PROTOCOL TITLE: *Screen to Save 2*

Cover page

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PROTOCOL TITLE:

Screen to Save 2

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Version 15: 09/25/2025

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	03/10/2020	Updated protocol and information sheets for consent, per Christina Moord's requests; Updated protocol language on Intervention Arm 2 from web-based video to web-based module that includes a video; Updated protocol's surveying of Intervention Arm 1 and Intervention Arm 2 participants to include dummy questions from control arm; Updated consent script to complement changes to protocol; Uploaded draft video script attachment; Uploaded all surveys; Updated recruitment language	Yes
2	06/08/2020	Removed age language from sample online recruitment text (Experimental Arms 2 & 3); Revised eligibility screening questions and multiple choice response options; revised protocol order for online participants (Experimental Arm 2 and Control) so that potential participants will answer the eligibility screening questions before being presented with consent process (if eligible) or informed that they aren't eligible; Updated online arm	No

		descriptions to specify use of Qualtrics for survey administration where before had indicated Qualtrics or RedCap; Updated online protocol to indicate that answering pre/post-test knowledge questions, colorectal cancer behavior intentions questions, and age will be required; Updated online protocol to indicate that other demographic, personal health, and family health questions will either be required with a "decline to answer" option or optional; Added "decline to answer" option to online survey questions now marked as required; Updated tailored education information related to colorectal cancer risk assessment; adapted some survey questions and/or response options for enhanced clarity and functionality when administered using the online format; updated aims and hypotheses to make use of originally planned control group as an experimental arm related to tobacco and lung cancer screening, rather than only a control arm for the colorectal cancer screening intervention arms; updated lung cancer screening "dummy" questions to include additional questions related to lung cancer screening and tobacco aims; updated electronic gift card information to indicate that unclaimed gift cards may be deactivated after 6 months; updates to data collection and storage procedures; uploaded PDFs showing online survey content (modified from original NCI content and formatting) to be administered to participants	
3		Updated Primary Investigator (PI) and related contact information on Protocol; updated information sheets for informed consent to include new PI, eligibility criteria, study coordinator name and email and adjusted language on contact information and compensation for added clarity; updated Study Arm 1 Consent script to align with consent form updates; revised Arm 2 & 3 Pre/Post survey so that eligibility screening takes place after consent process; removed Arm 2 & 3 optional risk assessment and two extra	Yes

		questions related to that risk assessment from pre/post survey; adjusted some Tobacco and Lung Cancer Screening health behavior questions; clarified the webpage for the lung cancer screening video; updated linkage to care information for use in Pre/Post survey (deleted gastroenterology contact info; added questions for talking with healthcare provider and health insurance/benefits resources for NH and VT residents);changed order of Pre/Post survey so that post-education questions about cancer screening and other health behavior intentions come after linkage to community resources;modified response language to some 3- and 6-month participant answers; added a recruitment approach; updated recruitment language and added potential images for social media recruitment; added final colorectal cancer screening video for use in Study Arm 2; added colorectal cancer screening website text	
4	9/29/2020	Updated consent form/information sheet for study arms 2 & 3 to match content already shown in Pre/Post Qualtrics Survey.	Yes
5	10/12/2020	Updated information pertaining to compensation in situations of incomplete participation and withdrawal; updated information pertaining to Pre/Post Qualtrics survey's use of timer features and updated related settings and text in Qualtrics Pre/Post Survey; added a reminder of how to contact a study team member by email or phone in the event of technical difficulties; added Pre/Post questions pertaining to participant's level of engagement with educational content to Qualtrics survey; uploaded website used for Study Arm 2 colorectal cancer screening educational intervention; updated recruitment language to indicate possible use of synonyms.	No
6	1/18/2021	Inclusion of participants who "do not know" if or when last received colorectal cancer screening in follow-up surveys; Added experimental study arm for partnering with healthcare systems (e.g. Little Rivers Health Care, Inc) to reach participants for online	Yes

		participation (e.g. recruitment via online patient portal(s)), which may replace experimental arm 1 (in-person engagement); updated eligibility information as it pertains to study arm 4; added sample recruitment language for study arm ; added pre/post survey PDF for study arm 4; updated data management section to indicate that additional study team members will have access to study data and add updates pertaining to study arm 4; removed Tracy Onega (former PI) at two points where updated PI (Anna Tosteson) had not been noted in previous modification	
7	03/23/2021	Clarified recruitment size intentions; On consent/information sheets and Qualtrics survey, removed study coordinator phone number as method of contact (leaving email as method of contact), due to changing phone numbers for Dartmouth College employees; in protocol added that Study Arm 4 healthcare system partner(s) may provide reminder message(s) to their patients and/or inform patients when the option to enroll in the study is no longer available; Removed lung cancer screening knowledge questions from Study Arm 4 pre/post survey; Added Study Arm 4 Three-Month Follow-Up Qualtrics PDF (adapted version of the survey used for study arms 2 and 3).	Yes
8	04/22/2021	Discontinue accrual into Study Arm 3; Remove random assignment to Study Arm 3 from Qualtrics survey used for Study Arms 2 and 3 and some lung cancer screening questions associated with that random assignment; access to website and video will not be entirely restricted to study participants (e.g. DCC may allow other healthcare systems to view or use the educational webpage and video without their users enrolling in a study); Add Judith Reese and Regina-Anne Cooper as a study team members'	No
9	08/13/2021	Inclusion criteria lowered from starting at age 50 to age 45, to align with new US Preventive Service Task Force (USPSTF) colorectal	Yes

		cancer screening guidelines for people with average risk and corresponding materials (e.g. four Pre/Post knowledge questions, two 3 month follow-up survey question, web module consisting of webpage and video, recruitment language, consent forms) updated to reflect age 45;Noted Regina-Anne Cooper, previously approved study team member, as member of DDCC Community Outreach and Engagement team; removed student study team member Haider Ghiasuddin	
10	09/27/2021	Switched Anna Tosteson and Judith Rees's roles on study team, making Judith Rees the new PI; updated consent forms/information sheets and surveys to indicate Judith Rees as the PI; added DDCC Community Outreach and Engagement team member Heather Carlos to research study team; removed research study coordinator phone number from 3 and 6 month follow-up surveys to correspond with telephone number removal approved in modification 7 (leaving email as the method by which participants can contact the study coordinator)	Yes
11	04/12/2022	Added new team member, Edgard Ngono to protocol and removed Katie Lenhoff, who resigned from program.	No
12	09/14/2022	Removal of some names; replacing with title/role only. Rebranding. Correction of age range for the study as noted in Revision 9.	NO
13	9/28/2022	Added details about in-person recruiting at community events for web-based module. See page 25.	
14	10/6/2022	Per the request from the IRB, we have clarified that in person	
15.	09/25/2025	To be in compliance with outcomes reporting requirements for clinicaltrials.gov, this revision is being submitted to update the protocol to reflect the work that was accomplished. Many aims and outcome measures had to be curtailed because of delays and constraints relating to the COVID-19 pandemic. This revision is a simplification of the original aims and reflects the work that was conducted, removing aims	

		and hypotheses that could not be completed. The protocol is greatly simplified, consisting of one intervention with pre- and post- surveys.	

Table of Contents

1.0 Study Summary

Study Title	Screen to Save 2
Study Design	Prospective Observational/Cohort Study Pre-/Post-/Follow-up (via surveys)
Primary Objective	Implement and evaluate Screen to Save (S2S) outreach and educational activities to improve knowledge of colorectal cancer screening methods, to increase intent to get screened for colorectal cancer, and connect screening services to 45-74 year-old residents living in NH and VT—focusing on the most rural counties (RUCC 7—9).
Research Intervention(s)	Education about colorectal cancer screening via online video and written education materials.
Study Population	The target population is adults aged 45-74 years old who reside in rural New Hampshire or Vermont; "rural" = Rural Urban Continuum Codes (RUCC) 7—9 counties (Coos and Sullivan County, NH; Caledonia, Windsor, Windham, Orange, Orleans, Lamoille, and Essex County, VT) To be eligible to enroll in the study, people must meet the following eligibility criteria: -Be a resident of one of the RUCC 7—9 counties in NH and VT and -Be 45-74 years-old at the time of enrollment except in the instance of recruitment via Experimental Arm 4 (e.g. recruitment through Little Rivers Health Care, Inc.), in which case individuals may enroll in the study if age 45-74 and if residing in states or counties other than those specified above, if agreed upon by the research study team and partner institution
Sample Size	Our target recruitment size is 196-225 participants completing the pre/post survey in each of two arms (Arms 2 and 4). Recruitment into study arm 3 will be discontinued in April 2021 due to changes in lung cancer screening guidelines affecting the educational intervention content, resulting in fewer than 196 participants completing that arm. Projecting that up to 50% of people who consent may not complete the pre/post survey, we project that up to 950 people may be enrolled total.
Study Duration for individual participants	Up to 7.5 months
Study Specific Abbreviations/ Definitions	S2S= Screen to Save CRC= Colorectal Cancer LCS= Lung Cancer Screening NCI= National Cancer Institute CRCHD=Center to Reduce Cancer Health Disparities (a division of the National Cancer Institute) NON= National Outreach Network (an effort of CRCHD) CHE= Community Health Educator

	COE= Community Outreach and Education (a focus of the Dartmouth Cancer Center) DH = Dartmouth Health DCC= Dartmouth Cancer Center RUCC= Rural-Urban Continuum Codes (a U.S. Department of Agriculture schema for defining communities as rural/urban)

2.0 Objectives*

2.1 The primary purpose of this project is to: (1) contribute to a nation-wide initiative to educate the public about colorectal cancer risk factors and colorectal cancer screening, (2) evaluate the effectiveness of education about colorectal cancer in changing knowledge, behavioral intentions, and behaviors related to colorectal cancer screening and prevention.

Aim 1: Implement and evaluate Screen to Save (S2S) outreach and educational activities to improve knowledge of colorectal cancer and colorectal cancer screening methods, to increase intent to get screened for colorectal cancer, and connect screening services to 45-74 year-old residents living in NH and VT—focusing on the most rural counties (RUCC 7—9 designations- see figure 1). The study utilizes web-based module to conduct targeted outreach about colorectal cancer screening using the S2S framework and materials and refer them to locally-available screenings, healthcare provider system, and/or healthcare coverage systems.

2.2 Hypotheses:

Online/video outreach about CRC will be effective in: a) increasing adults' knowledge of CRC risk factors, CRC screening recommendations and options, and CRC prevention; b) increasing unscreened adults' intent to get screened for CRC

3.0 Background*

3.1 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. The U.S. Preventive Services Task Force recommends that all adults 45-74 years old get screened for colorectal cancer. Yet, some populations do not get screened as often as they should. In the Dartmouth Cancer Center's (DCC) 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—including rural communities.

3.2. In 2017, the National Cancer Institute's (NCI) Center to Reduce Cancer Health Disparities (CRCHD) launched a nationwide CRC initiative called *Screen to Save.* The goal is to increase CRC screening rates among 45-75 year old adults—especially from racially and ethnically diverse populations and people living in rural areas. The initiative initially involved about 49 sites—including DCC—that received NCI/CRCHD funding to support Community Health Educators (CHEs). CHEs were expected to utilize a set of key messages about CRC risk factors, screening, and prevention to educate the public via educational

outreach events in settings such as health fairs, festivals, and other community settings. Data was collected to assess participants' knowledge change from pre- to post- intervention, and NCI's preliminary national analyses show positive changes.

In New Hampshire, the 30-day prevalence of tobacco use among adults is approximately 15.7%. In Vermont, it is about 15.8%. Tobacco use is a risk factor for more than a dozen cancers and chronic diseases, including colorectal cancer and lung cancer.

3.3 In 2019, DCC and about 23 other cancer centers received a new award from NCI/CRCHD to re-launch Screen to Save. The basic framework for the initiative is similar to the original framework, with the following key changes:
-DCC will more specifically prioritize rural populations in NH and VT,
-DCC will need to collect additional data elements from the participants, including follow-up data to assess whether the intervention is effective in increasing uptake of colorectal cancer screening; data will look at knowledge, behavioral intentions, and behavior change as a result of the education
-DCC will implement the initiative in an online module
-DCC will provide participants with information about local CRC screening services available and, where feasible, will coordinate with local screening service providers (though actual rendering of screening services is outside of the scope of this project).

This effort will contribute to a national evaluation of Screen to Save and will help NCI/CRCHD with future planning of national initiatives. It will also influence DCC's Community Outreach and Engagement program's planning for future interventions to reach the rural populations of New Hampshire and Vermont. Additionally, it will add to the literature base regarding group education interventions for colorectal cancer screening, which currently is rated as having 'insufficient evidence' by The Guide to Community Preventive Services.

4.0 Study Endpoints*

4.1. Knowledge, attitudes, and behavioral intentions related to colorectal cancer risk factors, screening, and prevention (assessed via pre/post/follow-up surveys)

4.2 Uptake of colorectal cancer screening (behavior change) as a result of the outreach models (assessed via follow-up survey)

5.0 Study Intervention

5.1 DCC's Community Outreach and Engagement Team will implement Screen to Save in an online format. The education will be based on a set of key messages that cover information about colorectal cancer, including risk factors, prevention, screening recommendations, and screening options (see attached PowerPoint presentation with key messages *Screen to Save: Colorectal Cancer Basics.120916*). NCI/CRCHD's key messages will be tailored to the local context of NH and VT, including information about local options for getting screened for colorectal cancer (see draft outline of talking points- attached).

Web-based module- Participants who access the study will be directed to watch a video/review online information that includes the key messages about colorectal cancer, risk factors, prevention, screening recommendations, and screening options.

6.0 Procedures Involved*

6.1—6.5. This study uses a pre/post/follow-up design utilizing surveys.
See below for more information about the surveys.

Our CHE will use a web-based educational-format with video and accompanying educational information shared through social media outreach to conduct a similar intervention as described in experimental arm 1. Recruitment will be facilitated through paid advertisements in Facebook, which will be targeted to 4574 year-old residents in RUCC, 7, 8, and 9 counties throughout VT and NH. The advertisements will ask the prospective participants to click to 'learn more' and will be directed to a Qualtrics survey, which will lead them through:

a- A consenting process utilizing the research information sheet (see enclosed information sheet and waiver of signature).
b- Screening for eligibility- Prospective participants will be asked a) to select the age group that they are part of; b) Which state they live in; and c) Which county they live in. Participants indicating that they are between the ages of 45—74 years old and live in one of the nine RUCC 7—9 counties in NH and VT will be eligible. Prospective participants will be required to answer the eligibility screening questions in order to advance to the remainder of the study content: the rest of the survey and educational intervention. Participants who do not meet eligibility criteria will be informed that they do not meet the eligibility criteria.
c- A pre-test survey - Answering pre-test and post-test knowledge questions about colorectal cancer and screening and colorectal cancer behavior intentions questions will be required in order for participants to progress through the study, as will answering a question about the participant's age in years. Answering all other demographic questions and questions about

personal or family health experiences will either be required with a "decline to answer" option or optional. Some online questions (i.e. lung cancer and colorectal cancer knowledge questions) will be presented in a random order using Qualtrics features for randomization.

d- Educational intervention (described in section 5) based on NCI/CRCHD's key messages (see CRC Website Link document for webpage) uses a web-based educational-format containing a video (see S2S CRC Video attachment) and accompanying educational information (not visible to the general public) with additional information on colorectal cancer and colorectal cancer screening (See CRC Website Text attachment). Both the video and the website content are based on the NCI talking points and related, relevant information from content area experts. We will no longer use a timer setting in Qualtrics that prevents participants from moving forward to the next step in the online survey until a defined amount of time has passed to align with the minimum needed time to watch the video and view the website (e.g. 5 minutes). We may, however, continue to use the timer functionality allowing us to measure how much time participants spend on specific portion(s) of the online survey and educational intervention and in totality.

e- Question(s) asking participants how much of the online educational content they watched and/or read (see Qualtrics Pre/Post Survey)

f- A post-test survey as described earlier regarding colorectal cancer screening knowledge (see attachment)

After receiving the web-based education, participants will be asked about whether they have a healthcare provider to speak with about colorectal cancer screening and whether they currently have insurance. Participants who answer "yes" to the first question will be encouraged to talk with their healthcare provider about their individual cancer risk and cancer screening options and can download a document of CDC developed questions for talking to a healthcare provider about colorectal cancer. Participants answering "yes" to the second question (having insurance) will be informed that if they do not have an established healthcare provider they can consider contacting their insurance provider to find a provider in their network. Participants who do not indicate that they have a healthcare provider to speak with by answering "no" or "decline to answer" will be informed that talking with a healthcare provider can be useful and will be provided with a downloadable list of some healthcare systems that provide primary care services in the counties we are targeting for our interventions or nearby. This list will include a statement indicating that other healthcare providers may be available in or near their communities so that participants wishing to explore other options are reminded of their autonomy to research on their own. This document will also include the same CDC adapted questions for talking to a healthcare provider about colorectal cancer provided to those who do report having a healthcare provider. Participants who do not indicate that they have insurance by answering the second question with a "no" or "decline to answer" will be informed that talking with a healthcare provider can be useful and receive information on local agencies or organizations in their state (New Hampshire or

Vermont) that may be of assistance in understanding and/or obtaining healthcare coverage. The study team will make updates to these linkage to care documents (see attached: guide for talking with healthcare provider; local healthcare systems providing primary care; local systems that provide help understanding or obtaining healthcare benefits) should new resources appropriate for the target audience be identified and/or entities discontinue or alter services and/or contact information or eligibility for any of the listed services change over the course of the project in the interest of providing up-to-date and relevant linkage to care.

See CRC Linkage to Care documents which will also be made available to all participants.

g- A post-test survey as described earlier addressing colorectal cancer screening and related behavior change intentions (see attachment)
h- Collection of contact information (name, email, phone number, address) and assignment of unique numeric identifiers for study participants.
i- After participants complete the first round of online activities as described above, a study team member will assign all participants a unique six-digit identifier to each participant, which will be used to track participants' data. Participants invited to participate in follow up surveys (three months; six months) will either be provided with a shortened (3 or 4-digit) version of this identifier and the month of their original participation to use in lieu of submitting their names or other personal contact information with those follow-up surveys or features within Qualtrics will used to automatically transfer this information onto the follow-up surveys for necessary tracking purposes. Setting up this automated system to minimize the risk of participant data-entry error does mean that within Qualtrics there would be a way to trace data collected from the follow-up surveys to the first survey in which participant contact information (e.g. name, address, phone number) is collected. Only members of the study team would have access to these Qualtrics files.
j- Administration of participant payments (e-gift cards)
k- A follow-up survey administered at three-months post intervention (and six-months post intervention, as needed).
l- E-mailing de-identified pre, post, and follow-up survey data to NCI/CRCHD and/or its contractor for data entry, quality control, and national aggregation
m- Local analysis of data to determine effect of study objectives

7.0 Data and Specimen Banking*

N/A- This study does not involve data or specimen banking.

8.0 Sharing of Results with Subjects*

8.1 Results of pre-/post-/follow-up survey scores/results will not be shared with individual study participants.

As described earlier, de-identified study data will be shared with CRCHD/its contractor for aggregation and evaluation.

At the conclusion of the study, we plan to develop a community report to share with relevant stakeholders (e.g., DCC Community Advisory Board, colorectal cancer screening professionals, primary care providers, cancer control professionals) to learn about the study; all data in this report will be de-identified and aggregated. We will also seek opportunities to disseminate the results through academic channels, such as conferences and publications.

9.0 Study Timelines*

9.1 Participants will conclude their participation within 7.5 months from enrollment. This timeline allows for a multi-week window for completion of the six-month follow-up surveys.

We anticipate enrolling all study participants within two years of study activation.

10.0 Subject Population*

10.1. The target population is adults aged 45-74 years old who reside in rural New Hampshire or Vermont; "rural" = RUCC 7—9 counties (Coos and Sullivan County, NH; Caledonia, Windsor, Windham, Orange, Orleans, Lamoille, and Essex County, VT).

10.2. To be eligible to enroll in the study, people must meet the following eligibility criteria:
-Be a resident of one of the RUCC 7—9 counties in NH and VT and
-Be 45-74 years-old at the time of enrollment
We have three eligibility screening questions that will be asked of all study participants:

1) What is your age? (in years)
2) What state do you live in?
3) What county do you live in?

Participants will be social media users. Social media advertising features will be used to target social media users in the appropriate age range and geographic locations of interest.

10.3 Regarding adults unable to consent: For online participants, there are several steps involved in accessing our study which, we feel, will safeguard adults unable to consent from participating in the study; for example, in order to access the study online, that will require having a social media account, navigating away from the social media account to our survey site, reading the information sheet, and proceeding forward to the survey.

Regarding individuals who are not yet adults: All participants will be screened to self-disclose whether they are in the study age range (45-74 years old) at the time of enrollment; hence, no minors will be enrolled. Further, recruitment for the web/video arms (intervention and control) will use Facebook's marketing features to target account holders in the age range of interest to the study.

Pregnant women: Given the 45-74 age group targeted by this study, it is possible but unlikely that pregnant women will be participating. Any inclusion of pregnant women will be strictly incidental and will not present any added risk should they choose to participate. We will not be asking any questions pertaining to pregnancy, and we will not specifically be targeting pregnant women. Regardless of whether or not a 45-74 year-old person is pregnant, receiving age-appropriate cancer screening education and discussing screening options with a medical provider can be beneficial, which is exactly what our study aims to provide and encourage. As such, we will not exclude pregnant women from participating.

Prisoners: We will not be initiating any research in institutionalized settings nor will we explicitly target prisoners. No questions, including screening questions, will be specifically asked about a person's incarceration status. Any inclusion of prisoners will be strictly incidental and will not present any added risk should they choose to participate.

For in-person events, *anyone* will be able to learn about colorectal cancer screening by participating in the education, as the events will be open to more than just study participants.

11.0 Vulnerable Populations*

11.1 It is likely that some participants may be elderly. It is also possible that some participants will be from an economically disadvantaged background, especially if partnering with a Federally Qualified Health Center such as Little Rivers, Healthcare, Inc. We feel that the payment amounts we plan to provide are appropriate given the participants' time involved and are not excessive or coercive.

As stated in Section 10, our study is not targeting any of the following vulnerable populations: pregnant women, neonates/non-viable neonates, prisoners, people who have not attained legal age to consent, or cognitively-impaired adults.

12.0 Local Number of Subjects

Our target recruitment size is 196-225 people completing the pre/post survey.

13.0 Recruitment Methods

13.1—13.4

For online recruiting, we will purchase advertisements on Facebook, which will be targeted to people who meet the age and geographic eligibility criteria for study participation. We will rely of Facebook's algorithms to direct our recruitment messages to individuals in the appropriate age range and geographies. Advertisements will use verbiage such as:

> "Researchers are looking for adults ages 45-74 to participate in a study about cancer screening. Residents of nine rural counties can enroll. Your voluntary and confidential participation will include reading information, watching a video, and answering survey questions. You will receive a gift card for your time. Click to learn more about participating in this research study by the Dartmouth- Cancer Center. "

See Recruitment Messaging document attached, and see attached Sample Images that may accompany the online recruitment text.

Additionally, we may post similar advertisements on other social media platforms such as Instagram and we may post the study announcement on the DCC and/or Dartmouth Health Facebook pages. Announcements posted on the DCC and/or Dartmouth Health Facebook pages would be visible to viewers of any age and geography, as the geotargeting features of Facebook Advertising would not apply, but only those people who meet the eligibility criteria based on their responses to the screening questions would be enrolled.

In addition, we have partnered with the study team administering Study00031200 (DHH IRB) / D20039 (OnCore): Education about Health and Cancer Study to assist with identifying prospective participants for our study. That study educates online adults (from the same nine New Hampshire and Vermont counties as we are targeting in this study) about cancer research studies and clinical trials, and that study is pre-screening their study participants for possible eligibility for other studies (such as ours). As part of their participation in that study, participants will be asked some questions to see if they may be

eligible to enroll in any active research studies. Screen to Save 2 will be one of the studies to which participants can be linked. Participants indicating that they are 45-74 years old will be provided with a brief description of the Screen to Save 2 study and asked for permission to share their contact information with the Screen to Save 2 study team. (See attached Recruitment Language document.) Those who give permission will have their contact information passed on to a designated Screen to Save 2 study team member, who will send an email to the STUDY00031200/D20039 participant about the Screen to Save 2 study. That email will contain a link to access the online Screen to Save 2 study. The email will also contain contact information for a Screen to Save 2 study team member, should the recipient have any questions or concerns. (See Sample Email for Participants Referred from Study D20039).

13.5 Participants will receive up to a total of $30 in gift cards (e.g. to Amazon.com). Participants will receive a $15 gift card for completing the pre-test, in-person or online learning, post-test, screening assessment questions (for online participants), and providing their contact information. Participants asked to complete the 3-month follow-up survey will receive an additional $10 gift card for their time completing that survey. Participants asked to complete the 6-month follow-up survey will receive the final $5 gift card for their time completing that survey.

The first gift card will be distributed to in-person participants in-person on the day of the event; the second and third gift cards will be sent by email, unless a participant does not have an email address or requests that the gift card be sent via regular mail; we will aim to distribute these gift cards/codes within 2 weeks of receiving completed surveys. For online participants, all gift cards will be distributed via email. Gift cards will be sent within 2 weeks of the study team receiving each completed survey.

Participants will have 6 calendar months to claim their electronic gift cards from the time that they are emailed to participants. Electronic gift cards that are not claimed after 6 months may be deactivated.

14.0 Withdrawal of Subjects*

14.1 Study subjects will be withdrawn from the study if they do not complete the pre-test, educational intervention, post-test, and provision of contact information—as we need the full set of information in order to evaluate our intervention. Additionally, as noted in Section 6, our study team will reach out to participants up to four times by email/phone (total) and up to one paper mailing for the three-month follow up survey and for the six-month follow-up survey. If no response is garnered, efforts to reach participants for the survey will be discontinued. Participants who do not respond to any of these efforts within 1.5 months of the first effort being made for that survey will be withdrawn from the study. Participants who do not complete the three-month survey will be disqualified from continuing on to the six-month follow-up survey.

Any participant can discontinue participation at any time by closing the window on their device's screen that contains our video/module or survey content. Because participant contact information will be collected only after the post-test is administered, individuals who do not complete the pre-test, video/web education, and post-test will not be eligible to receive a $15 gift card, except in instances where individuals report to the study team that they have enrolled as participants but were unable to complete the pre/post survey, despite their eligibility and intent to do so, for reasons attributable to an implementation error or substantive inconvenience in survey delivery (e.g. participant reports being unable to progress to the end of the survey). In this case, if the source of the problem cannot be remedied conveniently to facilitate completion of the survey, the $15 gift card will still be offered, so long as the information reported to the study team appears credible, given the study team's knowledge of the eligibility criteria, recruitment strategies, study content, and technology platforms. In this case, a designated study team member will still need to collect the individual's name and contact information so that the gift card can be distributed and proper financial records maintained; however, subsequent participation in the three and six month follow-up surveys will not be allowed. Individuals who report inability to complete the survey, whose reported participation began on or after October 8, 2020, will be informed of the opportunity to receive this compensation in accordance with the standards stated above.

Any participant who does not complete the pre-test, video/web education, and post-survey will not be contacted for 3- or 6-month follow-up.

Participants who do not respond to initial communications for three- and six-month follow-up surveys will be informed, at a minimum, in the final communication effort, of the deadline by which they must respond and complete the survey in order to remain in the study. Participants in telephone-based three- or six-month follow-up surveys who express a desire to withdraw from the study partially through the survey process will be provided a gift-card, but not contacted for six-month follow-up. Participants in the online three- and six-month surveys who withdraw from the study will only receive a gift card if they have submitted the specified online survey to the study team, again with the exception that participants will be compensated for the specified survey in the event that they are eligible and intend to complete the study but report to the study team that they are unable to do so for reasons attributable to an implementation error or substantive inconvenience in survey delivery, as described above for the pre/post survey.

15.0 Risks to Subjects*

15.1 Because this activity is primarily educational and seeking to increase knowledge and positive behavior change in relation to colorectal cancer and lung cancer, risks 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 colorectal cancer or lung cancer 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 Section 17 and in the attached document entitled *Screen to Save Data Collection Storage and Security.*

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 and DCC will gain.

15.2-15.4. N/A

16.0 Potential Benefits to Subjects*

16.1 We do not expect a direct benefit to participants. However, participants may learn new information about cancer screening. Participants who have never discussed cancer screening with a healthcare professional, participants who have never pursued cancer screening, and participants who do not have personal or family histories of cancer may be more likely to find that the information is new to them.

By attending our in-person education events people may also have the opportunity to speak with local healthcare providers about cancer screening or other topics, regardless of whether or not they enroll in our study.

As feasible, participants will receive tailored educational information based on their individual responses to the screening option assessment and pre-test, as well as information about locally-available screening services.

17.0 Data Management* and Confidentiality

17.1. Our sample size is based on a two-tailed test with 0.05 significance level, and 80% power to detect an effect size of 0.2 (20% difference in the before/after difference-in-difference estimates), with a standard deviation of 1.0. We will conduct various statistical tests on the data to determine whether participants experienced changes in knowledge, attitudes, behavioral intentions, and behavior as a result of the intervention, and changes will be look at across groups.

17.2. To ensure confidentiality of data, we will have several safeguards in place:

- Training: All research team members with access to study data will be trained on all procedures related to data management under this protocol.
- Access restrictions: Access to electronic research materials/data will be limited to those on the research team. This will include only granting electronic access to Qualtrics and One Drive/Sharepoint to study team

members, these sites/applications also require passwords to access. All laptops/computers being used will also be encrypted and password-protected. Access to physical research materials/data will also be limited by being stored in locked filing cabinets at DHMC.

Unique identifiers: We will assign a unique identifier to the study information using the numbers provided by NCI/CRCHD/its contractor. For study arm 1 participants, we will link the pre-, post-, and follow-up surveys using the unique identifiers/bar codes. Contact information requested from participants for purposes of follow-up and gift card distribution will be obtained, managed, and stored separately from the other study data. For study arm 2 and 3 participants, the pre- and post- survey data will be collected and stored in the same Qualtrics survey that solicits participant contact information for follow-up and gift card distribution. Only study team members will have access to this file, which has the access restrictions noted above. Once this data is collected via Qualtrics, a study team member will assign a unique identifier to each participant. After initial review of the online data as discussed in section 17.3 for data quality control, subsequent data review and analysis will be performed in a newly created electronic file where participant name and contact information is replaced with the participant's unique, assigned identifier. A separate document will be created consisting of participant name and contact information so that the Qualtrics survey containing participants' other responses does not need to be referenced for participant follow-up and electronic gift card dissemination. Participants asked to participate in follow-up surveys will either be emailed a shortened version of that unique identifier and the month of their original participation as part of the request for their participation in the follow-up and asked to manually enter those two pieces of data into the online follow-up surveys or the study team will use the features within Qualtrics to transfer the participant ID number and month of initial participation to the follow-up surveys so that it automatically populates to avoid the risk of participant error in transferring the code and month to the follow-up surveys. If these Qualtrics features are used to transfer the participant code and month of enrollment information, within Qualtrics there will be a way to trace the data collected at follow-up back to the initial survey in which participants provide their names and contact information (e.g. phone, email, address); however, only study team members will have access to these Qualtrics files. For all study participants, the key linking participants' identities and contact information to their unique identifier codes will be stores separately from other data.

17.3. Data quality control:

The DCC research team will review data collected from the first 5-10 respondents with each Facebook advertisement wave that is launched to check for possible problems such as errors in computer display to participants, errors in skip logic, and robotic responses. 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 work with the appropriate D-H and DCC colleagues (e.g. tech support) and NCI/CRCHD to address the issues, as needed.

As with any study that collects information about health, such as a person's family health history, it is important to secure this information. 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.

17.4. Original paper research forms/data will be kept in a locked filing cabinet at DHMC for five years. All electronic files will be stored on password-protected, encrypted computers that are property of the Dartmouth Cancer Center. Electronic data will also be stored in password-protected sites/applications supported by Dartmouth/DH, such as Qualtrics and Sharepoint/One Drive; access will only be granted to official study team members. All files, paper and electronic, at DHMC will be destroyed six years after the study is completed.

De-identified survey copies/survey data from the experimental arms will be emailed/mailed to NCI/CRCHD/its contractor for data processing on a quarterly basis. Data collected from participants to be shared include pre-test, post-test, and follow-up survey responses (all de-identified, using unique identifier) from our experimental arms (not control arm). We will also provide NCI/CRCHD/its contractor with general information about the in-person events (e.g., dates, locations, number of attendees), about the social media ad reach/metrics, and, as needed, cost. The study coordinators will be responsible for sharing the data with NCI/CRCHD/its contractor. Please see the attached document from NCI/CRCHD entitled *Screen to Save Data Collection Storage and Security* for additional information.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

N/A- This study involves only minimal risks.

19.0 Provisions to Protect the Privacy Interests of Subjects

Contact information requested from participants for purposes of follow-up and gift card distribution will be obtained at the time of the first (pre/post) survey in Qualtrics. When the data are converted to a data file for analysis, a study team member will assign and add a six-digit NCI code to each participant's responses or a shortened version of that code and upon doing so that study team member will remove the participant's name and contact information from that data file used for analysis. Separate documents will be created containing the participant name, contact information, and code for follow-up and gift card distribution. As noted in section 17 of this protocol, within the online Qualtrics platform there may be a way to link the three and six-month follow-up surveys back to

participants' first surveys where their names and contact information are provided; however, three- and six-month files used for data analysis will not contain participants' names or contact information, only their assigned NCI numbers or shorted versions of those numbers and the month of their original participation. Only study team members will have access to the Qualtrics online platform and the data analysis files produced from Qualtrics via the password protected systems and encrypted devices as noted in section 17.2 of this protocol.

The default method for completing the follow-up survey will be through the internet at a time/place of the participants' choosing. Should any participants choose to complete the survey by phone with a CITI trained research team member, the research team member will take steps to ensure that others are not able to overhear the phone call (e.g., closing door, not using speaker phone).

19.3 Only study team members will have access to forms containing identifiable information. This information will only be accessed for relevant study purposes such as gift card distribution, follow-up survey administration, and checking online survey data collected for authenticity to protect against including automated online responses (bots) and duplicate participation.

20.0 Compensation for Research-Related Injury

This study involves no more than minimal risk to subjects.

21.0 Economic Burden to Subjects

Study participants will not be subject to any costs for participating in the study/educational interventions.

Should our intervention be effective in encouraging them to get screened for colorectal cancer, all costs associated with screening and/or visiting a healthcare professional to discuss screening will be the participants' responsibility.

22.0 Consent Process

Once the prospective participant clicks the Facebook ad to learn more about the study and answers the initial eligibility screening questions, the prospective participant will be presented with an information sheet (attached) and asked to read it before proceeding. As part of the information sheet, participants will be provided with contact information for the study team should they have any questions before proceeding. Once they initial and click the arrow button to

provide implicit consent to participate in the study, they will be asked to complete the following components (in the same session):

- eligibility screening questions (participants not meeting eligibility age and geographic criteria will have their study participation end at that point; eligible participants will be able to advance to the next sections),
- pre-test with added tobacco and lung cancer screening questions
- educational module,
- tailored education/information about talking with a healthcare provider, local healthcare providers, and local insurance/benefits resources
- Post-test questions pertaining to cancer screening/prevention—including lung cancer screening—and other health behavior intentions,
- study participant providing name and contact information, and
- information about e-gift card distribution.

We will be following procedures outlined in HRP-090, with a few exceptions:

- Section 3 of HRP-090:
  - 3.8- If the prospective participant expresses interest in participating, based on clicking on the social media ad, the participant will then be invited to review an information sheet and continue into the study, if they are interested. They will also be provided with study team contact information, should they have questions before consenting to participate.
- Section 5 of HRP-090:
  - 5.3- An information sheet will be presented to the participants. See enclosed information sheet.
  - 5.4 and 5.5- Participants will be provided with study team contact information, should they have questions or want to talk with family/friends before consenting to participate.
  - 5.7- Participants will be completing an implicit consent process, which is explained in the information sheet. We will have participants read and confirm the following:

    Please confirm that you have done each of the following (by checking each box):

    _ I have read the above information about this study.

    _ I understand that I can contact the study team using the contact information provided, should I have any questions about the study.

    _ I understand that participating in this research study is completely voluntarily and that I can stop participating at any time.

    Clicking the button at the bottom of the screen to continue forward indicates your consent to participate in this study.

Non-English Speaking Subjects: At this time, we will not enroll non-English speaking subjects.

Subjects who are not yet adults: We will not enroll any subjects who are not yet adults. Our age requirements are 45-74 years old at the time of enrollment. Anyone outside of this age range will be screened-out of participating.

Adults unable to consent and cognitively-impaired adults: We do not intend to enroll adults who are unable to consent or cognitively-impaired adults. For online participants, there are several steps involved in accessing our study which, we feel, will safeguard against these populations participating in the study; for example, in order to access the study online, that will require having a social media account, navigating away from the social media account to our survey site, reading the information sheet, and proceeding forward to the survey.

23.0 Process to Document Consent in Writing

23.1. We will not be following SOP HRP-091, as we are requesting a documentation waiver. See enclosed waiver checklist.

23.2 and 23.3. Because this study involves no more than minimal risk, we are requesting that the documentation of signature be waived.

In place of obtaining written consent, we plan to provide an information sheet about the study to all participants whose eligibility screening responses indicate their eligibility to participate (see attachment). This information sheet includes the required HIPAA authorization content, for which we will not seek a signature due to the electronic nature of the intervention.

24.0 Setting

24.1 Study procedures will take place on-line:
Recruitment will take place through social media (e.g., Facebook), and the surveys/intervention will be accessed online through Qualtrics.

Follow-up surveys for this arm will also be administered online (when possible) and by phone (when needed). Study team members conducting follow-up calls to and three-month and six-month surveys with

participants will do so from a private room at the Dartmouth Cancer Center at Dartmouth Health in Lebanon, NH.

DCC does have a Community Advisory Board that is administered by a study member. Board members include cancer survivors and caregivers, community members, public health researchers, healthcare organizations, and non-profit representatives. We may consult with the Community Advisory Board or a subset of its members regarding:

-Content of video and educational module and/or review of video

-Review of aggregate, de-identified results

-Next steps after this study is complete; steps regarding sustainability of video/module and/or in-person events

25.0 Resources Available

25.1 Our study team has CITI-trained staff members who can be engaged for completing study procedures including, administering pre-tests and post-tests, providing education, and distributing gift cards. The study coordinator will be dedicated at about 0.5 FTE to the study and will serve as the primary study coordinator Additional CITI-trained staff or volunteers can be secured, if needed, in which case an IRB modification will be submitted.

Prior to conducting the first in-person event or launching the online study arms, team members will convene to review the protocol, discuss the logistics of implementation, and address team member questions. Study progress and update meetings will be scheduled on an as-needed basis for this purpose, and any new study team members will be trained before being allowed to conduct study procedures.

Study planning and procedures will mostly take place in office space in the Rubin 8 building at DH (although in-person events will take place throughout New Hampshire and Vermont). No special facilities/equipment is needed for the conduct of this study, aside from laptops and storage to secure study materials.

Additional resources available to our team include shared resources available through DCC and resources through Dartmouth/DH, including:

-Qualtrics support
-Data management and biostatistical analysis support

-Geo-spatial analysis support to identify population counts and rural communities
-Social media consultation support

Additionally, our team has funding and in-kind support from:
-National Cancer Institute
-Dartmouth Cancer Center (institutional/philanthropic funds)
-Dartmouth Health Marketing and Communications (for video and web development)

Finally, our study team has partnerships with non-profits, healthcare institutions, and other community organizations across New Hampshire and Vermont. We will leverage our partnership network for steps such as:
-identifying events where our research can be conducted
-identifying healthcare organizations that would like to be present at the in-person events to connect participants to screening services (e.g., Mt. Ascutney Hospital, DH, Little Rivers Healthcare)
-reviewing the educational module for accuracy and cultural appropriateness

While we will not be providing study participants with medical care, we will provide participants with information about local screening services and (as feasible at in-person events), work with healthcare/screening partners to connect participants with services related to colorectal cancer screening (E.g., schedule colonoscopy appointments); provision of any medical care and/or screening services.

Our recruitment targets are reasonable and feasible given that approximately 107,000 people meet the eligibility criteria.

26.0 Multi-Site Research* (Delete this section if this is not a Multi-Site Research Study.)

N/A- While about 23 other cancer centers are also conducting Screen to Save educational interventions and evaluation activities, we are all operating independently from each other, under our own institutions' IRBs.