SUPPLEMENTARY INFORMATION: The “Essentials of FDA Medical Device Regulations: A Primer for Manufacturers and Suppliers” seminar helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health by educating new entrepreneurs on the essentials of FDA device regulations. FDA has made education of the medical device community a high priority to assure the quality of products reaching the marketplace and to increase the rate of voluntary industry compliance with regulations.

The seminar helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The seminar also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed at small businesses.

The following topics, as well as others, will be discussed at the seminar:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- Overview of the quality system regulation;
- Design controls;
- Documents, records, and change control;
- Purchasing controls and acceptance activities;
- Production and process control;
- Corrective and preventive actions;
- Complaints, medical device reports, corrections, and recalls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—Where do you go for assistance?
- General question and answer session;
- Manufacturers and suppliers—the chain regulatory responsibility;
- Reimbursement of medical technology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

Dated: March 27, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08–1085 Filed 3–28–08; 11:48 am]
BILINGUE 4100-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program

Announcement Type: New and Competing Continuation Discretionary Funding Cycle for Fiscal Year 2009.


Catalog of Federal Domestic Assistance Numbers(s): 93.228.


Grant Writing Session: June 23–27, 2008.

Application Deadline Date: August 1, 2008.

Receipt Date for Final Tribal Resolution: October 3, 2008.

Review Date: October 6–10, 2008.

Application Notification Date: November 12, 2008.

Earliest Anticipated Start Date: January 1, 2009.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Tribal Management Grant (TMG) Program. This program is authorized under Section 103(b)(2) and Section 103(e) of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, as amended. This program is described at 93.228 in the Catalog of Federal Domestic Assistance (CFDA).

The TMG Program is a national competitive discretionary grant program pursuant to 45 CFR part 75 and 45 CFR part 92 established to assist Federally-recognized Tribes and Tribally-

1 FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.
sanctioned Tribal organizations in assuming all or part of existing IHS programs, services, functions, and activities (PSFA) through a Title I contract and to assist established Title I contractors and Title V compactors to further develop and improve their management capability. In addition, TMGs are available to Tribes/Tribal organizations under the authority of Public Law (Pub. L.) 93–638 section 103(c) for (1) obtaining technical assistance from providers designated by the Tribe/Tribal organization (including Tribes/Tribal organizations that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management and the development of cost allocation plans for indirect cost rates; and (2) planning, designing and evaluating Tribal health programs serving the Tribe/Tribal organization, including Federal administrative functions.

**Funding Priorities:** The IHS has established the following funding priorities for TMG awards:

- **Priority I—** Any Indian Tribe that has received Federal recognition (restored, un-terminated, funded, or unfunded) within the past five years, specifically received during or after March 2003.
- **Priority II—** All other eligible Federally-recognized Indian Tribes or Tribally sanctioned Tribal organizations submitting a competing continuation application or a new application for the sole purpose of addressing audit material weaknesses. The audit material weaknesses are identified in Attachment A (Summary of Findings and Recommendations) and other attachments, if any, of the transmittal letter received from the Office of the Inspector General (OIG), National External Audit Review Center (NEARC), Department of Health and Human Services (HHS). Please identify the weakness to be addressed by underlining the item on Attachment A. Please refer to Section 111.3, “Other Requirements,” for more information regarding Priority II participation.

Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations not subject to Single Audit Act requirements must provide a financial statement identifying the Federal dollars received in the footnotes. The financial statement must also identify specific weaknesses/recommendations that will be addressed in the TMG proposal and are related to 25 Code of Federal Regulations (Reg) Part 900, “Indian Self-Determination and Education Assistance Act Amendments,” Subpart F—“Standards for Tribes and Tribal Organizations.”

Priority II participation is only applicable to the Health Management Structure project type. For more information see Section H ELIGIBLE PROJECT TYPES, MAXIMUM FUNDING AND PROJECT PERIODS.

- **Priority III—** All other eligible Federally-recognized Indian Tribes or Tribal organizations submitting a competing continuation application or a new application.

The funding of approved Priority I applicants will occur before the funding of approved Priority II applicants. Priority H applicants will be funded before approved Priority if applicants. Funds will be distributed until depleted.

**II. Award Information**

**Type of Awards: Grant.**

**Estimated Funds Available:** Subject to the availability of funds, the estimated amount available is $2,529,000 in fiscal year (FY) 2009. There will be only one funding cycle in FY 2009. Awards under this announcement are subject to the availability of funds.

**Anticipated Number of Awards:** An estimated 20–25 awards will be made under the program.

**Project Periods:** Varies from 12 months to 36 months. Please refer to “ELIGIBLE PROJECT TYPES, MAXIMUM FUNDING AND PROJECT PERIODS” under this section for more detailed information.

**Estimated Award Amount:** $50,000/year–$100,000/year. Please refer to “ELIGIBLE PROJECT TYPES, MAXIMUM FUNDING AND PROJECT PERIODS” below for more detailed information.

**Eligible Project Types, Maximum Funding and Project Periods**

Applications may only be submitted for one project type. Applicants must state the project type selected. The TMG Program consists of four project types: (1) Feasibility study; (2) planning; (3) evaluation study; and (4) health management structure. Applications that address more than one project type will be considered ineligible and will be returned to the applicant. The maximum funding levels noted include both direct and indirect costs. Applicant budgets may not exceed the maximum funding level or project period identified for a project type. Applicants whose budget or project period exceed the maximum funding level or project period will be considered ineligible and will not be reviewed. Please refer to Section IV.6. “Funding Restrictions” for further information regarding ineligible activities.

1. **Feasibility Study (Maximum funding/project period: $70,000/12 months)** A study of a specific IHS program or segment of a program to determine if Tribal management of the program is possible. The study shall present the planned approach, training and resources required to assume Tribal management of the program. The study must include the following four components:

   - **Health needs and health care services assessments that identify existing health care services and delivery system, program divisibility issues, health status indicators, unmet needs, volume projections and demand analysis.**
   - **Management analysis of existing management structures, proposed management structures, implementation plans and requirements, and personnel staffing requirements and recruitment barriers.**
   - **Financial analysis of historical trends data, financial projections and new resource requirements for program management costs and analysis of potential revenues from Federal/non-Federal sources.**
   - **Decision statement/report that incorporates findings, conclusions and recommendations; the presentation of the study and recommendations to the governing body for Tribal determination regarding whether Tribal assumption of program(s) is desirable or warranted.**

2. **Planning (Maximum funding/project period: $50,000/12 months)** A collection of data to establish goals and performance measures for the operation of current health programs or anticipated PSFAs under a Title I contract. Planning will specify the design of health programs and the management systems (including appropriate policies and procedures) to accomplish the health priorities of the Tribe/Tribal organization. For example, planning could include the development of a Tribal Specific Health Plan or a Strategic Health Plan, etc. Please note: The Public Health Service urges applicants submitting strategic health plans to address specific objectives of Healthy People 2010. Interested applicants may purchase a copy of Healthy People 2010 (Summary Report in print; Stock No. 017–001–00547–9) or CD–ROM (Stock No. 107–001–00549–3) through the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, Pennsylvania 15250–7945, or (202) 512–1800. This information is available in electronic form at the following Web site: http://
III. Eligibility Information

1. Indian Tribe or Tribal organization as defined by Public Law 93–638, Indian Self Determination and Education Assistance Act, as amended. Eligible applicants include Tribal organizations that operate mature contracts that are designated by a Tribe to provide technical assistance and/or training. Only one application per Tribe or Tribal organization is allowed. This paragraph should be cross-referenced with Section IV. (Application and Submission Information/Subsection 3. Content and Form of Narrative Submission).

2. Cost Sharing or Matching—The TMG Program does not require matching funds or cost sharing. However, in accordance with Public Law 93–638 section 103(c), the TMG funds may be used as matching shares for any other Federal grant programs that develop Tribal capabilities to contract for the administration and operation of health programs.

3. Other Requirements

   The following documentation is required:

   A. Tribal Resolution—A resolution of the Indian Tribe served by the project must accompany the application submission. The IHS will accept the following as proper documentation:

   • If an official signed (passed) Tribal resolution, it must be submitted.

   B. Documentation for Priority I

   • Identify if any of the member Tribes overlap any objectives of the application does not duplicate or overlap any objectives of the other.

   • Identify all of the consortium organizations that operate mature Contract Management Systems through quality control measures, internal control reviews and audit report findings under the Office of Management and Budget (OMB) Circular No. A–133—Revised June 27, 2003, “Audits of States, Local Governments, and Non-Profit Organizations.” OMB Circular A–133, Audits of States, Local Governments and Non-Profit Organizations can be found at the following Web site: http://www.whitehouse.gov/omb/circulars/a133/a133.html.


   • Please see Section IV “Application and Submission Information” for directions about how to request a copy of the TMG application package.
IV. Application and Submission Information

1. The Application package may be found in Grants.gov (www.grants.gov) or at: http://www.ihs.gov/NonMedicalPrograms/gop.org. The entire grant application package is available at: http://www.ihs.gov/NonMedicalPrograms/tmg. Detailed application instructions for this announcement are downloadable on Grants.gov.

2. IHS Contacts:
   - Programmatic Concerns: Ms. Patricia Spotted Horse, Program Analyst, Office of Tribal Programs, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, (301) 443–1104 (Telephone), (301) 443–4666 (Fax).
   - E-Mail Address: Patricia.SpottedHorse@IHS.GOV.
   - Business Concerns: Mr. Pallop Chareonvootitam, Grants Management Specialist, Division of Grants Operations, Indian Health Service, 801 Thompson Avenue, TMP 360 Rockville, Maryland 20852, (301) 443–5204 (Telephone), (301) 443–9602 (Fax).
   - E-Mail Address: Pallop.Chareonvootitam@IHS.GOV.

   Grants.gov Contact for HIS:
   - Information regarding the electronic grants.gov process, issues, and waivers waiving the electronic process may be obtained from the following person: Ms. Michelle G. Bulls, Chief Grants Management Officer, Director, Division of Grants Policy, Indian Health Service, 801 Thompson Avenue, TMP 625, Rockville, Maryland 20852, (301) 443–6528 (Telephone), (301) 443–6528 (Fax).
   - E-Mail Address: Michelle.Bulls@IHS.gov.

3. Content and Form of Narrative Submission:
   - Abstract (one page) summarizing the project.
   - Introduction and Need for Assistance.
   - Project Objective(s). Approach and Results and Benefits.
   - Project Evaluation.
   - Organizational Capabilities and Qualifications.
   - Be typewritten and single spaced.
   - Use black type not smaller than 12 characters per one inch.
   - Margins must not be less than one inch.
   - Have consecutively numbered pages.
   - Contain a narrative that does not exceed 14 typed pages that includes the other submission requirements below. The 14-page narrative does not include the abstract, the work plan, standard forms, Tribal resolution(s), table of contents, budget, budget justifications, multi-year narratives, multi-year budget, multi-year budget justification, and/or other appendix items.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with exception of Lobbying and Discrimination policy.

4. Submission Dates and Times: Applications must be submitted electronically through Grants.gov by 12 midnight Eastern Standard Time (EST) on Friday, August 1, 2008. If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant must contact Michelle G. Bulls, Division of Grants Policy, fifteen days prior to the application deadline and advise of the difficulties that your organization is experiencing. The grantee must obtain prior approval, in writing (e-mails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the manually signed original and two copies of the application must be sent to the appropriate grants contact that is listed in Section IV.2. above. Applications not submitted through Grants.gov, without an approved waiver, will be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the applicant, and will not be considered for funding.

5. Intergovernmental Review: Executive Order 12372 requiring intergovernmental review is not applicable to this program.

6. Funding Restrictions:
   - Pre-award costs are not allowable.
   - The available funds are inclusive of direct and indirect costs.
   - Only one grant will be awarded per applicant.
   - Ineligible Project Activities
     - The TMG may not be used to support recurring operational programs or to replace existing public and private resources.
     - Note: The inclusion of the following projects or activities in an application will render the application ineligible and the application will be returned to the applicant:
       - Planning and negotiating activities associated with the intent of a Tribe to enter the IHS Self-Governance Project. A separate grant program is administered by the IHS for this purpose. Prospective applicants interested in this program should contact Mr. Matt Johnson, Office of Tribal Self-Governance, Indian Health Service, Reyes Building, 801 Thompson Avenue, Suite 240, Rockville, Maryland 20852, (301) 443–7821, and request information concerning the “Tribal Self-Governance Program Planning Cooperative Agreement Announcement” or the “Negotiation Cooperative Agreement Announcement.”
     - Projects related to water, sanitation, and waste management.
     - Projects that include direct patient care and/or equipment to provide those medical services to be used to establish or augment or continue direct patient clinical care are not allowable. Medical equipment that is allowable under the Special Diabetes Grant Program is not allowable under the TMG Program.
     - Projects that include long-term care or provision of any direct services.
     - Projects that include tuition, fees, or stipends for certification or training of staff to provide direct services.
     - Projects that include pre-planning, design, and planning of construction for facilities, including activities relating to program justification documents.
     - Projects that propose more than one project type. Please see Section H, “Award Information,” specifically “ELIGIBLE PROJECT TYPES, MAXIMUM FUNDING AND PROJECT PERIODS” for more information. An example of a proposal with more than one project type that would be considered ineligible may include the creation of a strategic health plan (defined by TMG as a planning project type) and improving third-party billing structures (defined by TMG as a health management structure project type).
   - Other Limitations—A current TMG recipient cannot be awarded a new, renewal, or competing continuation grant for any of the following reasons:
     - A grantee may not administer two TMGs at the same time or have overlapping project/budget periods.
     - The current project is not progressing in a satisfactory manner; or
     - The current project is not in compliance with program and financial reporting requirements.
   - Delinquent Federal Debts: No award shall be made to an applicant who has an outstanding delinquent Federal debt until either:
     - The delinquent account is paid in full; or
7. Other Submission Requirements

Electronic Submission—The preferred method for receipt of applications is electronic submission through Grants.gov. However, should any technical challenges arise regarding the submission, please contact Grants.gov Customer Support at 1–800–518–4726 or support@grants.gov. The Contact Center hours of operation are Monday–Friday from 7 a.m. to 9 p.m. EST. If you require additional assistance, please call (301) 443–6290 and identify the need for assistance regarding your Grants.gov application. Your call will be transferred to the appropriate grants staff member. The applicant must seek assistance at least fifteen days prior to the application deadline. Applicants that do not adhere to the timelines for Central Contractor Registry (CCR) and/or Grants.gov registration and/or requesting timely assistance with technical issues will not be candidates for paper applications.

To submit an application electronically, please use the www.Grants.gov apply site. Download a copy of the application package, on the Grants.gov Web site, 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 IHS.

Please be reminded of the following:
• Under the new IHS application submission requirements, paper applications are not the preferred method. However, if you have technical problems submitting your application on-line, please contact directly Grants.gov Customer Support at: http://www.Grants.gov/CustomerSupport.
• Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver request from Grants Policy must be obtained.
• If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (e-mails are acceptable), to Michelle.Bulls@ihs.gov that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded by the applicant from Grants.gov, and completed with appropriate manual signatures. An original and two copies of the application must be sent directly to the DGO.

A. Criteria

Introduction and Need for Assistance (20 points)
(1) Describe the Tribe’s/Tribal organization’s current health operation. Include what programs and services are currently provided (i.e., Federally funded, State funded, etc.), information regarding technologies currently used (i.e., hardware, software, services, etc.), and identify the source(s) of technical support for those technologies (i.e., Tribal staff, Area Office, vendor, etc.). Include information regarding whether the Tribe/Tribal organization has a health department and/or health board and how long it has been operating.

(2) Describe the population to be served by the proposed project. Include a description of the number of IHS eligible beneficiaries who currently use services.

(3) Describe the geographic location of the proposed project including any geographic barriers to the health care services in the area to be served.

(4) Identify all TMsG received since FY 2003, dates of funding and summary

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

Upon entering the Grants.gov site, there is information available outlining the requirements to the applicant regarding electronic submission of an application through Grants.gov, as well as the hours of operation. We strongly encourage all applicants not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov could take up to fifteen working days.

To use Grants.gov, you, as the applicant, must have a Data Universal Numbering System (DUNS) Number and must register in the CCR. You should allow a minimum of ten working days to complete CCR registration. See below on how to apply.

You must submit all documents electronically, including all information typically included on the SF–424, Application for Federal Assistance, and all necessary assurances and certifications.

Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS.

Final signed Tribal resolutions are required no later than October 3, 2008, if a draft resolution was submitted with the initial electronic or paper application.

Your application cannot exceed the 14-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 IHS DGO will retrieve your application from Grants.gov. DGO will not notify applicants that the application has been received.

You may access the electronic application for this program on www.Grants.gov.

You may search for the downloadable application package by either the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.

The applicant must provide the Funding Opportunity Number: HHS–2009–IHS–TMD–0001.

E-mail applications will not be accepted under this announcement.

DUNS Number

Applications are required to obtain a DUNS number from Dun and Bradstreet to apply for a grant or cooperative agreement from the Federal Government. 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 http://www.dunandbradstreet.com or call 1–866–705–5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

Applications submitted electronically must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.


More detailed information regarding these registration processes can be found www.Grants.gov.
of project accomplishments. State how previous TMG funds facilitated the progression of health development relative to the current proposed project. (Copies of reports will not be accepted.)

(5) Identify the eligible project type and priority group of the applicant.

(6) Explain the reason for your proposed project by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed project. Explain how these gaps/weaknesses were discovered. If a proposed project includes information technology (i.e., hardware, software, etc.), provide further information regarding measures taken or to be taken that ensure the proposed project will not create other gaps in services or infrastructure (i.e., IHS interface capability, Government Performance and Results Act reporting requirements, contract reporting requirements, Information Technology (IT) compatibility, etc.).

(7) Describe the effect of the proposed project on current programs (i.e., Federally funded, State funded, etc.) and, if applicable, on current equipment (i.e., hardware, software, services, etc.). Include the effect of the proposed project on planned/anticipated programs and/or equipment.

(8) Address how the proposed project relates to the purpose of the TMG Program by addressing the appropriate description that follows:

• Identify if the Tribe/Tribal organization is an IRS Title I contractor. Address if the self-determination contract is a master contract of several programs or if individual contracts are used for each program. Include information regarding whether or not the Tribe participates in a consortium contract (i.e., more than one Tribe participating in a contract). Address what programs are currently provided through those contracts and how the proposed project will enhance the organization’s capacity to manage the contracts currently in place.

• Identify if the Tribe/Tribal organization is an IRS Title V compactor. Address when the Tribe/Tribal organization entered into the compact and how the proposed project will further enhance the organization’s management capabilities.

• Identify if the Tribe/Tribal organization is not a Title I or Title V organization. Address how the proposed project will enhance the organization’s management capabilities, what programs and services the organization is currently seeking to contract and an anticipated date for contract.

Project Objective(s), Workplan and Consultants (40 points)

A. Identify the proposed project objective(s) addressing the following:

• Measurable and (if applicable) quantifiable.
• Results oriented.
• Time-limited.

Example: By installing new software, the Tribe will increase the number of bills processed by 15 percent at the end of 12 months.

B. Address how the proposed project will result in change or improvement in program operations or processes for each proposed project objective. Also address what tangible products are expected from the project (i.e., policies and procedures manual, health plan, etc.).

C. Address the extent to which the proposed project will build the local capacity to provide, improve, or expand services that address the need(s) of the target population.

D. Submit a workplan in the appendix which includes the following information:

• Provide the action steps on a timeline for accomplishing the proposed project objective(s).
• Identify who will perform the action steps.
• Identify who will supervise the action steps taken.
• Identify who will accept and/or approve work products at the end of the proposed project.
• Include any training that will take place during the proposed project and who will be attending the training.
• Include evaluation activities planned.

E. If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):

• Educational requirements.
• Desired qualifications and work experience.
• Expected work products to be delivered on a timeline.
• How the project will document any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.
• How the project will document what is learned throughout the project period.

F. Describe the ultimate benefit to the Tribe that is expected to result from this project. An example of this might be the ability of the Tribe to expand preventive health services because of increased billing and third party payments.

Organizational Capabilities and Qualifications (15 Points)

A. Describe the organizational structure of the Tribe/Tribal organization beyond health care activities.

B. Provide information regarding plans to obtain management systems if the Tribe/Tribal organization does not have an established management system currently in place that complies with 25 CFR Part 900, Subpart F, and “Standards for Tribal Management Systems.” If management systems are already in place, simply state it.

C. Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed.

D. Describe what equipment (i.e., fax machine, phone, computer, etc.) and facility space (i.e., office space) will be available for use during the proposed project on planned/anticipated dates for contract. Address how the proposed project will enhance the organization beyond health care.

E. Address how the proposed project will enhance the organization’s capacity to manage the contracts currently in place.

• Identify if the Tribe/Tribal organization is an IRS Title I contractor.
• Identify if the self-determination contract is a master contract of several programs or if individual contracts are used for each program.
• Include information regarding whether or not the Tribe participates in a consortium contract.

F. Address how the Tribe/Tribal organization entered into the compact and how the proposed project will further enhance the organization’s management capabilities.

• Identify if the Tribe/Tribal organization is not a Title I or Title V organization.
• Address how the proposed project will enhance the organization’s management capabilities, what programs and services the organization is currently seeking to contract and an anticipated date for contract.
project. Include information about any equipment not currently available that will be purchased through the grant.
F. List key personnel who will work on the project. Include title used in the workplan. In the appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed project. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities. If a position is to be filled, indicate that information on the proposed position description.
F. If the project requires additional personnel (i.e., IT support, etc.), address how the Tribe/Tribal organization will sustain the position(s) after the grant expires. (If there is no need for additional personnel, simply note it.)
Categorical Budget and Budget Justification (10 points).
A. Provide a categorical budget for each of the 12-month budget periods requested.
B. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.
C. Provide a narrative justification explaining why each line item is necessary/relevant to the proposed project. Include sufficient cost and other details to facilitate the determination of cost allowability (i.e., equipment specifications, etc.)
Multi-Year Project Requirements
Projects requiring a second and/or third year must include a narrative addressing the second and/or third year’s project objectives, evaluation components, work plan, categorical budget and budget justification. The same weights and criteria as noted in Section V. Application Review Information that is used to evaluate a one-year project or the first year of a multi-year project will be applied when evaluating the second and third years of a multi-year application. A weak second and/or third year submission could negatively impact the overall score of an application.
Appendix Items
A. Work plan for proposed objectives.
B. Position descriptions for key staff.
C. Resumes of key staff that reflect current duties.
D. Consultant proposed scope of work (if applicable).
E. Indirect Cost Rate Agreement.
F. Organizational chart (optional).
G. Multi-Year Project Requirements (if applicable).
2. Review and Selection Process
In addition to the above criteria/requirements, applications are considered according to the following:
A. Application Submission (Application Deadline: August 1, 2008). Applications received in advance of or by the deadline and verified by the tracking number will undergo a preliminary review to determine that:
- The applicant and proposed project type is eligible in accordance with this grant announcement;
- The application is not a duplication of a previously funded project; and
- The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise the application may be returned.
Applications meeting eligibility requirements that are complete, responsive and conform to this program announcement will be reviewed for merit by the Ad Hoc Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical 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 in Section V.1. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success and to assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of TMG funding is not sufficient to support all approved applications. Applications recommended for approval, having a score of 60 or above by the ORC and scored high enough to be considered for funding will be reviewed by the DGO for cost analysis and further recommendation. The program official accepts the DGO recommendations for consideration when funding applications. The program official forwards the final approved list to the Director, Office of Tribal Programs (OTP), for final review and approval. Applications scoring below 60 points will be disapproved. Applications that are approved but not funded will not be carried over into the next cycle for funding consideration.
3. Anticipated Announcement and Award Dates. The IEIS anticipates the earliest award start date will be January 1, 2009.
VI. Award Administration Information
1. Award Notices
ORC Results Notification: November 12, 2008.
The Director, OTP, or program official, will notify the contact person identified on each proposal of the results in writing via postal mail. Applicants whose applications are declared ineligible will receive written notification of the ineligibility determination and their grant application via postal mail. The ineligible notification will include information regarding the rationale for the ineligible decision citing specific information from the original grant application. Applicants who are approved but unfunded and disapproved will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted. Applicants who are approved and funded will be notified through the official Notice of Award (NoA) document. The NoA will be signed by the Grants Management Officer and is the authorizing document for notifying grant recipients of funding.
The NoA serves as the official notification of a grant award and 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. Any other correspondence announcing to the Applicant’s Project Director that an application was recommended for approval is not an authorization to begin performance. Pre-award costs are not allowable charges under this program grant.
2. Administrative Requirements
Grants are administrated in accordance with the following documents:
- This grant announcement.
- Health and Human Services regulations governing Public Law 93–638 grants at 42 CFR 36.101 et seq.
- 45 CFR part 92, “Department of Health and Human Services, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments Including Indian Tribes,” or 45 CFR part 74, “Administration of Grants to Non-Profit Recipients."
- Public Health Service Grants Policy Statement.
Governments,” or OMB Circular A–122, “Non profit Organizations.”
• OMB Circular A–133, “Audits of States, Local Governments and Non Profit Organizations.”
• Other Applicable OMB Circulars.
3. Indirect Costs
This section applies to all grant recipients that request indirect cost in their application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the awarding office, the award shall include funds for reimbursement of indirect costs. However, the indirect cost portion will remain restricted until the current rate is provided to the DGO.
• Generally, indirect costs rates for IRS Tribal organization grantees are negotiated with the Division of Cost Allocation (DCA) http://rates.psc.gov/ and indirect cost rates that are for IHS funded Federally recognized Tribes are negotiated with the Department of the Interior. If your organization has questions regarding the indirect cost policy, please contact the DGO at 301–443–5204. Additional information may be obtained at the following Web site for the National Business Center [Department of the Interior]: National Business Center (NBC). http://www.nbc.gov/acquisition/ics/icsprep.html.
Preparing and Submitting Indirect Cost Proposals
4. Reporting
A. Progress Report. Program progress reports are required either semi annually or annually. [Semi-annual] program progress reports must be submitted within 30 days at the end of the half year. These reports will include a brief comparison of actual accomplishments to the goals established for the period, reasons for slippage (if applicable), and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.
B. Financial Status Reports. Financial status reports are required either semi annually or annually. [Semi-annual] financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.
C. Reports. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due semi-annually. Financial Status Reports (SF–269) are due 90 days after each budget period and the final SF–269 must be verified from the grantees records on how the value was derived. Grantees must submit reports in a reasonable period of time.
Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.
VII. Agency Contact(s)
Interested parties may obtain TMG programmatic information from the TMG Program Coordinator listed under Section IV of this program announcement. Grant-related and business management information may be obtained from the Grants Management Specialist listed under Section IV of this program announcement. Grants.gov concerns submission, and waiver requests may be addressed by Ms. Michelle Bulls, Division of Grants Policy. Contact information is noted under Section IV of this program announcement. Please note that the telephone numbers provided are not toll-free.
VIII. Other Information
Training:
The IHS will conduct three training sessions to assist applicants in preparing their FY 2009 TMG applications. There will be three 2-day training sessions. In addition, there will be one 5-day training session on Gamesmanship. The 5-day training session will provide participants with basic grant writing skills, information regarding where to search for funding opportunities, and the opportunity to begin writing a TMG grant proposal or to finalize a draft proposal. The 2-day training sessions will focus specifically on the TMG requirements providing participants with information contained in this announcement, clarifying any issues/questions applicants may have and critiquing project ideas. In an effort to make the training sessions productive, participants are expected to bring draft proposals to these sessions.
Priority will be given to groups eligible to apply for the TMG Program. Participation is limited to two personnel from each Tribe or Tribal organization. All sessions are first come—first serve with the above limitations noted. All participants are responsible for making and paying for their own travel arrangements. Interested parties should register with the TMG staff prior to making travel arrangements to ensure space is available in selected sessions.
There is no registration fee to attend the training session(s). The registration form may be obtained from the TMG Web site at: http://www.ihs.gov/NonMedicalPrograms/tmg. The registration form may be faxed to (301) 443–4666. Note: A minimum of 10 attendees is required for the IHS to conduct the training sessions. The anticipated training dates and locations are listed below in chronological order:
• April 30–May 1, 2008—Minneapolis, Minnesota (Limit 25) (TMG Training).
IHS Checklist
The following IHS Checklist is included to assist applicants in proposal preparation and follow-up. Applicants are highly encouraged to employ this checklist for their benefit and to submit it as part of their proposal as an attachment in Grants.gov to allow for verification of receipt. This checklist will be utilized by the DGO during their initial screening for eligibility and will be utilized by the OTP during their programmatic review for content of the application to ensure required items requested are submitted and the application is eligible for further review via the ORC. This checklist is available on the TMG Web site at http://www.ihs.gov/NonMedicalPrograms/tmg.
IHS FY 2009 Tribal Management Grant Application Checklist

Applicant Name: ____________________________________________________________

Application Tracking Number: _______________________________________________

Electronic Submission: _____  Signed Paper Submission: _____  Waiver Obtained: _____

Title I: _____  Title V: _____  Project Type: ___________________________________

<table>
<thead>
<tr>
<th>Item</th>
<th>Applicant</th>
<th>Grants</th>
<th>Programs</th>
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<tr>
<td>1 IHS FY 2009 TMG Checklist</td>
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<td>2 Eligibility: (circle) Tribe  Tribal Organization</td>
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<td>3 501c(3) Non-Profit Organization</td>
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<td>4 Tribal Resolution</td>
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<td>a. Final signed resolution is due on or before October 3, 2008</td>
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<td>b. Draft unsigned resolution is due August 1, 2008 (if applicable)</td>
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<td>5 Priority I Documentation (if applicable)</td>
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<td>6 Priority II Documentation (if applicable)</td>
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<td>7 Consortium Participation Documentation (if appl.)</td>
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<td>8 SF 424 Application for Federal Assistance</td>
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<td>9 SF 424A Budget – Non Construction</td>
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<td>10 SF 424B Assurances</td>
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<td>11 Disclosure of Lobbying Activities</td>
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<td>12 Abstract</td>
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<td>13 Project Narrative (14 pages maximum)</td>
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<tr>
<td>a. Introduction and Need for Assistance</td>
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<td>b. Project Objective(s), Workplan &amp; Consultants</td>
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<td>c. Project Evaluation</td>
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<td>d. Organizational Capabilities and Qualifications</td>
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<td>14 Categorical Budget &amp; Budget Justification</td>
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<td>15 Multi-year Summary &amp; Budget Justification</td>
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<td>16 APPENDIX ITEMS</td>
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<tr>
<td>a. Work plan for proposed objectives.</td>
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</table>
b. Position descriptions for key staff.

c. Resumes of key staff that reflect current duties.

d. Consultant proposed scope of work (if applicable).

e. Indirect Cost Rate Agreement.

f. Organizational chart (optional).

g. Multi-Year Project Requirements (if applicable).

Applicant Signature / Date: 

IHS Grants Management Signature / Date: 

IHS Program Office Signature / Date: 

The Public Health Service (PHS) strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 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.

Date: 3/24/08

Robert C. McSwain
Acting Director
Indian Health Service
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: National Evaluation of the Addiction Technology Transfer Centers (ATTC)—NEW

In recognition that systematic evaluation of this and other government programs are part of good management and accountability and will inform program improvement efforts, the Substance Abuse and Mental Health Services Administration’s Center for Substance Abuse Treatment (CSAT) will conduct an independent evaluation of the ATTC Program. The purpose of the ATTC Program is to develop and strengthen the workforce that provides addiction treatment services to 23 million Americans age 12 and older who need treatment for alcohol or illicit drug problems. In partnership with Single State Authorities (SSAs), treatment provider associations, addiction counselors, multidisciplinary professionals, faith and recovery community leaders, addiction educators, and other stakeholders, the ATTCs assess the training and development needs of the substance use disorders workforce, and develop and conduct training and technology transfer activities to meet these needs. Particular emphasis is on raising awareness of and improving skills in using evidence-based and promising treatment/recovery practices in recovery-oriented systems of care.

The goals of the evaluation are to: (1) Identify the successes of technology transfer efforts and build upon them in the future; (2) share lessons learned across ATTC regions for the enhancement of all regions’ activities; and (3) identify region-specific and cross-regional processes and outcomes. The evaluation will consist of three studies. The Planning and Partnering Study will collect data on the processes and procedures related to the planning, partnering, and provision of ATTC services/activities. The Customer Satisfaction and Benefit Study will collect data on the extent to which ATTC services/activities are satisfactory and to meet the needs of identified partners and other program stakeholders. The Change in Practice Study will collect data to determine the extent to which ATTCs have enhanced the competencies, including cultural competencies, of specialty addictions treatment practitioners, paraprofessionals, and multidisciplinary professionals to strengthen the workforce and whether the ATTCs have provided these individuals with new skills that have led to changes in treatment practice.

This will be the first independent national evaluation of the ATTC Program since the program was first funded by SAMHSA in 1993. The evaluation approach will be formative and participatory, and the national evaluation team will collaborate with the ATTCs, CSAT, and other program stakeholders to implement the planned data collection activities. Surveys, interviews, and focus groups will be conducted over a three-year period with eight (8) main stakeholder groups who use or are among the target audiences for the ATTCs’ services or are otherwise associated with the ATTC program (e.g., as ATTC partners); ATTC directors and staff; customers/recipients of ATTC services/activities; ATTC Advisory Board members; partners who collaborate with ATTCs in planning and delivering ATTC services/activities; directors of state substance abuse agencies; directors of treatment provider and recovery organizations and directors of provider associations; addiction educators; and cultural leaders involved in addiction treatment.

The data collection instruments have been constructed to include information related to each stakeholder group, as identified above, and are expected to yield diverse perspectives related to the processes and outcomes of the ATTC Program. As a condition of their grant, each ATTC was required to budget .25 FTE to participate in data collection for the national evaluation.

The evaluation will collect new data that is necessary for the evaluation and will also use data and information collected under existing program requirements. (Each ATTC is required to submit GPRA data at the end of each ATTC training and technical assistance event, meeting/conference and 30 days after each event; each ATTC will conduct a workforce survey; and each ATTC also submits an annual report. None of the new data collection activities will be redundant with these existing reporting requirements.) CSAT plans the following new data collection activities:

(1) Semi-structured interviews with ATTC directors and other ATTC staff (e.g., co-directors, ATTC technology transfer specialists, ATTC evaluator) that are conducted during site visits to each ATTC. The purpose of the interviews will be to collect information on:

a. Goals and objectives of the ATTC.

b. Regional priorities and needs for technology transfer services.

c. Processes used to plan ATTC programs and services.

d. Collaborative relationships with organizations within and outside the ATTC region.

e. Organizational structure and staffing of the ATTC.

f. ATTC funding and leveraging of resources.

g. Efforts to coordinate services with other providers of training, technical assistance, or technology transfer services within the region.

h. Technology transfer strategies and services implemented by the ATTC to promote adoption of culturally appropriate, evidence-based, and promising practices.

i. Implementation and use of workforce surveys.

j. Participation in cross-regional and network-wide activities.

k. Background characteristics of the respondent.

(2) Focus groups with ATTC staff (including field staff who are assigned to work with specific states and may work in different locations throughout the ATTC region), to include information on:

a. Regional priorities and needs for technology transfer services.

b. Processes used to plan ATTC programs and services.

c. Efforts to coordinate services with other providers of technology transfer services within the region.

d. Technology transfer strategies and services implemented by the ATTC to promote adoption of culturally appropriate, evidence-based and promising practices.

e. Background characteristics of focus group participants.

(3) Telephone interviews with a sample of stakeholders of the ATTC program, including state substance abuse directors (SSAs), ATTC Advisory Board members, addiction educators, directors of treatment provider associations, cultural leaders, and leaders of recovery associations. The