“Community-based Organization (CBO) Monitoring and Evaluation Project of WILLOW (CMEP-WILLOW)”

Information Collection request under 0920-NEW

Section A: Supporting Statement

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Supporting Statement

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called "Community-based Organization (CBO) Monitoring and Evaluation Project (CMEP) of WILLOW (CMEP-WILLOW)" for 3 years.

Background

The CDC began formally partnering with CBOs in the late 1980s to expand the reach of HIV prevention efforts. CBOs were, and continue to be, recognized as important partners in HIV prevention because of their history and credibility with target populations and their access to groups that may not be easily reached. Over time, CDC's program for HIV prevention by CBOs has grown in size, scope, and complexity to respond to changes in the epidemic, including the diffusion and implementation of Effective Behavioral Interventions (EBIs) for HIV prevention.

CDC's EBIs have been shown to be effective under controlled research environments; however, there is limited data on intervention implementation and client outcomes in real-world settings (as implemented by CDC-funded CBOs). The purpose of CMEP-WILLOW is to a) improve the performance of CDC-funded CBOs delivering Women Involved in Life Learning from Other Women (WILLOW) by monitoring changes in clients' self-reported attitudes and beliefs regarding HIV and HIV transmission risk behaviors after participating in the intervention; and b) assess the fidelity of the implementation of WILLOW at the CBO. The project also plans to conduct process monitoring of the delivery of the intervention in terms of recruitment, retention, and data collection, entry, and management. Four CBOs will receive supplemental funding under PS 10-1003 over a five-year period to participate in CMEP-WILLOW.

Findings from this project may be used by the participating CBOs to a) improve the future implementation, management, and quality of WILLOW; b) better understand if there are differences in outcomes across demographic and behavioral risk groups for clients who participated in the WILLOW intervention at these four CBOs; and c) guide their overall HIV prevention programming for

women living with HIV. CDC and other organizations interested in behavioral outcome monitoring of WILLOW or similar HIV prevention interventions may also benefit from lessons learned through this project.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) to "… cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man…". (Attachment 1)

Privacy Impact Assessment

The funded CBOs will manage the names and contact information of study participants. Participants' names and contact information will be securely stored in a locked file cabinet housed within a locked room at each CBO. Each participant will be assigned a unique project identification number that is not based on any of the participants' personal identifying information (e.g. date of birth, race, gender and/or other descriptors). The unique project identification number will serve as the only identifier on all data collection instruments. A separate form, called the master list, will be used to link the names of participants with their unique project identification number. The master list will be stored separately from project data and will only be accessed in the event that the client needs to be contacted by the local project manager or other relevant CBO staff. CDC will not have access to or receive any participant's personally identifiable information. Data pertaining to participant contact information or the consent process will not be collected or stored in the Questionnaire Development System (QDS).

Overview of the Data Collection System

Information will be collected electronically using QDS software version 2.6 via handheld computerized devices and laptop computers. Electronic versions of the surveys will be downloaded onto the handheld devices and will utilize the QDS Handheld Assisted Personal Interview software. The electronic surveys downloaded onto the laptops will utilize the QDS Computer Assisted Personal Interview software. The survey content will be identical for each method of data collection. The responders will be volunteers who are recruited from the target population

served by the funded agency. The evaluation will involve quantitative data collection and will evaluate changes in client-level attitudes and risk behaviors at baseline and at 90- and 180-days following their participation in the HIV prevention intervention, WILLOW. This project is limited in scope and will only involve data collected from four agencies currently funded by CDC to deliver WILLOW. However, the development of new, efficient methods for collecting HIV-related data from the general public could be used in future HIV-related evaluation projects and may ultimately improve the quality of behavioral risk data and reduce the burden of future data collections.

Items of Information to be Collected

The baseline and follow-up QDS surveys will collect demographic and behavioral risk information as well as information regarding attitudes and beliefs about HIV (see Attachment 5 for the paper versions of the baseline and follow-up surveys).

The information collected by each of the four funded agencies may include personally identifiable information, such as name and contact information, in order to provide continuity of service, follow-up of referrals, schedule follow-up interviews and other outreach activities. Please note that we are not asking the four agencies to collect any information that they will not otherwise be collecting under the terms of their cooperative agreements and for purposes associated with serving their clients. Personally identifiable information will be kept in a locked file cabinet and will be accessible only to appropriate agency staff. Any individually identifiable information collected by funded agencies will not be submitted to CDC. All QDS data will be encrypted and submitted to CDC via the Secure Data Network (SDN).

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

This data collection does not involve websites or website content directed at children less than 13 years of age.

2. Purpose and Use of Information Collection

The purpose of CMEP-WILLOW is to a) assess the fidelity of the implementation of WILLOW at the CBO; and b)improve the performance of CDC-funded CBOs delivering WILLOW by monitoring changes in clients' self-reported attitudes and beliefs regarding HIV and HIV transmission risk behaviors after participating in the intervention. Process monitoring will be conducted to inform program improvement and outcome monitoring will be conducted to

determine the extent to which program goals and objectives are being met. Each CBO will recruit 400 women living with HIV who are 18 years of age and older and are enrolled in the WILLOW intervention, to participate in CMEP-WILLOW. Individuals who are recruited for CMEP-WILLOW must complete the Eligibility Screener Form (see Attachment 3) to determine eligibility for participation. Those who meet the eligibility criteria and agree to participate in CMEP-WILLOW will 1) sign the CMEP-WILLOW Participation Agreement Form (see Attachment 4); and 2) complete a 20-minute, self administered, computer based interview prior to their participation in the WILLOW intervention and an 18 minute, self administered, computer based interview at two follow-up time points (90 and 180 days following the WILLOW intervention) to assess their HIV-related attitudes and behavioral risks.

Throughout the project period, funded CBOs will be responsible for managing the daily procedures of CMEP-WILLOW to ensure that all required activities are performed, all deadlines are met, and quality assurance plans, policies and procedures are upheld. CBOs will be responsible for participating in all CDC-sponsored grantee meetings related to CMEP-WILLOW.

The data collected will provide CDC with data regarding intervention processes as well as client-level data. As expected with process and outcome monitoring evaluation, the results of site-specific and aggregate data analyses will be provided to funded CBOs throughout the course of the project and at the completion of data collection and reporting. Any changes in procedures due to the review of data will be documented.

Without these data, CDC would be unable to determine how the WILLOW intervention is being delivered at funded CBOs and whether participation in the WILLOW intervention is associated with client behavior change that is expected.

Privacy Impact Assessment Information

Individually identifiable information (IIF) will be collected by the CBO staff from the four funded agencies. IIF will be used by project staff to contact participants to remind them about follow-up data collection appointments. No IIF will be available to or shared with the CDC.

3. Use of Improved Information Technology and Burden Reduction

The “CMEP-WILLOW Baseline Survey” (see Attachment 5a), “CMEP-WILLOW 90-Day Follow-Up Survey” (see Attachment 5b), and the “CMEP-WILLOW 180-Day Follow-Up Survey” (see Attachment 5c) will

be administered to participants using QDS software version 2.6 (Handheld Assisted Personal Interview and Computer Assisted Personal Interview software (modules), allowing information to be stored as it is collected. Project participants will complete the QDS survey on a handheld device or laptop computer. If the participant is uncomfortable with using the computer or has literacy deficits that make using the computer impossible, a project staff member will administer the survey using a handheld devise or laptop computer. Surveys will be completed in private or semi-private areas as a measure to ensure participant privacy. Upon survey completion, agency staff will upload the survey data to the desktop computer, encrypt the data file and submit the file to CDC via the SDN.

4. Efforts to Identify Duplication and Use of Similar Information

NCHHSTP has verified that there are no other federal generic collections that duplicate the data collection tools and methods included in this request.

5. Impact on Small Businesses or Other Small Entities

Community-based organizations received federal funds under PS 10-1003 to conduct this evaluation.

6. Consequences of Collecting the Information Less Frequently

Participants will complete the following forms: 1) CMEP-WILLOW Eligibility Screener; 2) CMEP-WILLOW Participation Agreement Form; 3) CMEP-WILLOW Baseline Survey; 4) CMEP-WILLOW 90-Day Follow-Up Survey; and 5) the CMEP-WILLOW 180-Day Follow-Up Survey. The eligibility screener is completed at the time of recruitment to determine whether or not an individual meets the eligibility criteria for CMEP-WILLOW. The participation agreement form outlines the details of the project including the benefits and risks associated with participation. The baseline survey will be conducted prior to the individual participating in the WILLOW intervention. The follow-up surveys will be completed 90 and 180 days respectively, after the individual participates in WILLOW. The completion of the baseline, 90- and 180-day surveys is necessary to determine how the attitudes and beliefs about HIV and HIV risk behaviors of participants change over time after participating in HIV prevention intervention, WILLOW. Collecting information at 90 and 180 days allows CDC to evaluate if changes in attitudes, beliefs and behaviors are sustained over time in those who participate in the WILLOW intervention.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A 60-day notice to solicit public comments was published in the Federal Register on February 3, 2011, Volume 76, Number 23 6139-6140. (Attachment 2). A non-substantive comment was received on February 6, 2011.

9. Explanation of Any Payment or Gift to Respondents

All project participants will be offered a token of appreciation depending upon the practices at the funded agencies. Tokens of appreciation will be offered for the completion of the each of the following surveys; baseline, 90-day follow-up, and 180-day follow-up.

10. Assurance of Confidentiality Provided to Respondents

Certificates or Assurance of Confidentiality do not apply for this project.

<u>IRB Approval</u>

This data collection has been determined not research involving human subjects. Therefore, IRB approval is not required.

<u>Privacy Impact Assessment Information</u>

A. This information collection is not subject to the Privacy Act.

Respondents will be told that all individually identifiable information collected by the implementing agencies will not be submitted to CDC. A master list of assigned Client IDs with client names will be stored in a locked file cabinet and is intended for agency use only and will not be submitted to CDC. Participant names will not be recorded on any other data collection document and will not be stored on any handheld device or laptop.

B. Describe how information will be secured, addressing relevant technical, physical, and administrative safeguards.

The data will be collected and stored in the QDS warehouse manager. The QDS warehouse manager allows for data management and the export of data for analysis. Project data will be stored and maintained in a secure area at all times at each agency in a locked file cabinet in the office of the project's coordinator. All electronic data will be password protected and accessible only to project staff and direct supervisors. Data will be stored on network drives which are regularly backed up by staff.

C. Describe opportunities for obtaining respondent consent, if any.

Participation in this project is strictly voluntary. The consent process will be implemented according to the local/state policies of the funded agencies. Consent forms are provided in Attachment 2. The consent process for CMEP-WILLOW involves the agency staff providing an overview of the project that includes a description of the benefits of as well as the risks and discomforts to participation as well as the protections for the respondent's privacy and secure. Participants must sign the consent form prior to enrolling into the project.

D. Indicate whether respondents are informed about the voluntary or mandatory nature of their response.

Participation in this CMEP-WILLOW is strictly voluntary. The consent form clearly indicates that participation is voluntary and that there are no mandatory requirements, beyond eligibility, for participating in the project. Respondents are also informed that they may withdraw from the project at any time.

11. Justification of Sensitive Questions

The project asks WILLOW intervention participants questions that are of a sensitive nature. By nature of this project, WILLOW intervention participants are individuals who through self report are identified as being at high risk for HIV transmission. Asking these participants to describe and quantify their HIV attitudes, beliefs and risk behaviors before and after the intervention is necessary to determine the changes in participants risk over time. This request covers the collection of HIV behavioral risk and attitudes and beliefs data. Thus, participants will be asked to report on sensitive and private matters pertaining to their sexual practices and substance use. Some of the questions will ask about involvement in illegal activities (e.g., use of illegal substances, having sex in exchange for drugs or money) and about past HIV and STD diagnoses. This information may be considered by some

participants to be highly sensitive in nature. However, in order to successfully conduct an outcome monitoring project, it is necessary to include questions about sexual activity and substance use as they pertain to HIV transmission risk.

12. Estimated Annualized Burden Hours and Costs

A. This information collection will occur over three years. The population targeted by this project are women 18 years of age and older who are living with HIV and learned of their HIV status at least 6 months ago. The eligibility screener is completed to determine that the respondent is eligible to participate in CMEP-WILLOW and is estimated to take 2 minutes to complete. Respondents will be administered the questionnaire before participating in the intervention (baseline) and at 90 and 180 days after participating in the WILLOW intervention. The baseline survey is estimated to take 20 minutes to complete while the 90- and 180-day surveys are estimated to take 18 minutes to complete. Each of the four agencies funded to participant in CMEP-WILLOW will be required to submit to CDC four separate QDS data warehouses that include data collected via the screener, baseline interview, 90- follow-up interview, and 180-day follow-up interview respectively. Data submission will occur monthly and it is estimated that it will take 5 minutes to upload each warehouse to the CDC's SDN. There is no cost to respondents other than their time.

Exhibit 12.A Estimate of Annualized Burden Table

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Response (Hours)	Total Burden (Hours)
General population	Screener	500	1	2/60	17
CMEP-WILLOW grantees	Screener	4	12	5/60	4
General population	Baseline Interview	400	1	20/60	133
CMEP WILLOW grantees	Baseline Interview	4	12	5/60	4

General population	90-day Follow-up Interview	320	1	18/60	96
CMEP-WILLOW grantees	90-day Follow-up Interview	4	12	5/60	4
General population	180-day Follow-up Interview	320	1	18/60	96
CMEP-WILLOW grantees	180-day Follow-up Interview	4	12	5/60	4
Total		500			358

B. Annualized cost to respondents for the burden hours is provided in Exhibit 12.B. The estimate of hourly wages were obtained from the United States Department of Labor's Bureau of Labor Statistics and is based on the May 2009 National Occupational Employment and Wage Estimates for all occupations (http://www.bls.gov/bls/blswage.htm).

Exhibit 12.B Estimated Annualized Burden Costs

Respondent	**Form**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Cost**
General population	Screener	17	$20.90	$355.30
CMEP-WILLOW grantees	Screener	4	$20.90	$83.60
General population	Baseline Survey	133	$20.90	$2779.70
CMEP-WILLOW grantees	Baseline Survey	4	$20.90	$83.60
General Population	90-Day Follow-up Survey	96	$20.90	$2006.40
CMEP-WILLOW	90-Day Follow-up	4	$20.90	$83.60

grantees	Survey			
General population	180-Day Follow-up Survey	96	$20.90	$2006.40
CMEP-WILLOW grantees	180-Day Follow-up Survey	4	$20.90	$83.60
Total		358		$7482.20

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

The project is funded through a Cooperative Agreement to four community-based organizations (PS10-1003) for five years. The cost of the project for 5 years is estimated to be $3,762,375. The project will involve participation of one CDC project officer (USPHS Commissioned Corps Officer, 0-4) and a CDC Co-Principal Investigator (GS-14 level) who will be responsible for project design, project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote and onsite technical assistance to the agencies implementing the data collection. Three contractors (a project coordinator, a project consultant, and a data manager) will also work on the project. An estimated cost per individual activity is listed below.

Exhibit 14.A Estimate of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (Behavioral Scientist, USPHS Commissioned Corps Officer , O-4, .65 FTE)	$53,280
	CDC Co-Principal Investigator (GS-14, .05 FTE)	$5,400
Operational	Travel – two trips for Project	$5,000

Expense Type	Expense Explanation	Annual Costs (dollars)
	Officer	
	Subtotal, Direct Costs to the Government	$63,680
Contractor and Other Expenses	Project Coordinator (Manila Consulting Group, Inc., .75)	$100,230
	Project Consultant (Northrop Grumman, .12)	$12,420
	Data Manager (Manila Consulting Group, Inc.,.25)	$36,145
	Cooperative Agreement to AIDS Service Center: Manhattan, NY	$135,000
	Cooperative Agreement to Boston Medical Center: Boston, MA	$135,000
	Cooperative Agreement to Empower U: Miami, FL	$135,000
	Cooperative Agreement to Newark Beth Israel: Newark, NJ	$135,000
	Subtotal, Contracted and other expenses	$688,795
	TOTAL COST TO THE GOVERNMENT	$752,475

Salary estimates were obtained from the United States Public Health Service Commissioned Corps Website (http://dcp.psc.gov/) and the OPM salary scale (http://www.opm.gov/).

The annual cost to the government is $752,475.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit 16.A Project Time Schedule

Activity	Time Schedule
Grantee training on data collection methods using QDS survey and handheld devices/laptops computers	3 months prior to receiving OMB approval
QDS data collection begins	Within 1 month of OMB approval
QDS data submission to CDC	Monthly
QDS data collection ends	48 months after OMB approval
Analysis begins	48 months after OMB approval
Dissemination of results	60 months after OMB approval

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

No exception is requested.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h) (1)-(10)

No exception is requested.