local governments, academia, non-profit organizations, and many other community sectors to work together to enhance and promote health and prevent chronic disease in their communities.

This initiative is described in the Catalog of Federal Domestic Assistance Nos. 93.193 and 93.284 at: *http:/www.cfda.gov/* and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of the Indian Health Care Improvement Act, Title V, Sections 503 and 511, Public Law 94–437 as amended, Public Law 100–713, 101–630, and 102–572 also, the Public Health Service Act 203 and 301(a), as amended. The grant will be administered under the Public Health Service Grants Policy Statement an dother applicable agency policies.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2010,* a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Education and Community-Based Programs. Potential applicants may obtain a copy of *Healthy People 2000,* (Full Report; Stock No. 017–001–00474–0) or *Healthy People 2010* (Summary report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone 202–783–3238).

Background

Heart disease, cancer and unintentional injuries are the leading cause of morbidity and mortality among AI/AN. Many of these diseases and injuries are impacted by modifiable