

Information Collection Request

Reinstatement

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

Supporting Statement: Part B

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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 OMB Change Request Notice of Action (May 2018)
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- 3 WISEWOMAN MDE Manual DP18-1816 Edition 18.1
- 4a Screen Shot of MDE Web Portal login screen
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- 5 Annual Progress Report
- 6 Copy of MDE Submission Instructions
- 7 30-day Federal Register Notice
- 8 Consent to Participate in WISEWOMAN Program

**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)
Reinstatement Request**

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The respondents are the 21 WISEWOMAN grantees (see **Attachments 2a** and **2b**) that currently receive CDC funds to extend the services that are provided to women as part of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The WISEWOMAN program is funded to provide NBCCEDP participants with access to additional preventive health services by screening for cardiovascular risk factors and provision of services to reduce those risks through improved diet, physical activity, tobacco cessation, and medication adherence support. By screening for heart disease and stroke risk, the WISEWOMAN program provides health coaching and lifestyle programs that are specifically tailored to each woman.

The CDC expects a continued response rate of 100% for data reporting since an established working relationship currently exists between the WISEWOMAN awardees and the CDC. In addition, CDC requires the MDE data submissions as a stipulation of the WISEWOMAN Program Announcement and the cooperative agreement notice of grant awards to all awardees.

There are no generalized standards for sampling methods, awardees are solely required to sample the target population from the eligible NBCCEDP pool. Screening, lifestyle programs, and follow-up data collection are performed at the awardee level on every woman enrolled in the WISEWOMAN program. This is reported to the CDC semi-annually. WISEWOMAN requires awardees to submit cumulative datasets that date back to the beginning of the cooperative agreement.

B2. Procedures for the Collection of Information

CDC cooperative agreements specify the data requirements that programs are expected to report. CDC does not specify the procedures that awardees must use to obtain the required MDEs. CDC does specify the content and format of MDEs reported for WISEWOMAN program management, monitoring, and evaluation. WISEWOMAN requires a total of 59 standard MDEs to be submitted (see **Attachment 3**).

Awardees are expected to conduct quality assurance of their data. Awardees may rely on methods that they develop, or use the tool provided by CDC for this purpose. The validation tool provided by CDC can be accessed through the same secure WISEWOMAN website <https://wwwn.cdc.gov/WISEWOMAN/>) that awardees use to upload MDE data files. The validation tool can be run, prior to the transmission of the MDE files, to test the data for accuracy and to ensure that data is submitted with less than a 5% error rate.

On a semi-annual reporting basis, the MDE files are electronically submitted through a secure data reporting system (see **Attachment 4a** and **4b**). It is at this time that awardees are required to document any known data issues that accompany their MDE file. The WISEWOMAN data contractor extracts the data by retrieving one file per awardee; containing clinical assessments and healthy behavior support services. The contractor provides quality assurance steps, such as inspecting the raw data ensuring no two screenings were entered for the same day, no duplicates or missing values and no new records from a previous period have been submitted. After the preliminary data quality assurance steps are completed, the data contractor creates the composite analysis file. This composite analysis file is then used to generate standardized WISEWOMAN MDE reports (national and awardee-specific) and any other reports deemed necessary by CDC.

The MDE report provides an overview of services provided during the specified program year. Graphs and tables are used to display the demographics of the women served, delivery of health coaching and lifestyle programs, progress towards congressional justification measures, and the prevalence and incidence of cardiovascular health risk factors in the state and tribal populations served by awardees. In addition, awardees are required to provide the CDC with annual progress reports. The Annual Progress Report (APR) is a requirement for the funded programs to report on the program’s accomplishments and progress made for the 12-month budget period (see **Attachments 5**). WISEWOMAN staff members will have ongoing communication with the awardees to discuss the methods of their data management, and the quality of the submitted data.

The two data submission reporting dates are in June and December each program year. Historically, awardees have at times experienced delays between screening, health coaching, and lifestyle programs, completion of health coaching and lifestyle program sessions, and data entry of MDEs. CDC acknowledges that and so awardees will continue to be allowed to submit any corrections they have made to records submitted in the previous twelve months in reference to each submission date. The following table provides the semi-annual reporting dates for the three year period requested in this reinstatement and late file will be expected through December 31st, 2021.

Projected Date for Data Reporting by Awardees through 2021:

Semi-annual Reporting date
June 3, 2019
December 2, 2019
June 1, 2020
December 1, 2020
June 1, 2021
December 1, 2021

B3. Methods to Maximize Response Rates and Deal with Non response

As an established program, the CDC expects that all WISEWOMAN awardees will continue to report data in a timely manner with OMB approval of the requested reinstatement. In addition, the CDC requires the data submissions as a stipulation of the Funding Opportunity Announcement and the cooperative agreement notice of grant award. Respondents that have difficulty with a data submission are provided technical assistance by the WISEWOMAN Health Scientist, the WISEWOMAN Project Officer and/or the data contractor. The schedule for data reporting remains consistent each year as June and December of every program year.

Awardees can receive technical assistance regardless of the data management system they choose to utilize. Technical assistance will be consistently available to all grantees and is available for awardee Data Managers, Program Managers, and Program Directors through the data management contractor. Further technical assistance is available at all awardee meetings and live webinars (when necessary).

Awardees also receive a MDE Manual that provides complete written instruction regarding data submission requirements, data variables, and data field descriptions. The MDE manual supports consistent submissions across awardee programs. The manual (**Attachment 3**) is accessible through a secure, password-protected web site (**Attachments 4a and 4b**) for WISEWOMAN Data Managers, Program Managers, and Program Directors (**Attachments 2b**).

B4. Test of Procedures or Methods to be Undertaken

The data reporting system developed and maintained by the CDC have been internally tested by the WISEWOMAN staff and the data contractor. A revised information collection was approved on 12/02/2013. A non-substantive change request was approved on 08/10/2016. A two year extension without change was approved by OMB on 12/21/2016 which expires 12/31/2018. A non-substantive change request was approved on 05/03/2018 (see **Attachment 2c**) to delete obsolete MDEs. A 60 day federal registry notice was published on 12/26/2018. (**Attachment 2d**)

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The data collection was designed by the 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, Mail Stop F-75, Atlanta, GA 30341-3717.

The CDC personnel for the data management contract is Isam Vaid, Ph.D., MPH, (770-488-8000), Health Scientist for the 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, Mail Stop F-75, Atlanta, GA 30341.

The ORISE Fellow for the data management contract under the supervision of Dr. Isam Vaid is Ethan Blum, MS (404-498-5393), 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, Mail Stop F-75, Atlanta, GA 30341.

Data analysis is currently performed by the data management contractor, GDIT Inc. under the direction of Carla Linkous, MS, PMP, Contractor Lead, (470-419-6153), 2 Corporate Boulevard NE, Atlanta, GA 30329.

WISEWOMAN data collection and data quality standards are formulated by the WISEWOMAN Health Scientist based in the Advancing Health Equity Team, Program Development and Services Branch, Advancing Health Equity Team, in the Division of Heart Disease and Stroke Prevention and Control and is first approved by the WISEWOMAN internal data team, and final approval is granted by branch chief, Dr. Letitia Presley-Cantrell.