Supporting Statement: Part A

Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities

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Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities

A1. Circumstances Making the Collection of Information Necessary

Diabetes is a group of diseases marked by high levels of blood glucose resulting from defects in insulin production, insulin action, or both. Diabetes can lead to serious complications and premature death, but people with diabetes can take steps to control the disease and lower the risk of complications. These steps include dietary management, increased physical activity (and medication, where indicated). The interventions are directly related the area of "nutrition, physical activity, obesity and food safety," which CDC describes as one of the "Six Winnable Battles" in public health.

Type 2 Diabetes was rare among American Indians until the 1950s. Since that time, diabetes has become one of the most common and serious illnesses among American Indians and Alaska Natives (AI/AN). In 2002, the age-adjusted prevalence of diabetes was 15.3 percent among AI/AN adults, in contrast to 7.3 percent for the overall U.S. population. Alarmingly, the prevalence of diabetes is increasing among younger AI/ANs. From 1994 to 2004, the age-adjusted prevalence of diagnosed diabetes doubled (from 8.5 to 17.1 per 1,000 population) among AI/ANs less than 35 years of age who used Indian Health Service healthcare services.

The explanations for high rates of diabetes among AI/ANs are not limited to recent societal trends and individual lifestyle choices – they are rooted in historical legacies of forced dispossession of lands, cultures, and languages. Understanding and acknowledging the complex array of environmental factors involved in diabetes causation and care are important steps in addressing this phenomenon. For example, many AI/AN communities describe environments of food insecurity and lack of access to healthy food choices. One reservation – the size of Connecticut – has only one grocery store.

Public health approaches that support healthy environments, by incorporating traditional knowledge and establishing healthy community policies, are needed to help prevent diabetes, and may also promote health in physical, mental, spiritual, and emotional dimensions. In 2008, the CDC's Native Diabetes Wellness Program (NDWP), in consultation with American Indian/Alaska Native tribal elders, issued a cooperative agreement entitled, "*Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities*." The "Traditional Foods" program seeks to build on what is known about traditional ways in order to inform culturally relevant, contemporary approaches to diabetes prevention. Importantly, the cooperative agreement was structured to reflect the advice of Tribal elders, who urged the Native Diabetes Wellness Program leadership to "give us a chance to put into place old practices that we know will work," versus being directed to implement practices that were formulated outside the cultural context of American Indian/Alaska Native communities.

The resulting cooperative agreements thus represent a highly interactive and participatory way of working with Tribes and tribal organizations (see **Attachment 3** for a list of current awardees). Awardees have used Traditional Foods funding to sustain and re-energize a variety of community-specific approaches to diabetes prevention and control, reflecting the heterogeneity of American Indian/Alaska Native communities and the diverse geographic influences that shape each culture. In consultation with CDC's Native Diabetes Wellness Program, Tribes are encouraged to continually evaluate their project progress and barriers, encouraged to adapt locally-deemed "most promising" approaches in exchange for non-culturally appropriate approaches, and to make budgetary modifications accordingly. As a condition of award, each Tribal awardee allocates at least 10% of its budget to community-level data collection that can be analyzed for project evaluation and improvement.

As part of the annual continuation application for cooperative agreement funding, awardees describe their activities to CDC in narrative form. The narratives provide insight into a diverse array of Traditional Foods program activities, such as the production and/or dissemination of culturally appropriate stories; cultivation of community gardens; and efforts to enhance or re-introduce indigenous foods and practices specific to the landscape, history, and culture of the people. However, the narratives do not allow CDC to compile statistical summaries of awardee activities by type or outcome, thus limiting CDC's capacity to conduct an overall evaluation of the Traditional Foods program and to share successful community-based approaches to diabetes control with other communities, including other AI/AN communities that are not currently funded through the Traditional Foods initiative.

CDC requests OMB approval for three years to collect standardized information, called the Traditional Foods Shared Data Elements (SDE, see **Attachment 4a**), from Traditional Foods program awardees. Awardees have been notified of the NDWP's intent to collect SDE information electronically. The first notification was in the Traditional Foods Funding Opportunity Announcement, which described CDC's intent to collect community-specific activity information for aggregation and program evaluation. Since then, NDWP staff have discussed development of the SDE with awardees during routine conference calls, which occur on a regular basis to provide opportunities for discussion, performance monitoring and technical assistance.

CDC is authorized to conduct this activity under the Public Health Service Act (**Attachment 1**). The Traditional Foods SDE data collection form is provided as **Attachment 4a**. This is a new information collection request.

Privacy Impact Assessment

<u>Overview of the Information Collection System</u>

Information will be collected routinely twice per year using Survey Monkey, a web-based user interface. Because awardees already collect local data for their project improvement efforts, summarizing the local evaluation information in the Shared Data Elements format

will result in minimal additional burden to respondents. To further minimize burden, the survey will be programmed with skip patterns to route the respondent only to the most relevant questions.

Items of Information to be Collected

The Shared Data Elements are based on an evaluation construct that employs three domains: Traditional Local Healthy Foods, Physical Activity, and Social Support for Healthy Lifestyle Change and Maintenance. Information will be collected about activities that support the availability and use of traditional foods or alternative healthy foods, such as community/individual gardens and farmers' markets; storytelling, media and outreach activities; availability of places, equipment and educational programs that promote physical activity; social support for healthy lifestyles; collaboration with other agencies and programs; policy-level changes in communities; and program outcomes.

No individually identifiable personal information will be collected. The Survey Monkey system has the capability of collecting computer "cookies," however, this function will be de-selected for this data collection. The Survey Monkey privacy policy is posted on the website.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The Survey Monkey Web site does not have any content directed at children under 13 years of age. The web site for this data collection will only be available to Traditional Foods awardees.

A2. Purpose and Use of Collected Information

The overall goals of the Traditional Foods program are to:

- Support traditionally-oriented, sustainable, evaluable ecological approaches to diabetes prevention, focusing on community efforts to reclaim traditional foods and physical activity in their communities;
- Encourage local policy changes to increase access to traditional, local foods and forms of exercise; and
- Revive, create, and preserve stories of healthy traditional ways shared in homes, schools, and communities.

The Shared Data Elements information collection will support these goals by:

1) Supporting creation of a comprehensive inventory/resource library of diabetes primary prevention ideas and approaches for American Indian/Alaska Native communities;
2) Allowing data aggregation and analysis for improved overall program evaluation and reporting;
3) Improving feedback and technical support to awardees; and

4) Identifying culturally relevant outcomes and local health policies for health promotion and diabetes prevention.

The information submitted to CDC as part of the continuation application emphasizes community-specific program improvement and allows CDC to monitor individual awardees in an effective manner. The continuation application does not provide a systematic, quantifiable, or collective inventory of current awardee activities. The collection of information in Shared Data Elements (SDE) format will allow the NDWP, for the first time, to count the number of AI/AN communities engaged in specific diabetes control activities with Traditional Foods program funding (e.g., community garden projects), and to identify, in a more systematic manner, the specific products potentially available for dissemination (e.g., stories in written, video or audio form that draw on AI/AN storytelling traditions, see **Attachment 5** for an example). The Shared Data Elements will thus represent a resource of culturally relevant "grass roots" diabetes prevention strategies, products, policies and outcomes for AI/AN communities.

The SDE will have a number of uses for overall program monitoring and evaluation. CDC will use the aggregated data to conduct analyses that identify trends in diabetes prevention in AI/AN communities as well as unique or emerging practices. An anticipated long-term result of the information collection is the identification of common practices, which may develop into a set of culturally-relevant "best practices." In addition, the SDE data will improve the quality and specificity of CDC's reports to Congress and the interested public. The Shared Data Elements may thus be used to justify continuation or expansion of the Traditional Foods cooperative agreement beyond the current five-year timeframe, consistent with the regularly verbalized desires of the CDC Tribal Consultation Advisory Committee and the Indian Health Service Tribal Leader's Diabetes Committee. These committees have specifically requested assistance in articulating diabetes primary prevention ideas and approaches for AI/AN communities. Finally, the SDE were derived from the evaluation framework established by CDC's "*Recommended Community Strategies and Measurements to Prevent Obesity in the United States,"* published in the Morbidity and Mortality Weekly Report (CDC. MMWR 2009;58(No. RR-7)[1-30]). As a result, the SDE data may provide insights into the formulation and implementation of other community-based programs.

The Shared Data Elements information, in respective local and aggregate form, will be provided back to project partners, and provide a broader context for Principal Investigators to discuss their efforts with their collaborating tribal leaders. The Shared Data Elements provide awardees with an alternative, supplementary means of self-assessment beyond that provided by the narrative progress reports. The reports produced for the program, and the inventory of activities and products, will provide a mechanism for AI/AN tribes and tribal organizations to consider transferability of strategies across tribes. This type of information exchange would not be possible without aggregation and sharing of standardized information.

Privacy Impact Assessment Information

The data collection domains are Traditional Local Healthy Foods, Physical Activity, and Social Support for Healthy lifestyle Change and Maintenance. The evaluation questions are derived from constructs established by the "*Recommended Community Strategies and Measurements to Prevent Obesity in the United States.*" Information is requested about community-based activities in these domains and products, including stories and videos that communicate awardees' experiences in culturally appropriate ways. The SDE form requests the name of the responding awardee, which is a Tribe or tribal organization. No personal identifiers or personal information is requested in the Shared Data Elements.

A3. Use of Improved Information Technology and Burden Reduction

All data collected (100%) for this project will be reported to CDC using a web-based electronic survey. By using an electronic format for the evaluation instrument, this will reduce the burden of respondents having to use a paper format and then mail their responses back to CDC.

A4. Efforts to Identify Duplication and Use of Similar Information

Respondents are awardees funded by CDC. There are no complete sources of information about awardee activities other than the awardees themselves.

A5. Impact on Small Businesses or Other Entities

The information collection will have no impact on small businesses.

A6. Consequences of Collecting the Information Less Frequently

Without the SDE information collection, CDC will not have the capacity to identify and quantify specific awardee activities and products.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. As required by 5 CFR 1320.8 (d), a Notice announcing the proposed data collection was published in the Federal Register on November 17, 2010 (Vol. 75, No. 221, pages 70265-70276). No public comments were received.

B. CDC consulted extensively with Tribal elders before and during development of the Traditional Foods cooperative agreement, as well as during development of the comprehensive evaluation plan. Consultation occurred in the context of the Indian Health Service's twice yearly Tribal Leader's Diabetes Committee, which the Native Diabetes Wellness Program has participated in since year 2000. Seminal tribal

consultation also occurred from 1998-2000, during which time the Native Diabetes Wellness Program consulted with 471 representatives from 141 federally recognized tribes on the general direction of the Native Diabetes Wellness Program, including the Traditional Foods Program.

A9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gifts.

A10. Assurance of Confidentiality Provided to Respondents

Respondents will be Traditional Foods awardee organizations (see **Attachment 3**). The information to be collected relates to awardee activities and performance measures. No personal information, such as knowledge, attitudes, or opinions, will be collected. A contact person will be identified for each awardee, however, no personal information will be collected about that individual.

Privacy Act Determination

This information collection request has been reviewed by staff in CDC's Information Collection Review Office, who determined that the Privacy Act is not applicable. The only information in identifiable form (IIF) is the name and contact information of the contact person who submits the SDE form on behalf of the awardee organization. The contact person is speaking from his or her role as a representative of the awardee organization. The contact person will not report any personal or sensitive information.

Safeguards

CDC intends to report primarily on aggregated summaries, however, no guarantees of privacy will be offered. The majority of planned reports will be based on analysis of aggregate data, although individualized feedback will be provided to each awardee. The intent of the information collection is to improve CDC's ability to describe activities and products supported by the Traditional Foods program, and to facilitate sharing of successful community-based strategies for diabetes prevention and health promotion.

Consent

This information collection does not involve research with human subjects and does not require IRB approval or the consent of individual respondents.

Nature of Response

Awardees agreed to participate in the information collection as a condition of award. The nature of the data collection is explained in the advance notification letter to awardees (**Attachment 4b**) and the email cover letter that contains a link to the Survey Monkey website (**Attachment 4c**).

A11. Justification for Sensitive Questions

Respondents are organizational entities providing information on activities conducted with program funds. The proposed project does not involve the collection of personal or sensitive information.

A12. Estimates of Annualized Burden Hours and Costs

A12-1. Estimated Annualized Burden Hours

Respondents are 17 awardees funded through the Traditional Foods cooperative agreement (see **Attachment 3**). Eleven awardees were originally funded for FY2010 (October 2009 – September 2010). Funding for the Traditional Foods program was subsequently increased, and CDC awarded funding to six additional applicants over the next year.

The routine schedule for semi-annual SDE information collection is as follows. Awardees will submit their continuation applications to CDC in April of each year of the cooperative agreement. One of the two required SDE submissions will coincide approximately with submission of the continuation application for funding. On an annual basis, this will provide two complementary views of awardee activities: a narrative view (the continuation application) and a quantifiable view (the SDE). The second SDE submission will be scheduled annually in October, at approximately the midpoint between the April submissions.

The Traditional Foods Shared Data Elements (**Attachment 4a**) will be submitted to CDC using Survey Monkey, an electronic web-based interface. Each awardee will receive a personalized advance notification letter (**Attachment 4b**), followed by an email with a link to the Survey Monkey site (**Attachment 4c**). The average estimated burden per response is two hours. CDC anticipates that routine information collection will begin in April 2011 and will describe activities conducted during the period October 2010 – March 2011. Over the three-year period of this information collection request, the total annualized burden for routine information collection is 68 hours.

CDC also requests OMB approval to conduct one additional cycle of retrospective data collection during the first year of this three-year information collection request. The retrospective information collection will provide baseline SDE information about awardee activities conducted prior to October 2010. Although some of the activities were previously described through the continuation application process, the SDE cannot be systematically extracted from these narrative reports (see section A.1 for a summary of the limitations of the narrative progress reports). One cycle of retrospective SDE information collection is needed for comparison purposes and optimal overall program evaluation. Because awardees are expected to have already collected the information for their local program evaluation efforts, CDC does not believe that reporting the information to CDC will be overly burdensome. Inclusion of the retrospective data will enable CDC and

awardees to have a clearer, more quantifiable view of the growth of Traditional Foods activities over the five-year funding cycle for the cooperative agreement.

The total estimated burden for the retrospective data collection is 34 hours (17 respondents x 2 hours/response). Annualizing the retrospective information collection over the three-year clearance period results in an estimated annualized burden of approximately 12 hours (6 respondents per year). CDC believes that the annualized figures slightly over-estimate the actual burden to respondents. First, the number of respondents must be rounded up (from 17 to 18) for even allocation over the three-year clearance period. Second, some of the information could be collected through the pre-testing activity scheduled for Fall/Winter 2010 (see section B.4).

The total estimated annualized burden for both the routine (recurring) and retrospective (one-time) information collections is 80 hours.

Table A.12-1a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs)	Total Burden (in hrs)
AI/AN Tribal Awardees	Traditional Foods Shared Data Elements	17	2	2	68
	One-Time Retrospective Data Collection	6	1	2	12
				Total	80

A12-2.Cost to Respondents

The SDE form will be completed by the awardee's Principal Investigator, in consultation with the program evaluator as needed. The average hourly wage for a Principal Investigator is $40, based on program records. The total annualized cost to respondents for both the routine (recurring) and retrospective (one-time) information collections is estimated at $3,200.

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	Total Burden (in hrs)	Average Hourly Wage	Total Cost to Respondents
AI/AN Tribal Awardees	Traditional Foods Shared Data Elements	17	68	$40	$2,720
	One-Time Retrospective Data Collection	6	12	$40	$480
				Total	$3,200

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time.

A14. Annualized Cost to the Federal Government

Federal government staff will manage the data collection. Staff costs include 25% effort of a senior scientist (GS-13), 10% effort of a project officer, and 50% effort of a data manager and analyst. The specific responsibilities of each CDC staff member are itemized below in Table A.14-1. The total estimated annualized cost to the Federal Government is $63,955.00.

Table A.14-1. Estimated Annualized Cost to the Federal Government

CDC Personnel	% FTE and Base Salary	Responsibilities	Cost
GS-13	25% @ $98,074	Project evaluation planning, oversight of data collection and analysis, interaction with awardees, preparation of the request for OMB approval, and report writing	$ 24,519
GS-13	10% @ $98,074	Serving as project officer, interaction with awardees, project evaluation planning, and report writing	$ 9,807
GS-11	50% @ $59,258	Development of the Survey Monkey interface for electronic collection of the Shared Data Elements, development of an Excel spreadsheet for data analysis, and report writing	$ 29,629
		Total	$ 63,955

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1 Survey Time Schedule	
Activity	**Time Schedule**
Information Collection #1	October/November annually
Data analysis and report writing	December-March
Information Collection #2	April/May annually
Data analysis and report writing	June-September

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed in the upper right hand corner of the data collection instrument. No exceptions are requested.

A18. Exceptions to Certification for Paperwork Reduction Act

No exceptions are requested.