Extension Request

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System
OMB Control No. 0920-0612

Supporting Statement: Part A

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REFERENCES

ATTACHMENTS

1a Public Law 101-354, The Breast and Cervical Cancer Mortality Prevention Act of 1990
1b Section 301 of the Public Health Service Act [42 U.S.C. 241]
2a Map of WISEWOMAN Awardees
2b Contact Information for WISEWOMAN Program Managers, Program Directors, and Data Managers
2c 60-Day Federal Register Notice
3 WISEWOMAN MDE Manual DP18-1816 Edition 18.3
4a Screen Shot of MDE Web Portal login screen
4b Screen Shot of MDE Submission screen
5 Annual Progress Report
6 Copy of MDE Submission Instructions
7 Consent to Participate in WISEWOMAN Program

- Goal of the 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.

- 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 and are the recipients of targeted interventions at the state, tribal, or local level funded by WISEWOMAN grants.

- Methods to be used to collect: Minimum Data Elements (MDEs) are reviewed by the site's Program Manager, an electronic data file is then transmitted to CDC's secure web-based data reporting system.

- The subpopulation to be studied: WISEWOMAN awardees are state health departments and Tribal organizations. The population of interest is women in lower income brackets or without health insurance who are eligible for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and have an increased risk of CVD morbidity and mortality.

- How data will be analyzed: The data will be used to monitor continuous program improvement, as well as, evaluating the effectiveness and outcomes of the services and programs provided that aim to reduce the occurrence of CVD.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC) is requesting a two-year extension t of Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Program Reporting System (OMB No. 0920-0612). 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. CDC's WISEWOMAN prevention program was authorized by the U.S. Congress in 1993 to reduce cardiovascular disease risk factors among at-risk, low-income, uninsured, and underinsured women aged 40 to 64 by funding preventive services via state governments and tribal organizations (currently 27 and 3 respectively and five more may be added contingent on funding). WISEWOMAN was approved 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 risk factors for cardiovascular disease (CVD) among at-risk women. Addressing risk factors such as high blood pressure, elevated blood cholesterol, obesity, sedentary lifestyle, diabetes, and smoking, reduces a woman's risk of CVD-related illness and death. CVD, is a primary contributor to mortality, morbidity, and decreased quality of life, especially among older women. Health United States (2019) reported that CVD was the leading cause of death for women in the United States. Women in lower income brackets, or without health insurance have an increased risk of CVD morbidity and mortality, because they have limited access to health services such as screenings, medications, healthy behavior support services to manage their risk factors. State, and tribal organizations awarded with WISEWOMAN grants are expected to report information pertaining to the aforementioned factors for the purposes of program evaluation. The WISEWOMAN program shares data elements with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) so the burden of collecting additional information by awardees **(**see **Attachment 2a and 2b)** is minimized.

The MDE Manual 9.0 was initially approved by OMB on 12/2/2013, then reapproved on 12/21/2016 (see Attachment 3). One non-substantive change request which was approved by OMB on 05/10/2018, this was followed by a reinstatement on 08/24/2019 with MDE Manual 18.1 followed by non-substantive change requests approved of 03/20/2020, 04/27/2020, and 11/18/2020 after which the Manual was named 18.2 and 18.3, respectively. There have been no additional changes.

Overview of the Data Collection System

Twice a year, each awardee's Minimum Data Elements (MDEs) are reviewed by the site's Program Manager, and a data file is transmitted to CDC's secure web-based system managed by its data manager. CDC does not require an awardee to collect personally identifiable information. CDC provides the list of MDEs to awardees. Awardees are responsible for collecting and collating these MDEs and reporting to CDC. The MDEs include items relating to Screening and Assessment and healthy behavior support services (see **Attachment 3**). Upon receipt of each transmission, the data contractor, GDIT Inc. in Atlanta, Georgia, performs additional quality control checks and works with the WISEWOMAN awardee to resolve any discrepancies or problems with data integrity. GDIT Inc., 2 Corporate Boulevard NE, Atlanta, GA 30329, 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 **Attachments 4a** and **4b**. The aggregate

file is generated for data analysis and report dissemination. **The analysis file that CDC receives does not contain direct participant identifiers or Information in Identifiable Form.** Awardees also submit a written annual progress report (APR) to CDC annually in response to the APR template (see **Attachment 5**).

Items of Information to be Collected

The MDEs include items relating to Screening and Assessment and healthy behavior support services. Health outcome measures assessed include, but are not limited to, systolic and diastolic blood pressure readings, total cholesterol, weight, smoking status, nutrition, physical activity, and number of healthy behavior support services attended. 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 Funding Opportunity Announcement.

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, https://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 which is collected from awardees through an electronically secure web-based system has no relationship to the publicly available WISEWOMAN website. CDC maintains security of all data on networks, Web Servers, and the external partner entryway. Location of data is accountable and secured by lock/key and password protected at all times. GDIT, Inc. 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

WISEWOMAN awardee programs are respondents and they are required to participate in collecting information as a condition of the funding opportunity announcement. Prior to any services provided, participants in the program are made aware of the necessity to collect information specified in the MDE Manual. Respondents can access the MDE Manual and also submit information collected through a web portal by user-access at https://wwwn.cdc.gov/WISEWOMAN/. CDC requires Respondents to adhere to privacy safeguards as outlined in Section 10.

As a part of the funding opportunity announcement, respondents are to submit data twice a year. In order to maintain data quality, and ensure data integrity, submission instructions are sent out to twice a year (see **Attachment 6**). CDC provides the template for the APR at the beginning of the cooperative agreement (see **Attachment 5**) and at the conclusion of each program year awardees send an annual progress report directly to their CDC project officers by email.

The information collected through the WISEWOMAN Reporting System supports three major objectives: 1) public health practice through continuous program improvement, 2) program performance, and 3) assessing program health outcomes through evaluation. Ongoing evaluation and utilizing timely

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

3. Use of Improved Information Technology and Burden Reduction

All MDE data will continue to be submitted electronically by awardees to reduce the respondent burden and speed of delivery. The MDE data will be transmitted as electronic fixed-length text files consistent with prescribed file formats. Some awardees are able to leverage Electronic Health Record systems to facilitate the collection of data and increase efficiency. To ensure that the reporting burden is minimized, CDC and the data contractor will provide in-person and/or remote technical assistance to awardees upon request.

4. Efforts to Identify Duplication and Use of Similar Information

The MDE data are available exclusively from the WISEWOMAN awardees, and no other source of data exists that would allow for 1) improving public health practice through continuous program improvement, 2) determining program performance and 3) assessing program health outcomes through evaluation. 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 the target population served by the program.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be adversely impacted.

6. Consequences of Collecting the Information Less Frequently

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 Relating to the Guidelines of 5 CFR 1320.5

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

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

A. A 60-Day Notice was published in the *Federal Register* on June 2, 2022 (Vol. 87, No. 106, pp. 33488-33489). A copy of the notice is provided as **Attachment 2c**. No public comment(s) were

received.

B. The WISEWOMAN data collection and reporting infrastructure is based on the NBCCEDP data collection and reporting infrastructure (OMB control no. 0920-0571, expiration date 03/31/2022). 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), Program Development and Service branch (PDSB) chief, and WISEWOMAN data team led by a Health Scientist with four other CDC staff and an associate service fellow along with three representatives from the external data contractor, as well as representatives of WISEWOMAN awardees. WISEWOMAN also hosts all program calls in which the stakeholders mentioned above have the opportunity to review data issues. Additionally, WISEWOMAN staff periodically participate in NBCCEDP data conference calls to ensure collaboration across programs. Contact information for the primary stakeholders mentioned above are 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 awardees via the PDPM Work Group, and contacts other experts both within and outside the CDC prior to making changes to the reporting infrastructure.

9. Explanation of Any Payment or Gift to Respondents

No payment will be provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

NCCDPHP's Information Systems Security Offices reviewed this submission and determined that the Privacy Act does not apply. CDC requires that awardees have a process in place to obtain prior consent from WISEWOMAN participants before joining the program. CDC will instruct awardees to describe the program's purpose, procedures, the types of clinical assessments that will be completed, and privacy safeguards (see **Attachment 8**). Individual WISEWOMAN awardees develop consent forms that meet these standards.

CDC does not require awardees to collect personally identifiable information or direct participant-level identifying information to be reported. Awardees generate a unique identifier (encode ID) and assign it to each WISEWOMAN participant. This allows awardees to anonymously serve women throughout their association with WISEWOMAN. Data is kept by awardees in accordance with their state/tribal organization medical information archiving protocols which also utilize unique methods of encryption.

Awardees in turn utilize clinical providers that perform clinical assessments. Clinical providers exist in the healthcare landscape independent of awardees and are subject to the Privacy Rule in the form of the Health Insurance and Portability and Accountability Act of 1996 which addresses standards for individuals' privacy rights to understand and control how their health information is used.

Awardees aggregate data from clinical providers, which does not contain PII, into a data file. This data file is uploaded by awardees to CDC through a secure data reporting system. These data are 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 data files from all awardees are collated into a national data file and used in biannual programs data summary reports such as WISEWOMAN Quick Scan, Program Briefs and other program documents. Awardee specific data summaries are shared with each individual awardee.

Finally, WISEWOMAN data files do not contain personally identifiable information so inadvertent disclosure of coded data will not have an impact on participants' personally identifiable information. This method of serving WISEWOMAN participants without using names or other personally identifying information maintains confidentiality.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

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. 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 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. If secondary analyses of the data are proposed by individual sites or other investigators, they will be required to obtain IRB-supervised consent. Race and Ethnicity are asked in line with the mission of the WISEWOMAN program to address health equity in reducing heart disease risk factors across the population.

12. Estimates of Annualized Burden Hours and Costs

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

B. Awardees also submit a written annual 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 anticipated OMB approval, the number of respondents will be 35 programs.

Table A.12-A summarizes the existing number of respondents and estimated burden hours. The total estimated annualized burden hours are 2,240.

Table A.12-A. 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	35	2	24	1680

Annual Progress Report	35	1	16	560
Total		3	40	2,240

Table A.12-B. Estimated Annualized Burden Cost

Form Name	Mean Hourly Wage Plus Benefits	Total Burden (in Hours)	Total Annualized Burden Cost
Screening and Assessment and Lifestyle Program MDEs	$27.10	1680	$45,528
Annual Progress Report	$27.10	560	$15,176
		Total	$60,704

The total estimated annualized cost to respondents is $ 60,704. 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. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

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 $350,000 per year. In addition, CDC personnel costs are estimated at $12,600 for the Technical Monitor and $16,200 for an Associate Service Fellow. Table A.14-1 summarizes the estimated federal government cost distribution. The total estimated annualized cost to the Federal government is $378,800.

Table A14-A. Estimated Annualized Federal Government Cost Distribution

	Annualized Cost
CDC - GS 13 Technical Monitor at 10% FTE	**$12,600**

CDC – ASSOCIATE SERVICE FELLOW (GS-12) at 20%	**$16,200**
Data Contractor Total	**$350,000**
Data Collection	50,000
Data Analysis	54,000
Data Reporting	200,000
Data Training	46,000
Total	**$378,800**

Table A14-B. Estimated Annualized Federal Government Operational and Maintenance Costs

Equipment	Printing	Postage	Software Purchases	Licensing Costs	Other	Total
$0	$0	$0	$0	$5,950	$0	$5,950

Table A14-C. Total Cost to the Federal Government

Operational and Maintenance Costs	Estimated Annualized Federal Government Cost	Total Cost (O&M Costs + Labor Cost)
$5,950	$378,800	$384,750

15. Explanation for Program Changes or Adjustments

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. Plans for Tabulation and Publication and Project Time Schedule

CDC will continue to use healthy behavior support services and health risk assessment 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 a specified time frame after receipt of the information. These reports can be produced in both a graphical and a written form. 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 are developed periodically with input from branch leadership. Special interest projects that are research will require an IRB request which will be generated as appropriate. These projects, which are developed periodically, can include topics of interest to CDC, awardees, and other researchers and may be considered for publication in peer-reviewed journals.

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.

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.