

**Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young
Women Diagnosed with Breast Cancer**

Supporting Statement – Section A

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1LIST OF ATTACHMENTS

Attachment 1a – Education and Awareness Requires Learning Young (EARLY) Act of 2009

Attachment 1b – Section 301 of the Public Health Service Act

Attachment 2 – Federal Register Notice

Attachment 3 – Mail-in Survey Instrument English

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Attachment 4 – Web-based Survey Instrument English

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- Attachment 5** – Cover Letter/ Passive Consent English
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- **Goal of the study:** To assess insurance coverage, employment status and out-of-pocket health care expenses among young women diagnosed with breast cancer and to look at the relationship between these variables and treatment access, quality and compliance.
- **Intended use of the resulting data:** This study will provide data that can inform the delivery of breast cancer treatment, and reduce barriers to care and services for young, female breast cancer patients.
- **Methods to be used to collect:** Two cross-sectional cohort samples will be used. One sample will be randomly drawn from four state-based cancer registries and the other will be a self-selected convenience sample drawn from constituents of two non-profit advocacy organizations. Self-administered paper and Web-based surveys will be used to collect data.
- **The subpopulation to be studied:** Adult women between the ages of 18 and 49 who were diagnosed with ductal carcinoma in situ (DCIS) or invasive breast cancer.
- **How data will be analyzed:** Descriptive statistics and logistic regressions to understand the impact of insurance coverage, continuity of enrollment in insurance, patient factors, clinical factors and contextual factors on patient's treatment access, quality and compliance.

Section A – Justification

A.1. Circumstances Making the Collection of Information Necessary

The proposed project, “Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young Women Diagnosed with Breast Cancer,” is a new Information Collection Request (ICR) and OMB approval is requested for one year. CDC is authorized to conduct this information collection by the Education and Awareness Requires Learning Young (EARLY) Act of 2009 which is outlined in section 10413 of the Patient Protection and Affordable Care Act (**Attachment 1a**) and section 301 of the Public Health Service Act (**Attachment 1b**). The EARLY Act directs the CDC to fund research and initiatives that increase knowledge of breast health and breast cancer among women, particularly among those under the age of 40. The Public Health Service Act authorizes the CDC to conduct research that will inform the prevention of physical and mental diseases such as breast cancer.

Background

Although only about 5% of breast cancers are diagnosed in young women, breast cancer is the leading cause of cancer-related deaths in women 45 years of age and younger. In addition, survival rates are lower for young women with breast cancer than for older women (Gnerlich et al., 2009). Young women are also likely to be diagnosed at a stage in life when they serve multiple roles (including parenting young children, developing a career, completing education), which can result in significant disruptions in their lives. As a result, young women often report more anxiety than older women due to concerns about fertility, lack of information or support groups dedicated to issues specific to them, and concerns about whether physicians are able to provide them with high-quality and tailored care (Partridge et al., 2012). Moreover, young women are more likely than older women to be concerned with their attractiveness and body image (Baucom et al., 2006).

Racial Differences. Although white women overall have a higher incidence of breast cancer, black women are more likely to be diagnosed at a younger age (American Cancer Society, 2013). Among women younger than 45, the incidence of breast cancer is higher among blacks than for any other racial or ethnic group. Blacks are more likely to be uninsured than whites, and prior research indicates that they are more likely to receive non-optimal cancer care (Kaiser Family Foundation, 2014). Therefore, it is possible that young black women face higher barriers in accessing quality cancer care than white women.

Employment and Financial Burden. Several studies have reported on the impact of cancer on employment status. The findings from these studies indicate that cancer survivors face significant negative consequences due to their diagnosis and generally are worse off financially than their counterparts who have not been diagnosed with cancer. A detailed review of past studies concluded that cancer survivorship is associated with unemployment (de Boer et al., 2009). A recent study specifically related to breast cancer survivors found significant long-term impacts of cancer survivorship on financial burden and access to care, but this study did not have sufficient power to assess impacts specifically related to young women (Jagsi et al., 2014).

Long-Term Treatment Compliance. Some women diagnosed with breast cancer at a young age may need to continue treatment well beyond the immediate 6-12 months of initial cancer treatment. For example, research has shown that women treated for early-stage endocrine receptor (ER)-positive breast cancer benefit from receiving at least 5 years of adjuvant hormone therapy (National Cancer Institute [NCI]). Therefore, treatment and other follow-up procedures (e.g., procedures related to fertility issues) do not necessarily end in 6-12 months and can continue for many years after diagnosis. Women who experience disruptions in coverage are particularly vulnerable and may discontinue treatments or disregard follow-up recommendations because of cost; they may not experience optimal outcomes. Because young women are more likely than older women to lack insurance coverage, compliance with long-term treatment recommendations may be lower in this age group.

Some research has been conducted to show that employment status, financial stability, continuity of insurance coverage or enrollment are variables that individually impact young women with breast cancer's treatment compliance, access to quality care, and ultimately their quality of life. However, to date, no comprehensive assessment exists examining the impacts of these factors on young, female breast cancer patients' access to comprehensive high quality breast cancer treatment and care. The CDC's Division of Cancer Prevention and Control is funding a study aimed to address this research gap. This study, also known as the Breast Cancer in Young Women Survey, will assess how insurance coverage, employment status, and copayments/deductibles impact cancer treatment, compliance, access to quality care, overall health care, and ultimately quality of life of young women diagnosed with breast cancer.

This study will collect information from two groups of breast cancer survivors.

- Sample 1 will be a population-based cohort of an estimated 1,200 female breast cancer

survivors recruited from four state cancer registries. Respondents will choose between a mail-in survey (**Attachment 3**) and a Web-based survey (**Attachment 4**). The survey data will be linked to data maintained by their state's cancer registry, including information about tumor characteristics, date of diagnosis, and stage. The linked survey and cancer registry data will be used to answer research question about the factors that affect young breast cancer survivors' access to comprehensive, high quality care.

- Sample 2 will be a convenience sample of 2,000 breast cancer survivors affiliated with one of two national, non-profit breast cancer survivor advocacy groups: Living Beyond Breast Cancer and Young Survival Coalition. Sample 2 will respond using the web-based survey. The survey data will not be linked to any other data source but will allow us to obtain a more national perspective.

A.2. Purpose and Use of the Information Collection

The purpose of this new, one-time data collection is to understand the barriers young women face in receiving high-quality breast cancer treatment and care. Previous research has shown discrepancies in economic burden, such as employment, among breast cancer survivors of different racial backgrounds. New research is needed to thoroughly examine these characteristics for younger women, so that specific interventions may be developed that can improve the quality of care, health outcomes, and lives of all women. The lack of this research would prolong this knowledge gap about the magnitude of barriers the younger generation is experiencing and would limit the development of effective strategies for reducing this economic discrepancy among young breast cancer survivors.

Specifically, this study will answer these questions: 1) What are young, female breast cancer survivors experiencing after their diagnosis in terms of: (a) continuation of insurance coverage, access to care, and quality of care; (b) changes in employment status after breast cancer diagnosis; and (c) out-of-pocket medical costs?; and 2) What factors affect young breast cancer survivors' access to comprehensive, high quality care?

Findings from this study will help the CDC alleviate the burden experienced by young breast cancer survivors trying to access quality cancer treatment and care. Specifically, these burdens include those related to (1) insurance status; (2) financial burden and out of pocket costs; (3) employment

status; (4) access to cancer treatment and overall treatment compliance; (5) quality and coordination of breast cancer treatments received; (6) quality of life following breast cancer treatment; and (7) cancer history.

The scope of data collection is limited to female breast cancer survivors who were diagnosed between 18 and 49 years of age. Collection of these data for Sample 1 will only yield findings specific to female breast cancer survivors who were diagnosed between 18 and 39 years of age from state-based cancer registries in the following four states: California, Georgia, Florida, and North Carolina. Sample 2 data collection is a convenience sample of female breast cancer survivors who were diagnosed between 18 and 49 years of age and will target a nationwide cohort drawn from membership in two advocacy groups: Living Beyond Breast Cancer and the Young Survival Coalition.

Since the study uses two distinct samples and employs the same instrument with minor modifications, survey responses from the two samples can answer the following additional research questions: 1) Are there important differences in the variables of interest between young breast cancer survivors based on the length of time that has elapsed from cancer diagnosis? 2) Do the experiences and barriers faced by women diagnosed between 18 and 39 years of age differ from those of women between 40 and 44 years of age and 45 and 49 years of age? The results can help inform future survey data collection methodologies by showing whether drawing a convenience sample from survivorship groups can be a more feasible, less expensive, but generalizable method to recruit respondents for future breast cancer survivor surveys.

A.3. Use of Improved Information Technology and Burden Reduction

We will implement a multimode approach that will include mail-in or Web-based surveys. Both samples will use the same data collection instrument with minor modifications. Sample 1 respondents can complete a mail-in survey (see **Attachments 3 and 3s**) and send their responses via mail or complete a web-based questionnaire (see **Attachments 4 and 4s**) and submit their responses electronically. Sample 2 respondents will complete a web-based questionnaire only. Both versions of the survey instrument, mail-in and Web-based, contain the same questions that have been cognitively tested, tailored, and finalized based on feedback received from two non-profit breast cancer advocacy groups. The web-based survey will allow us to utilize skip patterns for efficient navigation of respondents through the survey, particularly in the introductory section

where screening questions are applicable to some respondents (i.e., respondents from Sample 2) but not all respondents (i.e., respondents from Sample 1 who prefer the web-based response option to the paper response option). Since the respondents are under 50 years old at the time of diagnosis, they are likely to be comfortable with a Web-based surveys. In addition, Web-based surveys reduce the overall burden on respondents, as it is often quicker to click submit on a Web page than to place a survey in a mailbox. This data collection protocol follows Dillman's tailored design method for maximizing survey response rates (Dillman et al., 2014).

A.4. Efforts to Identify Duplication and Use of Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source. A review of literature reveals that there are no existing data collection efforts, no comparable studies, and no available data focused on young, female, breast cancer survivors and the impact of their employment status, copayments/deductibles, and health insurance coverage on their cancer treatment access, quality and compliance.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection effort to provide information that could inform future efforts to improve access to comprehensive high quality breast cancer treatment, compliance and overall care among young women.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on August 19, 2015, Vol. 80, No. 160, pp. 50288-90 (**Attachment 2**). No public comments were received.

B. Efforts to Consult Outside the Agency

The National Cancer Institute (NCI) and Agency for Health Care Research and Quality (AHRQ) have reviewed the data collection instrument. NCI has provided a letter of support encouraging a favorable review, stating that the survey aims “are consistent with the mission of the National Cancer Institute’s Healthcare Delivery Research Program and ongoing activities related to the economics of cancer and the delivery of quality care” (**Attachment 11**).

In addition, RTI consulted with the two non-profit breast cancer survivor advocacy groups, Living Beyond Breast Cancer and Young Survival Coalition, to obtain their feedback and comments on the data collection instrument. Numerous staff within these two organizations reviewed the instrument and provided feedback.

Lastly, RTI reviewed the National Institutes of Health (NIH) RePORTER database to identify current surveys or studies that addresses similar topics. RTI reviewed the Medical Expenditures Panel Survey (MEPS)¹ to identify additional questions that could be included to address this research project’s topics. No other current study or survey was found.

A.9. Explanation of Any Payment or Gift to Respondents

To acknowledge the time and effort involved in study participation and to increase the response rate, we will send a \$10 monetary incentive (i.e., gift card) to participants upon return of the completed survey.

No incentive will be provided for Sample 2 respondents. We anticipate that the response rate for Sample 2 will be higher than Sample 1 since the former will be drawn from members of two active breast cancer advocacy groups.

¹ Medical Expenditure Panel Survey (MEPS): Your Experiences with Cancer. OMB # 0935-0118. Exp. Date: 1/31/2013.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

10.1.1. Overview of the data collection system

Respondents will include two samples of female breast cancer survivors.

Sample 1

Sample 1 includes female breast cancer survivors who were diagnosed between the ages of 18 and 39 that are identified through four state cancer registries. RTI is seeking cancer registry data from cancer registries that do not have an active physician notification requirement. Depending on cancer registry preferences, either RTI or the cancer registry will be responsible for directly mailing the physician passive notifications (if required) and survey materials to participants. If the registry prefers to do the mailings, RTI will select the survey sample using de-identified data and will not perform any direct patient contact. The mail-in survey will be sent along with the cover letter passive consent form and instructions for the web-based version of the survey (**Attachment 5**). The instructions for the web-based version include a website address where respondents can complete the survey electronically. All surveys will include an identification code to track responses and to link them to registry data.

A few weeks after the initial mailing, we will send a postcard to individuals that have not responded as a reminder to participate in the survey (**Attachment 6**). Approximately 6 weeks after initial mailing, we will send a reminder letter and second copy of the survey to individuals that have not responded to the survey (**Attachment 7**).

RTI will securely maintain identifiable information from Sample 1 respondents. Some cancer registries may prefer to only provide de-identifiable data, in which case, RTI will use demographic data along with a unique non-identifiable ID to select the sample for the cancer registry to mail. Also, RTI will link survey responses with the registry data via identification numbers that will be established in collaboration with each of the four state cancer registries. In some instances, the registries may prefer to link the data and provide coded data to RTI instead of data with PII. Only authorized RTI researchers, a programmer and analyst, will be approved by the study director for access to the secure network and linking information.

Sample 2

We will collaborate with breast cancer advocacy groups to contact their members and invite female

breast cancer survivors who were diagnosed with breast cancer at least 12 months ago and between the ages of 18 and 49 at diagnosis to participate in the web-based version of the survey (**Attachment 8**).

To prevent multiple responses from the same individual, the web-based version of the survey will include an initial screen that asks respondents if they received a mail-in version of the survey. Respondents will have the option of completing either the mail-in paper version or Web-based version of the survey, but will not complete both. The mail-in paper version of the survey includes an identification number and respondents will be asked to input this number if they choose to complete the Web-based version, which will allow respondents to bypass the screening questions, since eligibility has already been confirmed through the cancer registry. This Web-based response will be included in Sample 1 and linked to the appropriate state registry data. Respondents determined to be in Sample 2 by leaving the identification number blank in the Web-based version, will answer screening questions to determine eligibility and will also indicate if they live in one of the states that includes Sample 1 respondents, California, Florida, Georgia, and North Carolina.

10.1.2. Items of Information to be Collected

The instrument currently consists of 66 questions, including: 6 questions on insurance status at the time of survey completion (at least 12 months after diagnosis), at breast cancer diagnosis and during the 1-year period after diagnosis; 11 questions on financial burden and out-of-pocket costs; 13 questions on employment status; 10 questions on access to cancer treatment and overall treatment compliance; 7 questions on quality and coordination of breast cancer treatments received; 1 question on quality of life following breast cancer diagnosis; 5 questions on cancer history; and 13 questions on patient characteristics (including age, gender, race and ethnicity, primary language, education level, employment status, income, and health insurance status) (**Attachment 3**).

Dichotomous- and multiple-response types of questions are included. To minimize burden, there are no questions that require open-ended or narrative responses. There are a few questions with space to provide narrative responses only if the respondent wants to provide additional information. For Sample 1 respondents, their survey data will be linked with registry data which will include details regarding their diagnosis, initial treatment and insurance status.

10.1.3. Purpose and Use of the Information Collection.

This survey will answer the following research questions: (1) What are young, female breast cancer survivors experiencing after their diagnosis in terms of (a) continuation of insurance coverage, access to care, and quality of care; (b) changes in employment status after breast cancer diagnosis; and (c) out-of-pocket medical costs? (2) What factors affect young breast cancer survivors' access to comprehensive, high quality care? (3) How generalizable are the results from the four cancer registries included in Sample 1? (4) Are there differences between young breast cancer survivors based on the length of time that has elapsed from cancer diagnosis? (5) Do the experiences and barriers faced by women diagnosed between the ages of 18 and 39 (Samples 1 and 2) differ from those of women between 40 and 44 years of age and 45 and 49 years of age (Sample 2)?

Data collected through the survey will be presented and shared with key stakeholders. All data that are shared will be in aggregate form so that individual responses cannot be identified.

10.1.4. Respondent Participation

Participation in the proposed data collection is voluntary. The statement of voluntary participation is outlined in the survey cover letter (**Attachment 5**).

10.1.5. Respondent Consent

Participation in this survey is voluntary, as stated in the introductory cover letter that will accompany the mail-in survey, and in the reminder letter distributed to the study population that has not responded (**Attachment 7**). Respondents will be informed that their information will be maintained in a secure manner. In addition, respondents may decline to answer any question.

10.1.6. Information Security

All returned mail-in surveys will be stored in a locked and secure location. Only authorized project staff will have access to convert responses into electronic data. RTI will host the web-based version of the collection instrument using a secure submission web site. Their server is housed in a secure facility with user ID and password-restricted access. Networked systems are maintained in a locked room with access strictly limited to essential employees.

RTI will make every effort to keep all information private and secure to the extent permitted by law. All electronic study data will be stored on a limited-access project shared drive on RTI's secure network servers; only study staff that have been authorized by the study director can access the shared drive. After study completion, all electronic files (e.g., notes, documents, reports) will be

archived on RTI's project shared drive. Also, one year after the study has ended, no later than September 2018, RTI will destroy all personally identifiable information collected during the study. All RTI employees and contractors working on the project who have access to project data are required to sign a code of conduct that outlines how project staff should conduct research with human subjects which includes ensuring privacy and confidentiality (**Attachment 9**).

Periodic review and update of security processes will be conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the data.

10.1.7. Privacy Act Determination

CDC has determined that the Privacy Act does not apply. RTI will not use social security number or name to retrieve or link survey responses to registry data, and appropriate procedures will be confirmed and followed based on state requirements. No identifiable information will be collected by CDC. While the Privacy Act is not applicable, the appropriate security controls and Rules of Behavior will be incorporated to protect the confidentiality of information, proprietary, sensitive, and Personally Identifiable Information (PII) RTI International may come in contact with during the performance of this contract.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This study was approved by RTI's IRB on August 27, 2015 (**Attachment 10**). RTI's IRB approval of the evaluation's consent forms indicates that they conform to all informed consent requirements. RTI's IRB is required under the Code of Federal Regulations Title 45, Public Welfare, Part 46, "Protection of Human Subjects," to review biomedical and behavioral research conducted by RTI under contract from the Department of Health and Human Services to protect the rights of human subjects of research. The Office for Human Research Protections (OHRP) has granted a Federal wide Assurance (FWA #3331 effective until February 5, 2019) to RTI that allows it to review and approve studies independently. This study is also seeking CDC IRB approval, along with IRB approvals from California, Florida, and Georgia to receive state-based cancer registry data from the Cancer Registry of Greater California, Florida Data Collection System, and Georgia Cancer Surveillance System. RTI anticipates state IRB approvals by the end of April 2016. The North Carolina Central Cancer Registry does not require North Carolina State IRB approval for this study,

but requires RTI's IRB approval along with obtaining Central Cancer Registry director and State Center for Health Statistics director approval.

Sensitive Questions

This survey will collect information on employment and employment history. Also, potentially sensitive data elements include race/ethnicity, and income information. These data elements may be sensitive to the respondents and have been limited to the minimum required to adequately address the objectives of this study. Further, all data reported to CDC will be de-identified. Finally, participants may experience some psychological stress as they are reminded of past or present health issues while answering the questions. However, the survey is completely voluntary and respondents do not have to answer questions that make them feel uncomfortable.

A.12. Estimates of Annualized Burden Hours and Costs

Respondents drawn from Sample 1 will have the option of completing a paper, mail-in version of the questionnaire in English (see **Attachment 3**) or Spanish (**Attachment 3s**) or a web-based version in English or Spanish (see **Attachments 4 and 4s**). The estimated burden per response for either method is 22 minutes, based on cognitive interviews and pilot testing conducted during questionnaire development (≤ 9 respondents per language version). The burden per response does not include eligibility screening questions for respondents, since eligibility for Sample 1 respondents will be confirmed by the participating state cancer registries when the sample is drawn. Although the web-based version of the survey includes eligibility screening questions, embedded logic in the software will allow Sample 1 respondents to skip the unnecessary screening questions.

All respondents drawn from Sample 2 will complete the web-based version of the questionnaire which includes questions to confirm eligibility. (**Attachments 4 and 4s** are annotated with information that describes the slight differences in the respondent experience, depending on whether the respondent enters the web-based survey from Sample 1 or Sample 2). Due to the inclusion of additional screening questions for Sample 2, the estimated burden for a completed survey is 24 minutes. A few respondents may be determined to be ineligible, and will drop out after completing the screening questions ("incompletes"). The estimated burden per response for respondents who complete only the introductory screening section of the questionnaire is 2 minutes

and the portion of the instrument seen by these respondents drawn from Sample 2 is represented in **Attachment 4-scr** and **Attachment 4s-scr**.

The total estimated annualized burden for information collection is 1,241 hours (see **Table 1**).

The annualized wages presented in **Table 2** are based on data from the United States Department of Labor, Bureau of Labor Statistics (2014) for state, local, and private industry earning and assumes an average hourly wage rate for respondents who work an estimated 40-hour work week and usual hourly earnings of \$22.71². The total estimated annualized cost to respondents is \$28,183.

Table 1: Estimated Total Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Sample 1 -Breast cancer survivors recruited from state cancer registries	Breast Cancer in Young Women Survey (Mail-in or web-based questionnaire)	1,200	1	22/60	440
Sample 2 – Breast cancer survivors associated with advocacy groups (ineligible)	Breast Cancer in Young Women Survey (Screener only)	25	1	2/60	1
Sample 2 - Breast cancer survivors associated with advocacy groups (eligible and complete)	Breast Cancer in Young Women Survey (Screener and Web-based questionnaire)	2,000	1	24/60	800
				Total	1,241

² The Bureau of Labor Statistics estimates that individuals across all occupations, on average, earned \$22.71 hourly in 2014. http://www.bls.gov/oes/current/oes_nat.htm#00-0000

Table 2. Estimated Response Burden Table

Type of Respondent	Form Name	No. of Respondents	Total Burden Hours	Hourly Wage Rate	Total Costs
Sample 1 -Breast cancer survivors recruited from state cancer registries	Breast Cancer in Young Women Survey (Mail-in or web-based questionnaire)	1,200	440	\$22.71	\$9,992
Sample 2 – Breast cancer survivors associated with advocacy groups (ineligible)	Breast Cancer in Young Women Survey (Screener only)	25	1	\$22.71	\$23
Sample 2 - Breast cancer survivors associated with advocacy groups (eligible and complete)	Breast Cancer in Young Women Survey (Screener and Web-based questionnaire)	2,000	800	\$22.71	\$18,168
TOTAL					\$28,183

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

There are no direct costs to the respondents other than their time to complete the survey.

A.14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government will be the salary of CDC staff and funding for the contractor, RTI International, to support the development of the survey, data collection, and associated tasks.

Table 3 presents the costs to the CDC. These include the review of survey questions, the research plan and sampling analysis plan by CDC staff. CDC staff will also discuss analytic

approach, review initial findings, and result dissemination reports. Two senior level FTEs will conduct all related activities.

Table 4 shows the contractor costs associated with these data collection forms. These costs include contractor’s efforts to develop the questionnaire; and to review the data and report the findings.

Table 3. Costs to the Federal Government: CDC

Task	Total Hours per Staff	Number of Staff	Total Hours	Total Cost	Cost Description
Review survey questions, research and sample analysis plans	14	3	42	\$2,110	GS-13 staff: 14 hrs x 2x \$47.36 ³ GS-14 staff:14 hrs x \$55.97 ⁴
Discuss analytic approach, review findings and dissemination reports	13.3	3	39.9	\$2,004	GS-13staff: 13.3 hrs x 2 x \$47.36 ² GS-14 staff:13.3hrs x\$55.97 ³
Total Costs	27.3	3	81.9	\$4,114	

Table 4. Costs to the Federal Government: Contractor

Agency	Task	Total Cost Amount
Contractor ^{5,6}	Development of surveys	\$308,572
Contractor	Data collection, analysis and reporting of findings	\$431,272
Contractor	TOTAL	\$739,844

The total estimated annualized cost to the federal government is \$743,958.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

³ Used the Federal Pay Table for Atlanta and used Grade 13, step 5 salary amounts effective January 2015.

⁴ Used the Federal Pay Table for Atlanta and used Grade 14, step 5 salary amounts effective January 2015.

⁵ Overhead is included in all costs listed.

⁶ Cost estimates taken from contract budget.

A.16. Plans for Tabulation and Publication and Project Timeline

16.1 Time Schedule

OMB approval is requested for one year. The timeline for data collection and reporting is included in Table 5.

Table 5: Project Timeline (estimated)

Data Collection Activity	Timeline
Identify study participants	March 2016
Physician notification—passive consent ^a	September 2016 (week 1)
First mailing with Web-based survey instructions (passive consent) Thank you/reminder postcard	October 2016 (weeks 5-6) November 2016 (week 8)
Reminder letter with mail-in survey	December 2016 (week 11)
Data collection and retrieval	February 2017
Data entry and database management	March 2017
Create analytic files	May 2017
Complete data analysis	June 2017
Prepare final report and disseminate findings	August - September 2017

^a Physician notification letters will be sent if required by the state registries.

16.2 Publication Plan

The results of this data collection will be presented as PowerPoint presentations, research posters, one-page summaries, and peer-reviewed manuscripts. Also, RTI will prepare and submit a final report for CDC review. The report will include a brief summary of activities performed during the project period, including interpretations and commentary on the methods and results of the analyses.

16.3 Tabulation Plan

RTI will prepare the draft analyses, tables, and figures for scientific articles and study report that address the study research questions. Survey weights will be applied as necessary to compensate for the complex survey sampling design (i.e., oversampling of minorities and unequal distribution across the states) and nonresponse.

Descriptive statistics and logistic regressions to understand the impact of insurance coverage, continuity of enrollment in insurance, patient factors, clinical factors and contextual factors on patient's treatment compliance, access to quality care and quality of life. We will also run two logistic regression models – one that looks at whether a pattern emerges indicating that the same variables are significant in both samples, and another to assess the magnitude of impact as measured by an odds ratio.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exception. The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

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