

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

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### Colonoscopy 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 completed 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.
  - a. 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

A. **Section A** (Information About You) collects information that describes the patient.

- I. Questions A1 through A5 ask about the patient's age, gender, race, ethnicity, and primary language.
- II. 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.
  - a. Question A6 asks about the highest level of education completed.
  - b. Question A7 asks whether the patient is currently working.
    - i. If the patient is currently working, answer WORKING and proceed to question A8.
    - ii. 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.
  - c. Question A8 asks about how much time the patient spends working. Typically FULL-TIME is 40 hours per week.

- d. 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.
- e. 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.
- f. Question A11 asks about missing work for each part of the screening process (pre-colonoscopy, bowel preparation, colonoscopy, and post-colonoscopy).
- i. 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.
    - a. If the patient had to miss work to attend a pre-colonoscopy office visit, answer Yes in A11.a and report how much work time was missed (in HOURS and MINUTES) A11.b.
    - b. If the patient did not have to miss work to attend a pre-colonoscopy office visit, answer NO in A11.a and proceed to A11.c.
    - c. If the patient had to miss work to prepare for the colonoscopy (bowel preparation), answer Yes in A11.c and report how much work time was missed (in HOURS and MINUTES) A11.d.
    - d. If the patient did not have to miss work to prepare for the colonoscopy (bowel preparation), answer NO in A11.c and proceed to A11.e.
    - e. If the patient had to miss work for the colonoscopy, answer Yes in A11.e and report how much work time was missed (in HOURS and MINUTES) A11.f.
    - f. If the patient did not have to miss work for the colonoscopy, answer NO in A11.e and proceed to A11.g.
    - g. If the patient had to miss work to attend a post-colonoscopy office visit, answer Yes in A11.g and report how much work time was missed (in HOURS and MINUTES) A11.h.
    - h. If the patient did not have to miss work to attend a post-colonoscopy office visit, answer NO in A11.g and proceed to A12.

- III. 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.
  - a. If the patient has coverage, answer YES and indicate which type of health insurance they have by checking the appropriate option in A12.a.
  - b. If the patient does not have health insurance coverage, answer NO and move ahead to section B.
  
- B. **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.
  - a. 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.
  - b. 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.
  - c. Report the amount of time spent traveling to and from the doctor's office or clinic (in HOURS and MINUTES) in B1.b.
  
- II. Questions B2 through B4 ask about how the patient traveled to the doctor's office or clinic.
  - a. 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.
    - i. If the patient was driven by somebody else, answer YES in B2.a and proceed to B2.b.
      - a. 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.
    - ii. If the patient drove to doctor's office or clinic for the appointment, answer NO in B2.a and proceed to Question B2.d.
    - iii. 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.

b. 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.

c. 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.

C. **Section C** (Information About Bowel Preparation) asks about bowel preparation done before the patient received the colonoscopy.

a. Question C1 asks whether the patient had to pay for a bowel preparation product. If the patient had to pay out of pocket for the product, 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.

b. Report how much the patient paid for the bowel prep product (in dollars/cents) in C1.a.

II. Question C2 asks about the time spent reading the information and instructions for the bowel prep product. Report the amount of time spent (in HOURS and MINUTES) in C2.

a. Report the amount of time spent (in HOURS and MINUTES) prepping the bowel for the colonoscopy in C2.a (typically the patient will take the bowel prep medication the day before the colonoscopy is scheduled). Please count from the time the medication was taken until the patient left to travel to the colonoscopy appointment.

D. **Section D** (Information About Your Colonoscopy) asks about the time spent by the patient on the day of the colonoscopy and during recovery time (which may run into the next day or more) after the colonoscopy. This section also asks about how the patient traveled to the colonoscopy appointment and about any costs associated with traveling to the appointment.

I. Question D1 asks whether the patient (and anyone escorting the patient) traveled by car to the colonoscopy appointment. If the patient traveled by car, answer YES in D1 and proceed to D1.a. If the patient did not travel to the appointment in a personal car, answer NO in D1 and proceed to D2.

- a. If someone other than the patient drove the car to the colonoscopy appointment, answer YES in D1.a and proceed to D1.b. If the patient drove to the appointment, answer NO in D1.a and proceed to D1.c.
  - b. If the patient did pay someone to drive them to the colonoscopy appointment, answer YES in D1.b and report how much they paid (in dollars/cents) in D1.c. If the patient did not have to pay their driver, answer NO in D1.b and proceed to D1.d.
  - c. If the patient or the patient's driver had to pay to park during the colonoscopy appointment, answer YES in D1.d and report the amount patient (in dollars/cents) in D1.e. If no payment was made, answer NO in D1.d and proceed to D4.
- II. 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 D2 and report how much they paid (in dollars/cents) in D2.a. If the patient did not pay to park, answer NO in D2 and move ahead to D3. Write in a brief description of how the patient traveled to the appointment in the space provided in D3.
- III. Question D4 asks about the time spent at the colonoscopy appointment. Report how much time (in HOURS and MINUTES) the patient spent at the appointment in D4. 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 as well as any recovery time before the patient was authorized to leave.
  - a. Because the patient is usually sedated during the colonoscopy, an escort often accompanies the patient. Question D4 notes that it may be necessary for the escort to answer; if the patient does not have an escort to answer the question, it will be helpful if a staff member from the endoscopy center can answer this question.
  - b. Report time spent traveling to and from the colonoscopy appointment (in HOURS and MINUTES) in D4.a.
  - c. Report time spent recovering from the colonoscopy (in HOURS and MINUTES) in D4.b. This question refers to time spent after returning home from the appointment until the patient was able to return to normal activity.
- E. **Section E** (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.
  - a. Question E1 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 the colonoscopy, answer NO and move ahead to Section F.

b. 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 E1.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.

c. Report the amount of time spent traveling to and from the doctor's office or clinic (in HOURS and MINUTES) in E1.b.

II. Questions E2 through E4 ask about how the patient traveled to the doctor's office or clinic.

a. If the patient rode in a personal car to get to the appointment, answer YES in E2 and proceed to E2.a. If they did not travel in a personal car, answer NO and proceed to E3.

i. If the patient was driven by somebody else, answer YES in E2.a and proceed to E2.b.

a. If the patient had to pay someone for a ride to the doctor's office or clinic, answer YES in E2.b and report how much (in dollars/cents) in E2.c.

ii. If the patient drove to doctor's office or clinic for the appointment, answer NO in E2.a and proceed to Question E2.d.

iii. If the patient had to pay to park while at the appointment, answer YES in E2.d and indicate how much they paid (in dollars/cents) in E2.e. If the patient did not pay to park, answer NO in E2.d and move ahead to Section F.

b. 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 E3 and report how much they paid in E3.a.

c. If the patient did not travel by bus, train, or taxi, answer NO in E3 and proceed to E4. Write in a brief description of how the patient traveled to the appointment in the space provided in E4.

F. **Section F** (Information About the Person Accompanying You) collects information about the person escorting the patient to any office visits and/or the colonoscopy appointment.

I. If someone accompanied the patient to any pre- or post-screening doctor's visits or to the colonoscopy appointment, answer YES in F1 and proceed to F2. If the patient went alone to all appointments, answer NO in F1 and move ahead to Section G.

II. Describe the patient's escort in F2. 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.

- III. Question F3 asks whether the escort is currently working.
  - a. If the escort is currently working, answer WORKING and proceed to question F4.
    - i. 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 G.
  - b. Question F4 asks about how much time the escort spends working. Typically FULL-TIME is 40 hours per week.
  - c. Question F5 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.
  - d. Question F6 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.
- G. **Section G** (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.
  - I. If the patient or escort usually cares for a child or elderly person during the day answer YES in G1 and proceed to G1.a. If neither the patient nor the escort care for another person during the day, answer NO in G1; the survey is now complete.
    - a. 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 G1.a and proceed to G1.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 G1.a; the survey is now complete.
    - b. If the patient or escort had to pay for substitute child or elder care (during any time in the screening process) answer YES in G1.b and report the amount paid (in dollars/cents) in G1.c. If no payment was made for substitute care, answer NO in G1.b; the survey is now complete.