Colorectal Cancer Control Program Indirect/Non-Medical Cost Study

OMB Supporting Statement

Part A: Justification

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March 1, 2013

TABLE OF CONTENTS

Section **Page**

EXHIBITS

Number **Page**

LIST OF ATTACHMENTS

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Division of Cancer Prevention and Control (DCPC) is funding colorectal cancer (CRC) screening programs in 25 states and 4 tribes through the Colorectal Cancer Control Program (CRCCP) to increase screening rates among men and women aged 50 years and older. CDC requests approval from the Office of Management and Budget (OMB) for a one-year study to collect individual patient-level indirect/non-medical cost data from a subset of patients being screened for CRC through the program. CDC is authorized to conduct this information collection by section 301 of the Public Health Service Act (**Attachment A**).

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths among adults in the United States (USCS, 2010). The U.S. Cancer Statistics Working Group reported that in 2007 there were 142,672 new cases and 53,219 deaths from colorectal cancer (USCS, 2010). Strong scientific evidence shows that regular screening is effective in reducing CRC incidence and mortality through early detection and removal of polyps and the early detection of cancers (Yang et al., 2011; Stock et al., 2011; Pignone et al., 2011).

Regular CRC screening is now recommended for average-risk persons with one or a combination of the following tests: high-sensitivity fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT), flexible sigmoidoscopy, or colonoscopy. These tests vary in their costs, availability, and associated risks, and current evidence does not clearly demonstrate which of these tests is most effective.

Despite strong scientific evidence that regular screening decreases the incidence and mortality of colorectal cancer, screening remains underused. While screening rates have been increasing over the past decade, findings from a state-based survey data collection system indicate that CRC screening prevalence among adults aged 50-75 was 62.9% in 2008 (CDC, 2010). The rate of compliance with screening guidelines is much lower among persons without health insurance, as roughly 25% of uninsured persons have been screened according to guidelines (Shapiro et al., 2008; Subramanian et al., 2005; Seeff et al., 2004). Screening programs that specifically target the uninsured might help reduce disparities in colorectal cancer screening, incidence, and mortality (Seeff et al., 2004).

The population-based Colorectal Cancer Control Program (CRCCP) was funded for five years beginning in 2009 to address low screening rates and screening disparities. The goal of the CRCCP is to increase CRC screening rates among men and women aged 50 years and older. Specifically, as a result of the five-year program CDC aims to facilitate an increase in screening rates in the funded states from approximately 64% to 80% by 2014. The program has two components: screening promotion and screening provision.

Local CRCCP programs use evidence-based strategies recommended by the Task Force on Community Preventive Services to increase CRC screening, adapting them to their unique needs and situations (Joseph et al., 2011). Programs collaborate with local comprehensive cancer control programs and other partners to share resources related to screening promotion. Programs are able to choose which screening test(s) they will use from the above list of recommended tests. The priority population for screening through the CRCCP is persons aged 50 to 64 years who are uninsured or underinsured for screening.

Disparities in screening rates have been well documented, however, the sources of these disparities have not been studied in depth. The indirect and non-medical costs associated with colorectal cancer (CRC) screening may pose barriers to patients seeking CRC screening. Previous studies have identified cost/insurance coverage, low knowledge/awareness of CRC, and lack of time as barriers to CRC screening (O'Malley et al., 2004; Natale-Pereira et al., 2008; Cai, 2009). Collecting data on the time spent and the non-medical costs incurred by patients obtaining screening will provide CDC with information on costs, which may be significant barriers to low-income and un- or under-insured patients who are the population with the lowest screening rates (James et al., 2008; von Wagner et al., 2011; Whitaker et al., 2011).

Little is known about the total time commitment required of patients obtaining CRC screening through colonoscopy and FIT, including associated office visits and preparation in addition to time spent on the screening test itself. Additional time may be required by others if the patient requires a companion for office visits and/or the screening test itself (for example, patients screened with colonoscopy typically are not able to drive after the screening test due to the use of anesthesia during the procedure). Further resources may be required if the patient and/or companion must arrange for substitute child or elder care while obtaining screening and related services. In addition to costs associated with the time required throughout the screening process, patients may incur non-medical costs (for example, parking fees, expenses associated with bowel preparation or dietary changes, transportation costs).

The indirect and non-medical costs described above have not been measured in detail nor have they been measured for the low-income population among whom screening prevalence is inadequate (Heitman et al., 2008; Jonas et al., 2007). CDC plans to conduct a study to measure the time and costs incurred by patients screened for CRC with colonoscopy or FIT.

Privacy Impact Assessment

The proposed study will involve data collection from patients screened through the CRCCP. The CDC will collect patient-level data about the indirect/non-medical costs of obtaining CRC screening. These data will be collected by providers contracted by CRCCP programs, working as subcontractors to RTI International (CDC's contractor for this study), the economic evaluation contractor to CDC. The data collection method is a survey questionnaire. Two survey versions have been developed, one for colonoscopy screening and the other for FIT

screening. RTI will also host a web-based version of each patient-level survey, which will be available to those who prefer this method to a paper and pencil version.

The CRC screening providers will collect personal identifiers on each person selected to complete the survey (e.g., name, address). This information will be collected on a routine basis by the programs and providers to individuals to whom they provide colorectal cancer screening. Programs or their contracted providers will remove personal identifiers prior to transferring the data to RTI. At no point in the data collection process will RTI nor CDC have access to identifiable patient information.

Overview of the Data Collection System

Using the criteria developed by CDC to determine eligibility for screening through CRCCP, participating programs will identify patients appropriate for the proposed study. Patient navigators will reach out to patients screened through the program.

The programs or their contracted providers will administer either the Colonoscopy Questionnaire (**Attachment C**) or the FIT Questionnaire (**Attachment E**) asking each consecutive patient to participate, until a target number of surveys have been completed. Questionnaires will be available in English or Spanish. In many cases the participant may need help reading and/or answering the questions. Each site has made arrangements to make patient navigators (who work with the patient throughout the screening process) available to assist participants as needed. CDC and RTI have developed Protocol Instructions (see **Attachments D and F;** available in English only) to guide patient navigators through the data collection process. The programs have included funding for patient navigator time in their budget for the subcontract. Patient navigators will be available to walk participants through the survey and record answers to questions, or to answer questions about the survey as needed.

Providers in five states will partner with CDC to administer the survey: Alabama, Arizona, Colorado, New York, and Pennsylvania. Draft versions of the questionnaires were shared with these programs. Feedback was obtained from programs and providers, and incorporated into the draft questionnaires. The questionnaires were granted Institutional Review Board (IRB) exemption and were pilot tested in three states. The colonoscopy questionnaire was pilot-tested in New York. The FIT questionnaire was pilot-tested in Arizona. A Spanish version of the colonoscopy questionnaire was piloted in Colorado. Changes to the data collection instruments were made in response to comments from CDC and participating CRCCP programs, feedback from pilot testers, and comments from colleagues at the Centers for Medicare and Medicaid Services (CMS).

Items of Information to be Collected

The survey instruments for the proposed study will obtain information regarding: (1) patient characteristics (including age, gender, race and ethnicity, primary language, education

level and employment status, and health insurance status); (2) time and expense associated with a pre-screening office visit (including travel time, time spent in the office waiting for and meeting with the provider and transportation and parking expenses incurred); (3) time and expense associated with preparing for the screening test (including purchase of bowel preparation medication and food to comply with dietary restrictions and time spent preparing the FIT test or on bowel preparation prior to colonoscopy screening); (4) time and expense associated with the screening test (collecting specimens for the FIT test, travel time and expense incurred during colonoscopy screening, and time spent during screening with and recovery after the colonoscopy); (5) time and expense associated with a post-screening office visit; and (6) information about additional resources (such as replacement child or elder care and time required of a companion during the screening process).

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.

The survey material will be available in a web-based format (see **Attachments G and H**) hosted by RTI, however, the survey respondents will be adults age 50 and older. A coding system will be developed with input from participating programs to allow programs to track completion by patients and ensure privacy standards are met.

The indirect and non-medical cost data reporting web sites do not have content directed at children under 13 years of age.

A.2 Purposes and Use of the Information Collection

The proposed study will collect the first-ever data on the indirect and non-medical costs incurred by low-income patients screened for CRC with FIT or colonoscopy. Data will be collected from patients in three U.S. regions (South, West, and Northeast) and from a variety of racial and ethnic backgrounds (including patients screened through tribal organizations). The objectives of the survey are to provide: (1) estimates of the non-medical costs associated with CRC screening among the low-income population; (2) estimates of the indirect costs incurred by the low-income population screened through CRCCP; and (3) information on variation in the indirect and non-medical costs by type of screening test (FIT and colonoscopy).

Without this research, the CDC, other Federal agencies, state public health departments, tribal organizations, and CRC screening providers have little information about the true costs incurred by the low-income patients screened through CRCCP. CDC is working in partnership with CRCCP grantee programs to promote screening with the aim of increasing screening rates among the low-income population aged 50 and older with inadequate or no health insurance. In the face of these efforts, it is necessary to determine the true costs incurred by the patient population targeted by CRCCP.

The results of this study may be useful in the design of future screening programs. Study findings will be disseminated through presentations, data reports, and peer-reviewed publications.

A.3 Use of Improved Information Technology and Burden Reduction

In an effort to minimize respondent burden, CDC will offer survey respondents the option of reporting data through a web-based questionnaire (see **Attachments G and H**). The Colonoscopy Questionnaire and FIT Questionnaire data elements were selected because they will provide the minimum amount of data required to accomplish the study objectives.

The study investigators have carefully considered the content, appropriateness, and phrasing of the questions. All respondents will be asked to report the same data elements. Any additional data elements to be collected by the programs will be identified as separate from the study data.

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

As this is the only federally funded program that currently exists which offers CRC screening in community settings to this identified population, there are no existing, comparable data sources available for the collection of this information. The reported time and expense data will provide information about persons specifically enrolled and screened through the CRCCP and other patients screened by participating providers; the data will be available exclusively through providers affiliated with CRCCP programs.

CDC has partnered with colleagues at CMS to maximize the benefits of the proposed study to the Federal government. This collaboration will extend from the refinement of the data collection instruments to the dissemination of the study findings.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses are involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time data collection; less frequent data collection would result in no data being collected. Were the data not collected, there would continue to be an information gap regarding the indirect and non-medical costs of CRC screening. Failing to collect these data would result in a missed opportunity to measure costs that could be barriers to screening for low-income and uninsured patients. These data may provide information that could inform future efforts at improving screening rates among the low-income and uninsured populations.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR1320.5

These data are collected in a manner consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances contained within this application.

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

A. As required by 5 CRF 1320.8(d), a notice of this data collection was published in the Federal Register on March 29, 2012, in Volume 77, No. 61: pp. 19015-19016 . A copy of the Federal Register notice in included as **Attachment B**. No public comments were received.

B. The Division of Cancer Prevention and Control (DCPC) has employed several methods of consultation with individuals outside of the agency regarding the proposed data collection. Colleagues at CMS, such as Dr. Gerald Riley in the Division of Research on Health Plans and Drugs, have been consulted on the appropriateness and completeness of the data to be collected. Dr. Riley can be contacted at Gerald.riley@cms.hhs.gov. Grantee programs have played a substantial role in designing the data collection instruments, providing guidance on the necessary data elements, the readability of the questionnaires, and methods for ensuring adequate patient response. RTI translators provided guidance on adjusting question structure to ensure the same level of readability for the Spanish versions of the questionnaires. Patient navigators at participating sites provided feedback based on the pilot testing experience, as did patients who generously completed the pilot questionnaires.

A.9 Explanation of Any Payment or Gift to Respondents

Study participants are eligible to receive a small incentive in the form of a gift card upon completing the survey. The gift card amount of $20 was determined based on feedback from each participating grantee program. This incentive is made available to encourage completion of the surveys.

Retrospective reporting of the proposed data (in particular those data related to time associated with screening) would significantly reduce the quality of the data to be collected. Furthermore, retrospective reporting would require the development and maintenance of additional systems to follow up with patients regarding data collection. To ensure the quality of the data and an adequate sample size, each program suggested amounts for a small patient incentive that would be necessary to generate the targeted patient response.

A.10 Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

A. CDC has determined that the Privacy Act does not apply. Although the CRC screening providers have access to identifiable information on patients who receive screening services, the CRC screening providers (and their patient navigators/contractors) will not report client-level identifiers to CDC or CDC's data analysis contractor, RTI. Any personally identifiable data will be available only to the patient navigators who interact with the patients to facilitate their care.

B. The CRCCP Indirect/Non-medical Cost Study data are secured by technical, physical and administrative safeguards as outlined below.

Technical

- The CRCCP Indirect/Non-medical Cost Study data collected via patient survey reside on a dedicated server that resides on the contractor's local area network behind the contractor's firewall and is password protected on its own security domain. Access to the server is limited to the contractor's authorized project staff. No non-project staff are allowed access to the data. All of the contractor's project staff are required to sign a non-disclosure agreement before passwords and keys are assigned.
- The CRCCP Indirect/Non-medical Cost Study data that are submitted electronically through the online version of the survey are encrypted during transmission from the respondents and arrive on a server behind the data collection contractor's firewall. Once a questionnaire is submitted, respondents no longer have access to their or any other respondent's data.

Physical

- The contractor's server is housed in a secure facility with restricted access.
- Receipt and processing logs are maintained to document data receipt, file processing and report production. All reports and electronic storage media containing CRCCP Indirect/Non-medical Cost Study data are stored under lock and key when not in use and will be destroyed when no longer needed.
- Once data have been compiled by the data contractor and delivered to CDC, all CRCCP Indirect/Non-medical Cost Study datasets are maintained for restricted access on a secure LAN server, which is housed in a secure facility. All CDC staff are issued identification badges and access to the building is controlled by key cards.

Administrative

- CDC and contract staff have developed and implemented an information system security plan to ensure that the data are kept secure. Periodic review and update of the data contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the data.
- The contractual agreements between CDC and both contractors include non-disclosure terms. The contractor's project security team oversees operations to

prevent unauthorized disclosure of the CRCCP Indirect/Non-medical Cost Study data.

- Once the data have been delivered to CDC, access to these datasets will be overseen by the CRCCP data manager as appropriate.

C. Patient consent is not needed in collecting CRCCP Indirect/Non-medical Cost Study data. A written or verbal advisement will be given to all potential participants. This is located in **Attachment D** for the Colonoscopy questionnaire and in **Attachment F** for the FIT questionnaire.

D. Participation in the CRCCP Indirect/Non-medical Cost Study data collection is voluntary for patients screened during the data collection period at participating sites.

A.11 Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status, and employment history. No information regarding these topics will be collected or reported to the CDC. Potentially sensitive data elements include race/ethnicity, employment, and wage information. These data elements are not highly sensitive 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.

A.12 Estimates of Annualized Burden Hours and Costs

Exhibit 1 presents the estimated respondent and total burden associated with the study. CDC plans to collect 315 surveys from patients screened with colonoscopy and 300 surveys from patients screened with FIT. Patients may choose to complete English or Spanish language versions of the questionnaires. A web-based option is also available. The average completion time for the Colonoscopy Questionnaire (see **Attachment C** and **Attachment G**) was 25 minutes, resulting in a total burden of 131 hours for patients screened with colonoscopy. Colonoscopy Questionnaire Protocol Instructions (see **Attachment D;** English only) will be available to the patient navigator to assist in responding to any questions the study participant may have. The average completion time for the FIT Questionnaire (see **Attachment E** and **Attachment H**) was 10 minutes, for a total burden of 50 hours. Similarly, FIT Questionnaire Protocol Instructions (see **Attachment D;** English only) will be available to the patient navigator to assist in responding to any questions the study participant may have. The total respondent burden for the proposed study is estimated at 181 hours.

Exhibit 1. Number of respondents and estimated burden hours:

Form	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Colonoscopy questionnaire	315	1	25/60	131
FIT questionnaire	300	1	10/60	50
			Total	**181**

Using the Federal minimum wage to estimate the cost of respondent time, we estimate the opportunity cost to respondents in Exhibit 2. The estimated cost to respondents completing the Colonoscopy Questionnaire is $952, while the estimated cost to respondents completing the FIT Questionnaire is $363. This results in a total estimated opportunity cost to respondents of $1,313.

Exhibit 2. Estimated cost to respondents:

Form	Number of Respondents	Responses per Respondent	Total Burden (in hours)	Average Hourly Wage	Total Respondent Cost
Colonoscopy questionnaire	315	1	131	$7.25	$950
FIT questionnaire	300	1	50	$7.25	$363
				Total	**$1,313**

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

A.14 Annualized Cost to the Federal Government

Total operation and maintenance costs include work performed by the economic evaluation contractor, Research Triangle Institute (RTI). RTI is funded at an annual cost of $108,175 for a one-year total of $108,175. RTI activities include management of the data collection process (including subcontracts to programs/providers), management, and analysis of survey data, used for evaluation of the patient's indirect/non-medical costs associated with CRC screening.

A.15 Explanation for Program Changes or Adjustments

This is a new Information Collection Request.

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

A.16.1 Time Schedule

The CDC requests a one-year clearance for this data collection. We will use a convenience sampling method. At the participating sites each patient screened will be asked to participate until a total of 75 to 150 questionnaires have been completed. The completed survey target varies by grantee/provider and was agreed upon between CDC and the grantee/provider based on volume and grantee/provider costs associated with data collection. This approach ensures that the entire population of patients screened at each site (in the timeframe required to reach the site's target) has the opportunity to participate in the study, which reduces any impact from non-random sampling. The time required for each grantee/provider to collect their targeted number of surveys will depend on screening volume and willingness of patients to participate in the study.

A.16.2 Publication Plan

The CDC plans to use the patient-level survey data to produce reports, presentations, and peer-reviewed publications. These reports and publications will also be posted to the CDC web site and included in peer reviewed journals. The CDC expects that these publications will be produced upon completion of data collection and analysis. The CDC does not anticipate the development of a public use data set using the CRCCP Indirect/Non-medical Cost Study data. Analysis of data for the purposes of research will be conducted to address specific research questions concerning the indirect and non-medical costs incurred by low-income patients being screened for CRC through CRCCP.

A.16.3 Tabulation Plan

The patient-level survey data will be analyzed (see **Attachment I**) using standard univariate and bivariate descriptive statistics (e.g., means, frequencies, crosstabs). First, univariate analysis will be conducted on all items in the survey questionnaire. Following the univariate analysis, bivariate analyses will be conducted to examine differences among particular various subsets of survey respondents (e.g., by region or health insurance status).

Both the univariate and bivariate data analysis will focus on two major issues: (1) time spent by patient while obtaining CRC screening; and (2) out-of-pocket costs incurred in the process of obtaining CRC screening.

Patient characteristics. Analysis will begin with a description of the survey participants that obtained CRC screening through one of the participating providers. Patient characteristics

captured through the survey include age, sex, race/ethnicity, insurance coverage, education level, and employment status.

Indirect costs associated with CRC screening. A primary objective of the study is to identify and measure indirect and non-medical costs associated with CRC screening. Specifically, we seek to estimate time spent traveling to and from clinical appointments, time spent preparing for a screening test (e.g., dietary changes or bowel preparation), time spent obtaining screening, and time spent recovering from screening tests. In addition, patients may require accompaniment to one or more screening-related appointments. It is important to also capture the indirect costs associated with the time of individuals accompanying the patient during screening. Information about patients' work status, job type, and field will allow us to estimate the cost of patient time.

Non-medical costs associated with CRC screening. In addition to time estimates, we also seek to measure the cost outlays faced by patients while obtaining CRC screening. These non-medical costs can include transportation and/or parking fees, costs associated with child care or elder care, and costs associated with having someone accompany the patient to provider visits or screening tests (in the case of colonoscopy).

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

These data are collected in a manner consistent with the certification statement identified in Item 19 "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I. No exceptions are requested.

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