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

(OMB #0920-0612)

Revision Request

Supporting Statement Part A: Justification

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Attachment 1a: Public Law 101-354, The Breast and Cervical Cancer Mortality Prevention Act of 1990

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

Attachment 2a: Federal Register Notice

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Attachment 3a: WISEWOMAN MDE Manual Version 9.00

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Abstract

CDC currently collects progress reports and minimum data elements (MDE) from 21 WISEWOMAN program awardees (OMB No. 0920-0612, WISEWOMAN Reporting System, exp. 1/31/2014). All information collection is conducted semi-annually. CDC uses the progress reports and MDE to monitor awardee activities and program outcomes.

Under a new Funding Opportunity Announcement (FOA), new WISEWOMAN cooperative agreements were awarded on July 1, 2013. The new FOA places increased emphasis on monitoring program outcomes. CDC is initiating changes to reporting requirements to support FOA goals.

1) The number of MDE reported to CDC will increase from 66 to 85. New items will allow CDC to more effectively monitor changes in blood pressure from diagnosis through treatment, and to monitor dietary behaviors, adherence to prescribed medications, and the effects of participating in risk reduction counseling (including changes in participants' stated readiness to change behaviors relating to nutrition, physical activity, medication compliance, etc.).
2) In previous years MDE were transmitted to CDC in two file uploads. Grantees have requested that CDC integrate the files into one combined file. In response to awardee feedback, MDE will be reported in one combined file transmission instead of two file transmissions. The estimated burden for reporting the new combined MDE file is the same as the total estimated respondent burden for transmitting the two MDE files that were used in previous years.
3) The progress report will be collected once per year instead of twice per year, as outlined in the requirements in the new FOA. There is no change in the estimated burden per response. There is a decrease in total respondent burden due to the change in frequency of progress reporting.

OMB approval is requested for three years. Information collected through the WISEWOMAN Reporting System will be used to support continuous program improvement, evaluation, and assessment of program health outcomes.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Background

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC) is requesting approval for three years to collect information from awardees funded through the Well-Integrated Screening and Evaluation for Women Across the Nation (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. WISEWOMAN was authorized in 1993 through a legislative supplement to the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354, see **Attachment 1a**). CDC's authority to collect information from WISEWOMAN program awardees is established by Section 301 of the Public Health Service Act [42 U.S.C. 241] (**Attachment 1b**).

WISEWOMAN programs are administered by state, territorial, and tribal organization health departments, with approximately 2/3 of program funding provided by CDC and 1/3 of program funding provided by the state, territory, or tribal organization. WISEWOMAN funding is used to provide heart disease screening services and lifestyle programs to women who also participate in the National Breast and Cervical Cancer Early Detection Program.

The WISEWOMAN program focuses on reducing cardiovascular disease (CVD) risk factors among at-risk women. CVD, which includes heart disease, myocardial infarction, and stroke, is the leading cause of death for women in the United States. It is a primary contributor to mortality, morbidity, and decreased quality of life, especially among older women. Addressing risk factors such as high blood pressure, elevated blood cholesterol, obesity, sedentary lifestyle, diabetes, and smoking greatly reduces a woman's risk of CVD-related illness and death. Women in lower income brackets, with lower levels of education, or without health insurance have an increased risk of CVD morbidity and mortality, as they have limited access to health services and have been shown to be more likely to smoke cigarettes, engage in limited physical activity, and have poor nutrition.

WISEWOMAN awardees are expected to report information pertaining to the aforementioned factors for the purposes of program monitoring and evaluation. From July 1, 2008 to December 31, 2012, the WISEWOMAN Program provided a total of 194,370 screenings to 137,708 unique women. These unique women received 210,381 Lifestyle Intervention (LSI) contacts during this time period. Of the unique women screened, 123,183 (89.5%) had at least one risk factor. Among those with at least one risk factor, 75,267 (61.1%) had received at least one LSI contact.

CDC collected cost data from WISEWOMAN awardees from 07/01/2008 to 12/31/2009. The cost data collection was discontinued and CDC does not anticipate collecting cost data from WISEWOMAN awardees during the period of this request.

Privacy Impact Assessment

WISEWOMAN awardees will provide preventive services to underserved women, such as blood pressure, cholesterol, and diabetes testing, as well as lifestyle programs (LSP) targeting poor nutrition, physical inactivity, and smoking. The LSPs may vary from program to program, but all are designed to promote healthy lifestyle changes. Because WISEWOMAN programs are coordinated within existing health department operations, WISEWOMAN awardees collect identifiable client-level information in order to track and support client services at the local level. In addition, some awardees offer and track ancillary services that are not specified by the WISEWOMAN FOA (for example, referrals to local health care providers). CDC does not monitor the ancillary activities or request information about them. WISEWOMAN awardees

only report to CDC information that is specific to WISEWOMAN client services and outcomes assessment (MDE) and programmatic activities (progress reports).

No direct client-level identifier information is reported to CDC. Prior to electronic data transfer to the data contractor, each WISEWOMAN awardee removes all personal identifiers and assigns a unique code for each woman in the database. CDC's data collection contractor, SciMetrika, will not accept a method of record identification, such as social security number, that may be linked to other databases. The identifying information provided to the data contractor will be patient ID number, county of residence, state of residence, zip code of residence, race, date of birth with the day noted as '01' for all WISEWOMAN participants, and ethnicity. In WISEWOMAN, the zip code field is requested for participants, unless fewer than five participants live in one zip code; see details in the zip code field description in the MDE Manual 9.00 **(**see **Attachment 3a).**

The development of a unique method of record encryption and identification by each awardee program will allow CDC to anonymously track women served throughout their association with WISEWOMAN, without the use of names. The foci of the data collection are to evaluate activities that are designed to improve public health practice, program performance, and assess program outcomes.

The awardee programs will maintain the encryption information between their unique codes and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the contractor. Direct client identifiers are not included in the information that is transmitted to CDC for program monitoring and evaluation.

The aggregate data provided to the data management contractor is archived on secure network servers with user ID and password restricted access at the location of the data contractor and 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.

Overview of the Data Collection System

Twice a year, each WISEWOMAN awardee site's Minimum Data Elements (MDE) are reviewed by the site's Program Manager, and a de-identified electronic data file is transmitted to CDC's data collection contractor. The MDE include items relating to Screening and Assessment and items relating to the Lifestyle Programs (see **Attachment 3a**). Upon receipt of each transmission, the contractor performs additional quality control checks and works with the WISEWOMAN awardee to resolve any discrepancies or problems with data integrity. The contractor 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 **Attachment 4**. The aggregate file is used for data analysis and report generation. The analysis file does not contain direct client identifiers such as name or SSN, but it does contain indirect client identifiers (Information in Identifiable Form, IIF), such as demographic information.

Awardees also submit a written progress report to CDC once per year (see **Attachment 5**). A list of awardees is provided in **Attachment 6**.

CDC is currently exploring various web-based MIS platforms. It is possible that in the future CDC may consider transitioning from the narrative, paper-based progress report to a web-based MIS platform for progress reporting. If that should that happen, CDC will process a Change Request or Revision ICR to obtain OMB approval for the modified reporting method.

Items of Information to be Collected

The MDE (**Attachment 3a**) include information about the screening site, client demographics, risk factors and clinical assessment, and lifestyle programs in which clients have participated. Health outcome measures assessed include but are not limited to systolic and diastolic blood pressure readings, total cholesterol, weight, waist-to-hip ratio, smoking status, quality of life, nutrition, and physical activity variables. The written progress report (**Attachment 4**), 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 cooperative agreement.

This Revision request incorporates changes to the MDE that will improve CDC's ability to monitor WISEWOMAN program outcomes. New data items improve the ability to monitor adherence to medications (#5d-5e); changes in blood pressure (#6a-6c); dietary behavior (#7a-7g); quality of life (#10a-10c); effects of risk reduction counseling (#17a-17f); readiness to change behavior (#18a-18b); the impact of Lifestyle Programs (#20a,20c,20d,20g), and referrals to community based tobacco cessation resources (#21a-21c). The wording and/or response options for a few variables will be updated based on prior years of experience with the WISEWOMAN program and helpful feedback from awardees. Finally, a number of variables which are no longer useful for analysis will be deleted. A summary of changes is included as **Attachment 3b**.

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, http://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

A.2 Purpose and Use of Information Collection

The information collected through the WISEWOMAN Reporting System supports three major objectives: 1) continuous program improvement, 2) evaluation of the program, and 3) assessing program health outcomes. Ongoing evaluation and utilizing timely information improves 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 minimum data elements (MDE) allow for identifying the number of women screened over a given reporting period at each awardee site. Because each location has a target number of women who are expected to be screened upon full implementation, the MDE can be used to assess whether specific locations are on track to meet their stated screening goals. WISEWOMAN MDE have also been chosen so that they could be presented as summary measures that assess overall cardiovascular health risk of WISEWOMAN participants. The measures were selected because they provide an assessment of the overall cardiovascular health risk and cardiovascular health risk reduction among WISEWOMAN participants and can be easily implemented based on risk scoring algorithms. The summary measures are important because they allow for assessing the benefits using comparable metrics that can be conveyed to policy makers. The cardiovascular health risk estimators that have been selected can be used with WISEWOMAN data to detect changes in risk and capture its nuances. The number of MDEs will increase from 66 to 85. The information will be used to answer specific questions related to cardiovascular health risk and risk reduction among low-income, at-risk, women.

We simulated various combinations of improvements in blood pressure, cholesterol, and smoking status for a random subset of women and identified one estimator that assesses participants' cardiovascular health risk and one estimator that is appropriate for evaluating the effectiveness of cardiovascular health risk reduction programs. The new data elements strengthen CDC's ability to assess health outcomes according to Life's Simple Seven™ cardiovascular health risk assessment model developed by the American Heart Association (2010).

Life's Simple Seven™ takes into account seven health measures which include physical activity, cholesterol levels, dietary habits, managing blood pressure, weight loss, reducing blood sugar, and smoking cessation. A numerical heart health score as well as individualized goals and targets for a healthy lifestyle are provided at the end of each assessment. The score is on a scale of 1 to 10 where 10 references ideal heart health and the lowest possible risk of developing cardiovascular disease. The other cardiovascular health risk estimator is an algorithm for the 10-year risk of coronary heart disease (CHD) developed by Anderson et al. (1991) and modified by Wilson et al. (1998). This estimator was derived based on the data from the Framingham Heart Study and includes age, systolic and diastolic blood pressures, total cholesterol or LDL cholesterol as well as HDL cholesterol, diabetes, and smoking status as input risk factors. Anderson's estimator consists of a set of formulas that calculate risk as a continuous variable. Historically, WISEWOMAN has used this estimator to assess changes in cardiovascular health risk among its participants from baseline to follow-up.

The ultimate goal of the information collection will be to assess overall performance to determine if the program warrants continuation and expansion.

Privacy Impact Assessment

Current WISEWOMAN awardees collect personal identifiers on each client served (e.g., name, address, social security number, age, race/ethnicity) along with information about the client's medical history, results of the screening exam, and participation in lifestyle programs. It is anticipated that awardees in the new FOA will collect personal information that is necessary in order for awardees to provide medical services and to track clients. The WISEWOMAN awardees

will then assign a unique identifier (ID) code to each client served through the program, and the ID code is used to identify records when information is transmitted from the awardee to collection contractor, or from the contractor to CDC. Awardees are instructed not to send information that will allow participants to be identified. Prior to electronic data transfer to the data contractor, each WISEWOMAN awardee will remove all personal identifiers and assigns a unique code for each woman in the data base. The CDC Contractor will not accept a method of record identification, such as social security number, that may be linked to other databases. The identifying information that will be provided to the data contractor will be patient ID code, county of residence, state of residence, zip code of residence, race, date of birth, and ethnicity. In WISEWOMAN, the zip code field is requested for participants, unless fewer than five participants live in one zip code. Additional details about the zip code field description are provided in the MDE Manual 9.00 **(**see **Attachment 3a).**

The development of a unique method of record encryption and identification by each awardee program will allow CDC to anonymously track woman served throughout their association with WISEWOMAN, without the use of names. The awardee programs will maintain the encryption information between their unique codes and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the data management contractor. Direct client identifiers will not be included in the information that is transmitted to CDC for program monitoring, evaluation, and assessment of program outcomes.

The aggregate data provided to the contractor will be archived on secure CDC network servers with user ID and password restricted access at the location of the data contractor and 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 awardee is solely responsible for maintaining the unique list linking ID code with the client's name.

Information regarding health screening results will be shared; however, personal participant (identifying) information is not shared. Prior to electronic data transfer to the data contractor, each WISEWOMAN awardee shall remove all personal identifiers and assign a unique code for each woman in the data base. As iterated previously, the awardee is solely responsible for maintaining the unique list linking ID code with the client's name. The screening results are aggregated and used in biannual programs data summary reports. Individual awardees and aggregated data summaries will be shared with all selected awardees. Additionally, aggregated data may be used in WISEWOMAN At-A-Glance, Program Briefs and other program documents.

Because data are only shared in de-identified form, inadvertent disclosure of coded data would not have an impact on clients.

A.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 delivery. The MDE data will be transmitted as an electronic fixed-

length text files consistent with prescribed file formats. To ensure that the reporting burden is minimized, CDC and the contractor will provide in-person and/or remote technical assistance to awardees upon request.

Hardcopy progress reports will be submitted annually. In the future, CDC may transition to electronic progress reporting.

A.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 continuous program improvement, evaluation, and assessment of program health outcomes. 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.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be adversely impacted.

A.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. Historically, the submission periods established for WISEWOMAN have been identical to those established for NBCCEDP and are frequent enough to allow for ongoing evaluation, but not too frequent to be overly burdensome. The new FOA reporting periods will allow CDC and awardees to assess performance at regular intervals, and to make adjustments as necessary. Less frequent data collection would compromise the ability to successfully do both of these things.

A.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.

A.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 May 24, 2013 (Vol. 78, No. 101, pp. 31554-31555). A copy of the Notice is provided as **Attachment 2a**. One public comment was received and acknowledged (**Attachment 2b**).

B. The WISEWOMAN data collection and reporting infrastructure is based on the NBCCEDP data collection and reporting infrastructure (OMB 0920-0571, current expiration date 10/31/2015). 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), WISEWOMAN Data Team lead by a Health Scientist with three other CDC staff and three representatives from the external data contractor, as well as two formal advisory committees consisting of representatives from all WISEWOMAN awardees (Data Managers Work Group and the Program Director/Program Manager Work Group). WISEWOMAN also hosts an annual grantee conference in which the stakeholders mentioned above can review data issues. Additionally, WISEWOMAN staff periodically participates in NBCCEDP data conference calls to ensure collaboration across programs. Contact information for the primary stakeholders mentioned above is listed below:

Robin Roberts
Michigan Program Director
Current MDE Committee Chair
Michigan Department of Health
109 W. Michigan Avenue, 5th Floor
P. O. Box 30195
Lansing, MI 48909
(517)335-1178

Diane Ollivier
Pennsylvania Program Director
Current Program Manager Committee Chair
Pennsylvania Department of Health
Health and Welfare Building
625 Forster St, Rm. 1008
Harrisburg, PA 17120
717-547-3222

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 Data Managers Work Group and Program Director/Program Manager Work Group, and contacts other experts both within and outside the Agency prior to making changes to the reporting infrastructure.

A.9 Explanation of Any Payment or Gift to Respondents

No payment will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The WISEWOMAN data collection is conducted primarily for continuous program improvement, evaluation, and assessment of program health outcome. CDC has determined that this is a public health practice activity that does not require IRB approval.

A. The CDC National Center for Chronic Disease Prevention and Heath Promotion has reviewed this submission and determined that the Privacy Act is not applicable. Respondents are WISEWOMAN awardees. The awardees maintain identifiable information about clients in their established record systems. The information transmitted to CDC by awardees does not contain direct client identifiers such as names or SSNs.

B. Ensuring that the data are kept secure is of utmost importance to CDC and the awardees. The WISEWOMAN awardees collect personal identifiers about each woman served (e.g., name, address, social security number, age, race/ethnicity) along with information about the client's medical history, results of the screening exam, and Lifestyle Program participation. The collection of identifiable personal information is necessary in order for awardees to provide medical services and to track participants. However, awardees do not transmit identifying information to CDC's data collection contractor or to CDC. CDC does not collect Information in identifiable form (IIF) or require awardees to collect SSN. Awardees own the identifiable data. Only coded (de-identified) information is transmitted to CDC.

The WISEWOMAN awardees assign a unique identifier (ID) code to each program participant, and the ID code is used to identify records when records are transmitted to data contractor and CDC. The de-identified data submitted by the awardees is a CDC required subset of their larger clinical dataset. This data will be kept by awardees in accordance with their state/tribal medical information archiving protocols. Data are encrypted during transmission. The awardee is solely responsible for maintaining the unique list linking ID and name at each site. The awardee programs will maintain the encryption information between their unique codes and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the data contractor. This method of record identification allows each client served to be tracked throughout their involvement with WISEWOMAN without using names or other identifying information.

The aggregate data provided to the contractor is archived on secure network servers with user ID and password restricted access at the location of the data contractor and 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 awardee is solely responsible for maintaining the unique list linking ID code with the client's name.

The contractor is required, at the end of the contract option period, to provide CDC with all de-identified data, and other program materials. The contractor shall retain no information, data, software, source code or other materials developed or obtained under this contract unless expressly authorized in writing by the Government. All such information, software, source code, or other materials shall be delivered to the Government.

The CDC does not anticipate the development of a public use data set using WISEWOMAN data. In limited circumstances, CDC may allow secondary analysis of WISEWOMAN data 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.

C. CDC requires that awardees have a process in place to obtain consent from WISEWOMAN clients for participating in the program based on CDC guidance (see **Attachment 7**). Individual WISEWOMAN awardees may develop customized consent forms based on the required elements described in the guidance. CDC will instruct awardees to describe the program's purpose, procedures, the types of tests that will be completed, and privacy safeguards. If secondary research uses of the data are proposed by individual sites or other investigators, they will be required to obtain IRB-supervised consent.

D. Respondents are WISEWOMAN awardee programs, and participation in the information collect is a condition of award. Clients who obtain services through the WISEWOMAN program are made aware of the need to collect information prior to any services provided.

A.11 Justification for Sensitive Questions

Awardees collect sensitive, identifiable information from women participating in the program, such as medical history and race/ethnicity. This information is required to support verification of eligibility, the delivery of medical services, and data analysis as defined by WISEWOMAN program objectives. The sensitive information is used to insure services are provided that meet the specific needs of participants.

A.12 Estimates of Annualized Burden Hours and Costs

A. The MDE file transmission involves extracting specified data elements (see **Attachment 3a**) from each awardee's existing record system, and uploading the de-identified information to a web portal (see **Attachment 4**). The MDE will be submitted to the data contractor two times per year. The combined estimated burden per response for the Screening and Assessment MDE (MDE 1 to 77) and Lifestyle Program MDE (MDE 78 to 85) is 24 hours. Because most health departments have advanced electronic records management systems, the amount of time needed to set up and run the electronic extraction, and to upload the de-identified file, does not depend on the number of MDE requested.

Upon request, CDC will provide technical assistance (including software support) to minimize respondent effort associated with set-up or modification of data elements or response options. The total estimated burden per response is the same as in previous years of WISEWOMAN clearance. However, in this Revision

request, CDC is changing the procedure so that awardees will submit one combined MDE file with a burden of 24 hours. In previous years, awardees submitted two MDE files with a combined burden of 24 hours.

B. The 21 WISEWOMAN awardees also submit a written progress report once a year that provides an overall summary of programmatic activity (see **Attachment 5**). The estimated burden per response is 16 hours. The estimated burden for the progress report has not changed. The frequency has been reduced from twice a year to once a year.

Table A.12-1 summarizes the existing number of respondents and estimated burden hours. The total estimated annualized burden hours are 1,344.

Table A.12-1. Number of Respondents and Estimated Burden Hours

Type of Respondents	Form Name	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
WISEWOMAN Awardees	Screening and Assessment and Lifestyle Program	21	2	24	1,008
	MDE Annual Progress Report	21	1	16	336
				Total	1,344

B. The total estimated annualized cost to respondents is $ 36,423. 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. This is an empirical average based on a review of awardee budget submissions not an estimate of Department of Labor (DOL) wage category.

Table A.12-2. Estimated Annualized Cost to Respondents

Form Name	Mean Hourly Wage Plus Benefits	Total Burden (in Hours)	Total Annualized Cost to Respondents
Screening and Assessment and Lifestyle Program MDE	$27.10	1,008	$27,317
Annual Progress Report	$27.10	336	$9,106
		Total	$36,423

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

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

A.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 $8,835 for the Technical Monitor and $13,363 for a Fellow. Table A.14-1 summarizes the estimated federal government cost distribution. The total estimated annualized cost to the Federal government is $372,198.

Table A.14-1. Estimated Annualized Federal Government Cost Distribution

	Annualized Cost
Data Contractor Total	**$350,000**
Data Collection	50,000
Data Analysis	54,000
Data Reporting	200,000
Data Training	46,000
CDC - GS 13 Technical Monitor at 10% FTE	**$8,835**
CDC – ORISE FELLOW (GS-9) at 20% FTE	$13,363
Total	**$372,198**

A.15 Explanation for Program Changes or Adjustments

The number of respondents, 21, has not changed from the previous clearance period. However, there is a net reduction in annualized burden from 1,680 hours to 1,344 hours. This reduction is due to a change in the frequency of progress reporting, from twice per year to once per year. The estimated burden for each progress report has not changed (16 hours per response).

There is no net change in the estimated respondent burden for MDE (24 hours). There is a change in reporting procedure. In previous years, MDE were reported in two separate file transmissions. During the period of this Revision request, all MDE will be reported in one combined file transmission.

A.16 Plans for Tabulation and Publication and Project Time Schedule

CDC will continue to use the screening and lifestyle program data reported by awardees to produce three categories of publications: Preliminary MDE Summary Reports, Planned Publications, and Special Research 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 90 working days of receipt of the information. Planned Publications are formal reports that include multivariate analyses of the MDE. These reports are produced annually for inclusion in publications and presentations at conferences. These publications are also posted to the CDC web site and may also be included in peer-reviewed journals. In the case of planned Special Research Projects an IRB request will be generated. These projects include topics of interest to CDC and other researchers that are for publication in peer-reviewed journals. These projects are developed periodically with input and collaboration from awardees and outside researchers.

A.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.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.