PROTOCOL TITLE:

Education about Health and Cancer Study

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

Version 1: 1/29/2020

Version 2: 2/10/2020

Version 3: 3/17/2020

Version 4: 6/12/2020

Version 5: 8/31/2020

Version 6: 9/21/2020

Version 7: 10/15/2020

Version 8: 12/8/2020

Version 9: 4/20/2021

Version 10: 7/13/2021

Version 11: 9/10/2021

Version 12: 3/3/2022

Version 13: 04/2022

Version 14: 02/2023

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
2	2/10/2020	Removing language of HIPAA waiver. Information sheets updated to include HIPAA and data use language.	Y

3	3/172020	Consent Changes: For Experimental Arm 2 and Control Arm (both online: Adding language to Information sheets to include information about participant ability to download e-signed consent form. For Experimental Arm 1: Adding HIPAA language to consent script (which should have been done during our 2/10/2020 modification) and adding a signature line to information sheet since we are able to collect actual written signatures from those participants. For All Arms: Adding privacy/confidentiality risk language and request for personal information and that data will be stored for 6 years No longer requesting waiver of signature	Y

		(except that Experimental Arm 2 and Control are e-signatures). See information sheets, script, and protocol section 18 for changes. <u>Other Changes:</u> Changing length of time data is stored (6 years). Adding the six control arm dummy questions to all arms of study (not just control arm). Clarifying identifying information to be included in Experimental Arm 2 and Control Arm (to match Experimental Arm 1 information) Clarifying that all participants who pre-screen as eligible for both identified PI studies and DCC clinical trials and agree to have contact information shared will be referred (not just Experimental Arm 1 participants) Modifying online format for Experimental Arm 2 from just a video to an online module to include a video plus written education. Updating recruitment verbiage to reflect the video plus written education. Adding documents for review: -Video script -Referrals data tracking sheets (referrals to research nurses and research teams/PIs for possible enrollment in studies)	
4	6/12/2020	Consent Form changes, including initials; see tracked changes on consent forms Other revisions within protocol: -Clarifying sample size for Exp. Arm 2 and Control Arm. -Modified recruitment plans for Exp Arm 2 and Control Arm (unpaid social media posts)	Yes

		Re-ordering of study procedures; notably: Eligibility to come before consent, post-test to come before pre-screening for trials/studies questions -Most survey questions programmed as mandatory response - Updated online arm descriptions to specify use of Qualtrics for survey administration where before had indicated Qualtrics or RedCap - Updates to data collection and storage procedures (including collection of contact information within the survey, not separate, to facilitate referrals to studies/trials) -Updated electronic gift card information to indicate that unclaimed gift cards may be deactivated after 6 months -Updated data management -Updated privacy (team member access to data) Other revised documents for review: -Revised Studies Referral Tracker -Revised Pre-Screening Questions and Information about trials/studies for referral -Revised eligibility questions (new questions/answer options), pre- and post-test surveys (new and revised questions), and pre-screening questions/information about trials/studies for referrals (new and revised questions), revised contact and identifying information questions (now all combined as a Qualtrics PDF) Adding documents for review: -Website education content -Clinical trials video Please note: Experimental Arm 1 (in-person) will not commence until Dartmouth/D-HH guidance supports in-person activities, in order to minimize risk of COVID-19 transmission.	
5	8/31/2020	Updated procedures in protocol regarding order of study procedures (consent first, screening second; re-ordering of some post-test questions versus clinical trials linkages); updated	Y

		recruitment procedures; updated PI Documents for review:	

		Change of PI from Tracy Onega to Anna Tosteson Update of consent forms to include new PI Update Info Sheet Experimental Arm 2 with screening language Update to recruitment language to include screening language Update of study design from Observational to Interventional Updated Qualtrics survey (reorder question sequence) Updated screening question/information form Update of educational web site link Addition of potential images for advertising/recruitment Considering addition of a setting in Qualtrics with accompanying instructions that will provide the participant with a time allocation for the intervention	
6	9/21/2020	Change in protocol file name	
7	10/15/2020	Added two Qualtrics survey questions pertaining to participant's level of engagement with educational content (participants are required to respond)	
8	12/8/2020	Protocol edits: -Changes and clarifications to study procedures for online study arms, resources/team members, other procedures (see tracked changes throughout); please note: some edits are simply corrections overlooked in past modifications (e.g., eligibility screening process that was changed in modification #4 above—some residual edits were needed for clarity only). -Updated contact information form (Exp Arm 1-document; other arms- see Qualtrics survey) -Updated survey (instructions throughout, logic/flow, question language, contact/personal information form, linkage/referral questions) -Updated consent/information sheet for clarity (see tracked changes in enclosed document) -Updated tracking sheet for study teams/nurses -Updated linkage/referral questions document	Y
9	4/20/2021	Study team edits: -Adding Judith Rees as Co-I -Removing Inger Imset as study team member Protocol edits:	Y

		-Removing control group -Updating experimental arm 1 procedures -Minor other edits Updated survey for experimental arm 2 (and former control group) -Removing control group intervention and 'dummy' questions from the control group -Updating contact information throughout -Providing clarifying instructional language -Adding two qualitative questions about the intervention Providing electronic surveys (pre and post) for experimental arm 1 Updated consent for experimental arm 2 (and former control group): -Updating contact information Updated consent for experimental arm : -Updating study details -Updating compensation -Updating contact information	
10	7/13/2021	-Updating contact information for research team (instructional language in surveys, consent) -Updating participant instructions related to timeline for compensation -Updating study procedures for identifying bot/fake survey responses	Y
11	9/10/2021	-Updating PI -Updating documents (including consents) to reflect updated PI -Updating materials related to trials/studies we will refer to, as they also are experiencing changes in their PIs	Y
12	3/3/2022	-Updating recruitment plans/verbiage for Experimental Arm 2 -Clarifying team members mentioned in protocol (though they've previously been updated in eIRB system)	N
13	05/02/2022	Name change from Norris Cotton Cancer Center to Dartmouth Cancer Center -Addition of new employees; removing previous employees -Updating info for new Best Practice Alert for provider access to connect patients with clinical trials education -Updating/clarifying listserve & Front Porch Forum information for advertising purposes	
14	02/15/2023	-Addition new employee; remove former employee -Addition After Visit Summary (AVS) for Epic to BPA -Study Population Arm 2 updated to include listserves and flyers in addition to social media	

Table of Contents

1.0 Study Summary

Study Title	Education about Health and Cancer Study
Study Design	Interventional/Cohort Study Pre-/Post-/Follow-up (via surveys and research records)
Primary Objective	Aim 1: Implement and evaluate educational activities to improve knowledge of, attitudes and behavioral intentions toward, and participation in clinical trials and cancer research studies among rural residents living in NH and VT (Rural = RUCC 7-9 counties).
Secondary Objective(s)	Aim 1a: Implement electronic portal access to educate regarding what clinical trials and cancer research are and evaluate the effect on knowledge of, attitudes and behavioral intentions toward, and actual enrollment into clinical trials and cancer research studies. Aim 1b: Implement online education regarding what clinical trials and cancer research are and evaluate the effect on knowledge of, attitudes and behavioral intentions toward, and actual enrollment into clinical trials and cancer research studies. Aim 1c: Compare the impact of education about clinical trials with the impact of an innovative outreach modality using social media and web-based technology for educating the public about clinical trials; provider portal Epic (EDH) for patients.
Research Intervention(s)	Experimental arm 1 (Aim 1a): Education about clinical trials and cancer research via provider portal education to cancer survivors, caregivers, and the public. Experimental arm 2 (Aim 1b): Education about clinical trials and cancer research via online video and module.
Study Population	The main target population is adults aged 18 or older 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 experimental arm 1, people must be 18 years or older at the time of enrollment. To be eligible to enroll in experimental arm 2, people must meet the following eligibility criteria: -Be a resident of one of the RUCC 7—9 counties in NH and VT and -Be 18 years or older at the time of enrollment Aim 1: The target population is adult cancer survivors, caregivers, and patients who are connected with the Dartmouth Cancer Center. Aim 2: The target population is adult**s** who reside in rural New Hampshire or Vermont.
Sample Size	Experimental Arm 1: up to 50 Experimental Arm 2: 200-250
Study Duration for individual participants	Up to 7.5 months
Study Specific Abbreviations/ Definitions	BPA=Brief Provider Alerts CHE= Community Health Educator 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) COE= Community Outreach and Education (a focus of the Norris Cotton Cancer Center) DCC=Dartmouth Cancer Center DHH=Dartmouth Hitchcock Health NCCC= Norris Cotton Cancer Center NCCC North= Norris Cotton Cancer Center North in St. Johnsbury RUCC= Rural-Urban Continuum Codes (a U.S. Department of Agriculture schema for defining communities as rural/urban)

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2.0 Objectives*

2.1 The purpose of this project is to: (1) contribute to a nation-wide initiative to educate the public about clinical trials, (2) evaluate the effectiveness of education about clinical trials/research in changing knowledge, behavioral intentions, and behaviors related to clinical trials/cancer research enrollment.

Aim 1: Implement and evaluate educational activities to improve knowledge of, attitudes and behavioral intentions toward, and participation in clinical trials and cancer research studies among rural residents living in NH and VT (Rural = RUCC 7-9 counties).

Aim 1a: Implement electronic portal education regarding what clinical trials and cancer research are and evaluate the effect on knowledge of, attitudes and behavioral intentions toward, and actual enrollment into clinical trials and cancer research studies.

Aim 1b: Implement online education regarding what clinical trials and cancer research are and evaluate the effect on knowledge of, attitudes and behavioral intentions toward, and actual enrollment into clinical trials and cancer research studies.

Aim 1c: Compare the impact of electroniceducation about clinical trials with the impact of an innovative outreach modality using social media, patient portals and web-based technology for educating the public about clinical trials.

2.2 Hypotheses:
1- Accessingeducation about clinical trials will be effective in: a) increasing knowledge of clinical trials; b) increasing intent to participate in clinical trials; and c) increasing clinical trials/research project enrollment within six-months post-outreach.

2- Online/video outreach with online module about clinical trials will be effective in: a) increasing knowledge of clinical trials; b) increasing intent to participate in clinical trials; and c) increasing clinical trials/research project enrollment within six-months post-outreach.

3.0 Background*

3.1 Since 2010, The Center to Reduce Cancer Health Disparities (CRCHD) has managed the NON, (National Outreach Network) of CHEs (Community Health

Educators) located within NCI-funded cancer research programs. The program seeks to enhance the integration of underserved communities into the research and mission of NCI and strengthen NCI's responsiveness to the cancer information needs of underserved communities. It is expected that the close affiliation of NON CHEs with other NCI-research programs will further strengthen the ability of NCI and DCC to reach underserved communities through region-based community education/outreach activities to disseminate cancer information aligned with NCI's research priorities. Through embedding this national network of CHEs in cancer centers throughout the nation, this has led to the development, implementation, and assessment of a broad range of culturally-tailored community outreach activities.

In 2019, DCC received a supplemental grant from NCI to continue to participate in the National Outreach Network and to continue to employ a Community Health Educator at the cancer center. Under the new award, NCI/CRCHD requires that every cancer center with the supplemental grant participate in a national effort to educate underserved communities (in our case, rural communities) about clinical trials/research, because underserved communities are often also underrepresented in trials/research.[1]

3.2 A 2007 systematic review looking at the barriers to recruiting underrepresented populations into cancer clinical trials found that lack of education about clinical trials was among the most commonly-reported barriers to participating in cancer clinical trials.[1] The review did not identify any studies that reported on effectiveness of culturally-tailored education on clinical trials enrollment,[1] and more research is needed in this area. A 2001 study also found that improving awareness/understanding of clinical trials may be an important step in improving attitudes toward clinical trials and, possibly, participation in trials.[2]

3.3. In order to implement education about clinical trials across 24 cancer centers, NCI/CRCHD has developed a set of key messages that all cancer centers must include in their educational activities, and the cancer centers are tailoring the educational messaging/curriculum and delivery of activities to be locally-relevant and tailored to the needs of our catchment area. NCI/CRCHD has also developed a pre-test and a post-test (surveys- see attached) that will be administered immediately preceding and proceeding our educational activities, with the intent of evaluating whether the educational interventions changed the participants' knowledge of, attitudes toward, and behavioral intentions regarding taking part in clinical trials and research. NCI/CRCHD has asked us to track whether participants in our interventions go on to enroll in trials/studies in the six-months following our intervention (via our PIs' and Office of Clinical Trials' research records).

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This study will help measure and evaluate the effectiveness of different models of educating people about clinical trials. The data will be aggregated at a national level to assess the overall NCI/CRCHD activity. The data will be analyzed at the local/regional level to inform DCC's Community Outreach and Engagement program's future outreach models. Given the limited literature regarding the effectiveness of education on clinical trials knowledge, attitudes, and enrollment, this study will contribute meaningful and important information.

References:

1 Ford, J. G., Howerton, M. W., Lai, G. Y., Gary, T. L., Bolen, S., Gibbons, M. C., ... & Powe, N. R. (2008). Barriers to recruiting underrepresented populations to cancer clinical trials: a systematic review. Cancer: Interdisciplinary International Journal of the American Cancer Society*, 112(2), 228-242.*

2. *Taylor, H., & Leitman, R. Misconceptions and lack of awareness greatly reduce recruitment for cancer clinical trials.[article online, Health Care News, Vol. 1, Issue 3]. Rochester (NY): Harris Interactive, Inc.; 2001 Jan 22 [cited 2001 Mar 29].[3 p].*

4.0 Study Endpoints*

4.1 Knowledge, attitudes, and behavioral intentions (assessed via surveys)

4.2 Actual enrollment into a clinical trial or cancer research study (assessed via DCC Office of Clinical Research enrollment records over 6 months post intervention and enrollment records for specified DCC trials/research studies (see enclosed document with information about those studies)

5.0 Study Intervention

5.1 DCC's Community Outreach and Engagement Team (Jenna Schiffelbein, , Regina-Anne Cooper, Anna Tosteson, Judith Rees, Lisa Purvis, Stephanie Papas, Kathy Stroffolino, Andrew Cowenhoven) will implement the clinical trials education in experimental arms— 1) education using electronic provider alerts (BPA) and 2) an online website/video format. The education in both formats will be based on a set of key messages that cover information about clinical trials, including what they are, the benefits, the risks, and how to locate available clinical trials (see attached outline of education).

<u>Experimental Arm 1 (Aim 1a):</u>

We will evaluate educational outputs from electronic portal regarding what clinical trials and cancer research studies are. The educational content for videos was developed with the National Cancer Institute (NCI) toolkit as a foundation, with additional content added to adapt to our local institution, culture, and patient needs. The videos learning objectives focus on improving participants' knowledge about what clinical trials and cancer research studies are and how to access trials and studies, increase positive attitudes toward participating in trials and studies, and increase their intent to enroll in trials and studies.

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Providers will receive a BPA indicating patient may qualify to participate in the education survey. See enclosed invitation language. Providers will also have the option to include After Visit Summary (AVS) to Patient Notes that will contain invitation link. Patients will receive a link to the survey. If they choose to take part in the study, they will do so by completing the online consent, eligibility screening, pre-test, and contact information before the class they are registered for; attend the class; and complete the post-test after the class to assess achievement of the learning objectives. They will also be asked a series of questions to assess their eligibility for existing DCC clinical trials and research studies (see enclosed Qualtrics PDF).

Experimental Arm 2 (Aim 1b):
Participants will watch a video and view website materials ('online module') developed by DCC using messaging provided by the National Cancer Institute (NCI) and tailored to our local context. The online module's learning objectives will focus on improving participants' knowledge about what clinical trials and cancer research studies are and how to access trials and studies, increase positive attitudes toward participating in trials and studies, and increase their intent to enroll in trials and studies. Eligible participants will complete pre- and post-surveys to assess achievement of the learning objectives, and they will also be asked a series of questions to assess their eligibility for existing DCC clinical trials and research studies (see enclosed questions).

6.0 Procedures Involved*

6.1 Experimental Arm 1 (Aim 1a):
Out study will be largely advertised to DCC's patients and caregivers (e.g., through Patient and Family Support Services' catalog, DH events calendar, DCC/ DH Facebook, online listserves, waiting rooms)..

a- Recruitment- recruitment to participate in the study will happen after a patient or caregiver receives a link to participate in survey from provider BPA. DCC porviders open a message from electronic provider portal BPA. The BPA promps an alert to providers – who open a message indicating the option to send a patient information about accessing the survey or, to be connected with a clinical nurse/coordinator who can walk the patient through the process of accessing the survey.
1 – Provider portal option using electronic medical record portal EDH/Epic includes option inviting providers to click on Best Practice Alert when prompted.

b- The recruitment language provides prospective participants with a link to an online survey where they can consent, complete eligibility screening, the pre-test, and contact information. Contact information (name, email, phone number, address) and date of birth is collected to facilitate: 1) hand-off to open studies/trials' teams and clinical staff (Research Nurses/Nurse Navigators) for recruitment, 2) tracking subsequent enrollment into any study/trial, 3) gift card distribution for their time, and 4) to invite them to

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complete the post-test.

d- Provision of participant compensation for completing pre-test. E-gift cards that have not been claimed six months after being emailed may be deactivated.

e- Assignment of unique numeric identifiers to link records

f- Completion of an online post-test survey (see attached Qualtrics PDF for Experimental Arm 1)- including:

- Post-intervention knowledge
- Pre-screening for eligibility into pre-selected open trials/studies at DCC (see attachment with study details and questions).
- Post-intervention attitude and behavioral intention questions

g- Provision of participant compensation for completing the post-test. E-gift cards that have not been claimed six months after being emailed may be deactivated.

h- Referral to pre-screened (possibly eligible) participants to PI's of pre-selected open studies/trials, as well as DCC clinical staff (research nurses, nurse navigators). This will entail providing participant contact/health information to PIs/study teams/DCC clinical staff of studies/trials that the participant may be eligible for. Participants will have provided permission for their information to be shared (see information sheet and pre-screening section of the Qualtrics post-survey). Tracking of participants' enrollment status into studies/trials over six months (via PI/study team records and DCC Office of Clinical Research records/Oncore).

This will entail providing our participants' identifying information to the PIs/research teams of selected studies and to DCC's Office of Clinical Research and asking them to identify which participants have enrolled in studies/trials since the educational intervention. With permission/direction from DCC's Office of Clinical Research, our study team members may track enrollment via Oncore. See enclosed Excel spreadsheet that will be used for tracking. [We will also collect aggregate enrollment in trials/studies at DCC for comparison with our participants.]

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i- Transmission of de-identified pre and post survey data files to NCI/CRCHD and/or its contractor for data entry, quality control, and national aggregation; e- mailing of tracking excel spreadsheet to NCI/CRCHD and/or its contractor.
j- Local analysis of data to determine effect of study objectives

Experimental Arm 2 (Aim 1b):

The video and online education module arm will feature the following key elements:

a- Geo-targeted paid advertisements and other unpaid posts on social media (e.g., Facebook), listserves, or flyerswill invite prospective participants to our study by asking them to click 'Learn More' to open the surveys in a new page in Qualtrics (see enclosed recruitment messaging). We will also recruit through other online opportunities, such as Front Porch Forum, e-newsletters and listservs, online community forums/groups, partner organizations, etc.
b- A consenting process utilizing a downloadable information sheet (see attachments- information sheet with e-signature)
c- Screening for eligibility questions- Prospective participants will be asked a series of questions to ascertain if they are adults living in rural VT or NH (see Qualtrics survey PDF). Those who are eligible and consented will be told they are eligible and invited to continue forward into the study. Those who are not eligible will be thanked for their time. All questions will be programmed as required.
d- Completion of a pre-test survey (see Qualtrics survey PDF)- includes demographics; baseline knowledge, attitudes, and behavioral intentions. (see Qualtrics survey PDF). All questions will be programmed as required.
e- Delivery of online module as the educational intervention (as described earlier- see enclosed link to module: https://cancer.dartmouth.edu/node/1167). The online module will include a video and accompanying educational information (not yet visible to the general public but may be used in select venues outside of research project).
p- Completion of a post-test survey (see Qualtrics survey PDF)- includes knowledge and attitudes questions. All questions will be programmed as required.

q- Pre-screening for eligibility into pre-selected open studies and other clinical trials at DCC (see Qualtrics survey PDF). All questions will be programmed as required.

r- Completion of a post-test survey (see attachment and Qualtrics survey PDF)- behavioral intention questions. All questions will be programmed as required.

s- Collection of contact information (name, email, phone number, address) and date of birth to facilitate: 1) hand-off to open studies/trials' teams and clinical staff (Research Nurses/Nurse Navigators) for recruitment, 2) tracking subsequent enrollment into any study/trial, and 3) gift card distribution for their time. All components of the contact information/identifying information fields will be programmed as required (see PDF of Qualtrics survey).

t- Provision of participant compensation for their time via emailed e-gift cards. E-gift cards that have not been claimed six months after being emailed may be deactivated.

u- Assignment of unique numeric identifiers to de-identify all survey data for sharing with NCI/CRCHD

v- Connection of pre-screened (possibly eligible) participants to PI's of pre-selected open studies/trials. This will entail providing participant contact/identifying information to PIs/study teams of studies/trials that the participant may be eligible for, as well as connection of pre-screened (possibly eligible participants) to the cancer center's clinical team (Research Nurses/Nurse Navigators) to explore available clinical trials/establish care. Participants will have provided permission for their information to be shared (see information sheet and Qualtrics survey PDF).

w- Tracking of participants' enrollment status into the pre-selected open studies/trials and other DCC clinical trials over six months (via PI and DCC Office of Clinical Research records/Oncore). This will entail providing our participants' identifying information to the PIs of selected studies and to DCC's Office of Clinical Research and asking them to identify which participants have enrolled in studies/trials since the educational intervention. With permission/direction from DCC's Office of Clinical Research, our study team members may track enrollment via Oncore. See enclosed Excel spreadsheet that will be used for tracking.

x- E-mailing de-identified pre and post survey data to NCI/CRCHD and/or its contractor for data entry, quality control, and national aggregation. E-mailing of tracking excel spreadsheet to NCI/CRCHD and/or its contractor.

y- Local analysis of data to determine effect of study objectives

If any individuals contact the research team indicating they had difficulties completing the surveys online, we will seek information from them to match their survey record (e.g., their initials, time of day/date they were completing the survey) and provide them with assistance by phone and/or email to enable them to complete the study procedures. In some cases, this may entail providing a separate survey link to them by

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We are discontinuing our control arm. Because the control arm was part of our local research procedures and not part of NCI's national initiative, we will not be providing any control arm data to NCI or its contractor.

7.0 Data and Specimen Banking*

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

8.0 Sharing of Results with Subjects*

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 commencement of the study, we plan to develop a community report to share with relevant stakeholders (e.g., DCC Community Advisory Board, cancer center researchers and clinicians, clinical trials staff, primary care providers, cancer control professionals, cancer center researchers) 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 obtaining the follow-up clinical trials/research study enrollment records.

We anticipate enrolling all study participants within fouryears of study activation as study team's grant has been extended.

10.0 Subject Population*

10.1 The main target population is adults 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), though others are eligible to enroll in Experimental Arm 1, as described below.

10.2 To be eligible to enroll in experimental arm 1, people must be 18 years or older. We will measure whether they are a resident of RUCC 7—9 counties in NH and VT, but we will not limit their eligibility based on residency.

To be eligible to enroll in experimental arm 2, people must meet the following eligibility criteria:

-Be a resident of one of the RUCC 7—9 counties in NH and VT and

-Be 18 years or older at the time of enrollment

Experimental Arm 1 (Aim 1a): Participants will come from Electronic provider portal EDH/Epic. They will receive an invitation to participate in this research study only after accessing a Qualtrics survey.

Experimental Arm 2 (Aim 1b): Participants will be social media or listserve users. Flyers may be used in targeted areas. Social media advertising features will be used to target social media users in the appropriate age range (18+) and geographic locations of interest.

13.1 Regarding adults unable to consent: 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 experimental arm 2, 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. To access experimental arm 2, that will require first accepting a link for the Qualtrics survey, deciding to follow the instructions in the invitation email, navigating away from the email 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 (18+) at the time of enrollment; hence, no minors will be enrolled. Further, for some participants, recruitment for Experimental Arm 2 will use Facebook's marketing features to target account holders in the age range of interest to the study (adults).

Pregnant women: 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 a person is pregnant, receiving education about clinical trials and research does not pose a risk and has the potential to be beneficial.

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.

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. 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 sample size for completing the study is

-Experimental Arm 1: up to 50
-Experimental Arm 2: 200-250

Because of the nature of the study being primarily online, we anticipate additional people consenting into the study and not being eligible and/or not completing the study. As such, we anticipate consenting up to 900 people to have about 1/3 complete all study procedures.

13.0 Recruitment Methods

13.1-13.4

<u>Experimental Arm 1 (Aim 1a):</u>

To recruit participants for the evaluation/data collection, we will rely on people who are registered for an existing class at the Dartmouth Cancer Center ('Clinical Trials: Another Approach to Cancer Treatment').
See recruitment messaging document attached.
Using DHH electronic medical reporting system Epic a Best Practice Alert (BPA) for cancer providers at point of care prompts to ask patients if a connection to education survey about clinical trials can be sent to them. Patient is sent information to access survey, or, to be connected with clinical coordinator/nurse who can talk them through accessing the survey link.

<u>Experimental Arm 2 (Aim 1b):</u>

We will purchase advertisements on social media (e.g., Facebook), listserves, or via flyers, which will be targeted to adults in VT/NH RUCC 7-9 counties. 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

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as:

> "Researchers at the Dartmouth-Hitchcock Norris Cotton Cancer Center are looking for adults to watch a video, read some information, and answer surveys. Participation is voluntary and confidential. You will be compensated for your time. Click the "Learn more" button to learn more and to participate in this RESEARCH survey."

We may also post the same recruitment message in unpaid social media posts and may also share our recruitment verbiage with partner organizations (e.g., Vermonters Taking Action Against Cancer, UVM, New Hampshire Department of Health and Human Services) and through other online opportunities (e.g., Front Porch Forum, e-newsletters and listservs, online community forums/groups, etc) to post our messaging in settings where their followers/members may view it (e.g., their website, social media, newsletters). See recruitment messaging document attached with sample messaging.

13.5 Participants in Experimental Arm 1 will receive a $5 gift card/e-gift code for completing the pre-test and will receive an additional $10 gift card/e-gift code after completing the survey and completing the post-test. Participants of Experimental Arm 2 will receive $10 in gift cards/e-gift codes (e.g. to Amazon.com) for completing the surveys and interventions. E-gift cards that have not been claimed six months after being emailed 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, and post-test—which are the minimum data we need in order to evaluate a portion of our intervention.

14.2

Experimental Arm 1 (Aim 1a):
A person can discontinue participation at any time by indicating for any reason that they no longer wish to participate. Individuals who do not complete the in-person pre-test, education, post-survey, and contact/identifying information will not have their clinical trials/research enrollment followed at six-months.

Experimental Arm 2 (Aim 1b):
Any participant can discontinue participation at any time by closing the window on their device's screen that contains our survey content. Individuals who do not complete the pre-test, education, post-survey, and contact/identifying information will not have their clinical trials/research enrollment followed at six-months.

15.0 Risks to Subjects*

15.1 Because this activity is primarily educational, the risks are minimal. However, some participants with a family history of cancer or who have had negative experiences with clinical trials and research may be distraught by participating. 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 *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*

16.1-16.2. We do not expect a direct benefit to participants. However, participants may learn new information about clinical trials and research.

As feasible, participants will be referred to research nurses and/or research teams if they are identified as possibly eligible for a study/trial and interested in being contacted.

17.0 Data Management* and Confidentiality

17.1. We will conduct various statistical tests on the data to determine whether participants experienced changes in knowledge, attitudes, behavioral intentions, and behavior as a results of any of the study arms, 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 DHH.
- Unique identifiers: We will assign a unique identifier to the study information using the numbers provided by NCI/CRCHD/its contractor. We will link the pre-, post-, and follow-up enrollment data using the unique identifiers. Contact information requested from participants for purposes of follow-up to be referred and gift card distribution will be managed and stored separately from the study data but will be obtained in

the same survey; after data are downloaded from Qualtrics, participant contact information will be stored and managed separately, with use of unique identifiers. The participant contact information and key to link data back to identifiers will be stored separately from the research data.

- Experimental Arm 1 participants asked to participate in a follow-up survey (post survey) will receive a shortened version of their unique identifier as part of the request for their participation in the follow-up/post survey and asked to manually enter their number into Qualtrics to facilitate our linking of their research records. See Experimental Arm 1 Qualtrics survey.

Data quality control:

Experimental Arm 1 (Aim 1a):
The DCC research team will review results from Qualtrics survey. . If the review reveals a potential data quality issue, the research team will 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.

Experimental Arm 2 (Aim 1b):
The DCC research team will review data collected from 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 DHH and DCC colleagues (e.g. tech support) and NCI/CRCHD to address the issues, as needed. To aid in identifying bot and fake responses and support data integrity, we will use several features in Qualtrics, including the bot detector and turning 'location' settings to 'on' to track location of respondents (e.g., IP address).

As with any study that collects information about health, 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.

17.3. Original paper research forms/data will be kept in a locked filing cabinet at DHMC for six 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 College/DHH, such as Qualtrics and /Sharepoint/One Drive; access will only be granted to official study team members. All files, paper and electronic, at DHH will be destroyed after six years.

De-identified survey copies/survey data 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

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data (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 outreach (e.g., dates, locations, number of attendees), about the social media ad reach/metrics, and, as needed, cost. Judy Rees, Regina-Anne Cooper, Lisa Purvis, Jenna Schiffelbein, Kathy Stroffolino, Andrew Cowenhoven and the research team will be responsible for sharing the data with NCI/CRCHD/its contractor. Please see the attached document from NCI/CRCHD entitled *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. The primary risk is related to privacy/confidentiality, however, we are addressing that risk on the Information sheet by stating that we are putting in place the following processes for participant protection:

- Study team members are trained on all procedures
- Study computers are encrypted and have passcodes, study data collection will have passcode access only, and the physical location of the research material is locked
- All study participants will have a unique identifier code assigned to them stored separately from identifiable study information that will be collected for follow-up and gift card distribution

19.0 Provisions to Protect the Privacy Interests of Subjects

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19.1 and 19.2

Experimental Arm 1 (Aim 1a)*:* Participants will complete the information sheet and study surveys online.

The information sheet provides information about how participants' contact/identifying information will be used. Those who pre-screen as being potentially eligible for an open study/trial will provide permission for their contact/identifying information to be shared with the study teams and/or the clinical team (e.g., Research Nurses/Nurse Navigators) (see enclosed pre-screening question sheet with permission question and information sheet).

Experimental Arm 2 and Control Arm (Aim 1b):
Contact/identifying information requested from participants will be managed and stored separately from the study data.

The information sheet provides information about how participants' contact/identifying information will be used. Those who pre-screen as being potentially eligible for an open study/trial will provide permission for their contact/identifying information to be shared with the study teams and/or the clinical teams (e.g., Research Nurses/ Nurse Navigators) (see enclosed information sheet and see Qualtrics PDF).

19.3 Any study forms containing identifiable information will not be available to all study members, with an exception of the Qualtrics account/survey, which will be managed by most study team members. Only the study coordinators and a manager/sub-investigator will have access to any other identifying information, and this information will only be accessed for purposes of gift card distribution and follow-up data tracking.

20.0 Compensation for Research-Related Injury

N/A- This study involves no more than minimal risk to subjects.

21.0 Economic Burden to Subjects

21.1 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 participate in a clinical trial or research study, all costs associated with those trials/studies are beyond the scope of this study.

22.0 Consent Process

22.1. Experimental Arm 1 (Aim 1a):

23 Once the prospective participant clicks the link in the email invitation to learn more about the study, they will be presented with an information sheet with HIPAA authorization (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. They will e-sign the form with initials before continuing forward (see enclosed PDF of Qualtrics survey for consent, as well as information sheet file). They will then be presented with eligibility questions. If they are eligible for the study, they will be asked to move forward to complete the remaining study procedures.

Experimental Arm 2 (Aim 1b):

Once the prospective participant clicks the Facebook ad, link in listserve ads or flyers to learn more about the study, they will be presented with an information sheet with HIPAA authorization.

(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. They will e-sign the form with initials before continuing forward (see enclosed PDF of Qualtrics survey for consent, as well as information sheet file). They will then be presented with eligibility questions. If they are eligible for the study, they will be asked to complete the following components (in the same session): pre-test, educational module (video and website materials), pre-screening for eligibility for open trials/studies [for experimental arm], post-test, contact information, and e-gift card components.

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 in Experimental Arm 2 or Arm 1(both online), based on clicking on the social media ad or email invitation, 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- For participants in Experimental Arm 2 and Arm 1(both online), an information sheet will be presented (rather than read) to the participants. See enclosed information sheets.
    - 5.4 and 5.5- For participants in Experimental Arm 2 and Arm 1 (both online), they 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- For participants in Experimental Arm 2 and Arm 1 (both online), they will be completing a consent process, which is explained in the information sheet—with an e-signature/initials. See enclosed information sheet and PDF of Qualtrics surveys for exact signature/initial verbiage as part of the consenting process.

Non-English Speaking Subjects: At this time, we will not enroll non-English speaking subjects. We plan to conduct our study in English with individuals who

are able to participate in the consenting process and other study components in English. If any of the sites that we are working with to deliver in-person education indicate that providing materials in additional languages is needed, we will send materials to MasterWord (https://www.masterword.com/) for translation. This company provides all translation services to Dartmouth-Hitchcock Medical Center, provides excellent quality, and can translate materials into 250 different languages. If our event partners indicate that there is a likely, foreseeable opportunity that individuals will attend the event who do not speak English and may wish to participate in the study, we will assess the viability of including additional languages and submit an IRB modification if deemed viable. The online study will only be available in English.

Subjects who are not yet adults: We will not enroll any subjects who are not yet adults. Our age requirements are 18+ 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. 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 or email account, navigating away from the social media or email 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 be using collecting electronically-signed Information Sheets for Experimental Arm 2 and the Arm 1 (via providing initials and checking boxes—see information sheets and Qualtrics surveys).

23.2 and 23.3. We will provide an information sheet about the study to all eligible participants. Participants in Experimental Arm 2 and Arm 1 will be asked to print/save a copy of the information sheet for their records.

24.0 Setting

24.1 Study planning and procedures will mostly take place in office space in the Rubin 8 building at DHMC (although in-person events will take place throughout New Hampshire and Vermont).

Experimental Arm 1 (Aim 1a):
Recruitment for Experimental Arm 1 will take place through email invitation, and the surveys will be accessed online through Qualtrics. Participants will attend the class by Zoom or in-person at an DCC site.

Experimental Arm 2 (Aim 1b):
Recruitment for Experimental Arm 2 and Control Arm will primarily take place through social media (e.g., Facebook), listserves, flyers, and other online opportunities (as described earlier), and the surveys/intervention will be accessed online through Qualtrics.

DCC does have a Community Advisory Board that is administered by study member Jenna Schiffelbein and/or Lisa Purvis. 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 regarding:

-Content of video and/or review of video and website materials

-Review of aggregate, de-identified results

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

We will also work with our Patient Family Advisory Committee (composed of cancer survivors, family members to cancer survivors, and community-based allies) to receive and incorporate input on the educational video and website materials. We will also work with our internal Clinical Trials Advisory Board members (composed of Clinical Trials staff, Radiation Oncologists, Senior Leadership and our DCC Marketing & Communications Team, etc.) for the same purpose.

25.0 Resources Available

Our study team has several CITI-trained staff members (Jenna Schiffelbein, Regina-Anne Cooper, Kathy Stroffolino, Stephanie Papas, Lisa Purvis, Andrew Cowenhoven, and Judith Rees) who can be engaged for completing study procedures, including administering pre-tests and post-

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tests, providing education, pre-screening for eligibility into other studies/trials, distributing gift cards, and collecting follow-up data from PIs and DCC's Office of Clinical Research. Additional CITI-trained staff or volunteers can be secured, if needed, in which case an IRB modification will be submitted.

Prior to conducting research activities, 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 DHH (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 College/DHH, including:

-Qualtrics support
-Data management and biostatistical analysis support
-Geo-spatial analysis support to identify population counts and rural communities
-Social media consultation support
-Provider portal EDH support

Additionally, our team has funding and in-kind support from:

-National Cancer Institute
-Dartmouth Cancer Center (institutional/philanthropic funds)
-Dartmouth-Hitchcock Marketing and Communications (for video development)

Finally, we have support from our internal clinical trials leadership and staff and our Community Advisory Board. We will leverage our partners for steps such as:

- Identifying trials/research studies that participants could be screened for in terms of eligibility
- Reviewing educational intervention content for accuracy

- Identifying mechanisms by which any successful interventions could be sustained after the study period

While we will not be providing study participants with medical care, we will provide participants with information about how to access clinical trials and cancer research studies. Any costs associated with future enrollment in other trials/studies will be outside of our scope.

Our recruitment targets are reasonable and feasible given that:

- DCC has about 4,000 new patients annually
- About 15% of NH and VT residents live in the rural communities of interest

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 education about clinical trials, we are all operating independently from each other, under our own institutions' IRBs.