provisions, and obtain input from interested parties. Since establishing the docket over a year ago, the agency has received quite a few comments from its stakeholders on a number of MDUFMA provisions, including the application and refund of user fees. During the drafting of this guidance, the agency specifically solicited comments to the docket in recognition of the interest in this issue. The agency has considered all comments received to date and believes that the approach presented below is a fair application of its refund policy. FDA will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on user fees and refunds for 510(k)s. 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 statute and regulations.

III. Electronic Access

To receive ''User Fees and Refunds for Premarket Notification Submissions (510(k)s)'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1511) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This 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 USC 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB No. 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12103 Filed 5–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 14, 2004, 10 a.m.–5 p.m., EDT.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The full ACCV will meet on Monday, June 14, from 10 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–888–790–6041 on June 14 and providing the following information:

Leader's Name: Joyce Somsak.

Password: ACCV.

Agenda: The agenda items for June 14 will include, but are not limited to: a presentation on the Institute of Medicine's Immunization Safety Review Committee Report, ''Vaccines and Autism''; an overview of the Centers for Disease Control and Prevention's and the National Institutes of Health's research on thimerosal; an overview of the Vaccine Adverse Event Reporting System (VAERS) reports for influenza vaccine; a presentation on adding the influenza vaccine to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation, the Department of Justice, and the National Vaccine Program Office. Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, Room 16C–17, 5600 Fishers Lane, Rockville, MD 20857 or by e-mail at *clee@hrsa.gov*. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of his/her assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as time permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, Room 16C–17, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–2124 or e-mail: *clee@hrsa.gov.*

Dated: May 21, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–12082 Filed 5–27–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Special Diabetes Program for Indians Competitive Grant Program; New Request for Application of Funds

CFDA Number: 93.442.

Key Dates:

Letter of Intent Deadline: June 1, 2004.

Application Deadline: July 15, 2004.

Overview

The Indian Health Service (IHS) announces a new initiative under the Special Diabetes Program for Indians

(SDPI). This funding mechanism is a competitive grant program that will provide funding to selected SDPI grantees for a demonstration project to implement and evaluate defined activities in one of two areas (primary prevention of diabetes or prevention of cardiovascular disease in people with diabetes). The total amount of funding available is $23.3 million annually and the number of anticipated awards will be approximately 60 grants (30 for each demonstration project). Eligible applicants include grantees that have received SDPI funding. Applicants may submit one application per demonstration project (*i.e.*, primary prevention of diabetes or prevention of cardiovascular disease in people with diabetes). Therefore, while most programs will only submit one application for one demonstration project, some may choose to submit one application for each demonstration project, for a total of two applications. However, applicants will only be eligible to receive one award for funding for one demonstration project. Competing grant applications will be accepted with a receipt date of July 15, 2004. There will be only one funding cycle for the project period FY2005–FY2009. The anticipated start date for the awards will be September 29, 2004. Applications will be mailed to all current SDPI grantees on or before June 1, 2004, and will be available on request from the IHS Grants Management Branch and the IHS National Diabetes Program. The application will also be posted on the IHS National Diabetes Program website.

Awards will be subject to the availability of funds and grants will be administered in accordance with applicable Office of Management and Budget (OMB) Circulars, Department of Health and Human Services grant regulations at 45 CFR parts 74 and 92, the Public Health Service Grants Policy Statement, and other applicable IHS policies and procedures such as the regulations governing protection of human subjects at 45 CFR part 46.

This initiative is described in the Catalog of Federal Domestic Assistance Nos. 93.442. Sections 301(a) and 405 of the Public Health Service Act, as amended, authorize these awards, and these are administered under PHS grants policies and Federal Regulations 42 CFR parts 52c, 74, and 92.

The 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, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a 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 PHS mission to protect and advance the physical and mental health of the American people.

I. Funding Opportunity Description

The Indian Health Service (IHS) has developed a new competitive grant program under the Special Diabetes Program for Indians (42 U.S.C. 254c–3). In response to Congressional direction (letter to IHS Director dated February 10, 2003) from Rep. George R. Nethercutt, Chair of the Diabetes Caucus for Congress, and subsequent Conference Language the purpose of this initiative is to provide funding to selected SDPI grantees for a demonstration project to implement and evaluate defined activities in each of two intervention areas (primary prevention of diabetes or prevention of cardiovascular disease in people with diabetes).

1. Background

Diabetes is a serious problem for American Indians and Alaska Natives (AI/AN), and the prevalence of diabetes is increasing over time in this population (Burrows, 2000). In 1997, Congress appropriated funding in the amount of $30 million per year for the Special Diabetes Program for Indians (SDPI) to the Indian Health Service for the prevention and treatment of diabetes in AI/ANs (Roubideaux, 2001). This program of grants to Indian Health Service (IHS), tribal and urban Indian health programs has resulted in over 300 diabetes prevention and treatment programs in Indian communities. In 2003, Congress increased the SDPI funding to $150 million per year and directed the IHS to use a portion of the increase in funding for a ''competitive grant program'' to fund grantees to implement activities in two areas: (1) Primary prevention of diabetes; and (2) cardiovascular disease risk reduction in people with diabetes. In 2003, the Director of the IHS held a tribal consultation meeting to gather input from tribes on the SDPI competitive grant program. The resulting program is described in this Request for Applications.

2. Primary Prevention of Diabetes

Research studies have recently shown that the risk of developing diabetes can be reduced in at-risk individuals through lifestyle changes and medication. The Diabetes Prevention Program, a randomized clinical trial funded by NIH, recruited 3234 individuals with Impaired Glucose Tolerance (IGT) to receive a lifestyle modification program, metformin or usual care. The study announced results in 2002 that the lifestyle modification program was associated with a reduction in the risk of diabetes by 58 percent. Metformin reduced the risk of diabetes by 31 percent (Knowler, 2002). Forty-five percent of participants were from minority groups, and 171 individuals in this study were American Indian. Importantly, the beneficial effects of these interventions were equal in all groups enrolled in the study, including American Indians. Other smaller studies have also shown that lifestyle changes can reduce the risk of developing diabetes, such as the Finnish and Da Qing studies (Pan XR, 1997; Tuomilehto J, 2001).

3. Cardiovascular Disease Risk Reduction

Individuals with diabetes are at risk for cardiovascular disease (CVD), and the incidence of CVD in AI/ANs now exceeds rates in the general population. The Strong Heart Study, a longitudinal cohort study of the risk factors for cardiovascular disease in American Indians, has demonstrated that diabetes is a major risk factor and accounts for the majority of risk for cardiovascular disease events in American Indians (Howard, 1999). The risk of cardiovascular disease in individuals with diabetes can be reduced through control of blood pressure, reduction in cholesterol levels, glycemic control, aspirin use, smoking cessation, physical activity and weight management (ADA, 2004).

4. Summary of Demonstration Projects

Eligible Applicants

SDPI grant recipients are eligible to apply for the SDPI Competitive Grant Program if they are one of the following entities:

A. Indian Health Service hospital or clinic
B. Federally-Recognized Tribes
C. Title V Urban Indian Health Programs
D. Consortium of any of the above

Non-profit Tribal organizations and Area Indian/tribal health boards are not eligible to apply for these grants, consistent with recent tribal consultation on this issue. These organizations may be funded by eligible entities to assist with the demonstration project.

Eligible entities may apply for one or both demonstration projects, but will only be funded for one project (primary prevention of diabetes or cardiovascular

disease risk reduction). Eligible entities may only participate in a consortium once for each demonstration project area (primary prevention of diabetes or cardiovascular disease).

Setting

Applicants must demonstrate the following:

- Minimum burden of diabetes in population served—applicants must submit information to show that the burden of diabetes in their community is significant and justifies funding for this demonstration project, such as the user population of their health program, the number of individuals in their diabetes registry, and any other descriptive data quantifying the problem of diabetes in the population served. In general, successful applicants will have at least a user population of 2500 and/or a diabetes registry of at least 250 individuals. Eligible entities that have a diabetes registry of less than 250 people are encouraged to form a consortium with other eligible entities. In general, the minimum size of a consortium should be a total combined user population of ≥ 2500 and /or a total combined diabetes registry ≥ 250.
- Prior success in diabetes prevention and treatment activities—applicants must demonstrate prior successful activities to prevent or treat diabetes, including a description of the activities, any evaluation or outcomes so far, and evidence of successful compliance with SDPI requirements.
- Basic health infrastructure to participate in project—the applicant must demonstrate that the following basic health infrastructure is in place or a plan for putting it into place with this funding mechanism:
- Clinical services—such as a health clinic or center
  - Laboratory—available for testing associated with the demonstration project.
  - Administrative and financial staff to manage and monitor the project.
  - Health professionals—on site health educator/diabetes educator, dietitian, physical activity specialist, full-time clerk/recruiter for this project, and physician consultant.
  - Pharmacist—available for project.
  - Data Coordinator—at least one person on site to manage data collection for the project and to report data to Coordinating Center.
  - RPMS site manager to use DMS, Lab, and Pharmacy packages.
  - Additional staff are recommended for each demonstration project:
  - Primary Prevention of Diabetes—diabetes educator and/or nurse to teach curriculum.
  - Cardiovascular Disease Risk Reduction—nurse case manager(s).

Structure

The overall structure of the SDPI Competitive Grant Program will include:

- IHS National Diabetes Program—general oversight, coordination and leadership of SDPI Competitive Grant Program.
- IHS Grants Management Branch—general oversight of grant administration, financial audits, monitoring and reporting.
- Grantees—approximately 30 grantees in each of the two demonstration projects, approximately 60 total grantees.
- Coordinating Center—responsible for day-to-day coordination of data collection, evaluation, and certain logistics related to the Competitive Grant Program activities.
- Resource Center—responsible for providing technical assistance to grantees, including availability of medical experts related to the activities of the project.

Organizational Chart for SDPI Competitive Grant Program

See Section VIII—Other Information.

5. Description of Each Demonstration Project

In the following section, the primary prevention of diabetes demonstration project will be described first in terms of the participants and planned activities. Then, the cardiovascular disease risk reduction demonstration project will be described in a similar manner.

Primary Prevention of Diabetes

Participant Eligibility, Recruitment, and Retention (Participants in demonstration project activities). Applicants must provide a plan for identifying, recruiting, screening and retaining individuals at risk for diabetes to participate in activities to prevent diabetes. Individuals recruited to participate in the activities of the primary prevention of diabetes demonstration project must meet the following criteria:

- Age > 18.
- At Risk for Diabetes/Pre-Diabetes—grantees will screen individuals at high risk for developing diabetes and recruit them to participate in activities to prevent diabetes as follows:
  - Screening for pre-diabetes—individuals with any of the following risk factors for diabetes or components of the Metabolic Syndrome will be identified and screened for pre-diabetes:
    - Family member with diabetes.
    - Prior diagnosis of gestational diabetes.
    - Any component of Metabolic Syndrome (Grundy, 2004):
    — Overweight or Obesity, especially abdominal obesity (BMI > 30; waist circumference > 40 inches in men and 35 inches in women; or waist:hip ratio > 0.9 in men, 0.85 in women).
    — Blood pressure ≥ 130/85 mm Hg or previous diagnosis of hypertension.
    — Fasting glucose ≥ 100 mg/dl.
    — Low HDL Cholesterol (< 40 mg/dl in men, < 50 mg/dl in women).
    - High Triglycerides (≥ 150 mg/dl).
  - While fasting blood glucose may be used for screening, the diagnosis of pre-diabetes will be by Oral Glucose Tolerance Test (2-hour blood glucose: 100–125 mg/dl = IFG; 140–199 mg/dl = IGT). For further information on the definition of pre-diabetes, see Section VIII—Other information.
  - Intensive activities—individuals who are screened and diagnosed with pre-diabetes [Impaired Glucose Tolerance (IGT) or Impaired Fasting Glucose (IFG)] will be recruited to participate in intensive diabetes prevention activities.
  - Less-Intensive, community/group activities—All Individuals with risk factors for diabetes, but not diagnosed with pre-diabetes, will participate in other less intensive diabetes prevention activities in the demonstration project.
  - Individuals with the diagnosis of diabetes are not eligible to participate in the diabetes prevention activities and should be referred to the local health facility for diabetes care services.
- Exclusion Criteria—individuals not eligible to participate in the activities of the demonstration project will include:
  - Current diagnosis of pregnancy.
  - Active alcohol or substance abuse by provider judgment.
  - End Stage Renal Disease on Dialysis.
- Recruitment of participants—grantees will develop strategies to recruit eligible individuals to participate in activities. Some of these activities may include:
  - Sending an invitation letter after identification of eligible individuals for possible participation using RPMS or other clinic records, consistent with HIPAA regulations.
  - Advertisements in local media sources, including radio, newspaper.
  - Recruitment during screening or health events in the community.
  - Targeted home visits to eligible individuals, perhaps by Community Health Representatives.
  - Recruitment activities will be further refined and clarified through a

collaborative process with grantees during the first (planning) year of the demonstration project.

- Target Number(s) of Participants

○ Primary Prevention of Diabetes—grantees will be required to recruit, screen and enroll individuals at risk for diabetes to reach minimum recruitment goals as follows: For the intensive activity, the 16-week DPP-Like curriculum will be taught on average twice a year for 12 people with pre-diabetes. The class can be taught twice in one week (same content) to help reduce attrition. For example, 12 people per class, times 2 classes per week, times 2 curricula per year, equals a minimum of 48 people participating in the intensive activity per year, 144–192 people over 3–4 years.

○ The exact target numbers of participants will be determined through a collaborative process with grantees in the first (planning) year of the demonstration project.

- Retention Plan

Grantees will meet in the first year (planning year) to discuss plans for retention of participants in a collaborative process.

Description of Primary Prevention Demonstration Project Activities. Grantees will be required to implement all components of the activities described below:

- Intensive Activities—individuals diagnosed with pre-diabetes will undergo an intensive diabetes education intervention similar to the Diabetes Prevention Program. The key components of this educational intervention include the following:

○ Initial physical exam and baseline weight, height, laboratory tests and other measures.

○ Intensive education curriculum—modeled after the DPP 16-week curriculum but using a group approach, taught by a diabetes educator and/or nutritionist and/or physical activity specialist, weekly for 16 weeks, then quarterly classes. Curriculum may be offered for an average of 12 individuals at a time, repeated once during week, so that the total number of participants averages 24 for the duration of the curriculum. The curriculum will be offered up to 3 times per year.

○ Individual coaching sessions—participants will meet with coach monthly during curriculum and quarterly thereafter to review progress, encourage retention, use tool box strategies for motivation/retention, and meet with family at least once.

- Less Intensive/Community/Group activities—individuals with pre-diabetes and those at risk for diabetes will participate in community based motivational activities such as monthly walks, health fairs, competitions, etc. Families can participate in these activities, and diabetes prevention awareness activities should be incorporated. This activity provides an opportunity for the grantees to tailor activities to community needs.

Cardiovascular Disease Risk Reduction

Participant Eligibility, Recruitment, and Retention (Participants in demonstration project activities). Applicants must provide a plan for identifying, recruiting, and retaining individuals with diabetes to participate in activities to reduce the risk of cardiovascular disease. Individuals recruited to participate in the activities of the cardiovascular disease risk reduction demonstration project must meet the following criteria:

- Age > 18.
- Diabetes and At Risk for Cardiovascular Disease—grantees will recruit participants who meet the following criteria:

○ Diagnosis of type 2 diabetes.

○ Individuals with the diagnosis of type 2 diabetes and any components of the Metabolic Syndrome and/or a prior history of CVD may serve as a special group in this project.

○ Intensive Activities—individuals with diabetes will be recruited to participate in an intensive clinical activity to reduce their risk for cardiovascular disease.

○ Less Intensive/Community Activities—Individuals at risk for diabetes and/or cardiovascular disease will be recruited to participate in community-based activities to raise awareness of the risk of cardiovascular disease in those with diabetes.

- Exclusion Criteria—individuals not eligible to participate in the activities of the demonstration projects will include:

○ Current diagnosis of pregnancy.

○ Active alcohol or substance abuse by provider judgment.

○ End Stage Renal Disease on Dialysis.

- Recruitment of participants—grantees will develop strategies to recruit eligible individuals to participate in activities. Some of these activities may include:

○ Sending an invitation letter after identification of eligible individuals for possible treatment using RPMS or other clinic records, consistent with HIPAA regulations.

○ Advertisements in local media sources, including radio, newspaper.

○ Recruitment during screening or health events in the community.

○ Targeted home visits to eligible individuals, perhaps by Community Health Representatives.

○ Recruitment activities will be further refined and clarified through a collaborative process with grantees during the first (planning) year of the demonstration project.

- Target Number(s) of Participants

○ Grantees will be required to recruit and enroll individuals with diabetes into this intensive activity to meet recruitment goals as follows: The minimum diabetes registry will be 250, therefore, the minimum number of people with diabetes to recruit is 150–200 over the duration of the project (50 people per year), after exclusions and attrition.

○ The exact target numbers of participants will be determined through a collaborative process with grantees in the first (planning) year of the demonstration project.

- Retention Plan

○ Grantees will meet in the first year (planning year) to discuss plans for retention of participants in a collaborative process.

Description of Cardiovascular Disease Risk Reduction Demonstration Project Activities. Grantees will be required to implement all components of the activities described below:

(1) Intensive Activities—individuals with type 2 diabetes will undergo an intensive, clinical and case management approach to reducing their risk factors for CVD. The key components of this activity include the following:

(a) Initial physical exam and baseline weight, height, laboratory tests, ECG and other measures.

(b) Intensive case management approach—this clinic/health center, team-based strategy to reducing risk factors for diabetes will include a case management approach in which key risk factors for CVD will be monitored and treated to recommended targets at monthly clinic visits. The strategies and targets will include:

i. (i) Blood pressure control (< 130/80) through diet and/or medication as indicated.

ii. (ii) Lipid reduction (LDL < 100; HDL > 40; Triglycerides < 150) through diet and/or medication as indicated.

iii. (iii) Glycemic control (A1C < 7.0) through diet and/or medication as indicated.

iv. (iv) Weight management/reduction including nutrition and physical activity (BMI < 30; Waist circumference < 40 inches in men, 35 inches in women).

v. (v) Smoking cessation in those who smoke.

vi. (vi) Aspirin use daily as indicated.

vii. (vii) Stress reduction/management as indicated.

viii. (viii) Clinic visits for individual treatment monthly (risk reduction

phase), then quarterly if targets met (risk maintenance phase).

ix. (ix) Flowsheets will be used to manage and monitor risk factors and treatment.

x. (x) Education on diabetes and CVD risk reduction—can occur in individual or group visits.

xi. (xi) Participants will follow a schedule of regular laboratory tests and other measures.

(2) Less Intensive/Community awareness activities—individuals identified to be at risk for diabetes or cardiovascular disease and the participants and their families will participate in community-based awareness activities that help educate the community on ways to reduce their risk of diabetes and/or cardiovascular disease. This provides an opportunity for the grantees to tailor activities to community needs.

6. Evaluation of Demonstration Projects

The Congressionally mandated evaluation of the SDPI Competitive Grant Program demonstration projects will include the following components:

A. Process Evaluation—documentation of the implementation of, and participation in, all activities.

B. Outcome Evaluation—the design of the outcome evaluation is dependent on the duration of the demonstration projects. Since the initiative is funded for only 5 years, with the first year being a planning year and the last year being partially a dissemination year, the duration of the actual demonstration project activities then will be approximately 3–4 years. Given this timeline, only short and intermediate outcome will be actively measured. Long term outcome (*e.g.*, changes in incidence and/or event rates) will be identified, codes will be established, and a tracking system will be developed within RPMS for evaluation beyond the 5 years of the project. Measurement will include comparisons over time (time series design) and comparisons between participants and non-participants (case-control design). Data collection will include primary data collection of key measures for each initiative and analysis of existing data including RPMS data (DM, Lab, Pharmacy packages) and the IHS Diabetes Care and Outcomes Audit. Evaluation measures will be further defined through a collaborative process in the first (planning) year and collection of data for certain measures will be required of all grantees. Key measures for each initiative may include:

(1) Primary Prevention of Diabetes—baseline and yearly OGTT, weight, height, BMI, waist circumference, waist-hip ratio, assessment of participation in physical activity, body fat measurement, blood pressure, lipid panel, knowledge of diabetes and its prevention, barriers and challenges to participation, food intake/exercise journals.

(2) Cardiovascular Disease Risk Reduction—baseline and quarterly A1C, blood pressure, lipid levels, weight, height, BMI, waist circumference, waist-hip ratio, liver/kidney function testing, smoking status, assessment of participation in physical activity, body fat measurement, knowledge of cardiovascular disease and its prevention, barriers and challenges to participation, food intake/exercise journals.

7. Participant Protections and Institutional Review Board Approval

Applicants must describe their procedures relating to Confidentiality, Participant Protection, the Protection of Human Subjects Regulations, and compliance with Health Insurance Portability and Accountability Act (HIPPA) regulations, using the guidelines provided below. Problems with confidentiality, participant protection and protection of human subjects identified during peer review of the application may result in the delay of funding. Further guidance on this topic is provided in the description of the content and format of the application—Section IV.

8. Report of Results and Dissemination of Effort

Given the importance of the outcomes of this demonstration project to future funding of the SDPI, particular emphasis will be placed on the timely and comprehensive reporting of results through a variety of mechanisms. These mechanisms include, but are not limited to: Internal NDP/IHS reports, regular briefings of the TLDC, Congressional testimony and supporting documentation, presentations to appropriate advocacy groups, other potential funding agencies, other SDPI grantees, I/T/U diabetes programs and scientific presentations/publications. Consistent with the government-to-government relationship between the federal government and tribes, all reports, presentations, and manuscripts for publications will be provided to the appropriate tribal or local organizational authority for review and approval prior to dissemination. However, by virtue of application under this announcement, and as a condition of award, grantees must agree to conduct said review within 30 days of notice of intent to disseminate. Failure to respond will be treated as concurrence and dissemination will proceed as proposed.

Given the diversity and need for culturally appropriate activities, some of the specifics of the project activities will be developed through a collaborative process in the first (planning) year. Grantees must agree to attend at least quarterly meetings in the first year, and at least one annual meeting thereafter. Applicants should include travel costs for these required meetings in their proposed budgets.

Timeline

PGY–01 (FY2005, FY2004 funding): Planning Year

PGY–02—PGY–4 (FY2006–2008, FY2005–2007 funding): Demonstration Project Activities

PGY–05 (FY2009, FY2008 funding): Dissemination/Training

II. Award Information

The SDPI Competitive Grant Program will provide funding for selected SDPI grantees to demonstrate the implementation of a set of defined activities in one of two areas:

A. Primary Prevention of Diabetes

B. Prevention of Cardiovascular Disease in People With Diabetes

The total estimated amount of funding available for each year of this initiative is $23.3 million and the number of anticipated awards will be approximately 60 grants. The expected amount of individual awards will vary based on the size of the program, and will range from $250,000 to $400,000 per year in total costs (direct and indirect costs combined). Applicants may request up to but no more than $400,000 in total costs (direct and indirect costs combined) per year in any year of the grant project. The actual amount may vary, depending on availability of funding, projected target numbers of participants, unanticipated program requirements, the number and quality of applications received, and the final judgment of the IHS National Diabetes Program. A sample budget is included in Section VIII—Other Information. Competing grant applications will be accepted with a receipt date of July 1, 2004. There will be only one funding cycle for FY2004–FY2008. The anticipated start date for the awards will be September 29, 2004. This funding will be awarded as a grant, renewable annually for up to 5 years. The IHS NDP will determine if grants are renewable after 5 years depending on funding levels and congressional actions. Therefore, awards may be requested for up to 5 years of support. Applicants should request the first year

as a planning year, and the next 4 years as full implementation of demonstration project activities. A sample budget is included in Section VIII—Other Information.

Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS. The responsibility for planning, directing and executing the program, as well as data acquisition and analysis and evaluation of the proposed program, lies solely with the applicant organization. However the grantee must comply with IHS National Diabetes Program requirements for implementation of the intervention and the evaluation.

Annual continuation of awards will depend on availability of funds, grantee progress meeting goals and objectives, and timely submission of requested data and reports.

III. Eligibility Information

1. Eligible Applicants

Applicants eligible to receive an award under this announcement are SDPI grantees. The applicant must be one of the following:

A. Indian Health Service program (hospital or clinic)
B. Federally-Recognized Tribe
C. Title V Urban Indian Health Program
D. A Consortium of any of the above

If one of the above entities is sanctioned to serve as an applicant for more than one SDPI grantee(s), then a letter of support must be included in the application from each SDPI grantee the applicant is representing. The letter must specifically state that the applicant is officially representing that SDPI grantee in this application. Applicants for consortia who do not submit these letters of support at the time of the application receipt date will not be reviewed and are ineligible for the award. If an SDPI grantee sanctions a consortium to apply, that SDPI grantee may not submit another application by itself. Smaller applicants are encouraged to apply as a consortium, especially if their diabetes registry is < 250.

Applicants are strongly encouraged to establish eligibility of their proposed applications prior to submission. Inquiries about eligibility should be addressed to Mary Tso at the National Diabetes Program, (505) 248–4182.

Applicants that are not SDPI grantees are not eligible. Non-profit tribal organizations or national/area health boards are not eligible, consistent with recent tribal consultation on this issue.

Applications that do not meet these eligibility requirements will be returned to the applicant without further review.

2. Cost Sharing or Matching

The proposed application may include additional affiliated organizations to implement the activities of the demonstration project, and these organizations may include colleges or universities, additional tribes, or other Indian organizations/health boards. Applicants must include letters from these affiliated organizations indicating their agreement to participate in this project. The applicant must include information on any cost sharing and/or funding for subcontracts to these organizations in the budget.

Applicants must submit a letter indicating their agreement to work with the SDPI Competitive Grant Program Coordinating Center and comply with all requirements for implementation of the interventions and the collection of data for the evaluation. A sample letter is included in the application materials.

3. Other

Other Applicant Requirements

The applicant must be an SDPI grantee that has demonstrated prior compliance with SDPI grant requirements.

The Project Director, the individual responsible for the administration (including fiscal management) of the overall project, must have his/her primary appointment with the applicant organization. Special arrangements of employment, such as interorganizational personnel agreements, are permissible. The Project Director may be, but is not required to be, the Project Coordinator.

The Project Coordinator is the individual responsible for the day-to-day leadership and management of the activities within the project.

The Project Coordinator for the application must meet the following requirements:

- A relevant health professional degree.
- Experience with project management, including skills in project coordination, budgeting, reporting and supervision of staff.
- Working knowledge of diabetes, or a plan to receive relevant training.

Tribal Approval of Application/Letters of Support

It is the policy of the IHS that all projects involving AI/AN Tribes be approved by the Tribal governments with jurisdiction. Therefore, the following documentation is required as a part of this application:

- For a federally recognized Indian Tribe—a resolution of support from the Tribal government must be part of the application. Applications that involve more than one Indian Tribe must include resolutions of support from all participating Tribes.
- For an eligible consortium of Tribes—a resolution of support from each Tribe of the consortium must be included.
- For Title V Urban Indian health programs—a letter of support from the program's board must be included.
- For IHS hospitals or clinics—a letter of support from the Service Unit Director or Chief Executive Officer must be included.
- For all applicants—letters of support from all partners and collaborating entities.

Mechanism of Support

Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS. The responsibility for planning, directing, and executing the program, as well as data acquisition and analysis and evaluation of the proposed program, lies solely with the applicant organization. The maximum grant period may not exceed five years, with the opportunity for a competing renewal at the end of that period if Congressional funding continues.

IV. Application and Submission Information

1. Address To Request Application Package

Applications will be sent to all SDPI grantees. Applications may be requested at the following addresses:

- Denise Clark, Grants Management Branch, Indian Health Service, Reyes Building, 801 Thompson Avenue, Suite 100, Rockville, MD 20852–1627 (ZIP Code is unchanged for express/courier services), Telephone: (301) 443–5204.
- Area Diabetes Consultants within each IHS Area Office. Contact information for Area Diabetes Consultants is available on the IHS Web site at: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.asp*.
- Applications will also be posted on the IHS National Diabetes Program Web site at: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.asp*.

2. Content and Format of Application Submission

The application for this initiative must follow a required format that includes:

- SF 424 Application Forms; and
- Application Narrative and Supporting Documentation.

The order of the application must follow the format below:

• SF 424 Face page.

• Applicant contact and administrative information.

• DUNS Number—As of October 1, 2003, applications must have a DUNS and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number may be obtained by calling (866) 705–5711 or through the Web site at *http://www.dunandbradstreet.com/*. The DUNS number should be entered on the SF 424 face page. Internet applications for a DUNS number can take up to 30 days and this could cause organizations to lose opportunities to apply, or delay them. It is significantly faster to obtain one by phone. You will need the following information to request a DUNS number:

• Organization name.

• Organization address.

• Organization telephone number.

• Name of CEO, Executive Director, President, etc. (the person in charge).

• Legal structure of the organization.

• Year organization started.

• Primary business (activity) line.

• Total number of employees.

• SF 424A Budget pages—Summary budget by category (a more detailed, line-item budget is required below in Supporting Documentation listed below).

• Application Narrative: the applicant must include narrative (written) responses to the following questions/statements:

• Statement of Need (10 points).

■ State the demonstration project for which you are applying (primary prevention of diabetes or cardiovascular disease risk reduction—only one demonstration project per application).

■ Clearly identify yourself or your consortium as the applicant and indicate the basis for its eligibility under this initiative as described above in Section III.

■ Define the target populations that will receive and participate in the demonstration project and provide a rationale for selecting those target populations, as well as the geographic area to be served. (**Note:** Extensive demographic information is not required.) If you plan to focus on a specific segment of the at-risk community, explain why this is necessary or desirable. Include a description of Tribe(s) or communities served. If the applicant is a consortium, describe all partners and communities served.

■ Describe the burden of diabetes, the nature of the problem and extent of the need for the demonstration project in the target population(s). Documentation of need may come from quantitative as well as qualitative sources. The quantitative data could come from community assessments you or others have conducted, or from local data or trend analyses, diabetes registry numbers and/or IHS Diabetes Care and Outcomes Audit data. Qualitative sources could include focus groups and key informant interviews you or others have conducted with the targeted community, as well as anecdotal reports. Based on your quantitative and qualitative findings, discuss your understanding why and how your community or population served is affected by diabetes and the issues facing the targeted individuals, family members/significant others, and community.

○ Organizational and Community Readiness and Feasibility (10 points)

■ Discuss previous efforts to address the problem of diabetes in the community, the capability and experience of the applicant organization and other participating organizations with similar projects and populations, including experience organizing and mobilizing the community, and providing relevant diabetes services, as well as culturally appropriate/competent services.

■ Describe your previous efforts at organizing and mobilizing the targeted individuals, families, and community (by your organization and/or others), and explain why you think the community is ready to participate in this particular approach to preventing diabetes or cardiovascular disease.

■ Describe the extent to which the community indicates support for your proposed project.

■ Describe the extent to which other stakeholders indicate support for your proposed project. Identify categories of stakeholders—for example, treatment and other professional groups, civic groups, governmental organizations, faith-based groups, and others—and discuss the role you expect them to play in the project. (You should include letters of support showing stakeholder interest in the project with this application).

○ Project Approach (30 points)

■ Clearly state the purpose, goals, and objectives of your proposed demonstration project activities. Describe how achievement of goals will produce meaningful and relevant results (*e.g.,* decrease the incidence of diabetes or cardiovascular disease, increase individual and community involvement; help increase healthy behaviors; increase support for sustained community awareness and involvement, *etc.*).

■ Discuss and explain the core values that will guide the implementation of project activities, and explain how each of these values will be operationalized. At a minimum, discuss each of the following as it relates to the proposed project: (a) Healthy lifestyles; (b) participatory process; (c) authentic community voice; (d) leadership development; and, (e) cultural context for engaging and involving individuals and community. You may identify and discuss other values important to your targeted individuals and community.

■ Describe how the demonstration activities will be implemented for the area you selected (primary prevention of diabetes or cardiovascular disease prevention) for both the intensive and community level activities as described in Section I. Funding Opportunity Description. Clearly explain each activity you plan to provide, in terms of mobilizing and engaging the community, screening eligible participants, and actual delivery of the activities. Demonstrate how the proposed activities will meet your goals and objectives.

■ Clearly state the unduplicated number of individuals you propose to serve (annually and over the entire project period) with grant funds. Applicants should propose to serve no fewer than 48 individuals with pre-diabetes per year for the primary prevention of diabetes project, or 50 individuals per year for the cardiovascular disease risk reduction project.

■ Describe how the target population will be identified, recruited, screened and retained.

■ Describe how the proposed project will address issues of age, race, culture, language, disability, literacy, and gender in the target population.

■ Describe how community members helped prepare the application, and how they will help plan, implement, and evaluate the project.

■ Discuss how you plan to develop effective partnerships with community organizations and other groups, so as to minimize duplication of services and perceived threats of encroachment on established ''territory.''

■ Describe the potential barriers to successful conduct of the proposed demonstration project and how you will overcome them.

○ Staff, Management, and Relevant Experience (30 points)

■ Provide a list of staff who will participate in the project, showing the role of each and their level of effort and qualifications. Include the Project

Director, Project Coordinator, and other key personnel as listed above (see Section 1, basic health infrastructure). Provide an organizational chart for the administration of the project. Describe any plans for recruitment of key personnel not already on staff in your health program.

■ Show that the necessary groundwork (*e.g.,* planning, consensus development, memoranda of agreement, identification of potential facilities) has been completed or is near completion so that the project can be implemented and the demonstration project can begin as soon as possible, and no later than 12 months after grant award. If applicable, identify any cash or in-kind contribution that you or your partnering organizations will make to the project.

■ Describe the resources available for the proposed project (*e.g.,* facilities, equipment), and provide evidence that services will be provided in a location that is adequate, accessible, compliant with the Americans with Disabilities Act (ADA), and amenable to the target population.

■ Provide a proposed timeline for Years 1–5 of the project (table, chart or graph), which corresponds to Year 1 (Planning Year) and Years 2–5 (Implementation of activities) showing key activities, milestones, and responsible staff. (**Note:** The timeline should be part of the Project Narrative. It should not be placed in an appendix). Please note that some details in the timeline may be modified after the collaborative process in the planning year; therefore, for this application, please propose a timeline for your activities.

○ Capacity Building (10 points)

■ Describe how the demonstration project activities supported by this grant will fit with other existing services or programs.

■ Describe how the proposed demonstration project will build upon and complement existing private, Tribal, and/or IHS services in your community.

■ Indicate the gaps that the demonstration project activities supported by this grant will fill or the manner in which they will extend/expand current efforts.

■ Identify new knowledge and skills that staff and local programs will acquire by participating in this demonstration project.

■ Describe strategies for sustaining the demonstration project activities beyond the project period if Congress does not continue funding for this initiative after 2008.

○ Evaluation and Data (10 points)

■ Document your ability to collect, manage, and report on required evaluation measures as outlined above (use examples listed in Section I). The IHS/NDP will provide the necessary protocols and forms for collecting and reporting data, so you do not need to include data collection forms in your application. Describe current use of RPMS, and whether you are using the RPMS packages such as pharmacy, laboratory and DMS. If you are not using RPMS, please describe your current health data system and its compatibility or comparability to RPMS.

■ In general terms, describe any experience in collecting similar data, in its quality control, and transfer to external programs such as the IHS/NDP.

■ Describe the local process for reviewing and approving all reports and publications based on data such as these.

Provide appropriate assurance/commitment as to compliance with the required review timelines.

○ Supporting Documentation:

■ Detailed Budget, for Years 1–5, to include the following items:

■ Staff/Personnel
■ Travel
■ Equipment
■ Supplies
■ Operational Costs
■ Consultant
■ Contractual
■ Total Direct Costs
■ Indirect Costs
■ Total Budget Amount
■ Budget Justification

■ **Note:** Although the budget for the proposed project is not a review criterion, the Review Group will be asked to comment on the appropriateness of the budget after the merits of the application have been considered. The final amount of the award will vary based on factors as detailed in Section II. A sample budget is included in Section VIII—Other Information.

○ Position descriptions of key personnel and CV/resumes of identified key personnel.

○ Required documentation, including:

■ Letters of support from key stakeholders

■ Tribal resolutions or equivalent (urban board, IHS SUD/CEO).

○ Assurances (SF424 Forms).

Participant Protection Plan

Applicants must describe their procedures relating to Confidentiality, Participant Protection, and Health Insurance Portability and Accountability Act (HIPPA) regulations, using the guidelines provided below. Problems with confidentiality, participant protection, and compliance with HIPPA regulations identified during review of the application may result in the delay or denial of funding.

All Applicants must address each of the following elements relating to confidentiality and participant protection. The application must briefly document how these requirements will be addressed or why they are not applicable.

○ Protect Clients and Staff from Potential Risks

• Identify and describe any foreseeable physical, medical, psychological, social, legal or other risks or adverse affects.

• Describe the procedures that will be followed to minimize or protect participants against potential risks, including risks to confidentiality.

• Identify plans to provide help if there are adverse effects to participants.

○ Fair Selection of Participants

• Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background and note if the population includes pregnant women or other vulnerable groups.

• Explain the reasons for including or excluding participants.

• Explain how participants will be recruited and selected. Identify who will select participants.

• Please remember that the grant must be used to serve only those eligible under applicable statutes and regulations. If a Tribe contracting for IHS programs under the Indian Self-Determination and Education Assistance Act attempts to add this grant to the Title V funding agreement after award, an appropriate eligibility determination must be made by the Tribe and IHS before ineligibles may be served under 25 U.S.C. 1680c(b)(1)(B).

○ Absence of Coercion

Explain if participation in the project is voluntary or required.

• If the project plans to pay participants, state how participants will be awarded money or gifts.

• State how participants will be told that they may receive services even if they do not participate in the project.

○ Data Collection

• Identify from whom data will be collected. Describe the potential settings for data collection.

• Identify what type of specimens (*e.g.,* blood) will be used, if any. Describe how the material will be monitored to ensure the safety of participants.

○ Privacy and Confidentiality

• Explain how privacy and confidentiality will be ensured. Include who will collect the data.

• Describe:

■ Where data will be stored.
■ Who will or will not have access to information.
■ How the identity of participants will be kept private, for example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.
○ Adequate Consent Procedures
• List what information will be given to individuals who participate in the project. Notice given to participants must, at a minimum, include:
■ The individual's right to a genuine, free, and independent choice among eligible providers, that includes the individual's right to an alternative provider to which the individual has no religious objection.
■ A description of the data to be collected, how the data will be used, and how the data will be kept private.
■ The participant's right to leave the project at any time.
■ Possible risks from participation in the project.
■ Plans to protect participants from these risks.
• Explain how consent will be elicited from people with limited reading skills, and people who do not use English as their first language.

Note: If the project poses potential physical, medical, psychological, legal, social or other risks, written informed consent is necessary.

• Indicate if informed consent will be requested from participant. Describe how the consent will be documented. For example: Will consent forms be read? Will prospective participants be questioned to be sure they understand the forms? Will they be given copies of what they sign?

Note: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases the project or its agents from liability for negligence.

• Risk Benefit Discussion

Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

• Protection of Human Subjects Regulations

Applicants for the Competitive Grant Program are not required to address Protection of Human Subjects Regulations (45 CFR part 46). However, the IHS National Diabetes Program will conduct a cross-site evaluation of the Competitive Grant Program Grantee activities. The evaluation may require grantees to comply with the Protection of Human Subjects Regulations, consistent with an evaluation design to be developed. In that event, the IHS National Diabetes Program will assist grantees in obtaining Institutional Review Board (IRB) approval for their projects.

Additional information about Protection of Human Subjects Regulations can be obtained on the Web at *http://ohrp.osophs.dhhs.gov*. Applicants may also contact OHRP by e-mail *ohrp@osophs.dhhs.gov* or by phone (301) 496–7005.

• References—list any references cited in the application narrative

• Appendix items—include any additional required or supplementary materials not already included in the format for the application

The total length of the Application Narrative should not exceed 15 pages, typed, single spaced, in size 11–12 font in Arial or Times New Roman, with 1 inch margins, on 8 x 11.5 inch paper. The application should be assembled in the order as listed above.

Applicants must send the original application by mail to IHS Grants Management Branch and 2 copies of the application by mail to the IHS National Diabetes Program.

3. Submission Dates and Times

A. Letter of Intent Deadline: June 1, 2004

Prospective applicants are asked to submit a letter of intent that includes the selected demonstration project for the application (primary prevention of diabetes or prevention of CVD in people with diabetes), the name, address, and telephone number of the Project Director and its Project Coordinator, and the number and title of this RFA. The letter of intent must be received by the IHS National Diabetes Program, 5300 Homestead Rd, NE., Albuquerque, NM, 87110, telephone (505) 248–4182, FAX (505) 248–4188, e-mail: *mary.tso@mail.ihs.gov*, before 6 m.d.t. on June 1, 2004. Letters may be submitted by mail, fax or e-mail.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows the IHS staff to estimate the potential review workload and avoid conflict of interest in the review.

B. Application Due Date: July 15, 2004

The applications must be received before 6 p.m. m.d.t. on July 15, 2004. If an application is received after that date, it will be returned to the applicant without review. To be considered timely, an application must be received on or before the deadline date. No additional materials received after the deadline will be considered. Applications not meeting the deadline date specified in the announcement are considered late applications and will not be considered for funding under the announcement.

Receipt of applications will be acknowledged by postcard.

4. Intergovernmental Review

This funding opportunity is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' A State approval is not required.

5. Funding Restrictions

Allowable Administrative Costs

Certain administrative costs for managing a comprehensive program are allowable and may vary, depending upon the size and complexity of the program's activities. The costs budgeted for this grant may not duplicate items already budgeted in other cost centers, such as Facilities and Administration (F&A) or ''Indirect'' cost pool. The grantee receiving the award must be prepared to provide documentation showing the direct relationship of proposed costs to the program, and that costs of this type are charged in a uniform manner.

Allowable Costs:

• Project Director, up to 25% effort
• Project Coordinator, up to 50% effort
• Project Director, Project Coordinator, and key personnel travel to 4 grantee meetings in the first (planning year) and 1 meeting per year during Years 2–5 in Albuquerque or another location determined by the Coordinating Center. Applicants should not assume that they will be able to drive to these meetings if the location of these meetings is not in Albuquerque. To ensure enough funding is budgeted for travel to grantee meetings, applicants may project costs assuming Washington, DC, is the location for these meetings.
• Limited salary support for secretarial or clerical help is allowable only when in direct support of the proposed project. For guidance, applicants should refer to the OMB Circular appropriate for them, A–87 (Cost Principles for State, Local, and Indian Tribal Governments), at *http://www.whitehouse.gov/omb/circulars* or A–122 (Cost Principles for Non-Profit Organizations), *http://www.whitehouse.gov/omb/circulars,* should contact the grants management officer under INQUIRIES.
• Data manager, up to 50% effort
• Other remaining key personnel as described above at percent effort

appropriate for scope of work at each site.

• Consortium and Contract Arrangements—subcontracts may be used to work with other entities to implement the project activities.

Unallowable Costs

• No construction activity is allowed.

Grantees will be allowed a reasonable period of time in which to submit required financial and performance reports.

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 the imposition of special award provisions, or cause other eligible projects or activities involving the grantee organization, or the individual responsible for the delinquency to not be funded.

Failure to obtain prior approval for change in Scope, Project Director, Project Coordinator, undertaking any activities disapproved or restricted as a condition of the award, may result in fund restrictions or termination.

6. Other Submission Requirements

Submit a typed and signed original application, including appendices and supporting documents, in one package to:

Grants Management Branch, Indian Health Service, Reyes Building, 801 Thompson Avenue, Rockville MD 20852–1627 (ZIP Code is unchanged for express/courier services), Telephone: (301) 443–5204.

Also, at the time of submission, send 222214 additional single-sided photocopied and signed applications, including the appendices and supporting documentation to: IHS National Diabetes Program, Indian Health Service, 5300 Homestead Road, NE., Albuquerque, NM 87110, Telephone: (505) 248–4182, FAX: (505) 248–4188.

V. Application Review Information

Upon receipt, IHS will administratively review applications for completeness and responsiveness. Applications that are incomplete, non-responsive to this RFA, do not meet eligibility criteria or do not follow the guidelines of the SF 474 will be returned to the applicant without further consideration.

Applications will be evaluated for technical merit by appropriate peer review groups convened by the IHS National Diabetes Program in accordance with the criteria stated below.

1. Criteria

Priorities for funding will be based on the technical merit of the application, the assessed potential of the applicant and the likelihood of the applicant to successfully implement the defined interventions. Awards will be made only to applicants with financial management systems and management capabilities that are acceptable under PHS policy. Awards will be administered under the PHS Grants Policy Statement.

Applications will be reviewed and scored according to the quality of their responses to the requirements listed below for developing the application narrative. The number of points after each heading is the maximum number of points a review committee may assign to that section of the application narrative:

• Statement of Need (10 points).

• Organizational and Community Readiness and Feasibility (10 points).

• Project Approach (30 points).

• Staff, Management, and Relevant Experience (30 points).

• Capacity Building (10 points).

• Evaluation and Data (10 points).

Suggested content for each of the above sections of the Project Narrative are detailed in the application format section.

Reviewers will assess the application by considering the Application Narrative, Supporting Documentation, and Appendices.

2. Review and Selection Process

The IHS NDP will convene 2 review groups, one for each demonstration project in this initiative, which will consist of the following types of individuals:

• IHS staff.

• Tribal/Community representatives.

• Scientific experts.

The reviewers cannot be affiliated with any applicants.

The IHS National Diabetes Program will develop the review selection process consistent with the review criteria and will ensure appropriate representation of relevant expertise.

The Director of the IHS National Diabetes Program will make the final funding decisions in consideration of the following points, some of which were based on input from the Tribal consultation:

• The strengths and weaknesses of the application as identified by peer reviewers;

• The likelihood of success in implementation of the activities;

• Demonstrated capacity of the applicant for programmatic implementation;

• Availability of funds, and;

• Other factors based on Tribal consultation, including distribution of awards in terms of geography and balance among program size, program type (*i.e.*, IHS, Tribal, urban vs. rural, hospital vs. clinic, *etc.*).

3. Anticipated Announcement and Award Dates

Anticipated Selectee Date: August 30, 2004.

Anticipated Notice of Grant Award Date: September 29, 2004.

VI. Award Administration Information

1. Award Notices

Grants Management will not award a grant without an approved application in conformance with regulatory and policy requirements and 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 with special terms and conditions binding upon the award and refer to all general terms applicable to the award.

2. Administrative and National Policy Requirements

None.

3. Reporting

The IHS NDP and the Grants Management Office have requirements for the progress reports and financial reports based on the terms and conditions of this grant. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports, which are generally due annually. Financial Status Report (SF 269) is due 90 days after each budget period and the final SF 269 must have no unliquidated obligations and must indicate the exact balance of unobligated funds.

Grantees will be allowed a reasonable period of time in which to submit required financial and performance reports.

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 the imposition of special award provisions, or cause other

eligible projects or activities involving the grant recipient, or the individual responsible for the delinquency to not be funded.

Progress reports will be required on an annual basis.

VII. Agency Contacts

Questions on the SDPI Competitive Grant Program may be directed to: Mary Tso, National Diabetes Program, Indian Health Service, 5300 Homestead Road, NE., Albuquerque, NM 87110, Telephone: (505) 248–4182, FAX: (505) 248–4188, E-mail: *mary.tso@mail.ihs.gov.*

Questions on grants management and fiscal matters may be directed to: Denise Clark, Grants Management Branch, Indian Health Service, Reyes Building, 801 Thompson Avenue, Rockville MD 20852–1627, Telephone: (301) 443–5204, FAX: (301) 443–9602, E-mail: *dclark@hqe.ihs.gov.*

VIII. Other Information

1. Primary Prevention of Diabetes

Applicants are encouraged to learn more about the Diabetes Prevention Program through the following resources:

- Original journal article: Knowler WC, Barrett-Conner E, Fowler SE *et al.* Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine 2002; 346:393–403.
- Diabetes Prevention Program Results Press Release: *http://www.niddk.nih.gov/welcome/releases/8_8_01.htm.*
- Diabetes Prevention Program website with study documents, including lifestyle manuals: *http://www.bsc.gwu.edu/dpp/index.htmlvdoc.*

2. Cardiovascular Disease Risk Reduction

- Applicants are encouraged to familiarize themselves with the American Diabetes Association Clinical Practice Recommendations: *http://www.diabetes.org/for-health-professionals-and-scientists/cpr.jsp.*

3. The Indian Health Service National Diabetes Program

- Mission Statement—The mission of the IHS National Diabetes Program is to develop, document, and sustain a public health effort to prevent and control diabetes in American Indian and Alaska Native peoples.
- Applicants are encouraged to refer to the IHS National Diabetes Program website for further information, such as the standards of diabetes care or best practices documents: *http://www.ihs.gov/MedicalPrograms/diabetes/index.asp.*

4. Definition of Pre-Diabetes

The term ''Pre-diabetes'' is a lay term that was coined as a simple way to describe a group of people who are at very high risk for diabetes. Translated to slightly more precise clinical terms, pre-diabetes is used to classify people with blood glucose levels that are higher than normal but not yet in the diabetic range have ''pre-diabetes.'' Pre-diabetes may be impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), depending on the test used to diagnose it and the particular abnormality suffered by the patient. Not everyone with IGT has IFG, nor do all patients with IFG have IGT.

A fasting plasma glucose test measures plasma glucose after an overnight fast of at least 8 hours. This test is most reliable when done in the morning. Fasting glucose levels of 100 to 125 mg/dl are above normal but not high enough to be called diabetes. This condition is a form of pre-diabetes called impaired fasting glucose (IFG). IFG is considered a pre-diabetic state, meaning that the individual is more likely to develop diabetes but does not have it yet.

The oral glucose tolerance test (OGTT) consists of measures of plasma glucose levels after an overnight fast and after a glucose challenge. After a fast of 8 to 12 hours, blood glucose is measured before and 2 hours after drinking a glucose-containing solution, a glucola load of 75 grams or its equivalent. If the 2-hour blood glucose is within the range between 140 and 199 mg/dl, glucose tolerance is above normal but not high enough for diabetes. This condition, also a form of pre-diabetes, is called impaired glucose tolerance (IGT and, like IFG, it points toward a history of insulin resistance and a risk for developing diabetes.

5. Sample Budget

Applicants should submit a proposed budget for each year of this 5-year initiative. Year 1 will be a planning year, in which grantees prepare to implement activities. Years 2–5 will be for implementation of the proposed activities.

Applicants should include the following items in their budgets each year as appropriate for their selected area (primary prevention of diabetes or cardiovascular risk reduction) and activities.

- Personnel (may include funding for some or all of the following new staff and percent FTE for current staff to work on the demonstration project).
  - Project Director (up to 25%)
  - Project Coordinator (up to 50%)
  - Administrative Clerk/Recruiter (consider full time person)
  - RPMS Site Manager (only if not already funded by health program)
  - Health Educator/Diabetes Educator
  - Dietitian
  - Physical Activity Specialist
  - Pharmacist (CVD risk reduction)
  - Data Coordinator
  - Nurse Case Manager (CVD risk reduction)
  - Other

Funding for some of these positions may also be put in the consultant or contractual budget categories. Do not include funding for these positions if already paid through another source *i.e.* dietitian already on staff.

Include base salary, fringe benefits rate and amount, and total salary for each position.

- Travel (4 grantee meetings in Year 1, 1 grantee meeting each year in Years 2–5—assume Albuquerque and/or Washington DC for travel cost calculations).
- Equipment—as needed for project.
- Supplies (general office supplies, supplies needed for activities in project).
- Operational Expenses (consider incentives for activities, promotional items for both intensive and community based activities; consider buying computer equipment for this project, including internet access, for communication with Coordinating Center; other costs may include telephone, voice mail, computer support, shipping, copying, printing materials, etc).
- Consultants (for project staff if not already included in Personnel).
- Contractual (partners, collaborators).
- Total Direct (Sum of a–g).
- Indirect Costs (negotiated rate with BIA).
- Total Budget (Total Direct plus Indirect Costs).

6. Sample Participant Protection Plan

See Supplemental Instructions.

7. Organizational Chart for SDPI Competitive Grant Program

See Supplemental Instructions

8. Sample Letter of Support

See Supplemental Instructions.

9. References

American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2004; 27, Suppl 1: S15-S35.

Burrows NR, Geiss LS, Engelgau MM, Acton KJ. Prevalence of diabetes among

Native Americans and Alaska Natives, 1990–1997: an increasing burden. Diabetes Care 2000 Dec; 23(12):1786–90.

Grundy SM, Brewer HB, Cleeman JI, *et al.* Definition of Metabolic Syndrome. Report of the National Heart, Lung and Blood Institute/American Heart Association Conference on Scientific Issues Related to Definition. Circulation 2004;109:433–438.

Howard BV, Lee ET, Cowan LD *et al.* Rising tide of cardiovascular disease in American Indians. The Strong Heart Study. Circulation 1999;99:2389–95.

Knowler WC, Barrett-Connner E, Fowler SE *et al.* Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine 2002; 346:393–403.

Pan XR, Li GW, Hu YH, *et al.* Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance: the Da Qing IGT and Diabetes study. Diabetes Care 1997;20:537–544.

Roubideaux Y, Acton K. Diabetes in American Indians. In: Dixon M, Roubideaux Y. Promises to Keep: Public Health Policy for American Indians and Alaska Natives in the 21st Century. American Public Health Association, 2001.

Tuomilehto J, Lindstrom J, Eriksson JG, *et al.* Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance New England Journal of Medicine 2001; 344:1343–1350.

Dated: May 21, 2004.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 04–12083 Filed 5–27–04; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods for Producing Biliverdin

Michael L. Pendrak, David D. Roberts (NCI)

U.S. Provisional Application No. 60/554,369 filed 19 Mar 2004 (DHHS Reference No. E–040–2004/0–US–01)

Licensing Contact: Michael Ambrose; 301/594–6565; *ambrosem@mail.nih.gov.*

This invention details methods of use and composition of matter for preparing biliverdin. Biliverdin has been shown to have cytoprotective properties similar to bilirubin and can be used in the treatment of cardiovascular diseases, cancer, organ transplantation and other indications where inflammation occurs.

Incubating bilirubin with a bilirubin oxidase from various biological sources produces biliverdin. Like bilirubin, biliverdin has been shown to have these cytoprotective properties but is more soluble, reduced toxicity and as such, reduced side effects. Thus biliverdin is a safer alternative to bilirubin for therapeutic treatment of cardiovascular disease, cancers, inflammation and Alzheimer's in both human and non-human mammals.

The current technology involves methods of use and compositions of matter for the production and collection of biliverdin from microorganisms, including the yeast Candida albicans. Further claims include methods to enhance biliverdin production in microorganisms and use of biliverdin in the production of pharmaceuticals.

Vaccines Using Universally Inactivated Viruses, Parasites, and Tumor Cells

Yossef Raviv *et al.* (NCI)

U.S. Provisional Application filed 22 Mar 2004 (DHHS Reference No. E–303–2003/0–US–01)

Licensing Contact: Susan Ano; (301) 435–5515; *anos@mail.nih.gov.*

The current technology describes the universal inactivation of viruses, parasites, and tumor cells by hydrophobic, photoactivatable compounds. These non-toxic compounds, such as 1,5-iodoanpthylazide (INA), will selectively accumulate in the innermost regions of biological membrane bilayers, where the compounds will bind to proteins and lipids upon irradiation with light, thus inactivating deeply embedded proteins while maintaining integrity and activity of the proteins on the surface. This inactivation preserves the structural and conformational integrity and therefore immunogenicity of the agent in question, which overcomes a potential problem associated with some other vaccines such as those containing killed pathogens. Furthermore, the inactivation approach presented in this technology provides for a safe, non-infectious composition for vaccination against the corresponding agent, whereas some vaccines, such as those involving live-attenuated microbial agents, still have a risk of infectivity associated with them.

Quinoline Inhibitors of Retroviral Integrase

Drs. Yves Pommier and Christophe Marchand (both of NCI); Drs. Roberto Di Santo, Marino Artico, and Roberta Costi (all of Pharmacy University of Rome ''La Sapienza'')

U.S. Provisional Application filed 10 Mar 2004 (DHHS Reference No. E–187–2003/0–US–01)

Licensing Contact: Sally Hu; (301) 435–5606; *hus@mail.nih.gov.*

The subject invention describes certain diketo quinolin-4-1 derivatives and their use as integrase inhibitors in the treatment of HIV infection. The results of in vitro integrase inhibition studies show that these derivatives have significant anti-integrase activity (*e.g.*, an IC50 for strand transfer inhibition of not greater than 2 μM). Thus, these derivatives might be potentially important lead compounds for the development of integrase inhibitors. Since HIV integrase is an essential enzyme for effective viral replication, the development of such inhibitors of HIV integrase would thus potentially be useful and effective in the treatment of HIV infection.

Dated: May 21, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–12127 Filed 5–27–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the