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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Supporting Statement for Paperwork Reduction Act Generic Information Collection Submissions for Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System (OMB #0920-0612) Extension Request

A. JUSTIFICATION

- Goal of the study: 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.

- Intended use of the resulting data: The data collected by the WISEWOMAN program are used to evaluate activities that are designed to improve public health practice, program performance, and assess program outcomes which are all aimed at reducing cardiovascular disease (CVD) risk factors among at-risk women.

- Methods to be used to collect: Minimum Data Elements (MDEs) are reviewed by the site's Program Manager, a de-identified electronic data file is then transmitted to CDC's secure web-based system managed by its data collection contractor.

- The subpopulation to be studied: Women in lower income brackets, with lower levels of education, or without health insurance who have an increased risk of CVD morbidity and mortality and are the recipients of targeted interventions at the state, tribal, or local level funded by WISEWOMAN grants.

- How data will be analyzed: Trend analysis for continuous program improvement and to gauge the effectiveness of services and programs provided aimed at reducing occurrences of cardiovascular disease.

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 a **two-year extension**, without changes, of the data collected for the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program (OMB No. 0920-0612). One year to enable reporting for the final year of activities funded under the current cooperative agreement and an option year, subject to the availability of funds. There are no changes to the information collected, the burden per response, reporting frequency, the number of awardees, or the total annualized burden hours. 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 risk factors such as high blood pressure, elevated blood cholesterol, 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.

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 awardees provide preventive services to underserved women, such as blood pressure, cholesterol, and diabetes testing, as well as lifestyle programs (LSP) targeting poor nutrition, physical inactivity, and smoking. The LSPs may vary from program to program, but all are designed to promote healthy lifestyle changes. WISEWOMAN awardees 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 will not send information that will allow participants to be identified. Prior to electronic data transfer to the data contractor, each WISEWOMAN awardee removes all personal identifiers and assigns a unique code for each woman in the database. The CDC contractor, SRA (A CSRA Company) 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. The MDE Manual 9.0 was approved by OMB on 12/2/2013 (see Attachment 3). One MDE, that had become obsolete, was formally deleted from the MDE through a non-substantive change request which was approved by OMB on 08/10/2016 (see **Attachment 2a**). The MDE Manual 9.0 is the most recent and there have been no additional changes.

The development of a unique method of record encryption and identification by each awardee program will allow 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, program performance, and assess program outcomes.

The awardee 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 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 awardee 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 secure web-based system managed by its data collection contractor. The MDEs include items relating to Screening and Assessment and Lifestyle Programs (see **Attachment 3**). Upon receipt of each transmission, the contractor, SRA International, Inc. (A CSRA Company) in Atlanta, Georgia, performs additional quality control checks and works with the WISEWOMAN awardee to resolve any discrepancies or problems with data integrity. SRA International, Inc. (A CSRA Company), 2 Corporate Boulevard NE, Atlanta, GA 30329, then creates an aggregate file that is encrypted prior to transmission to CDC via a secure website. A screen shot of the web portal are included as **Attachment** 4. 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**. Awardees also submit a written progress report to CDC once 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 lifestyle programs in which clients have participated. Health outcome measures assessed include, but are not limited to, systolic and diastolic blood pressure readings, total cholesterol, weight, waist-to-hip ratio, smoking status, quality of life, nutrition, and physical activity variables. The written progress report, which will be submitted annually, is primarily a narrative description of the program's activities and accomplishments and is a requirement for awardees as outlined in the FOA.

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

Information about the WISEWOMAN program is posted on a publicly accessible CDC public information website, http://www.cdc.gov/WISEWOMAN/ . This website 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 awardees electronically from a secure web-based system. The MDE has no relationship to the Agency WISEWOMAN publicly accessible website. CDC maintains security of all data on network, Web Servers, and the external partner entryway. Location of data is accountable and secured by lock/key and password protected at all times. SRA International, Inc. (A CSRA Company) maintains different levels of access for awardees, and WISEWOMAN Project Officers as determined by the WISEWOMAN Contracting Officer's Representative.

2. Purpose and Use of the Information Collection

The information collected through the WISEWOMAN Reporting System supports three major objectives: 1) continuous program improvement, 2) evaluation of the program, and 3) assessing program health outcomes. Ongoing evaluation and 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 as well as participation in Lifestyle Programs. 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.

Life's Simple Seven™ is a cardiovascular health risk assessment developed by the American Heart Association (2010). It takes into account seven health measures which include physical activity, cholesterol levels, dietary habits, managing blood pressure, weight loss, reducing blood sugar, and smoking cessation. A numerical heart health score as well as individualized goals and targets for a healthy lifestyle are provided at the end of each assessment. The score is on a scale of 1 to 10 where 10 references ideal heart health and the lowest possible risk of developing cardiovascular disease. The other cardiovascular health risk estimator is an algorithm for the 10-year risk of coronary heart disease (CHD) developed by Anderson et al. (1991) and modified by Wilson et al. (1998). This estimator was derived based on the data from the Framingham Heart Study and includes age, systolic and diastolic blood pressures, total cholesterol or LDL cholesterol as well as HDL cholesterol, diabetes, and smoking status as input risk factors. Anderson's estimator consists of a set of formulas that calculate risk as a continuous variable. Historically, WISEWOMAN has used this estimator to assess changes in cardiovascular health risk among its participants from baseline to follow-up. The information will be used to answer specific questions related to cardiovascular health 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 awardees 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 programs. The collection of personal information is necessary in order for awardees to provide medical services and to track clients. As discussed previously, Awardees are instructed not to send information that will allow participants to be identified.

The development of a unique method of record encryption and identification by each awardee program allows CDC to anonymously track woman served throughout their association with WISEWOMAN, without the use of names. The awardee 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 will not be included in the information that is transmitted to CDC for program monitoring, evaluation, or assessment of program outcomes.

The aggregate data provided to the contractor is archived on secure CDC network servers with user ID and password restricted access 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 awardee is solely responsible for maintaining the unique list linking unique identifier code with the client's name. CDC never has access to this information.

Information regarding health screening results is shared; however personal participant (indirect information in identifiable form) information is not shared. Prior to electronic data transfer to the data contractor, each WISEWOMAN awardee removes all personal identifiers and assigns a unique identifier code for each woman in the database. The awardee 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 awardees and aggregated data summaries are shared with all twenty-one awardees. Additionally, aggregated data may be used in WISEWOMAN At-A-Glance, Program Briefs and other program documents.

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

3. Consideration Given to Information Technology

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

4. Duplication of Information

The MDE data are available exclusively from the WISEWOMAN awardees, and no other source of data exists that would allow for continuous program improvement, evaluation, and assessment of program health outcomes. Although national data sets with questions related to cardiovascular health currently exist [e.g., the state-based Behavioral Risk Factor Surveillance System (BRFSS)], these data do not capture information about the WISEWOMAN program and its target population derived from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

5. Reducing the Burden on Small Entities

No small businesses will be adversely impacted.

6. Consequences of Not Conducting Collection

Continuous program improvement and ongoing evaluations are necessary components of the program and neither can be accomplished without the requisite data. The current reporting periods allow CDC and awardees to assess performance at regular intervals, and to make adjustments as necessary.

7. Special Circumstances

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

8. Consultations with Persons Outside the Agency

A. A 60-day Notice was published in the *Federal Register* on July 26, 2016 (Vol. 81, No. 143, pp. 48806-48808). A copy of the notice is provided as **Attachment 2b**. No public comments were received.

B. The WISEWOMAN data collection and reporting infrastructure is based on the NBCCEDP data collection and reporting infrastructure (OMB 0920-0571, current expiration date 12/31/2018). 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 (DHDSP), WISEWOMAN Team Lead, and WISEWOMAN Data Team lead by a Health Scientist with four other CDC staff and an ORISE fellow along with three representatives from the external data contractor, as well as a formal advisory committees consisting of representatives from all WISEWOMAN awardees (Program Director/Program Manager Work Group). WISEWOMAN also hosts all program calls in which the stakeholders mentioned above have the opportunity to review data issues. Additionally, WISEWOMAN staff periodically participates 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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Health Scientist
WISEWOMAN Program
Advancing Health Equity Team

Program Development and Services Branch
Division of Heart Disease and Stroke Prevention
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop F-75
Atlanta, GA 30341
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Derrick Gervin, PhD, MSW
Team Lead, Advancing Health Equity Team
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National Center for Chronic Disease Prevention and Health Promotion
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Atlanta, GA 30341
(770)-488-5004

Erica Sandoval
Oregon Program Director
Current PD/PM Committee co-Chair
Oregon Health Authority/Public Health
800 NE Oregon Street
Portland, OR 97232-2162
971-673-2282

Lori Byrd
Intervention/Community Resource Coordinator
Current PD/PM Committee co-Chair
Iowa Department of Public Health
321 E. 12th Street
Des Moines, IA 50319
515-281-7709

Janet Royalty
Data Computer Programmer
NBCCEDP Program
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop K-57
(770-488-3085)

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 awardees via the Program Director/Program Manager Work Group, and contacts other experts both within and outside the Agency prior to making changes to the reporting infrastructure.

9. Payment or Gift

No payment will be provided to respondents.

10. Confidentiality

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

A. Staff in the CDC National Center for Chronic Disease Prevention and Health Promotion have reviewed this submission and determined that the Privacy Act is not applicable. Respondents are WISEWOMAN awardees. The awardees maintain identifiable information about clients in their established record systems. **The information transmitted to CDC by** awardees **does not contain direct client identifiers such as names or SSNs**.

Ensuring that the data are kept secure is of utmost importance to CDC and the awardees. The WISEWOMAN awardees 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 Lifestyle Program participation. The collection of identifiable personal information is necessary in order for awardees to provide medical services and to track participants. However, awardees 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 awardees to collect SSN. Awardees own the identifiable data. Only coded (de-identified) information is transmitted to CDC.

The WISEWOMAN awardees 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 awardees is a CDC required subset of their larger clinical dataset. This data will be kept by awardees in accordance with their state/tribal medical information archiving protocols. Data are encrypted during transmission. The awardee is solely responsible for maintaining the unique list linking ID and name at each site. The awardee 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 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 awardee 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 de-identified data, and other program 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 limited secondary analysis of WISEWOMAN data related to publication or 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.

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

C. Respondents are WISEWOMAN awardee 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.

11. Sensitive Nature

Awardees 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 and Health Equity focus. The sensitive information is used to insure services are provided that meet the specific needs of participants.

12. Burden of Information Collection

A. The MDEs are submitted to the data contractor two times per year (see **Attachment 3**) via a web portal (see **Attachment 4**). The estimated burden per response for the Screening and Assessment MDEs and Lifestyle Program MDEs is 24 hours.

B. Awardees also submit a written progress report once a year that provides an overall summary of programmatic activity (see **Attachment 5**). The estimated burden per response is 16 hours.

Because much of the data are collected and maintained by WISEWOMAN awardee 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 one electronic data file and write brief responses for attached forms. The respondent burden will be further reduced by the electronic data submission and consistent reporting schedule. During the period of the FOA extension, the number of respondents will be 21 programs.

Table A.12-1 summarizes the existing number of respondents and estimated burden hours. The total estimated annualized burden hours are 1,344.

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

Type of Respondents	Type of Collection	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
WISEWOMAN Awardees	Screening and Assessment and Lifestyle Program MDEs	21	2	24	1008
	Annual Progress Report	21	1	16	336
	Total		3	40	1,344

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 and Lifestyle Program MDEs	$27.10	1008	$27,317
Annual Progress Report	$27.10	336	$9,106
		Total	$36,423

The total estimated annualized cost to respondents is $ 36,423. The estimate is based on an average hourly wage of $27.10 for awardee' staff, who compile and transmit information to the data collection contractor.

13. Cost to Respondents

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

14. Costs to 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 $350,000 per year. In addition, CDC personnel costs are estimated at $10,008 for the Technical Monitor and $10,242 for a Fellow. Table A.14-1 summarizes the estimated federal government cost distribution. The total estimated annualized cost to the Federal government is $370,250.

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

	Annualized Cost
Data Contractor Total	**$350,000**
Data Collection	50,000
Data Analysis	54,000
Data Reporting	200,000
Data Training	46,000
CDC - GS 13 Technical Monitor at 10% FTE	**$10,008**
CDC – ORISE FELLOW (GS-9) at 20% FTE	$10,242
Total	**$370,250**

15. Reason for Change

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

16. Tabulation of Results, Schedule, Analysis Plans

CDC will continue to use the screening and lifestyle program data reported by awardees to produce three categories of publications: Preliminary MDE Summary Reports, Planned Publications, and Special Projects. The Preliminary MDE Summary Reports are standardized, semi-annual reports that include basic statistics summarizing risk factor variables for each awardee. These reports are produced within 90 working days of receipt of the information. Planned Publications are formal reports that include, 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 information from them may also be included in peer-reviewed journals. In the case of planned Special Projects that are research an IRB request will be generated as appropriate. These projects can 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 awardees and outside researchers.

17. Display of OMB Approval Date

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

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.