

# Supporting Statement for the Multisite Evaluation of the *In Community Spirit* Program—Prevention of HIV/AIDS for Native/American Indian and Alaska Native Women Living in Rural and Frontier Indian Country

## A. Justification

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The Office on Women’s Health (OWH) within the Office of the Assistant Secretary for Health is requesting clearance for the data collection associated with the multisite evaluation of the *In Community Spirit* Program—Prevention of HIV/AIDS for Native/American Indian and Alaska Native Women Living in Rural and Frontier Indian Country (*In Community Spirit* Program).

The mission of the OWH is to provide leadership to promote the health equity for women and girls through sex/gender-specific approaches across various populations, including American Indian and Alaska Native (AI/AN) women and girls. In 2009, OWH funded six cooperative agreements through the *In Community Spirit* Program, which is designed to increase HIV prevention knowledge and reduce the risk of contracting HIV among AI/AN women living in Indian country through three program components/interventions. Specifically, grantees received funding to implement one or more of the following program components: (1) Community Awareness for Local Native Community (*Community Awareness*), (2) Capacity Building and Technical Assistance to Providers of Services for Native Women (*Capacity Building*), and (3) Direct Demonstration of an HIV/STD Prevention Education Intervention for Women and Girls (*Prevention Education*).

The goals of the *In Community Spirit* Program are:

- Community Awareness—Develop and sustain HIV/STD prevention services to increase awareness of and receptivity to HIV prevention information among the community at large and AI/AN women in rural/frontier Indian country
- Capacity Building—Increase capacity and foster sustainability of HIV/AIDS prevention programs serving AI/AN women living in rural/frontier Indian country through efforts aimed toward organizations serving Native women
- Prevention Education—Develop and demonstrate gender-specific prevention education on HIV/AIDS, as well as implement culturally and linguistically appropriate prevention education that builds on strengths of traditions, cultural, spirituality, and traditions of indigenous AI/AN communities

The objectives of the *In Community Spirit* Program are:

- Improve receptivity to and awareness of HIV prevention education necessary to reduce the stigma among women and the local Native community;
- Increase the number of women voluntarily receiving HIV testing and knowing their serostatus;

- Increase knowledge of accurate HIV prevention information among women;
- Improve and increase access to quality HIV prevention and reproductive health screening and services to women living with or at high risk for HIV infection; and
- Increase awareness of intersection of HIV risk and intimate partner violence, substance use/abuse, and STD infection.

OWH supports collaborative efforts to provide accurate prevention education to AI/AN women covering the full spectrum of primary (prevention education) and secondary (outreach and awareness) prevention adapted to be culturally and gender responsive. This initiative is intended to demonstrate a non-research, collaborative partnership approach between the grantee and local health or social service providers, such as community or rural health centers, family planning clinics, Indian Health Service facilities, faith-based organizations, public assistance programs, and local/State health departments. This collaborative effort is expected to be a viable strategy for identifying and educating AI/AN women in a culturally appropriate manner that reduces denial, clarifies false information, increases knowledge for self protection, demystifies stigma, and increases access to counseling and testing resources. It is expected that the project will demonstrate and provide accurate, culturally, linguistically, and gender appropriate information to women at risk for or living with HIV/AIDS in Indian Country, and that the program model will integrate the strengths of traditions, values, culture, and spirituality of the indigenous communities.

The multisite evaluation of the project can provide information on the content of program implementation, the experience of program participants, and the outcomes of program activities on participant knowledge and behavior related to sexual health. The multisite evaluation is comprised of two main activities across three program components: (1) surveys and (2) key informant interviews. There are two versions of key informant interviews: baseline and follow-up. There is one version of the HEAL survey—Prevention Education to be administered to women who receive prevention education through the program. See Section A.1.b for a detailed description of the multisite study.

Program Component	Evaluation Activities
Community Awareness	<ul style="list-style-type: none"> <li>• Key Informant Interviews (<i>Attachments A.1 and A.2</i>)</li> </ul>
Capacity Building	<ul style="list-style-type: none"> <li>• Key Informant Interviews</li> </ul>
Prevention Education	<ul style="list-style-type: none"> <li>• Women’s HEAL Survey—Prevention Education (<i>Attachment B</i>)</li> <li>• Key Informant Interviews</li> </ul>

\*HIV Education, Awareness, and Lifestyle (HEAL) survey

## **1. Circumstances Making the Collection of Information Necessary**

### **a. Background**

In the United States, AI/AN citizens comprise a small percentage of the population, but a complex interaction of factors puts them at increased risk for preventable, infectious diseases, including HIV. According to the Centers for Disease Control and Prevention (CDC), HIV/AIDS affects 11.9

per 100,000 AI/ANs compared to 8.2 per 100,000 for Caucasians, and AI/ANs rank third in rates of HIV/AIDS diagnoses. AI/AN women account for approximately one-third of all HIV/AIDS diagnoses in AI/AN communities and are infected at a rate of 6.9 per 100,000.<sup>1,2</sup> Inadequate AI/AN specific resources and interventions make HIV/AIDS prevention challenging in Indian Country.<sup>2,3</sup> Culturally specific approaches to prevention must account for the interplay of health disparities, intergenerational trauma, and risky behaviors that contribute to their current health outcomes.<sup>3</sup>

Growing evidence suggests AI/AN women exhibit high levels of risky behaviors and low levels of self-protection and HIV/AIDS knowledge. They have the second highest rates of Chlamydia, gonorrhea, and syphilis—all of which can increase their susceptibility HIV/AIDS infection.<sup>1,4,5</sup> Substance use rates are high in AI/AN communities, and studies indicate that AI/AN women display more risky sexual behavior than men, such as drinking alcohol before sexual activity.<sup>6,7</sup> A study on Alaska Natives found that White men who have sex with both White and AN women are less likely to use condoms with AN women.<sup>8</sup> Another study revealed AI/AN women who did not use condoms consistently felt less vulnerable to HIV and were less ready to change their risky sexual behaviors.<sup>9</sup>

AI/AN communities, like others affected by colonization and forced migration, settled in primarily rugged and rural areas with weak service infrastructure, where people cannot readily access appropriate HIV counseling or testing.<sup>10</sup> Fears of compromised confidentiality, especially in rural areas, dissuade individuals from seeking prevention measures like HIV testing.<sup>1,4,11</sup> When services are provided, however, outcomes are positive. For example, 82% of expecting Native American mothers received prenatal HIV screenings in 2008, and mother-to-child transmission is rare.<sup>10</sup> Since 2005, there have only been three children under the age of 13 diagnosed with HIV.<sup>10</sup> AI/AN communities have many advantages that can foster behavior change and control the spread of a preventive, infectious disease like HIV/AIDS. Interventions that use an “indigenist” perspective of health can support behavior change in AI/AN women by strengthening their connection to their communities and culture.<sup>12</sup>

The *In Community Spirit* Program grantees are using diverse approaches to conducting HIV/AIDS prevention in AI/AN communities, ranging from information-sharing with domestic violence programs and drug- and alcohol-related programs to training HIV primary care professionals, as well as conducting safer sex workshops. Multisite evaluation of these efforts can facilitate and strengthen HIV/AIDS prevention for AI/AN women through the development and use of culturally appropriate and gender based adapted best practices.

## **b. The Need for Evaluation**

Evaluation is essential for enriching our understanding of the way in which innovative programs impact quality and access to prevention and intervention services. Data collected through the proposed multisite evaluation of the *In Community Spirit* Program will serve a variety of overarching purposes/goals:

1. Gather systematic information on knowledge, awareness, and behavior outcomes with AI/AN women who have participated in or been exposed to *In Community Spirit* activities;

2. Expand the database on innovative programs by studying the adaptation of evidence based interventions for HIV and its prevention for AI/AN women;
3. Expand understanding of collaboration and cooperation of grantee organizations and partner organizations, agencies, and providers to implement HIV prevention; to increase our understanding of effecting behavior change in AI/AN women through culturally and linguistically appropriate strategies; to understand sustainability strategies, including facilitators and barriers to sustaining programs beyond grant funding; and
4. Inform local programmatic decision making and ensure accountability to stakeholders, including Federal agencies and the women served by the *In Community Spirit* Program, by informing them of progress made by the program.

A detailed description of the multisite evaluation goals, questions, and revisions to measures is described below.

OWH Research Objectives	Research Questions	Current Measures
Understand the context and implementation of community awareness activities and the perceived outcomes with AI/AN women	What are/were the grantee specific goals of community awareness efforts? Have those goals been achieved?	Key informant interviews (Baseline: 17-22)
	What are the barriers to community awareness HIV prevention program implementation?	
	What are the facilitators to community awareness HIV prevention program implementation?	
	Are AI/AN women receptive to community awareness efforts?	
	Are AI/AN women following up for additional information about HIV and its prevention after the community awareness activity?	
Gather and understand program-specific prevention education outcomes	Are AI/AN program participants aware of HIV issues and its prevention?	Question 21 (Women's HEAL Survey)
	What is their knowledge of HIV/AIDS myths and facts?	Question 21 (Women's HEAL Survey)
	What are their sexual behaviors (risk and protective)?	Questions 10-20 (Women's HEAL Survey)
	Have AI/AN program participants been tested for HIV and why/why not?	Questions 4-8 (Women's HEAL Survey)
	Do AI/AN program participants know where to be tested for HIV?	Question 9 (Women's HEAL Survey)
	What are AI/AN program participants condom negotiation efficacy?	Questions 19 and 20 (Women's HEAL Survey)
	What is AI/AN program participants stigma related to HIV testing?	Question 7 (Women's HEAL Survey)
Understand collaboration and	How did overall capacities change as	Key informant interviews (Baseline:

OWH Research Objectives	Research Questions	Current Measures
sustainability efforts of program grantees	a result of the capacity-building engagement?	3-9, 23-26; Follow-up 4-8) and grantee quarterly and final report review and abstraction
	How did overall service provision change as a result of capacity building and technical assistance?	Key informant interviews (Baseline: 3-9, 15-22; Follow up 6) and grantee quarterly and final report review and abstraction
	What sustainability plans were implemented? To what extent were grantee programs sustainable after funding?	Key informant interviews (Baseline: 24; Follow up 4-10) and grantee quarterly and final report review and abstraction
	What were the facilitators and challenges to program implementation?	Key informant interviews (Baseline: 18, 22, 26 Follow up: 7-8 and 13-14) and grantee quarterly and final report review and abstraction
Ensure accountability of program efforts	What were the grantee level program components?	Key informant interviews (Baseline: 13, 15, 16, 19, 20 and grantee quarterly and final report review and abstraction
	What was the reach of program efforts (number of women and girls reached, communities reached, etc.)?	Key informant interviews (Baseline: 15, 19). Grantee quarterly and final report review and abstraction

Evaluation data provide the information necessary to assess the evidence for significant overall programmatic effects on process and outcome performance measures, as well as evidence for significant programmatic impacts. Therefore, the data gathered through the multisite evaluation will be used to understand the extent to which the *In Community Spirit* Program has been able to achieve its goals and the program’s accountability to the Federal government and other stakeholders.

The legal basis and authorizing law for conducting the multisite evaluation of the *In Community Spirit* Program can be found in Section 301 of the Public Health Services Act (42 U.S.C.241). See *Attachment C*.

**c. Clearance Request**

This submission requests OMB clearance for multisite evaluation activities associated with the *In Community Spirit* Program for a **2 year clearance period**. The multisite evaluation is supported by 3 data collection instruments: (1) Key Informant Interviews—Baseline; (2) Key Informant Interviews—Follow-up; and (3) HEAL Survey—Prevention Education. Detailed information about individual data collection activities is described in Section 2.

**2. Purpose and Use of Information Collection**

Data collected as part of the multisite evaluation will be useful to OWH and its partners, other Federal agencies, legislators, federal administrators, the fields of HIV prevention and minority

health, tribal communities, service providers, AI/AN women, and others implementing gender- and/or culturally-specific prevention programs. Information gathered from multiple communities implementing various approaches to HIV prevention with AI/AN women, including adapting existing evidence-based interventions for AI/AN women, will expand the existing knowledge base for gender-specific and culturally appropriate approaches to HIV intervention.

The proposed multisite design of *In Community Spirit* grantee programs serves to inform the content and context of programs, the experience of program partners and stakeholders, and the outcomes of program activities on participant knowledge and behavior related to sexual health. Further, and in the larger context of program accountability, the proposed multisite evaluation serves to inform the OWH by providing useful data that supports and informs decision-making in communities across Government and private organizations. The proposed research questions and data collection approach reflect the need to understand and gather data around the varied interventions being implemented to service AI/AN women.

Specifically, information gathered through the multisite evaluation will encompass three types of program components being implemented with women in AI/AN communities for HIV prevention: (1) community awareness, (2) capacity building, and (3) prevention education. Research questions are described below in Table 1, as well as in the matrix located in section A.1.b.

**Table 1. Multisite Evaluation of the *In Community Spirit* Program Research Questions**

Intervention	Research Questions	Data Source
Community Awareness	<ul style="list-style-type: none"> <li>• What are/were the grantee specific goals of community awareness efforts? Have those goals been achieved? What are the barriers to community awareness HIV prevention program implementation? What are the facilitators to community awareness HIV prevention program implementation? Are AI/AN women receptive to community awareness efforts? Are AI/AN women following up for additional information about HIV and its prevention after the community awareness activity?</li> </ul>	<ul style="list-style-type: none"> <li>• Key Informant Interviews</li> </ul>
Capacity Building	<ul style="list-style-type: none"> <li>• How did overall capacities change as a result of the capacity-building engagement? How did overall service provision change or improve as a result of capacity building and technical assistance implementation? What sustainability plans were implemented as a result of the capacity-building engagement? To what extent were grantee programs sustainable after funding?</li> </ul>	<ul style="list-style-type: none"> <li>• Key Informant Interviews</li> </ul>
Prevention Education	<ul style="list-style-type: none"> <li>• What prevention education interventions did grantees implement?</li> <li>• Are AI/AN women aware of HIV issues and its prevention? What is their knowledge of HIV/AIDS myths and facts? What are their sexual and risk behaviors? Have women been tested for HIV and why/why not?</li> <li>• Did knowledge, awareness, and HIV testing increase after prevention education intervention for the AI/AN women</li> </ul>	<ul style="list-style-type: none"> <li>• Grantee quarterly and final reports</li> <li>• HEAL Survey—Prevention Education</li> </ul>

	targeted with the prevention curriculum? Did increase in knowledge, awareness, and behavior change sustain over time?	
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**Community Awareness.** As part of the multisite evaluation, findings related to community awareness activities will inform OWH about community awareness goals, barriers and facilitators to HIV prevention program implementation through community awareness efforts, and whether women are receptive to community awareness efforts and follow up for additional information.

**Capacity Building.** Findings from the evaluation of the capacity building component will detail for OWH the types of increases and enhancements made to local infrastructure to provide HIV prevention services to AI/AN women in the community. These include, but are not limited to, service testing and availability; policy and protocol development; creation of sustainability plans; resource availability; and collaborative activities and networking with service providers, agencies, organizations and other programs.

**Prevention Education.** The multisite evaluation will provide OWH with information about prevention education curricula used by grantees and, the evaluation will inform OWH about women in the community and their level of knowledge about HIV and its prevention, status of HIV testing, knowledge of serostatus, level of stigma about HIV and testing, knowledge of where to get tested, willingness to get tested, sexual risk factors, and the disclosure of serostatus to sexual partners.

Because of the lack of information on evidence based practices for AI/AN women, the multisite evaluation provides an opportunity to collect meaningful data on adapting existing evidence based practices for AI/AN women. Data gathered from the HEAL Prevention Education participants will be utilized to understand knowledge, awareness, and behavior outcomes with AI/AN women participating in prevention education curricula. OWH will use the results from the multisite evaluation to understand the processes, outcomes, and effectiveness of adapting evidenced-based interventions for HIV prevention to AI/AN women. Information from the multisite evaluation may also help other OWH programs in developing and implementing gender specific interventions with Native women. These data will expand the resources available to assist Federal, state, and local stakeholders in making programmatic decisions affecting high-risk populations. If these data are not collected, policymakers and program planners at the federal and local levels will not have the necessary information to determine the extent to which these activities are effective and having an impact on Native women. Federal and local officials will not know whether the program has an impact on HIV prevention with AI/AN women and whether *In Community Spirit* cooperative agreements are meeting the goals of the project and the data on evidence based practices for AI/AN women will remain limited.

### **3. Use of Improved Information Technology and Burden Reduction**

Multisite evaluation staff and local project staff will conduct data collection via standard mail, telephone, and in person. Because the availability of technology (e.g., computers, internet connections) varies across communities, the HEAL survey will be designed for paper and pencil administration. Project staff will mail completed surveys to the multisite evaluation team for

scanning and uploading to the evaluation database. Key informant interviews will be scheduled and administered by multisite team members via telephone.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

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The evaluation team, in developing the data collection activities for the multisite evaluation, conducted a literature review to avoid duplication in data collection activities and the use of similar information. Specifically, existing research studies and the efforts of other federal initiatives designed to evaluate HIV prevention with AI/AN women and adapting HIV prevention curricula to minority populations were reviewed.

##### **a. Existing Research**

There is a plethora of existing research on the evaluation of Diffusion of Evidence-Based Interventions for HIV prevention curricula. However, while these findings inform HIV programming generally and with specific target populations, there is a dearth of information on adapting and implementing culturally competent and gender-based HIV prevention education with AI/AN women. Conducting HIV/AIDS prevention education with AI/AN women living in rural and frontier Indian Country areas requires a culturally congruent intervention that builds on community strengths and can model positive individual sexual activity and health seeking behaviors, increase the availability of appropriate treatment, and generate a greater understanding of partner management strategies and social and sexual networks. Still, few HIV/AIDS prevention education interventions have been developed or adapted for AI/AN communities. Agencies have tried Sisters Informing Sisters on Topics about AIDS, Healthy Relationships, and 3MV adaptations, with limited success. Other prevention education curricula, such as Red Circle Project, Shawl Circle, Project HOPE, and Native Women Speaking, appear promising.<sup>13</sup>

Because Native populations value relationships of trust, cultural humility, attunement, and responsiveness in the service provider, and most likely the health educator, it is crucial to modify programs specifically to the needs and values of AI/AN women, as well as to train the health educator and provider to deliver services and curricula with cultural competence.<sup>14</sup>

#### **5. Impact on Small Businesses or Other Small Entities**

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Some of the data for this evaluation will be collected from individuals involved with private and/or public agencies, such as public health, hospitals, mental health, and STD clinics. While most data will be collected from community members and cooperative agreement staff, it is possible that some individuals may also be employed by small businesses or other small entities; however, these data collection activities will not have a significant impact on these agencies or organizations.

#### **6. Consequences of Collecting the Information Less Frequently**

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If administered less frequently, key informant interviews would not yield information on the context, change, and impact of program activities over time and the sustainability of programs.



Because these interviews are to be conducted with the same individuals during the evaluation contract, they will result in information about each program’s implementation, change over time, lessons learned, and sustainability. Conducting interviews less frequently would result in a lack of context and ability to measure program impact and sustainability of the program. The HEAL Survey is scheduled to be administered with each individual a total of three times: (1) before the intervention, (2) immediately after the intervention, and (3) three months after the intervention. Collecting this information less frequently will result in the inability to measure change at the individual level over time, as well as the impact of the intervention on knowledge, attitudes, and behaviors.

There are no legal obstacles to reduce the burden.

## **7. Special Circumstances Related to Guidelines of 5 CFR 1320.5(d)(2)**

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The data collection fully complies with the requirements of 5 CFR 1320.5(d)(2).

## **8. Comments in Response to the FRN/Outside Consultation**

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### **a. Federal Register Notice**

A 60-day Federal Register Notice was published in the *Federal Register* on June, 17, 2011, vol. 76, No. 117; pp. 35443-35444 (see *Attachment E*). There were no public comments.

### **b. Consultation Outside the Agency**

In FY 2011, we consulted with two experts outside of OWH on the multisite evaluation of the *In Community Spirit* Program. Gina Wingood, ScD, has provided consultation on evaluation design and instrumentation, integrating gender into implementation and evaluation activities, and developing gender-specific indicators. Dr. Wingood is recognized nationally and internationally for designing gender and culturally congruent HIV prevention programs. Christine Walrath, PhD, is a program evaluation expert and Vice President of ICF Macro. Dr. Walrath has helped to create the overall evaluation design, as well as evaluation instruments. Dr. Walrath is the principal investigator for the multisite evaluation. Contact information is listed below for Dr. Wingood and Dr. Walrath.

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In addition, the multisite team met with project staff from each of the 6 cooperative agreement sites to provide them an overview of the evaluation design.

## **9. Explanation of any Payment/Gift to Respondents**

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Remuneration is a standard practice in longitudinal studies in efforts to maintain participation in the study. Recontacting survey respondents for follow-up is difficult given the lapse in time between the original survey and the follow-up survey. Compounding the difficulty is when respondents are not directly affiliated with the programs being evaluated. Given the hard to reach nature of these populations, an incentive will be provided for multisite evaluation data collection activities.

**Key Informant Interviews—Baseline and Follow-up Versions.** Key informant interview respondents will participate in baseline and follow up interviews. Participants will include project staff members, partners, and representatives from other organizations for a total of 5 participants in each of the 6 funded communities. Each respondent will receive \$20 at the time of each interview.

Grantee project staff will *not* receive incentives for their participation in the key informant interviews (i.e., project staff that are supported with Federal funds to implement the In Community Spirit program). Staff from organizations or agencies who are affiliated with or work with the *In Community Spirit* program will receive \$20 incentive for their baseline participation and an additional \$20 for their follow-up participation. The justification for this incentive is that some of the key informants, while important to the *In Community Spirit* effort, do not work for or are not supported through this initiative and may need some incentive for the time spent participating in this data collection effort.

**Heal Survey—Prevention Education.** Women from 3 communities implementing the Prevention Education program component will complete the HEAL—Prevention Education. These women, who will receive a prevention education curriculum intervention through the program, will complete the survey at three points in time: baseline, post-curriculum, and 3-month follow up. Participants will receive a \$5 monetary incentive for participation at each wave of survey administration.

The use of incentives in data collection has been demonstrated to increase participation rates and specifically be influential with AI/AN populations.<sup>15,16</sup> Recontacting and recruitment of prevention education participants for follow-up survey participation will be challenging given the lapse in time between the prevention education curriculum and the 3-month follow-up survey. Further, the AI/AN women to be recruited for 3-month follow-up are not directly affiliated with the programs being evaluated; therefore, incentives would be recommended at pre,

post, and 3-month follow up to encourage participation in the cycle of the survey data collection component.

## **10. Assurance of Confidentiality Provided to Respondents**

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Data from the multisite evaluation of the *In Community Spirit* Program will be kept private to the extent allowed by law. The multisite team will secure and maintain all data from the evaluation using the following software: ATLAS.ti, SPSS, and Microsoft Access. Data from the HEAL surveys will be scanned and uploaded to an electronic database (SPSS) and interview data will be maintained in qualitative software (ATLAS.ti). All data will be maintained by the multisite team and access will be limited. For activities that require the collection of identifying information, the multisite team will store this information in a password-protected Access database separate from the evaluation data. Identifying information will not be stored with responses and specific procedures to protect the privacy of respondents are described below for each data collection activity. In addition, the multisite team will obtain approval through the ICF International Institutional Review Board (IRB) for this evaluation.

**Key Informant Interviews—Baseline and Follow-up Versions.** Identifying information of potential key informant interview participations will be obtained from grantees to identify appropriate respondents and schedule interviews. However, no identifying information will be entered or stored in the qualitative database, nor will identifying information be linked to responses. Key informant interviews will be conducted by the multisite team, audio recorded with the permission of the interviewee, and transcribed; recordings will be destroyed after transcription. Contact data will be kept in a password-protected Microsoft Access tracking database separate from the qualitative database. Other procedures for assuring the privacy of respondents will include limiting the number of individuals who have access to identifying information, using locked file cabinets to store hardcopy forms that include identifying information, assigning unique code numbers to each participant to ensure privacy, and implementing guidelines pertaining to data submission and dissemination. Interviewers will be extensively trained and will be responsible for entering responses into the qualitative database. The key informant interviews include a verbal consent (see *Attachment D.1*).

**Women’s HEAL Survey—Prevention Education.** Women participating in a prevention education curriculum intervention will complete the HEAL—Prevention Education at three points in time: baseline, post-curriculum, and 3-month follow up. The multisite team will work with local grantees to develop a tracking system so that each woman receives a unique participant ID, which will be used to track change over time. The multisite team will not have access to the tracking system and therefore will not be able to link respondent information (e.g., name, phone number) with individual responses. Completed surveys will contain the respondent’s unique ID in order to track responses. The survey includes a written consent form (see *Attachment D.3*). This form will not be attached to the survey nor will it contain the participant’s unique ID; thus, responses will not be linked to participants’ names. Staff at the local level will maintain the tracking system, which will not be accessed by the multisite evaluation team.

## **11. Justification of Sensitive Questions**

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The Women’s HEAL Survey instrument includes questions that may be considered sensitive. These questions collect information about respondents’ sexual history, birth control practices, exposure to risk factors, and behaviors related to HIV prevention and safety. These questions are central to OWH’s goal of learning about the impact of the *In Community Spirit* Program. Race/ethnicity data also will be collected from survey respondents. This information will ensure that the target population (AI/AN women) is being reached.

Written consent forms explicitly advise potential respondents and participants about the sensitive nature and content of the data collection protocol as well as the voluntary nature of all data collection activities.

Unanticipated or negative consequences will be reported immediately to the multisite team’s Institutional Review Board (IRB), as well as local IRBs as necessary. The principal investigator and project director will also consult with appropriate clinical professionals and immediately determine if a participant is in need of clinical help.

## **12. Estimates of Annualized Hour and Cost Burden**

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Data collection for the multisite evaluation in each of the Native communities will begin in the second quarter of FY 2012 and continue into FY 2013, ***covering a 2-year data collection period.*** Grantee participation in data collection activities is dependent upon program components being implemented; thus, the number of programs participating in each data collection activity is as follows:

- Key Informant Interviews—Baseline and Follow-up Versions, 6 grantees
- Women’s HEAL Survey—Prevention Education, 3 grantees

Section 12a includes estimated annualized burden Section 12b describes the estimated annualized burden costs for one year of data collection through the multisite evaluation. Annualized burden tables represent one of two total years of data collection.

All measures included below were developed for the multisite evaluation of the *In Community Spirit* Program. As such, the multisite evaluation team piloted each measure with less than 10 respondents to determine burden estimates. The cost was calculated based on the hourly wage rates for appropriate wage rate categories using the May 2009 National Occupational Employment and Wage Estimates from the Bureau of Labor Statistics, U.S. Department of Labor<sup>17</sup> and the 2011 HHS Poverty Guidelines.<sup>18</sup>

a.

**Table 2. Estimated Annualized Burden Hours**

Type of Respondent	Form Name	Number of Respondents	Total Number of Responses per Respondent	Average Burden per Response (hrs)	Total Burden Hours**
Agency Provider (Health Educators)	Key Informant Interviews	6	2	50/60	10
Agency Staff (Healthcare support workers)	Key Informant Interviews	24	2	50/60	40
Community Member	HEAL Survey—Prevention Education	600	3	15/60	450
<b>Total</b>		<b>630</b>			<b>500</b>

\*\*Rounded to the nearest whole number

b.

**Table 3. Estimated Annualized Burden Costs**

Type of Respondent	Form Name	Estimated Annual Burden Hours	Hourly Wage Rate	Total Respondent Costs**
Agency Administrator (General Manager)	Key Informant Interviews	5	\$53.15 <sup>1</sup>	\$266
Agency Staff (Health Educators and Healthcare support workers)	Key Informant Interviews	20	\$19.33 <sup>2</sup>	\$387
Community Member	HEAL Survey—Prevention Education	225	\$10.74 <sup>3</sup>	\$2417
<b>Total</b>		<b>250</b>		<b>\$3070</b>

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

Multisite evaluation team members will collect the majority of the required data elements as part of the *In Community Spirit* Program Multisite Evaluation. There are no additional capital or start-up costs associated with the evaluation for communities. There will be some additional burden on record keepers to provide potential respondent lists for data collection activities. However, these operation costs will be minimal.

Other costs related to this effort, such as the cost of shipping completed surveys and consent

1 Bureau of Labor Statistics, U.S. Department of Labor, average salary of \$110,550/2080 based on general and operations managers

2 Bureau of Labor Statistics, U.S. Department of Labor, average salary of \$49,060/2080 based on health educator and \$31,340/2080 based on healthcare support worker

3 Due to high rates of unemployment and poverty in Indian country, figure is based on 2011 poverty guidelines for a family of four (\$22,350/2080)

forms and conducting interviews by telephone are costs to the Federal government as part of the evaluator’s contract for the multisite evaluation. Therefore, no cost burden is imposed on the community by this additional effort.

## **14. Annualized Cost to the Federal Government**

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The annualized cost to the government is estimated at \$110,203.

The multisite evaluation contract has been awarded to ICF Macro. The contract with OWH provides \$300,610 across three years, including two years of data collection in each community. The estimated average annual cost of the contract will be \$100,203. Included in these costs are the expenses related to developing and monitoring the multisite evaluation including, but not limited to, the following activities: development of the design and instrument package, provision of technical assistance to sites, travel to sites and relevant meetings, and data analysis and dissemination activities. Additionally, it is estimated that OWH will allocate \$10,000 a year in staff time for management of the contract, and coordination and oversight of the evaluation.

## **15. Explanation for Program Changes or Adjustments**

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This is a new data collection project.

## **16. Plans for Tabulation and Publication, and Project Time Schedule**

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### **a. Time Schedule**

The time schedule for implementing the multisite evaluation is summarized below. Data collection is scheduled to begin immediately upon receipt of OMB approval.

**Table 4. Data Collection and Analysis Time Schedule**

<b>Activity</b>	<b>Timeframe</b>
HEAL Survey—Prevention Education	June 2012 to June, 2013
Key Informant Interviews—Baseline	June 2012
Key Informant Interviews—Follow up	May 2013
Validate data	Ongoing through June 2013
Analyze data	Ongoing through June 2013
Produce quarterly reports	Quarterly beginning in the first year of the contract
Produce final report	August 2013
Draft article for publication	September 2013
Produce final briefing materials	September 2013

### **b. Publication Plans**

A final report on the results of the multisite evaluation will be produced by the evaluation team at the end of the 3-year contract period. Additionally, one peer reviewed publication will be developed to inform the research community as well as policymakers and program administrators. The peer reviewed publication will be submitted in the final year of the multisite evaluation when maximum data has been accumulated.

Examples of journals that will be considered as vehicles for publication include the following:

- AIDS Education and Prevention: An Interdisciplinary Journal
- AIDS Prevention and Mental Health
- American Journal of Health Promotion
- American Journal of Preventive Medicine
- American Journal of Public Health
- Evaluation Review
- Evaluation Quarterly
- Health Education and Behavior
- Health Education Research
- Health Promotion Practice
- Journal of Aboriginal and Indigenous Community Health
- Journal of AIDS/HIV
- Journal of Health and Social Behavior
- Journal of Women's Health and Gender-Based Medicine
- Sexually Transmitted Diseases

### **c. Analysis**

After the completion of data collection in the evaluation contract, descriptive analyses will be completed. Data will be analyzed at the aggregate level and the multisite team will conduct analyses for specific subgroups when a sufficient number of cases are available. It is expected that most of the routine analyses of quantitative data will involve descriptive statistics rather than inferential statistics (i.e., tests of statistical significance). Additionally, it is anticipated that most analyses will be conducted using Stata or SPSS and will involve simple descriptive statistics (e.g., frequencies, percentages, or averages by category), such as percentage of AI/AN women who reported receiving HIV counseling and testing. The multisite team will use the analyses described below to assess the evidence for significant overall programmatic effects on process and outcome performance measures, as well as evidence for significant programmatic impacts.

**Key Informant Interviews.** Qualitative data obtained from key informants during the multisite evaluation will be transcribed into word documents and imported into ATLAS.ti, a qualitative software program that supports the coding process by facilitating the marking and subsequent search, retrieval, classification, and cross-classification of text. The evaluation team will develop the initial list of coding categories based on the research questions and assign a set of deductive codes to each of the preliminary categories. Definitions, inclusion and exclusion criteria, and explicit guidance for applying codes will be developed. Once inter-rater reliability is established, codes will be applied to the transcripts and data analysis will begin. Themes and responses that were posed repeatedly by respondents will be noted. In addition to the identification of themes,

ATLAS.ti software also facilitates the comparison of themes and the identification of relationships between themes. The multisite evaluation team will use techniques from both theme and content analysis. This analytic process will allow us to determine thematic and content consistency, and variability within and across the two enhanced evaluation sites.

**Women’s HEAL Survey.** The majority of data for the HEAL surveys will be collected at multiple points in time. From these data, within and across time point summary information can be generated for any indicator of interest collected. Data collected at multiple points in time also provide the opportunity for trend analyses. Repeated measures analytic approach will be used to analyze the data collected pre- and post-intervention; this allows for an assessment of program outcome or impact. For example, inferential statistics and effect sizes can be calculated to assess the impact of receiving a particular prevention education intervention on AI/AN women. In addition to these summary statistics, analyses that will allow for the simultaneous assessment of multiple variables will be conducted to account for the interrelationships among and between indicators of interest (e.g., multiple regressions, hierarchical regressions, variants of factor analyses, and logistic regressions). The multisite approach provides an additional opportunity with regard to data analysis and inquiry. Within site analyses can be conducted using analysis of variance models, while multisite data can be analyzed with hierarchical linear modeling techniques that will account for variation within and across grantee communities.

**Table 5: Evaluation Questions, Data Sources and Analysis Techniques**

Evaluation Questions	Data Sources	Data Analysis
<ul style="list-style-type: none"> <li>Are AI/AN women aware of HIV issues and its prevention? What is their knowledge of HIV/AIDS myths and facts? What are their sexual and risk behaviors? Have women been tested for HIV and why/why not?</li> </ul>	<ul style="list-style-type: none"> <li>HEAL Survey— Prevention Education</li> </ul>	<ul style="list-style-type: none"> <li>Descriptive analysis</li> <li>Bivariate analysis</li> <li>Multivariate analysis</li> </ul>
<ul style="list-style-type: none"> <li>What are/were the grantee specific goals of community awareness efforts? Have those goals been achieved? What are the barriers to community awareness HIV prevention program implementation? What are the facilitators to community awareness HIV prevention program implementation? Are AI/AN women receptive to community awareness efforts? Are AI/AN women following up for additional information about HIV and its prevention after the community awareness activity?</li> </ul>	<ul style="list-style-type: none"> <li>Key Informant Interviews</li> </ul>	<ul style="list-style-type: none"> <li>Qualitative analysis</li> <li>Thematic analysis</li> </ul>
<ul style="list-style-type: none"> <li>How did overall capacities change as a result of the capacity-building engagement? How did overall service provision change or improve as a result of capacity building and technical assistance implementation? What sustainability plans were implemented as a result of the capacity-building engagement? To what extent were grantee programs sustainable after funding?</li> <li>What prevention educations were implemented by</li> </ul>	<ul style="list-style-type: none"> <li>Key Informant Interviews</li> <li>Review of grantee quarterly and final reports</li> </ul>	<ul style="list-style-type: none"> <li>Qualitative analysis</li> <li>Thematic analysis</li> </ul>



Evaluation Questions	Data Sources	Data Analysis
grantees?		
<ul style="list-style-type: none"> <li>Did knowledge, awareness, and HIV testing increase after prevention education intervention for the women targeted? Did increase in knowledge, awareness, and behavior change sustain over time?</li> </ul>	<ul style="list-style-type: none"> <li>HEAL Survey— Prevention Education</li> </ul>	<ul style="list-style-type: none"> <li>Descriptive analysis</li> <li>Bivariate analysis</li> <li>Multivariate analysis</li> </ul>

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

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All data collection instruments will display the expiration date of OMB approval.

## 18. Exceptions to the Certification for Paperwork Reduction Act Submission

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This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.

## C. References

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