## Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System (OMB #0920-0612)

### Extension Request Supporting Statement Part B: Statistical Methods

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#### **List of Attachments**

Attachment 1a: Public Law	101-354. The Breast and	Cervical Cancer Mortali	ty Prevention Act of 1990
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Attachment 1b: Section 301 of the Public Health Service Act [42 U.S.C. 241]

Attachment 2a: Change Request Notice of Action (non-substantive)

Attachment 2b: 60-day Federal Register Notice

Attachment 3: WISEWOMAN MDE Manual Version 9.0

Attachment 4: Screen Shots of MDE Web Portal

Attachment 5: Progress Report

Attachment 6: Contact Information for WISEWOMAN Program Managers, Program Directors, and

**Data Managers** 

Attachment 7: Map of WISEWOMAN Awardees

Attachment 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) Extension Request

#### **B. STATISTICAL METHODS**

#### 1. Universe and Respondent Selection

The respondents are the 21 WISEWOMAN grantees (see **Attachments 6 and 7**) 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) he WISEWOMAN program is funded to provide National Breast and Cervical Cancer Early Detection Program (NBCCEDP) participants with access to additional preventive health services by screening for heart disease and stroke risk factors and using national clinical care guidelines to refer women to quality care. The WISEWOMAN program also provides lifestyle programs that are tailored to each woman's heart disease and stroke risk factor screening results and her readiness to make lifestyle behavior changes.

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 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 from the eligible NBCCEDP pool. Screening, lifestyle programs, and follow-up data collection is performed at the awardee level on every woman enrolled in the WISEWOMAN program and is reported to the CDC semi-annually. WISEWOMAN requires awardees to submit cumulative datasets that date back to the beginning of the cooperative agreement.

#### 2. Procedures for Collecting Information

WISEWOMAN awardees are funded to deliver individual-level screening and assessment and lifestyle program data for the heart disease and stroke prevention services they provide. 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 84 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 <a href="https://wwwn.cdc.gov/WISEWOMAN/">https://wwwn.cdc.gov/WISEWOMAN/</a>) 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 no more than a 5% error rate. On a semi-annual reporting basis, the MDE files are electronically submitted to the data contractor (SRA International, Inc., a CSRA Company) via a secured online submission (see **Attachment 4**). It is at this time that awardees are required to provide documentations for any known data issues that accompany their MDE file. The data contractor extracts the data and retrieves one file per awardee; containing Screening records and Lifestyle Program information. 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 a detailed overview of baseline screenings, rescreenings, and lifestyle programs provided during the specified program year. Graphs and tables are used to display the demographics of the women served, the mode of lifestyle programs, progress towards target screening goals, and the prevalence and incidence of cardiovascular health risk factors in the State/Tribal populations served by awardees. In addition, State/Tribal programs 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 October and April of each program year. Historically, awardees have at times experienced delays between screening and lifestyle programs, completion of 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 through the extension period requested and late file will be expected through December 31st, 2018.

Projected Date for Data Reporting by Awardees:

Semi-annual Reporting date
April 1, 2017
October 1, 2017
April 1, 2018
October 1, 2018

#### 3. Methods to Maximize 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 extension. 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 (SRA International, Inc., A CSRA Company). The schedule for data reporting remains consistent each year as April and October of every program year.

Awardees are required to provide their own data management system for the WISEWOMAN program. Technical assistance is readily available regardless of the data management system used. Technical Assistance in the use of the data reporting system is available for awardee Program Directors, Program Managers, and Data Managers by the data management contractor (SRA International, Inc., A CSRA Company) as well as bi-monthly all-program calls, awardee meetings, and live webinars (when necessary).

Awardees also receive a MDE Manual 9.0 that provides complete written instruction regarding data submission requirements, data variables, data field descriptions, report descriptions, etc. The MDE manual supports consistent submissions across awardee programs. The manual is accessible through a secure, password-protected web site for WISEWOMAN Data Managers, Program Managers, and Program Directors maintained by the data management contractor (see **Attachments 3 and 4**).

#### 4. Testing of Procedures

The data management and reporting systems developed and maintained by the CDC have been internally tested by the WISEWOMAN staff and the data contractor. MDE data definitions and data collection were approved by OMB on 12/02/2013. OMB on 08/10/2016 (see **Attachment 2a**) approved a non-substantive change request to delete an obsolete MDE.

#### 5. Contacts for Statistical Aspects and Data Collection

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 Anisa Kelley, MPH, (770-488-7477), 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 performed by the data management contractor, SRA International, Inc., a CSRA Company, 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 Advancing Health Equity Team Lead, Derrick Gervin.