Form Approved

OMB No. \_\_\_\_\_\_\_\_\_\_\_\_\_

Exp. Date \_\_\_\_\_\_\_\_\_\_\_\_\_

**Colorectal Cancer Control Program Indirect/Non-medical Cost Study**

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-xxxx).

FIT Protocol Instructions

**1. Introduction**

*The following information should be provided to participants – either written or verbally.*

The Colorectal Cancer Control Program Indirect/Non-medical Cost Study is a research study paid for by the Centers for Disease Control and Prevention (CDC). The CDC has hired a contractor, Research Triangle Institute (RTI), to conduct the study. The purpose of this study is to understand the costs to patients of being screened for colorectal cancer through the Colorectal Cancer Control Program (CRCCP).

It is important to study the costs to patients of colorectal cancer screening because these costs may prevent some patients from being screened. If the costs to patients of being screened for colorectal cancer are understood, it may be possible to set up policies or programs that help patients with these costs. This may help more patients get screened for colorectal cancer.

**1.1 Information for participants**

You are one of the people screened through the CRCCP being asked to participate in this study. Your screening provider has chosen to work with CDC and RTI to conduct this study and will give you the survey questionnaire. You will only be contacted by your patient navigator or other representative from your screening provider’s office. You have a choice of whether or not to be a part of this study. You can say no to any part of this study and you can stop answering questions at any time. You can refuse to answer any question. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

If you agree to participate, you will be asked to complete a questionnaire. You can ask your patient navigator if you need help understanding and answering any questions.

You will be asked questions about the time you spent being screened for colorectal cancer (including any visits to the doctor or endoscopy center) as well as about any out-of-pocket costs you had to pay (such as paying for transportation, parking, or child care). You will also be asked questions that describe you (such as your age and race) and questions about your schooling and work.

You will receive a gift card for your time to participate in the study after you return the completed questionnaire.

Every effort to protect your information has been made. Your name will be replaced with a de-identified number and along with other personal information, will be kept separately from the answers you provide on the questionnaire. This personal information will only be seen by your provider. If the results of this study are presented at scientific meetings or published in scientific journals, no information will be included that could identify you or your answers personally.

**2. GUIDELINES FOR ADMINISTRATION OF QUESTIONNAIRES**

Survey questionnaires will be available on paper and online. The survey can be completed either by the respondent or by a patient navigator. For patients opting to complete the survey online, the information provided above will appear on the screen.

This study was determined to be exempt from Institutional Review Board (IRB) review (RTI#12459) and therefore it is not necessary to collect signed consent forms.

As described above and previously discussed, RTI will receive competed surveys without any personal identifiers. Your organization must therefore maintain a separate, secure method of tracking which patients have received and completed a survey.

Prior to survey administration:

1. Familiarize yourself with the survey questionnaire and information sheet (above).
2. Develop a process for distributing and collecting the questionnaires, record keeping, and distributing gift cards to patients who have completed the survey.
   1. If offering patients the option of completing the survey online, provide them with the web address where the survey is located (RTI will supply a printout with information about the survey and the URL where the survey is located).
3. Designate a place for patients to work with a patient navigator (this can be done in person or over the phone) if the patient requires assistance completing the survey.
4. Prepare to receive completed surveys from patients completing on their own at home (provide pre-addressed, stamped envelopes to return to your office).

At the time of survey distribution/administration:

1. Describe the survey to the patient (read the information on Page 1 above) and ask the patient if they are willing to participate in the survey by answering the questionnaire. Remind the patient that participation is voluntary and that they do not have to answer the questionnaire if they are not comfortable doing so.
2. If the patient is willing to participate, ask whether they are comfortable completing the questionnaire on their own or whether they would prefer to have a patient navigator assist them. Assistance may be as simple as clarifying a question or as complex as walking through each question and recording all answers. If the patient is not fluent in English or Spanish, the patient navigator may translate each question into the patient’s primary language as the survey is completed.

After survey administration:

1. Collect the completed survey from the patient/from the mail.
2. Check that online surveys have been completed.
3. Update records to indicate the patient completed the survey.
4. Distribute the gift card to the patient and update records to indicate receipt of the gift card.

**3. SURVEY DETAILS**

1. **Section A** (Information About You) collects information that describes the patient.
   1. Questions A1 through A5 ask about the patient’s age, gender, race, ethnicity, and primary language.
   2. Questions A6 through A10 ask about the patient’s education and employment status. The answers to these questions will help us to quantify (give a dollar value to) the patient’s time spent getting screened for CRC.
      1. Question A6 asks about the highest level of education completed.
      2. Question A7 asks whether the patient is currently working.
         1. If the patient is currently working, answer Working and proceed to question A8.
         2. If the patient is not working, prompt them to describe why they are not working and choose one of the following: NOT WORKING, Staying at home to work or keeping house, or Retired and skip ahead to Question A11.
      3. Question A8 asks about how much time the patient spends working. Typically Full-time is 40 hours per week.
      4. Question A9 asks about the patient is paid. If the patient earns an hourly wage, check By the hour. If the patient earns a salary, please check A certain amount every month.
      5. Question A10 uses Bureau of Labor Statistics categories to describe the patient’s job. Examples of each category are given. If no category matches, please check Other and write in a brief job description in the space provided.
      6. Question A11 asks about whether the patient had to miss work for each part of the screening process (pre-screening, screening preparation, screening test, and post-screening).
         1. If the patient had to miss work, answer YES and continue to answer the following questions. If the patient did not have to miss work, answer NO and move ahead to Question A12.
            1. If the patient had to miss work to attend a pre-screening office visit, answer Yes in A11.a and report how much work time was missed (in HOURS and MINUTES) A11.b.
            2. If the patient did not have to miss work to attend a pre-screening office visit, answer NO in A11.a and proceed to A11.c.
            3. If the patient had to miss work to prepare the screening test, answer Yes in A11.c and report how much work time was missed (in HOURS and MINUTES) A11.d.
            4. If the patient did not have to miss work to prepare the screening test, answer NO in A11.c and proceed to A11.e.
            5. If the patient had to miss work to complete the screening test, answer Yes in A11.e and report how much work time was missed (in HOURS and MINUTES) A11.f.
            6. If the patient did not have to miss work to complete the screening test, answer NO in A11.e and proceed to A11.g.
            7. If the patient had to miss work to attend a post-screening office visit, answer Yes in A11.g and report how much work time was missed (in HOURS and MINUTES) A11.h.
            8. If the patient did not have to miss work to attend a post-screening office visit, answer NO in A11.g and proceed to A12.
   3. Question A12 asks whether the patient has health insurance. It may be necessary to read through the options in A12.a to help the patient determine whether they have insurance or other health coverage.
      1. If the patient has coverage, answer YES and indicate which type of health insurance they have by checking the appropriate option in A12.a.
      2. If the patient does not have health insurance coverage, answer NO and move ahead to section B.
2. **Section B** (Information About Your Pre-Colonoscopy Office Visit) collects information about time spent traveling to and from the physician’s office or clinic in addition to time spent during the office visit, as well as information on costs associated with the visit.
   * 1. Question B1 asks whether the patient had a pre-screening office visit. A patient should answer YES if they saw a provider specifically to discuss or prepare for CRC screening. If the patient did not have a visit specifically related to screening before the colonoscopy, answer NO and move ahead to Section C.
     2. If the patient did have an office visit related to screening, report how much time (in HOURS and MINUTES) the patient spent at the appointment in B1.a. This should include the entire time spent, including time in the waiting room and waiting in the exam room for the physician or other provider.
     3. Report the amount of time spent traveling to and from the doctor’s office or clinic (in HOURS and MINUTES) in B1.b.
   1. Questions B2 through B4 ask about how the patient traveled to the doctor’s office or clinic.
      1. If the patient rode in a personal car to get to the appointment, answer YES in B2 and proceed to B2.a. If they did not travel in a personal car, answer NO and proceed to B3.
         1. If the patient was driven by somebody else, answer YES in B2.a and proceed to B2.b.
            1. If the patient had to pay someone for a ride to the doctor’s office or clinic, answer YES in B2.b and report how much (in dollars/cents) in B2.c.
         2. If the patient drove to doctor’s office or clinic for the appointment, answer NO in B2.a and proceed to Question B2.d.
         3. If the patient had to pay to park while at the appointment, answer YES in B2.d and indicate how much they paid (in dollars/cents) in B2.e. If the patient did not pay to park, answer NO in B2.d and move ahead to Section C.
      2. If the patient did not travel by car, ask if they traveled by bus, train, or taxi. If the patient used one of these methods to get to the doctor’s office or clinic, answer YES in B3 and report how much they paid in B3.a.
      3. If the patient did not travel by bus, train, or taxi, answer NO in B3 and proceed to B4. Write in a brief description of how the patient traveled to the appointment in the space provided in B4.
3. **Section C** (Information About Preparing for Your FIT) asks about bowel preparation done before the patient received the colonoscopy.
   * 1. Question C1 asks whether the patient had to pay for the FIT. If the patient had to pay out of pocket for the test kit, answer YES in C1 and proceed to C1.a. If the patient did not pay out of pocket for the product (for example, if they received the bowel prep product at no cost to them from the clinic), answer NO in C1 and proceed to C2.
     2. Report how much the patient paid for the bowel prep product (in dollars/cents) in C1.a.
   1. If the patient had to pay to mail the FIT test cards back to the doctor, clinic, or elsewhere (such as the laboratory) answer YES in C2 and report the amount paid (in dollars/cents) in C2.a. If the patient did not have to pay for postage to return the FIT test cards, answer NO in C2 and proceed to C3.
   2. Question C3 asks about the time spent reading the instructions for the FIT. Report the amount of time spent (in HOURS and MINUTES) in C3.
   3. Report the amount of time spent (in HOURS and MINUTES) collecting the sample for each stool card (CARD 1 and CARD 2) in C4.
   4. Question C5 asks whether the patient had to pay any other money out of pocket when preparing the FIT. If the patient did have other expenses not reported in earlier answers, briefly describe the expense and report the amount paid (in dollars/cents) in C5.
4. **Section D** (Information About Your Post-Screening Visit) collects information about time spent traveling to and from the physician’s office or clinic in addition to time spent during the office visit, as well as information on costs associated with the visit.
   * 1. Question D1 asks whether the patient had a post-screening office visit. A patient should answer YES if they saw a provider specifically to discuss the results of CRC screening. If the patient did not have a visit specifically related to screening after completing the FIT, answer NO and move ahead to Section E.
     2. If the patient did have an office visit related to screening, report how much time (in HOURS and MINUTES) the patient spent at the appointment in D1.a. This should include the entire time spent, including time in the waiting room and waiting in the exam room for the physician or other provider.
     3. Report the amount of time spent traveling to and from the doctor’s office or clinic (in HOURS and MINUTES) in D1.b.
   1. Questions D2 through D4 ask about how the patient traveled to the doctor’s office or clinic.
      1. If the patient rode in a personal car to get to the appointment, answer YES in D2 and proceed to D2.a. If they did not travel in a personal car, answer NO and proceed to D3.
         1. If the patient was driven by somebody else, answer YES in D2.a and proceed to D2.b.
            1. If the patient had to pay someone for a ride to the doctor’s office or clinic, answer YES in D2.b and report how much (in dollars/cents) in D2.c.
         2. If the patient drove to doctor’s office or clinic for the appointment, answer NO in D2.a and proceed to Question D2.d.
         3. If the patient had to pay to park while at the appointment, answer YES in D2.d and indicate how much they paid (in dollars/cents) in D2.e. If the patient did not pay to park, answer NO in D2.d and move ahead to Section D.
      2. If the patient did not travel by car, ask if they traveled by bus, train, or taxi. If the patient used one of these methods to get to the doctor’s office or clinic, answer YES in D3 and report how much they paid in D3.a.
      3. If the patient did not travel by bus, train, or taxi, answer NO in D3 and proceed to D4. Write in a brief description of how the patient traveled to the appointment in the space provided in D4.
5. **Section E** (Information About the Person Accompanying You) collects information about the person escorting the patient to any office visits and/or the colonoscopy appointment.
   1. If someone accompanied the patient to any pre- or post-screening doctor’s visits or to the colonoscopy appointment, answer YES in E1 and proceed to E2. If the patient went alone to all appointments, answer NO in E1 and move ahead to Section F.
   2. Describe the patient’s escort in E2. If the escort is the patient’s spouse (or equivalent) answer HUSBAND OR WIFE. If the escort is a child, sibling, or other family member answer OTHER FAMILY MEMBER. If the escort is a friend, answer FRIEND. If the answers above do not describe the patient’s escort, answer OTHER CAREGIVER.
   3. Question F3 asks whether the escort is currently working.
      1. If the escort is currently working, answer Working and proceed to question E4.
         1. If the escort is not working, prompt them to describe why they are not working and choose one of the following: NOT WORKING, Staying at home to work or keeping house, or Retired and skip ahead to Section F.
      2. Question E4 asks about how much time the escort spends working. Typically Full-time is 40 hours per week.
      3. Question E5 asks about how the escort is paid. If the escort earns an hourly wage, check By the hour. If the escort earns a salary, please check A certain amount every month.
      4. Question E6 uses Bureau of Labor Statistics categories to describe the escort’s job. Examples of each category are given. If no category matches, please check Other and write in a brief job description in the space provided.
6. **Section F** (Cost of Child or Elder Care) collects information about expenses related to substitute child or elder care to replace care normally provided by the patient or escort during any appointments, preparation for, and recovery from the colonoscopy.
   1. If the patient or escort usually cares for a child or elderly person during the day answer YES in F1 and proceed to F1.a. If neither the patient nor the escort care for another person during the day, answer NO in F1; the survey is now complete.
      1. If the patient or the escort had to find a child or elder care provider to substitute for care they normally provide, answer YES in F1.a and proceed to F1.b. Answer YES if substitute care was necessary for any time during the screening process (pre- and post-screening appointments, bowel preparation prior to the colonoscopy, the colonoscopy appointment, and recovery time following the colonoscopy). If no substitute care was necessary, answer NO in F1.a; the survey is now complete.
      2. If the patient or escort had to pay for substitute child or elder care (during any time in the screening process) answer YES in F1.b and report the amount paid (in dollars/cents) in F1.c. If no payment was made for substitute care, answer NO in F1.b; the survey is now complete.