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

Revision
Supporting Statement Part B: Statistical Methods

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Attachment 1b: Section 301 of the Public Health Service Act [42 U.S.C. 241]

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The 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 will also provide 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.

In June 2013, new cooperative agreements were awarded to 21 WISEWOMAN awardees (see **Attachment 6**). CDC expects a continued response rate of 100% for data reporting since an established working relationship expected 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 will be performed at the awardee level on every woman enrolled in the WISEWOMAN program and will be reported to the CDC semi-annually. As the WISEWOMAN programs extends services to women eligible for NBCCEDP, CDC estimates that this funding has enabled the programs to reach 13.2% of women aged 40-64 eligible for breast cancer screening and 8.7% of women aged 18-64 eligible for cervical cancer screening through the program. WISEWOMAN does not require awardees to submit cumulative datasets that date back to the beginning of the cooperative agreement. Awardees will only report data for the current six month submission period as well as have the opportunity to update data from the immediately preceding six month period.

The table provided below lists the number of women screened as well as the percent of the target screening goals met, collectively over the course of the most recent WISEWOMAN programs FOA. These estimates may change in the new cooperative agreement award period.

Number of Screenings provided by WISEWOMAN: 2008-2012

	Number of Screens	**Screening Goal**	**% of Screening Goal Met**
Year 1 (2008–2009)	32,218	38,779	83%
Year 2 (2009–2010)	43,702	43,220	101%
Year 3 (2010–2011)	46,860	47,118	99%
Year 4 (2011–2012)	47,342	48,185	98%

B2. Procedures for the Collection of 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. These requirements are known as Minimum Data Elements (MDE). CDC does not specify the procedures that awardees must use to obtain the required MDE. CDC does specify does specify the content and format of MDE reported for WISEWOMAN program management, monitoring, and evaluation. WISEWOMAN requires a total of 85 standard MDE to be submitted (see **Attachment 3a**) which includes both screening and assessment and intervention MDE. This Revision ICR includes changes that are summarized in **Attachment 3b**.

Awardees are expected to implement careful quality assurance practices. For quality assurance purposes, awardees will have the option of relying on methods they have developed, or use the validation tool provided by CDC. The validation tool provided by CDC can be accessed through the same secure WISEWOMAN website (www.wisewomandata.org) that awardees will use to upload MDE data files. The validation tool should be utilized prior to the transmission of MDE files. This should be done to test the data for accuracy and to ensure that data is submitted with no more than a 5% weighted-error score. Validation tool guidance will be provided to awardees prior to the start of the new FOA. In semi-annual reporting the MDE files are expected to be electronically submitted to the data contractor (SciMetrika) via a secured online submission (see **Attachment 4**). It is at this time that awardees will provide required documentation, if applicable, of any known data quality issues relevant to their MDE file. The data contractor will abstract data and retrieve one file per awardee that contains Screening and Assessment records and Lifestyle Program records. The contractor will then provide quality assurance steps such as inspecting the raw data to ensure 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 will create the composite analysis file. This composite analysis file will then be used to generate standardized WISEWOMAN MDE reports (National and awardee-specific) and any other reports deemed necessary by CDC.

The MDE report will provides a detailed overview of baseline screenings, rescreenings, and lifestyle programs provided during that specified program year. Graphs and tables will be 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, each State/Tribal program is required to provide the CDC with an Annual Progress Report (APR) which is a requirement for the funded programs. This is because awardees will report on the program's accomplishments and progress made for that 12-month budget period (see **Attachment 5**). WISEWOMAN staff members will have ongoing communication with the awardees to discuss these reports, data management methods, and the quality of submitted data.

The two data submission reporting dates are anticipated to be in October and April of each program year. Historically, awardees have at times experienced delays between screening and lifestyle program services, completion of lifestyle program sessions, and data entry of MDE. CDC acknowledges that and so awardees will continue to be allowed to submit any corrections they have made to records submitted in the previous six months in reference to each submission date. The following table provides the semi-annual reporting dates and the dates on which data may be updated for the previous six months.

Projected Cutoff Dates for Complete Data Reporting by Awardees:

Semi-annual Reporting date	Cutoff date for providing complete MDE data
April 2014	October 2014
October 2014	April 2015
April 2015	October 2015
October 2015	April 2016

April 2016	October 2016
October 2016	April 2017
April 2017	October 2017
October 2017	Final submission of FOA and no opportunity to correct data.

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. 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 Officers and/or the data contractor (SciMetrika). The schedule for data reporting will remain consistent each year as April and October of every program year.

Awardees will be required to provide their own data management system for the WISEWOMAN program. Technical assistance is readily available to awardees. Moreover, technical assistance in the use of the data reporting system is available for awardee Program Directors, Program Managers, and Data Managers by the data contractor (SciMetrika) as well as in bi-monthly all-program calls, awardee meetings, and live webinars (when necessary).

Awardees will receive an MDE Manual 9.00 that will provide complete written instructions regarding data submission requirements, data variables, data field descriptions, report descriptions, etc. The MDE manual will support consistent submissions across awardee programs. The manual will be accessible through a secure, password-protected web site for WISEWOMAN Data Managers, Program Managers, and Program Directors maintained by the data contractor (see **Attachment 4**).

B4. Tests of Procedures or Methods to be Undertaken

The data management and reporting systems developed and maintained by the CDC have been internally tested by the WISEWOMAN staff and the data contractor.

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

The data collection was designed by the WISEWOMAN program, 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-72, Atlanta, GA 30341-3717.

The CDC contact person for the data management contract is Isam Vaid, PhD, MPH,

(770-488-8000), Health Scientist for the WISEWOMAN program, 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-72, Atlanta, GA 30341-3717.

The ORISE Fellow for the data management contract under the supervision of Dr. Isam Vaid is Kaha Ahmed, MPH, CPH (770-488-7474), WISEWOMAN program, 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-72, Atlanta, GA 30341-3717.

Data analysis is performed by the data contractor, SciMetrika LLC, under the direction of Darryl Cooney, PhD, Lead Statistician (919-354-5212), 100 Capitola Drive, Suite 104, Research Triangle Park, NC 27713.

WISEWOMAN data collection and data quality standards are formulated by the WISEWOMAN Health Scientist based 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 Team Lead, Dianne May, MA, MPH.