Colorectal Cancer Screening Program

OMB No. 0920-0745
Extension Request

Supporting Statement Part B

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B. Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

Respondents are the 29 grantees funded through CDC's Colorectal Cancer Control Program (CRCCP). Statistical sampling methods are not applicable.

B.2 Procedures for the Collection of Information

In order to assess the quality, effectiveness, and appropriateness of the services delivered by the cooperative agreement recipients of the colorectal cancer screening program and to monitor program effectiveness, grantee programs will submit standardized data to CDC related to CRC screening, diagnostic follow-up, and treatment services that are part of the program. Development of the set of key Colorectal Cancer Clinical Data Elements (CCDEs), described in **Attachment 3b**, was informed through interactions involving CDC, grantees and the demonstration program with the assistance of outside experts providing consultation on data-related issues (**Attachment 6**). Grantees will also receive a Data User's Manual **(Attachment 3c)** developed by CDC and the data contractor that provides complete written instruction regarding CCDE data submission requirements, data variables, data field descriptions, report descriptions, etc. This document will support consistent submissions across grantee programs. The manual is accessible through a web-site for CRC screening program Data Managers and Program Directors maintained by the data contractor.

Individual patient-level data will be collected on a continuous basis, but prepared for semi-annual submission to CDC. Briefly, data will be entered into the grantee's electronic database and de-identified data will be exported to CDC on a semi-annual basis.

CDC has retained a contractor to assist CDC and programs with collection, management and analysis of clinical data. All data received from grantee programs will be submitted first to the data contractor, who will work with the each grantee to identify and address data questions,

provide data checks, and review the data for completeness, and if necessary, request clarification from grantees.

An analysis file will be created from the data, and will be used to produce three types of feedback reports: 1) an Error Summary Report, 2) a Data Quality Indicator Guide Report and 3) a Service Quality Indicator Guide Report (**Attachments 4a, b, and c**). Program site-specific Error Summary Reports will contain counts and associated percentages for blank field errors, inter-field relationship errors and inter-record relationship errors in each data set. Program site-specific Data Quality Indicator Guide Reports will be used to provide feedback to grantees about the quality, completeness and timeliness of their data within the most recent 18 months of data reporting, using tables and record audits. Finally, the contractor will create an aggregated analysis file to generate standardized, CRC screening program surveillance reports (Service Quality Indicator Guide Reports) and any additional special CDC requests. Plots or graphs will be generated to provide fiscal year data for age and race demographics, counts of persons served, procedures performed and cancer incidence. Once the feedback reports are distributed to CDC, they will be shared with grantees and used for quality improvement of the delivery of services. These data and reports will also be used as part of the overall evaluation of the screening program, which will include the development of evaluation reports. The feedback reports will be used for quality assurance in the short term, and as program evaluation tools in the long term.

Additionally, we are undertaking an economic analysis of this program, supported through a contractor. Program-level activity-based cost data will be collected to identify resources expended on the different activities and components of the program. In addition to direct service provision, grantees are required to engage in activities to support a public health approach to increase screening, including client recruitment, patient support services, professional education, partnerships, program management and evaluation. The cost information will be collected via a web-based tool (see **Attachments 5 and 5a**, CAT data collection). Cost data will be collected annually.

Upon submission of the data the evaluation contractor will analyze the CAT. The evaluation contractor will calculate the cost by activities and the cost by budget categories for each grantee's review and approval.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Grantees are required to participate in the information collection as described in the Funding Opportunity Announcement.

B.4 Tests of Procedures or Methods to be Undertaken

The data management and reporting systems developed and maintained by the CDC have been internally tested by CRC screening program funded site staff and the data contractor. Following the demonstration phase of the project, changes were made to streamline the collection and approved by OMB on 6/30/2010.. The web-based tool for activity-based cost assessment was developed by the evaluation contractor and was tested with 5 grantees during the Demonstration phase of the CRC screening program and.informed by CDC's experience with the instrument in the data collection entitled "Economic Analysis of the National Program of Cancer Registries (NPCR)" (OMB No. 0920-0812, exp. 6/30/2012).

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The data collection was designed by the Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-52, Atlanta, GA 30341-3717, with assistance from staff of CDC and data contractors Information Management Services, Inc., (IMS) and RTI International (RTI), including from CDC: Laura Seeff MD, Marion Nadel PhD, Blythe Ryerson MPH, Florence Tangka PhD, Djenaba Joseph MD, Amy DeGroff PhD, Janet Royalty MS; from IMS: Bill Helsel, Bill Kammerer, Cindy Mattingly and Steve Marroulis; and from RTI: Sujha Subramanian PhD and Sonja Hoover MPP. All CDC staff listed were involved in the design of the data collection and will be involved in analysis of the data for evaluation purposes.

The CDC Project Officer for the IMS data management contract is Janet Royalty, MS (770-488-3085), Data Manager at the Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-57, Atlanta, GA 30341-3717.

The CDC Project Officer for the RTI economic evaluation contract is Florence Tangka, PhD (770-488-1183), Senior Health Economist at the Epidemiology and Applied Statistics Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-57, Atlanta, GA 30341-3717. Evaluation activities performed by RTI are conducted under the direction of Sujha Subramanian PhD (781-434-1722), Senior Health Economist, RTI International, 3040 Cornwallis Road RTP, NC 27709.

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