Screen to Save: A Colorectal Cancer Educational Intervention

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SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

CPHS template v. 10/18/2016

Please complete: CPHS# STUDY00030077 PI: Onega, Tracy

Important Note: The CPHS Department (Chair & Scientific) Review Form is required with this application. Find the form in the RAPPORT Library or on the CPHS Website.

- **Respond to each item, even if to indicate N/A or not applicable**
- **Attach and/or upload this form as your 'Investigator Protocol' in Rapport**
- **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

1. Introduction and Background

Colorectal cancer (CRC) is the fourth most common type of cancer in men and women in the U.S. and is the second leading cause of death from cancer. Approximately 135,000 people are diagnosed with CRC each year in this country, and about 50,000 die from it. CRC is one of only a handful of more than 100 known types of cancer for which screening has been proven to reduce the risk of death. In fact, most CRC deaths can be prevented through early screening. The U.S. Preventive Services Task Force recommends that all adults 50-75 years old get screened for colorectal cancer. Yet, some populations do not get screened as often as they should. In the Norris Cotton Cancer Center's (NCCC) catchment area of Vermont and New Hampshire, these populations include, but are not limited to, the uninsured/underinsured, low socioeconomic status individuals, racial/ethnic minorities, and people living in certain geographic areas. Despite national and local efforts to get 80% of the eligible population screened by 2018, this goal has not yet been achieved national nor locally. Increasing CRC screening rates is part of the 10 recommendations by the Blue Ribbon Panel for the Cancer Moonshot, announced in October 2016.

In 2017, the National Cancer Institute's (NCI) Center to Reduce Cancer Health Disparities (CRCHD) is launching a nationwide CRC initiative called *Screen to Save.* The goal is to increase CRC screening rates among 50-75 year olds, especially from racially and ethnically diverse populations, people living in rural areas, and other populations that have historically had lower CRC screening rates than the general population. The initiative will involve up to 49 sites—including NCCC—that have received NCI/CRCHD funding to support Community Health Educators. Community Health Educators are expected to disseminate CRC information, education, and screening options in their communities, with the goal of increasing awareness, knowledge, and positive behavior change. Efforts will include educational social media messages; distribution of handouts, brochures, and other small media; and community-based outreach events. This last effort—the community-based outreach events—will take place at locations such as health fairs, festivals, and community-based organizations and will include data collection efforts.

Several public health interventions have been recommended by The Community Preventive Services Task Force to increase colorectal cancer screenings. Some of these interventions include client reminders, small media, one-on-one education, and the reduction of structural barriers. However, The Community Preventive Services Task Force has found insufficient evidence to determine the effectiveness of group education (e.g., lectures, interactive presentations using inflatable colons) in increasing colorectal cancer screening. Yet, some smaller studies have suggested that group education for colorectal cancer can be effective. As such,

NCI/CRCHD has asked its 49 funded sites to conduct group education activities/outreach events in their catchment areas and collect evaluation data to understand if knowledge and behavioral intention changed as a result of the education. This effort will contribute to the evidence-base for group education and will help NCI/CRCHD with future planning of national initiatives.

2. Objectives and Hypotheses

The purpose of this project is to: (1) contribute to a nation-wide initiative to educate the public about colorectal cancer and colorectal cancer screening, (2) evaluate the effectiveness of group education about colorectal cancer in changing knowledge and behavioral intention.

Through this project, NCI/CRCHD intends to answer the following question: Did the colorectal cancer outreach activity change participants' knowledge of colorectal cancer, risk factors, and screening options and recommendations?

3. Study Design

Describe all study procedures, materials, and methods of data collection:

Format and Sites:
NCCC's Community Health Educators (Jenna Schiffelbein and Daphne Ellis) will coordinate two to six group education activities/events in New Hampshire and Vermont starting in March 2017. Elements of the group education have been designed by NCI/CRCHD and center around a set of key messages that cover information about colorectal cancer, including incidence, risk factors, prevention, screening recommendations, and screening options (see attached PDF *NCI Colorectal Cancer Outreach and Screening Initiative Toolkit*, pgs. 3-4 and PowerPoint presentation *Screen to Save: Colorectal Cancer Basics*). Where feasible, education may also include information about local options for getting screened for colorectal cancer. Depending on the setting, education will be delivered to participants using one or more of the following educational tools: inflatable colon with educational signage, a PowerPoint presentation, a flipchart/flipbook, written materials/handouts, and verbal instruction. Education will take place in a variety of settings such as community-based organizations (e.g., community businesses, libraries, faith-based organizations, senior centers), fairs and community events, and clinical centers (e.g., health centers, local hospitals). We plan to conduct our first group education activity and data collection effort at the WZID Women's Expo in Manchester, NH on March 11, 2017. Dartmouth-Hitchcock is a sponsor of the event.

Eligible Participants and Data Collection:
Anyone, regardless of age, is welcome and encouraged to participate in the educational activities. However, our research team will be recruiting 100 to 150 people aged 50-74 years old at the time of the event to participate in the evaluation/data collection efforts. At the outreach event, each person recruited will be asked to:

1) Review our study information sheet with a CITI-trained research team member
2) Complete a pre-test that will be administered via paper/pencil at the group education activity/event. The participant will complete the pre-test immediately before being exposed to the educational content about CRC. The pre-test includes information about demographics, health insurance/health care coverage, prior CRC screening, family health history, and CRC knowledge (see attached).
3) Participate in a colorectal cancer education activity.
4) Complete a post-test that will be administered via paper/pencil at the group education activity/event. The participant will complete the post-test immediately after being exposed to the educational content about

CRC. The post-test includes information about CRC knowledge and behavioral intentions related to CRC (see attached).

Please note that the NCI toolkit included with this application indicates that subjects will be followed over three months. That is not the case, so identifying information will not be collected for subjects

Confidentiality:

Participant responses will be linked using unique identifiers that NCI/CRCHD (or its independent contractor) will be providing. Each participant will be assigned a 7-digit unique identification number. The first two digits identify the participating National Outreach Network (NON) site (i.e., that the data is coming from Dartmouth/NCCC); the next two digits identify the geographical region in which the NON site is located (i.e., that Dartmouth/NCCC is in CRCHD's Region 1 North); the last 3 digits will be sequentially assigned to participants. NCI/CRCHD (or its independent contractor) will provide NCCC with pre-printed labels containing unique identification numbers, 10 labels per unique identifier. The pre-printed label will be applied to each of the hard-copy forms that the participant is required to complete, which will include the pre- and post- tests.

When participants review the information sheet with a CITI-trained research team member, they will then be handed a card with a barcode/unique identifier on it. They will show the card to other research team members throughout the event to match to their pre-test and their post-test.

Because we will be offering gift cards to people who complete the pre-test, education, and post-test, we will also be required to collect names who takes a gift card for Dartmouth's financial records (http://www.dartmouth.edu/~sao/collis/treasurers/financialprocedures.html#gifts). We will collect their names on a tracking form that will be kept separate from other study materials at the events and will be in a monitored folder at all times. After the events, the names will be provided to the NCCC's finance office. We will not keep any copies of these names within the research team or link the participant names to the study data in any way. We are continuing to talk with the NCCC Finance office to determine if the name collection requirement can be eliminated.

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.

Storage and Maintenance:

Originals of the pre-tests and post-tests will be stored in a locked file cabinet drawer at Dartmouth-Hitchcock Medical Center for five years.

All data collected on hard copy forms will be mailed to NCI/CRCHD (or its independent contractor) for data entry, quality control and storage. This will include copies of the de-identified pre-tests and post-tests. NCI/CRCHD (or its independent contractor) will keep hard-copy data for five years from the completion of the study.

The independent contractor will enter data into the central database as it is received from each of the participating sites (including NCCC) and will therefore be updated on an ongoing basis throughout the duration of the S2S initiative. The central database will be retained indefinitely in compliance with NIH data sharing policy. Each site (including NCCC) will be offered an electronic copy of their data as a CSV file at completion of the study, but NCCC does not anticipate a need for receiving this file, as we do not plan to conduct a local analysis.

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.

Sample Size & Payments:
Because NCI/CRCHD wants a sample size of approximately 4,000 individuals nationally, each site (including NCCC) has been asked to get 100 people 50-74 years old to complete both surveys and the education. As such, our target recruitment size is 100-150 people, with the goal of 100 completing both surveys and the education. To minimize attrition and encourage people to stay at the event to complete both surveys, we will provide a $10 gift card to people who complete the pre-test, education, and post-test.

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

NCI/CRCHD's independent contractor provided our raw, de-identified data back to us. We would like to use the data to evaluate the program's effectiveness related to changes in knowledge and behavioral intention from pre- to post-intervention. We will also assess whether there are any differences in changes for audience subgroups (e.g., men/women, age groups, participants at different events).

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information about analysis.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:

- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

Recruitment:
The project recruitment will start in March 2017 and end by September 2017. To reach our enrollment goal of 100-150 people, we expect to conduct a minimum of two outreach events that include data collection/recruitment. After the first two outreach events, we will determine how many additional outreach events with recruitment are needed to have 100 people finish the pre-test, education, and post-test. If needed, we will schedule additional outreach events and coordinate with partner organizations in the community.

Timeline:
NCI/CRCHD has provided an ideal timeline (see page 12 of *NCI Colorectal Cancer Outreach and Screening Initiative Toolkit*) to all participating cancer centers, including NCCC. We will do our best to follow NCI/CRCHD's proposed timeline by implementing electronic reminders for the research team to review progress. We will also have periodic research team meetings to ensure the project is progressing appropriately.

Data Quality:

The NCCC research team will review up to 10% of pre-tests and post-tests after each outreach event as an audit for quality. If the audit reveals a potential data quality issue, the research team will review additional data to determine how widespread the issue is and will inform NCI/CRCHD (or its independent contractor) for guidance. At the end of the project, NCI/CRCHD plans to have its independent contractor review all data collected for quality.

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information about data quality.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

Risks involved are minimal. However, some participants with a family history of cancer or who have had negative experiences with past cancer screenings may have some discomfort with the topic of CRC and may be distressed by the nature of the survey questions. Additionally, as with the collection of any identifiable information, there is minimal risk that confidentiality could be breached. However, we will have several safeguards in place, as described in the section below and in the attached document entitled *Screen to Save Data Collection Storage and Security.*

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

Because this activity is primarily educational and seeking to increase knowledge and positive behavior change in relation to CRC, risks are minimal. Participants will be assured that their participation is voluntary and that they can drop out at any time.

To ensure confidentiality of data, we will have several safeguards in place:
Administrative: Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. We will assign a unique identifier to the study information using bar code stickers provided by NCI/CRCHD (or its contactor). We will link pre-test and post-tests using the unique identifiers/bar codes. No names or identifying information will be collected on research forms.

Physical: After the events, all of the coded information (the pre-tests and post-tests with barcodes/unique IDs) will be stored in locked file cabinets at Dartmouth-Hitchcock Medical Center. When data are provided to NCI/CRCHD (or its contractor), we will just provide copies of the pre and post tests; no identifying information will be provided.

Technical safeguards: All data will contain unique identifiers/bar codes for participants (no names or contact information will be included on research forms).

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

Because the risks are unlikely and minimal, we feel that they're reasonable in relation to the knowledge that participants will gain, as well as the knowledge that NCI/CRCHD will gain at the national level. Because CRC is preventable, yet still common, it's important to add to the evidence-base about how to increase CRC screenings.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

The pre-test has some family health history questions. For some participants, completing the family health history section may make them realize that they are at elevated risk for colorectal cancer. For participants that indicate a concern, we will let them know that the questionnaire is not a risk assessment tool, and we will provide them with educational materials about colorectal cancer and screening options and recommend that they follow-up with their healthcare providers for additional questions.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

Because NCI/CRCHD wants a sample size of approximately 4,000 individuals nationally, each site (including NCCC) has been asked to get 100 people 50-74 years old to complete both surveys. As such, our target recruitment size is 100-150 people, with the goal of 100 completing both surveys and the education. Once 100 people have completed both surveys and the education, we will stop recruitment efforts but continue with educational events (without data collection).

b. Provide a justification of the proposed sample size

NCI/CRCHD has set a minimum requirement that each cancer center reach at least 100 individuals, for a nationwide sample size of 4,000. NCI/CRCHD has indicated that this sample size will give them sufficient power for this project.

c. Define the target population:

The target population is adults aged 50-74 years old who attend selected public events/visit selected public venues in New Hampshire and Vermont.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates
☐ Children
☐ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

It is likely that some participants may be elderly. It's also possible that some participants will be from an economically disadvantaged background. We feel that the payment amounts we plan to provide are appropriate given the participants' time involved and are not excessive or coercive. The Research Team member(s) reviewing the information sheets with subjects will also be CITI trained and will ensure that participants comprehend the nature of the project and willingly agree to participate (as described below).

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

Anyone, regardless of age, is welcome and encouraged to participate in the educational activities.

To recruit participants for data collection, we will rely on people who are attending selected public events/public venues. Along with other community organizations, we will help promote the events ahead of time, but will not specifically do any recruitment for the study until the event. At the event, the research team will have signage with verbiage such as:

"Learn about colorectal cancer risks and prevention. We're offering gift cards to people 50-74 years old who participate in our surveys." Or "Are you 50-74 years old? Are you interested in learning how to prevent colorectal cancer? Talk with us about participating in our study today. You'll receive a gift card for your time."

Additionally, for any person appearing to be in the age range, the research team will ask if they would be interested in hearing about the data collection project and will educate interested participants.

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

An information sheet will be provided to every subject and will be reviewed with the subject by a CITI trained research team member. The subject will be asked if they would like to participate and will be provided with a copy of the information sheet. Those who agree to participate will then be asked to complete the pre-test, education, and post-test on the same day.

To ensure comprehension, the research team will ask the participant if they have any questions about the study and if they'd like to participate. We feel that the payment amounts we plan to provide are appropriate given the participants' time involved and are not excessive or coercive.

Please see attached information sheet.

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

- ☐ For the informed consent *process*
- ☐ For the *documentation* of informed consent
- ☐ For the HIPAA Authorization to use and/or disclose PHI
- ☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

To minimize attrition, we will provide a $10 gift card to people who complete the pre-test, education, and post-test. The gift card will be given at the event.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

The information sheets will be reviewed with subjects in public, but do not concern sensitive subjects or behaviors. Completion of pre-tests and post-tests will also be conducted in public, but participants will complete these paper forms by themselves. Clipboards will be available to participants, so they will be able to move to a space that is comfortable for them to complete the forms. Should any participant have a question about any potentially sensitive topics, the research team will make every effort to answer those questions out of ear-range of other participants.

14. Confidentiality of Data

Note: Any person engaged in research collecting information about illegal conduct may apply for a Certificate of Confidentiality from the National Institute of Health.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☐ **No** ☒ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

As with any study that collects information about health, such as a person's family health history, it is important to secure this information to prevent any issues of insurability. As stated below, multiple safeguards have been put in place to minimize the risk of possible data disclosures. We do not plan to obtain a certificate of confidentiality.

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

Administrative: Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. We will assign a unique identifier/bar-code to the study information. We will link pre-tests and post-tests using the unique identifiers. No names or identifying information will be collected on research forms.

Physical: After the events, all of the coded information (pre-tests and post-tests) will be stored in locked file cabinets at Dartmouth-Hitchcock Medical Center. When data are provided to NCI/CRCHD (or its contractor), we will just provide copies of the pre and post tests; no identifying information will be provided.

Technical safeguards: All data will contain unique identifiers/bar codes for participants (no names or contact information will be included on research forms).

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.

c. Describe the plan for storage or destruction of data upon study completion:

At completion of the project, paper copies of pre-tests and post-tests will be mailed to NCI/CRCHD's independent contractor. Original forms will be kept in a locked filing cabinet at DHMC for five years. All files, paper and electronic, at DHMC will be destroyed after five years.

Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.