Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System

(OMB #0920-0612)

Extension Request

Supporting Statement Part A: Justification

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Abstract

CDC currently collects progress reports and minimum data elements (MDE) from 21 WISEWOMAN program grantees (OMB No. 0920-0612, WISEWOMAN Reporting System, exp. 3/31/2013). Information is collected semi-annually. A one-year extension is requested to enable reporting for the final year of activities funded under the current Funding Opportunity Announcement. There are no changes to the items of information to be collected, the burden per response, reporting frequency, the number of grantees, or the total annualized burden hours.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Background

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC) is requesting approval for a one-year extension, without changes, of the data collected for the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program. The WISEWOMAN program was initiated in response to the Secretary of Health and Human Services' Continuous Improvement Initiative, asking for the development of programs that examine ways in which service delivery can be improved for selected populations. WISEWOMAN was authorized in 1993 through a legislative supplement to the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354, see **Attachment 1a**). CDC's data collection authority for this study is Section 301 of the Public Health Service Act [42 U.S.C. 241] (**Attachment 1b**).

The WISEWOMAN program focuses on reducing cardiovascular disease (CVD) risk factors among at-risk women. CVD, which includes heart disease, myocardial infarction, and stroke, is the leading cause of death for women in the United States. It is a primary contributor to mortality, morbidity, and decreased quality of life, especially among older women. Addressing such risk factors as elevated blood cholesterol, high blood pressure, obesity, sedentary lifestyle, diabetes, and smoking greatly reduces a woman's risk of CVD-related illness and death. Women in lower income brackets, with lower levels of education, or without health insurance have an increased risk of CVD morbidity and mortality, as they have limited access to health services and have been shown to be more likely to smoke cigarettes, engage in limited physical activity, and have poor nutrition. State, territorial, and tribal organizations awarded WISEWOMAN grants are expected to report information pertaining to the aforementioned factors for the purposes of program evaluation. Because the data collection system used by WISEWOMAN is based on the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), the burden of collecting the additional information has been minimized.

CDC collected cost data from WISEWOMAN grantees from 07/01/2008 to 12/31/2009. Analyses of the cost data was discontinued for the current OMB approval period (01/27/2010 through 03/31/2013) and will not be collected during the requested extension period.

Privacy Impact Assessment

In the OMB extension period, CDC will continue to fund 21 WISEWOMAN programs which operate on the local level in states and tribal organizations. WISEWOMAN grantees provide preventive services to underserved women, such as blood pressure, cholesterol and diabetes testing, as well as lifestyle programs targeting poor nutrition, physical inactivity, and smoking. The interventions may vary from program to program, but all are designed to promote healthy lifestyle changes. WISEWOMAN grantees collect identifiable client-level information in order to track and support client services at the local level, but **no direct client-level identifier information is reported to CDC**.

Programs are not to send information that will allow participants to be identified. Prior to electronic data transfer to the data contractor, each WISEWOMAN grantee removes all personal identifiers and assigns a unique code for each woman in the data base. The CDC contractor, SciMetrika will not accept a method of record identification, such as social security number, that may be linked to other databases. The identifying information provided to the data contractor will be patient ID number, county of residence, state of residence, zip code of residence, race, date of birth, and Hispanic origin. In WISEWOMAN , the zip code field is requested for participants, unless fewer than five participants live in one zip code, See details in the zip code field description in the MDE Manual 8.0 **(Attachments 3a and 4a).**

The development of a unique method of record encryption and identification by each grantee program will allows CDC to anonymously track women served throughout their association with WISEWOMAN, without the use of names. The foci of the data collection are to evaluate activities that are designed to improve public health practice and program performance.

The grantee programs will maintain the encryption information between their unique codes and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the contractor. Direct client identifiers are not included in the information that is transmitted to CDC for program monitoring and evaluation.

The aggregate data provided to the contractor is archived on secure network servers with user ID and password restricted access at the location of the data contractor and at the CDC. Access rights and restrictions to network resources are determined by user ID. Network systems are maintained in a locked room with access strictly limited to essential employees.

Overview of the Data Collection System

Twice a year, each grantee site's Minimum Data Elements (MDEs) are reviewed by the site's Program Manager, and a de-identified electronic data file is transmitted to CDC's data collection contractor. The Minimum Data Elements include items relating to Screening and Assessment (see **Attachment 3a**) and items relating to Interventions (see **Attachment 4a**). Upon receipt of each transmission, the contractor, SciMetrika, LLC, Durham, NC, performs additional quality control checks and works with the WISEWOMAN grantee to resolve any discrepancies or problems with data integrity. SciMetrika, LLC, 100 Capitola Drive, Suite 104 Durham, NC 27713-4451, then creates an aggregate file that is encrypted prior to transmission to

CDC via a secure website. Screen shots of the web portal are included as Attachment 3b/4b. The aggregate file is used for data analysis and report generation. **The analysis file does not contain direct client identifiers such as name or SSN, but it does contain indirect client identifiers (Information in Identifiable Form, IIF), such as demographic information**. Grantees also submit a written progress report to CDC semi-annually (see **Attachment 5**).

Items of Information to be Collected

The MDEs include information about the screening site; client demographics, risk factors and clinical assessment; and interventions in which clients have participated. Health outcome measures assessed include systolic and diastolic blood pressure, total and HDL cholesterol, body mass index (BMI), smoking rates, and project-specific nutrition and physical activity variables. The written progress report is primarily a narrative description of the program's activities and accomplishments and is a requirement for awardees as outlined in the FOA. Please see section A.10 for further description of the process for de-identifying data.

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

Information about the WISEWOMAN program is posted on a publicly accessible CDC public information website, http://www.cdc.gov/WISEWOMAN/ . The CDC (http://www.cdc.gov/WISEWOMAN), describes to the public the WISEWOMAN program and contains no participant data. There is no content directed at children under 13 years of age.

MDE information is collected from grantees electronically but is not collected from a web-based system. The MDE has no relationship to the Agency WISEWOMAN public accessible website. SciMetrika, LLC, maintains security of all data on network, Web Servers, and external medium. Location of data is accountable and secured by lock/Key and password protected at all times. SciMetrika, LLC maintains different levels of access for grantees, and WISEWOMAN Project Officers as determined by the WISEWOMAN Contracting Officer.

A.2 Purpose and Use of Information Collection

The information collected through the WISEWOMAN Reporting System supports two major objectives: 1) continuous program improvement, and 2) evaluation of the program. Ongoing evaluation, utilizing timely information, improves program performance. Moreover, performance must be assessed at least annually for compliance with the CDC's Government Performance and Results Act (GPRA) strategic plan.

The minimum data elements (MDEs) allow for identifying the number of women screened over a given reporting period at a given location. Because each location has a target number of women who are expected to be screened upon full implementation, the MDEs can be used to assess whether specific locations are on track to meet their stated screening goals. WISEWOMAN MDEs were also purposely chosen so that they could be combined into a summary measure that assesses overall CVD risk. This measure was chosen because it provides an assessment of the overall reduction in CVD among WISEWOMAN participants and can be easily implemented based on existing risk scoring algorithms. The summary measure is

important because it allows for assessing the benefits using a single, comparable metric that can be conveyed to policy makers. To determine which of the existing CVD risk estimators should be used for our analysis, we assessed the power of 11 CVD risk estimators that could be used with WISEWOMAN data to detect changes in risk due to changes in select inputs. We simulated various combinations of improvements in blood pressure, cholesterol, and smoking status for a random subset of women and identified two estimators that are most appropriate for evaluating the effectiveness of risk reduction programs. The two estimators are an algorithm for 10-year risk of coronary heart disease (CHD) developed by Anderson et al (1991) and a scoring sheet predicting 5-year probability of cardiovascular disease (CVD) developed by Jackson (2000). Both estimators were derived based on the data from the Framingham Heart Study and both include age, systolic blood pressure, total and HDL cholesterol, and smoking status as input risk factors. Jackson (2000) also accounts for diastolic blood pressure. Anderson's estimator consists of a set of formulas that calculate risk as a continuous variable. Jackson's estimator, on the other hand, is a color-keyed chart used to place individuals into one of the 8 risk categories (<2.5%; 2.5 – 5%, 5-10%, 10-15%, 15-20%, 20-25%, 25-30%, and >30%). We have used both of these estimators to assess changes in CVD risk among WISEWOMAN participants from baseline to follow-up. The information contained in the reports has been used for secondary data analyses to answer specific questions related to CVD risk among low-income at-risk women.

The ultimate goal of the information collection has been to assess overall performance to determine if the program warrants continuation and expansion.

Privacy Impact Assessment

The WISEWOMAN grantees collect personal identifiers on each client served (e.g., name, address, social security number, age, race/ethnicity) along with information about the client's medical history, results of the screening exam, and participation in lifestyle interventions. The collection of personal information is necessary in order for grantees to provide medical services and to track clients. The WISEWOMAN grantees assign a unique identifier (ID) code to each client served through the program, and the ID code is used to identify records when information is transmitted from the grantee to collection contractor SciMetricka, LLC, or from the contractor to CDC. Grantees are instructed not to send information that will allow participants to be identified. **Prior to electronic data transfer to the data contractor, each WISEWOMAN grantee removes all personal identifiers and assigns a unique code for each woman in the data base**. The CDC Contractor, SciMetrika, LLC. will not accept a method of record identification, such as social security number, that may be linked to other databases. The identifying information provided to the data contractor will be patient ID number, county of residence, state of residence, zip code of residence, race, date of birth, and Hispanic origin.. In WISEWOMAN , the zip code field is requested for participants, unless fewer than five participants live in one zip code, See details in the zip code field description in the MDE Manual 8.0 **(**see **Attachments 3a and 4a).**

The development of a unique method of record encryption and identification by each grantee program allows CDC to anonymously track woman served throughout their association with WISEWOMAN, without the use of names. The grantee programs will maintain the encryption information between their unique codes and the personal identifiers in their database.

Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the data contractor. Direct client identifiers are not included in the information that is transmitted to CDC for program monitoring and evaluation.

The aggregate data provided to the contractor is archived on secure network servers with user ID and password restricted access at the location of the data contractor and at the CDC. Access rights and restrictions to network resources are determined by user ID. Network systems are maintained in a locked room with access strictly limited to essential employees. The grantee is solely responsible for maintaining the unique list linking ID code with the client's name.

Information regarding health screening results is shared; however personal participant (identifying) information is not shared. Prior to electronic data transfer to the data contractor, each WISEWOMAN grantee removes all personal identifiers and assigns a unique code for each woman in the data base. The grantee is solely responsible for maintaining the unique list linking ID code with the client's name. The screening results are aggregated and used in biannual programs data summary reports. Individual grantees and aggregated data summaries are shared with all twenty-one grantees. Additionally, aggregated data may be used in WISEWOMAN At-A-Glance, Program Briefs and other program documents.

Because data are only shared in de-indentified form, inadvertent disclosure of coded data would not have an impact on clients.

A.3 Use of Improved Information Technology and Burden Reduction

All MDE data continue to be submitted electronically by grantees to reduce the respondent burden and speed delivery. The MDE data are transmitted as electronic fixed-length text files consistent with prescribed file formats. To ensure that the reporting burden is minimized, CDC and the contractor provide in-person and/or remote technical assistance to grantees upon request.

A.4 Efforts to Identify Duplication and Use of Similar Information

These data are available exclusively from the WISEWOMAN grantees, and no other source of data exists that would allow for determining program effectiveness. Although data-sets with questions related to cardiovascular disease currently exist [e.g., the state-based Behavioral Risk Factor Surveillance System (BRFSS)], these data do not include participants enrolled in the WISEWOMAN program. All WISEWOMAN participants also participate in the NBCCEDP program. Rather than require participants to provide duplicative information, WISEWOMAN relies on the NBCCEDP reporting system to provide demographic characteristics of participants, including age, race, gender, and education. This reduces participant's response burden and streamlines the data reporting process.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be adversely impacted.

A.6 Consequences of Collecting the Information Less Frequently

Ongoing evaluation is a necessary component of the program and the evaluation cannot be completed without the requisite data. The reporting periods established for WISEWOMAN are identical to those established for NBCCEDP and are frequent enough to allow for ongoing evaluation, but not too frequent to be overly burdensome. The current reporting periods allow CDC and grantees to assess performance at regular intervals, and to make adjustments as necessary. Less frequent data collection would compromise the ability to successfully conduct the evaluation.

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

The data collection described in this request for is consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances.

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

A. A Notice was published in the *Federal Register* on Monday, October 15, 2012 (Vol. 77, No. 199, pp. 62515-62516). The Notice is included as **Attachment 2a**. CDC received one public comment and provided a courtesy reply (**Attachment 2b**).

B. The WISEWOMAN data collection and reporting infrastructure is based on the NBCCEDP data collection and reporting infrastructure (OMB 0920-0571, current expiration date 11/30/2012). The NBCCEDP data collection was developed by the Division of Cancer Prevention and Control (DCPC) in collaboration with an external contractor. The WISEWOMAN data collection was developed and is continually reviewed by the Division of Heart Disease and Stroke Prevention, an external contractor and a formal advisory committee consisting of representatives from all WISEWOMAN grantees (MDE subcommittee). WISEWOMAN also hosts an annual conference in which the stakeholders mentioned above can review data issues. Additionally, WISEWOMAN and contract staff do participate in NBCCEDP data conference calls to ensure collaboration across programs. Contact information for the primary stakeholders mentioned above is listed below:

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These activities allow direct discussion of data issues between the CDC and key stakeholders. When data issues arise that cannot be resolved during the meetings, CDC confers with the data contractor, solicits continued feedback from grantees via the MDE subcommittee, and contacts other experts both within and outside the Agency prior to making changes to the reporting infrastructure.

A.9 Explanation of Any Payment or Gift to Respondents

No payment will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The WISEWOMAN data collection is conducted primarily for purposes of program evaluation and improvement, not research. IRB approval is not required for public health

practice.

A. Staff in the CDC Information Collection Review Office have reviewed this submission and determined that the Privacy Act is not applicable. Respondents are WISEWOMAN grantees. The grantees maintain identifiable information about clients in their established record systems. **The information transmitted to CDC by grantees does not contain direct client identifiers such as names or SSNs**.

B. Ensuring that the data are kept secure is of utmost importance to CDC and the grantees. The WISEWOMAN grantees collect personal identifiers about each woman served (e.g., name, address, social security number, age, race/ethnicity) along with information about the woman's medical history, results of the screening exam, and intervention participation. The collection of identifiable personal information is necessary in order for grantees to provide medical services and to track participants. However, grantees do not transmit identifying information to CDC's data collection contractor or to CDC. CDC does not collect Information in identifiable form (IIF) or require grantees to collect SSN. Grantees own the identifiable data. Only coded (de-identified) information is transmitted to CDC.

The WISEWOMAN grantees assign a unique identifier (ID) code to each program participant, and the ID code is used to identify records when records are transmitted to data contractor and CDC. The de-identified data submitted by the grantees is a CDC required subset of their larger clinical dataset. This data will be kept by grantees in accordance with their state/tribal medical information archiving protocols. Data are encrypted during transmission. The grantee is solely responsible for maintaining the unique list linking ID and name at each site. The grantee programs will maintain the encryption information between their unique codes and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the data contractor.This method of record identification allows each client served to be tracked throughout their involvement with WISEWOMAN without using names or other identifying information.

The aggregate data provided to the contractor is archived on secure network servers with user ID and password restricted access at the location of the data contractor and at the CDC. Access rights and restrictions to network resources are determined by user ID. Network systems are maintained in a locked room with access strictly limited to essential employees. The grantee is solely responsible for maintaining the unique list linking ID code with the client's name.

The contractor is required, at the end of the contract option period, to provide CDC with all data, and other materials. "The contractor shall retain no information, data, software, source code or other materials developed or obtained

under this contract unless expressly authorized in writing by the Government. All such information, software, source code, or other materials shall be delivered to the Government.

The CDC does not anticipate the development of a public use data set using WISEWOMAN data. In limited circumstances, CDC may allow secondary analysis of WISEWOMAN data for relevant research purposes. If granted permission to use the data by CDC, external researchers will be required to obtain IRB approval and to sign a Data Use Agreement form indicating that they agree to comply with the provisions outlined for data release. No identifying information will ever be granted to external researchers.

C. **CDC requires that grantees have a process in place to obtain consent from WISEWOMAN clients for participating in the program**. Individual WISEWOMAN grantees develop consent forms using suggested guidance from CDC. The guidance document (see **Attachment 8**) instructs grantees to describe the program's purpose, procedures, the types of tests that will be completed, and privacy safeguards. If secondary research uses of the data are proposed by individual sites or other investigators, they will be required to obtain IRB-supervised consent.

D. Respondents are WISEWOMAN grantee programs, and participation in the information collect is a condition of award. Participants in the program are made aware of the need to collect information prior to any services provided.

A.11 Justification for Sensitive Questions

Grantees collect sensitive, identifiable information from women participating in the program, such as medical history and Race/Ethnicity. This information is required to support verification of eligibility, the delivery of medical services, and data analysis as defined by WISEWOMAN program objectives. The sensitive information is used to insure services are provided that meet the specific needs of participants.

A.12 Estimates of Annualized Burden Hours and Costs

A. The MDEs are submitted to the data contractor two times per year (see **Attachments 3a and 4a**) via a web portal (see **Attachments 3b/4b**). In addition, grantees submit a paper Progress Report that provides an overall summary of programmatic activity (see **Attachment 5**). Because much of the data are collected and maintained by WISEWOMAN grantee programs as part of their internal evaluation, the additional burden for data reporting is small and only entails the time needed to generate and submit electronic data files and write brief responses for the quarterly reports. The respondent burden is further reduced by the electronic data submission, the consistent reporting schedule, and the similarity of WISEWOMAN and NBCCEDP data requirements. During the period of this OMB Extension, the number of respondents will continue to be the

existing 21 grantees (see **Attachment 6**). All information will continue to be reported to CDC twice per year.

Table A.12-1 summarizes the existing number of respondents and estimated burden hours. The total estimated annualized burden hours are 1,680

Table A.12-1. Number of Respondents and Estimated Burden Hours

Type of Respondents	Form Name	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
WISEWOMAN Grantees	Screening and Assessment MDEs	21	2	16	672
	Intervention MDEs	21	2	8	336
	Progress Report	21	2	16	672
				Total	1,680

B. The total estimated annualized cost to respondents is $ 45,528. The estimate is based on an average hourly wage of $27.10 for grantees' staff, who, compile and transmit information to the data collection contractor.

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

Form Name	Mean Hourly Wage Plus Benefits	Total Burden (in Hours)	Total Annualized Cost to Respondents
Screening and Assessment MDEs	$27.10	672	$18,211
Intervention MDEs	$27.10	336	$9,106
Progress Report	$27.10	672	$18,211
		Total	$45,528

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

Respondents will incur no capital or maintenance costs to complete this data collection.

A.14 Annualized Cost to the Federal Government

The total estimated annualized cost to the federal government includes the costs of a data collection contract and the cost of government personnel time for project oversight. The cost of the data collection contract with the current contractor is estimated to be $333,426 per year. In addition, CDC personnel costs are estimated at $10,000. Table A.14-1 summarizes the estimated federal government cost distribution. The total estimated annualized cost to the Federal government is $356,789.

Table A.14-1. Estimated Annualized Federal Government Cost Distribution

	Annualized Cost
Data Contractor Total	**$333,426**
Data Collection	47,469
Data Analysis	48,755
Data Reporting	199,511
Data Training	37,691
CDC - GS 13 Technical Monitor at 10% FTE	**$10,000**
CDC – ORISE FELLOW (GS-9) at 20% FTE	$13,363
Total	**$356,789**

A.15 Explanation for Program Changes or Adjustments

There are no changes to the number of grantees (respondents), the information collection requirements, the estimated burden per response, or the total estimated annualized burden hours.

A.16 Plans for Tabulation and Publication and Project Time Schedule

CDC will continue to use the screening and intervention data reported by grantees to produce three categories of publications: Preliminary MDE Summary Reports, Planned Publications, and Special Research Projects. The Preliminary MDE Summary Reports are standardized, semi-annual reports that include basic statistics summarizing risk factor variables for each grantee. These reports are produced within 60 working days of receipt of the information. Planned Publications are formal reports that include cost-effectiveness analyses, multivariate analyses of the MDEs, and an examination of specific hypotheses. These reports are produced annually for inclusion in publications and presentations at conferences. These publications are also posted to the CDC web site and may also be included in peer-reviewed journals. In the case of planned Special Research Projects an IRB request will be generated. These projects include topics of interest to CDC and other researchers that are for publication in

peer-reviewed journals. These projects are developed periodically with input and collaboration from grantees and outside researchers.

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

There is no request for an exemption from displaying the expiration date for OMB approval.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These data will be collected in a manner consistent with the certification statement identified in Item 19 "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I. No exceptions are requested.