

"Community-based Organization (CBO) Monitoring and Evaluation
Project of Respect (CMEP-Respect)"

OMB No. 0920-0895

Expires 8/31/2014

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 12-month extension to collect follow-up data for the "Community-based Organization (CBO) Monitoring and Evaluation Project (CMEP) of Respect (CMEP-Respect)" (OMB 0920-0895, Expiration Date 8/31/2014).

CDC funded CMEP-Respect for five (5) years (September 2010-August 2015). From April 1, 2012 through April 30, 2104 baseline surveys were conducted with an estimated 871 participants; 90-day follow up surveys were completed with 576 participants, and 180-day follow up surveys were completed with 484 participants.

We are requesting additional time to complete follow up surveys at 90- and 180-days for participants completing the intervention on or before 8/31/2014.

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-Respect is to a) improve the performance of CDC-funded CBOs delivering Respect 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 Respect at the CBO. Four CBOs received supplemental funding under PS 10-1003 over a five-year period to participate in CMEP-Respect.

Findings from this project may be used by the participating CBOs to a) improve the future implementation, management, and quality of Respect; b) better understand if there are differences in outcomes across demographic and behavioral risk groups for clients who participated in the Respect intervention at these four CBOs; and c) guide their overall HIV prevention programming for men who have sex with men (MSM). CDC and other organizations interested in behavioral outcome monitoring of Respect 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 manage the names and contact information of study participants. Participants' names and contact information are securely stored in a locked file cabinet housed within a locked room at each CBO. Each participant is 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 serves as the only identifier on all data collection instruments. A separate form, called the master list, is used to link the names of participants with their unique project identification number. The master list is stored separately from project data and only accessed in the event that the client needs to be contacted by the local project manager or other relevant CBO staff. CDC does not have access to or receive any participant's personally identifiable information. Data pertaining to participant contact information or the consent process is not collected or stored in the Questionnaire Development System (QDS).

Overview of the Data Collection System

Information is collected electronically using QDS software version 2.6 via handheld computerized devices and laptop computers. Electronic versions of the surveys are downloaded

onto the handheld devices and utilize the QDS Handheld Assisted Personal Interview software. The electronic surveys downloaded onto the laptops utilize the QDS Computer Assisted Personal Interview software. The survey content is identical for each method of data collection. The responders are volunteers who are recruited from the target population served by the funded agency. The evaluation involves quantitative data collection and evaluates changes in client-level attitudes and risk behaviors at 90- and 180-days following their participation in the HIV prevention intervention, Respect. This project is limited in scope and will only involve data collected from four agencies currently funded by CDC to deliver Respect.

Items of Information to be Collected

The follow-up QDS surveys collect demographic and behavioral risk information as well as information regarding attitudes and beliefs about HIV (**Attachments 3a and 3b**).

The information collected by each of the four funded agencies 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 would not otherwise be collecting under the terms of their cooperative agreements and for purposes associated with serving their clients. Personally identifiable information is kept in a locked file cabinet and accessible only to appropriate agency staff. Any individually identifiable information collected by funded agencies is not be submitted to CDC. All QDS data is encrypted and submitted to CDC via the Secure Data Network (SDN) (**Attachments 3c and 3d**).

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-Respect is to a) assess the fidelity of the implementation of Respect at the CBO; and b) improve the performance of CDC-funded CBOs delivering Respect by monitoring changes in clients' self-reported attitudes and beliefs regarding HIV/STDs and transmission risk behaviors after participating in the intervention. Process monitoring is conducted to inform funded CBOs of program status and improvement, while outcome

monitoring is conducted to determine the extent to which program goals and objectives are being met. Each CBO is expected to recruit 400 men who are 18 years of age and older, who report having had anal sex with a man in the last 12 months, and are enrolled in the intervention, Respect, to participate in CMEP-Respect. Individuals recruited for CMEP-Respect complete the approved Eligibility Screener Form to determine eligibility for participation. Those who meet the eligibility criteria and agree to participate in CMEP-Respect sign the approved CMEP-Respect Participation Agreement Form and complete the baseline survey. Under this data collection request, enrolled participants will complete an 18 minute, self administered, computer based interview at two follow-up time points (90 and 180 days following the Respect intervention) to assess their HIV-related attitudes and behavioral risks.

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

The data collected provides CDC with information 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 is 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 are documented.

Without these data, CDC would be unable to determine whether participation in the Respect intervention is associated with client behavior change that is expected.

Privacy Impact Assessment Information

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

3. Use of Improved Information Technology and Burden Reduction

The "CMEP-Respect 90-Day Follow-Up Survey" (**Attachment 3a**), and the "CMEP-Respect 180-Day Follow-Up Survey" (**Attachment 3b**) is 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 (**Attachment 4** for screen shots). Project participants 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 administers the survey using a handheld device or laptop computer. Surveys are completed in private or semi-private areas. Upon survey completion, agency staff upload the survey data to the desktop computer, encrypt the data file and submit the file to CDC monthly via the SDN.

4. Efforts to Identify Duplication and Use of Similar Information

NCHHSTP has verified that there are no other federal 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 project.

6. Consequences of Collecting the Information Less Frequently

Participants will complete the following forms: CMEP-Respect 90-Day Follow-Up Survey (**Attachment 3a**) and the CMEP-Respect 180-Day Follow-Up Survey (**Attachment 3b**). The follow-up surveys will be completed 90 and 180 days respectively, after the individual participates in Respect. The completion of the 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, Respect. 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 Respect 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 03/13/2014, Volume 79, Number 49, pages 14253-14254. No comments were received. No efforts were made to consult with others outside of the agency. Outcome monitoring projects on other evidence-based behavioral interventions have been successfully conducted by branch staff in the past.

9. Explanation of Any Payment or Gift to Respondents

All project participants are offered a token of appreciation depending upon the practices at the funded agencies. Tokens of appreciation have been offered for the completion of the 90-day follow-up survey (**Attachment 3a**) and 180-day follow-up survey (**Attachment 3b**). Specifically, we have offered gift cards ranging in value from \$30-\$50 for 90-day follow-up surveys and \$40-\$60 for 180-day follow-up surveys. The specific amount for tokens was determined by grantees based on local standards as local circumstances indicate. We propose to continue to offer the same tokens of appreciation already established, as not offering them in this proposed extension could potentially reduce the retention rate and bias the results.

In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions..."

The survey instrument contains highly sensitive questions regarding sexual history, drug use, and coping style. Providing tokens of appreciation to respondents will be critical to achieving acceptable response rates in this hard-to-find population as demonstrated in the survey literature (Kulka 1995).

Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (Thiede 2009; MacKellar 2005). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes (Whiteman 2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancey 2006).

10. Assurance of Confidentiality Provided to Respondents

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

IRB Approval

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

Privacy Impact Assessment Information

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

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

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

The data are 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 is 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 is password protected and accessible only to project staff and direct supervisors. Data is 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 is implemented according to the local/state policies of the funded agencies and the consent form is completed by all participants (OMB 0920-0895, Expiration Date 8/31/2014).

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

Participation in this CMEP-Respect 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 Respect intervention participants questions that are of a sensitive nature. By nature of this project, Respect 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/STD 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/STD behavioral risk and attitudes and beliefs data. Thus, participants are asked to report on sensitive and private matters pertaining to their sexual practices and substance use. Some of the questions 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 a twelve month period (September 2014 – August 2015). The population targeted by this project are men who have sex with men (MSM) who are 18 years of age or older and report having had sex with a male in the last 12 months. Respondents will be administered the questionnaire at 90 and 180 days after participating in the Respect intervention. Each of the four agencies funded to participant in CMEP-Respect will be required to submit to CDC two separate QDS data warehouses (**Attachment 3c and 3d**) that include data collected via 90- follow-up survey (**Attachment 3a**) and 180-day follow-up survey (**Attachment 3b**) 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	Average Burden Response	Total Burden
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			Respondent	(Hours)	(Hours)
General public	90-day Follow-up Survey (Attachment 3a)	320	1	18/60	96
CMEP-Respect grantees	90-day SDN Submission	4	12	5/60	4
General public	180-day Follow-up Survey (Attachment 3b)	320	1	18/60	96
CMEP-Respect grantees	180-day SDN Submission	4	12	5/60	4
Total					200

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 January 2011 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	90-day Follow-up Survey (Attachment 3a)	96	\$22.77	\$2185.92
CMEP-Respect	90-day SDN	4	\$22.77	\$91.08

grantees	Submission			
General Population	180-day Follow-up Survey (Attachment 3b)	96	\$22.77	\$2185.92
CMEP-Respect grantees	180-day SDN Submission	4	\$22.77	\$91.08
Total				\$4554.00

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 annualized cost to the government is \$755,325. 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 \$3,761,615. The project involves participation of one CDC project officer (GS-13 level) and a CDC Co-Principal Investigator (GS-14 level) who is responsible for project design, project oversight, and analysis and dissemination of the results. The CDC project officer provides remote and onsite technical assistance to the agencies implementing the data collection. Three contractors (a project coordinator, a project consultant, and a data manager) 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 (GS-13, .65 FTE)	\$56,130

Expense Type	Expense Explanation	Annual Costs (dollars)
	CDC Co-Principal Investigator (GS-14, .05 FTE)	\$5,400
Operational	Travel - two trips for Project Officer	\$5,000
	Subtotal, Direct Costs to the Government	\$66,530
Contractor and Other Expenses	Project Coordinator (Manila Consulting Group, Inc., .75)	\$100,230
	Project Consultant (Manila Consulting Group, .12)	\$12,420
	Data Manager (Manila Consulting Group, Inc., .25)	\$36,145
	Cooperative Agreement to Cascade AIDS Project: Portland, Oregon	\$135,000
	Cooperative Agreement to Fenway Community Health Center: Boston, Massachusetts	\$135,000
	Cooperative Agreement to FROST'D:New York, New York	\$135,000
	Cooperative Agreement to Life Foundation: Honolulu, HI	\$135,000
	Subtotal, Contracted and other expenses	\$688,795
	TOTAL COST TO THE GOVERNMENT	\$755,325

Salary estimates were obtained from the OPM salary scale (<http://www.opm.gov/>).

15. Explanation for Program Changes or Adjustments

This is a continuation of an already approved data collection (OMB 0920-0895, Expiration Date 8/31/2014). The OMB extension is sought in order to complete follow-up surveys for participants

already enrolled in the project, in order to obtain more complete data.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit 16.A Project Time Schedule

Activity	Time Schedule
QDS data collection begins	Following OMB approval
QDS data submission to CDC	Monthly
QDS data collection ends	12 months after OMB approval
Analysis begins	12 months after OMB approval
Dissemination of results	18 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.

References

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