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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Submitted by:

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The respondents are the 21 WISEWOMAN grantees 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) (see **Attachment 6**). The WISEWOMAN program is funded to provide 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 program also provides lifestyle interventions that are tailored to each woman's heart disease and stroke risk factor screening results and her readiness to make lifestyle behavior changes (see **Attachment 7**). The CDC expects a continued response rate of 100% for data reporting since an established working relationship currently exists between the WISEWOMAN grantees and the CDC. In addition, the CDC requires the data submissions as a stipulation of the WISEWOMAN Program Announcement and the cooperative agreement notice of grant awards to all grantees.

There are no generalized standards for sampling methods, grantees are solely required to sample from the eligible NBCCEDP pool. Screening, lifestyle interventions, and follow-up data collection is performed at the grantee level on every woman enrolled in the WISEWOMAN program and is reported to the CDC semi-annually. As the WISEWOMAN programs extends services to women eligible for NBCCEDP, the CDC estimates that the 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 grantees to submit cumulative datasets that date back to the cooperative agreement. Grantees will only report data set for the current six month submission period as well as have the opportunity to update data from the immediately preceding six month period. To date, 147,455 women have been screened for Cardiovascular Disease risk factors through the WISEWOMAN program.

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 WISEWOMAN programs FOA.

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) *6 month data only	24,675	48,185	N/A

B2. Procedures for the Collection of Information

WISEWOMAN grantees are funded to deliver individual-level screening and lifestyle intervention data for the heart disease and stroke prevention services they provide. Data

collection begins at the grantee (program) site where clients are enrolled in the program and screening procedures as well as lifestyle interventions are provided. The data is entered into a data management system used by the grantee to track patients and services. Of the data collected by the grantees, WISEWOMAN requires a total of 66 standard MDEs to be submitted (see **Attachments 3a and 4a**).

Grantees are expected to conduct quality assurance of their data. Grantees 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 (www.wisewomandata.org) that grantees 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% weighted-error rate. Guidance for the validation tool (i.e. validation edits) is provided to each grantee in the MDE manual.On a semi-annual reporting basis, the MDE files are electronically submitted to the data contractor (SciMetrika) via a secured online submission (see **Attachments 3b and 4b**). It is at this time that grantees are required to provide documentations for any known data issues that accompany their MDE file. The data contractor abstracts the data and retrieves two separate files per grantee; one containing Screening records and one containing Lifestyle Intervention records. The contractor provides quality assurance steps such as inspect 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 that is used to generate standardized WISEWOMAN MDE reports (National and grantee-specific) and any special request made by the CDC.

The MDE report provides a detailed overview of the baseline screenings, rescreenings and lifestyle interventions provided during a specified program year. Graphs and tables are used to display the demographics of the women served, the mode of lifestyle interventions used, determining if the programs have met their target screening goals, as well as describing the prevalence and incidence of risk factors in the State/Tribal populations served. In addition, State/Tribal programs are required to provide the CDC with Interim and Annual progress reports on an annual basis. The Interim Progress Report (IPR) serves as a non-competing continuation application and includes a concise description of the accomplishments and progress made in meeting the activities and objectives during the program's first 6 months of the budget period (see **Attachment 5**). Furthermore, 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 grantees to discuss the reports, the methods of their data management, and the quality of the submitted data.

The CDC acknowledges the potential delay between screening and lifestyle intervention services, completion of sessions, and data entry. Thus grantees are allowed to submit any corrections they have made to existing records submitted in the previous six months. Grantees are required to provide complete screening and lifestyle intervention data by October 15th for the April 15th reporting date. The following table provides examples of the cutoff dates for complete data reporting.

Cutoff Dates for Complete Data Reporting by Grantees:

Semi-annual Reporting date	Cutoff date for providing complete screening data	Cutoff date for providing complete lifestyle intervention data
April 15, 2013	October 15, 2013	October 15, 2013
October 15, 2013	No opportunity to update data (FOA ends)	No opportunity to update data (FOA ends)

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

As an established program, the CDC expects that all WISEWOMAN grantees 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 (SciMetrika). The schedule for data reporting remains consistent each year as April 15th and October 15th of every year.

Grantees 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 grantee Program Directors, Program Managers, and Data Managers by the data contractor (SciMetrika) as well as in monthly all-program calls, grantee meetings, and live webinars (when necessary).

Grantees also receive a MDE Manual 8.0 that provides complete written instruction regarding data submission requirements, data variables, data field descriptions, report descriptions, etc. The manual supports consistent submissions across grantee 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 contractor (see **Attachments 3 and 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. MDE data definitions and data collection were approved by OMB on 01/27/2010 and a subsequent change of events was approved by OMB on 01/31/2011.

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 personnel for the data management contract is Isam Vaid, Ph.D., 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, Ph.D., 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 and approved by the Senior Advisor to the Director, Deborah Borbely, M.S., of the Division of Heart Disease and Stroke Prevention and Control and the Division's WISEWOMAN internal data team.