

Colorectal Cancer Control Program Indirect/Non-Medical Cost Study

OMB Supporting Statement

Part B: Collection of Information Employing Statistical Methods

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TABLE OF CONTENTS

Section	Page
B. Collection of Information Employing Statistical Methods.....	1
B.1 Respondent Universe and Sampling Methods.....	1
B.2 Procedures for the Collection of Information.....	1
B.3 Methods to Maximize Response Rates and Deal with Nonresponse.....	2
B.4 Test of Procedures or Methods to be Undertaken.....	2
B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	2
References.....	4

LIST OF ATTACHMENTS

- A Authorizing Legislation
- B 60-day Federal Register Notice
- C Colonoscopy questionnaire
- D Colonoscopy questionnaire protocol instructions
- E FIT questionnaire
- F FIT questionnaire protocol instructions
- G Colonoscopy Web-based Questionnaire Screens (English and Spanish)
- H FIT Web-based Questionnaire Screens (English and Spanish)
- I Summary of Analysis Plan

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The respondents are patients screened for colorectal cancer (CRC) by a provider contracted by participating CRCCP programs. CDC has reached out to several programs to assess willingness and ability to partner for this study. Programs in five states have agreed to collaborate with CDC: Alabama, Arizona, Colorado, New York, and Pennsylvania. The geographic diversity will ensure variation in respondent characteristics. Providers associated with each program serve patients in tribal organizations, patients with a variety of primary languages, and patients of various ethnicities. CDC expects that the variation in respondent characteristics will yield meaningful results from the targeted sample size.

Convenience sampling will be employed. At the participating sites each patient screened will be asked to participate until a total of 75 to 150 questionnaires have been completed. This approach ensures that the entire population of patients screened at each site (in the timeframe required to reach the target number of completed questionnaires) has the opportunity to participate in the study, which reduces any impact from non-random sampling.

Because the program (and at a more specific level, each site) targets a particular population for screening provision, it is reasonable to assume that the sample used for this study is representative of the population served by the screening program. The sample surveyed will be representative of the population that have the lowest rates of screening compliance, and for whom indirect and non-medical costs are likely to be a substantial barrier to screening.

Additional information about the analysis plan is provided in Attachment I.

B.2 Procedures for the Collection of Information

The programs will be responsible for collecting completed paper surveys from participants as well as for recording completion of online surveys. In addition the programs will distribute the incentive (gift card) to participants who complete the survey. Each program will maintain a record of participants and their assigned (de-identified) number. The completed questionnaires will only contain the de-identified number and not any personal information. RTI will receive the completed paper questionnaires and the online survey data. RTI and CDC will not have access to personal information that could identify participants.

The programs and their contracted providers will be responsible for collecting completed surveys from and distributing the incentive (gift card) to participants who complete the survey. Programs will store all of the completed questionnaires until the target number of surveys has been completed for that site. Each site will maintain a record of participants and their assigned (de-identified) number. The patient identifier will be formatted as: XX-YY-ZZZZZ, where XX is the two-character state abbreviation, YY is a two-digit code to identify the site where the

survey was completed (as some programs will collect data through providers at multiple sites, each program will assign a site code to each provider site), ZZZZZ is the five-digit number used to identify the patient, the survey format, and the assistance of a patient navigator (the first three digits are assigned to the patient screened (using consecutive numbers based on the order of survey completion), the fourth digit is a code used to distinguish the format of the questionnaire (surveys will be completed on paper (P) or online (W) and the fifth digit denotes whether the patient completed the survey with (N) or without (S) assistance from a patient navigator). The completed questionnaires will only contain the de-identified number (XX-YY-ZZZZZ) and not any personal information. The economic evaluation contractor, RTI, will receive the completed questionnaires and will not have access to personal information that could identify participants.

Each grantee has made arrangements to make patient navigators (who work with the patient throughout the screening process) available to assist participants as needed. 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.

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

Professional training in the administration of the survey will be available to all patient navigators prior to beginning the study. Programs and their contractors will also receive Colonoscopy Questionnaire Protocol Instructions or the FIT Questionnaire Protocol Instructions, which provide complete written instruction regarding administering the survey. Small incentives in the form of gift cards will be made available to participants who complete the survey.

B.4 Test of Procedures or Methods to be Undertaken

Each questionnaire (colonoscopy and FIT) was pilot tested with patients screened by participating providers to test for survey quality and usability and as a tool to estimate time burden associated with completing the questionnaire. Feedback from pilot testing was incorporated into the final version questionnaires. The estimates of time burden presented in Part A of the Supporting Statement were generated from pilot testing results.

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

Florence Tangka, Ph.D., of the Division of Cancer Prevention and Control, is the Principal Investigator and Technical Monitor for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. She will approve and receive all contract deliverables. Telephone: 770-488-1183.

The survey instrument, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at Research Triangle Institute (RTI) International.

RTI will conduct data collection and will perform data analysis, in consultation with the CDC investigators.

Sujha Subramanian, Ph.D. [781-434-1749] has overall technical and financial responsibility for the study at RTI and led the RTI effort to design this protocol. Dr. Subramanian will direct the overall data collection and analysis effort.

Other personnel involved in design of the protocol and data collection instruments are:

Maggie Cole Beebe, Ph.D.
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