Official Title:	HPV Message Testing and Social Media Campaign
NCT number:	03747302
Document Type:	Study Protocol
Date of the Document:	02/27/2019

SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

CPHS template v. 04172017

Please complete: CPHS# STUDY00030772 PI: Ardis Olson, MD

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1. Introduction and Background

Within the Norris Cotton Cancer Center's (NCCC) catchment area of VT and NH, we have higher HPV vaccination rates than many other states, but are experiencing plateauing rates among females, and the male rates continue to lag behind female rates. Both the VT State Cancer Plan 2016-2020 and the NH State Cancer Plan 2015-2020 have goals related to HPV vaccination for adolescent boys and girls. Both states also have organizations working to educate healthcare providers about the vaccine, as well as quality improvement initiatives. Our two states also have several key political and programmatic differences that impact HPV vaccination work, including differences in the public health infrastructure and tracking of immunization rates.

A previous, limited environmental scan of NH and VT was conducted by NCCC member Dr. Ardis Olson (PI) in collaboration with the Dartmouth Primary Care Cooperative Research Network (Dartmouth COOP) and the NH State Immunization Program several years ago. The National Cancer Institute has now awarded NCCC funding to conduct an in-depth environmental scan of HPV vaccine barriers, facilitators, activities, and opportunities in our catchment area. This will entail semi-structured interviews with key informants (e.g., public health professionals, healthcare providers), surveys with healthcare providers, a quality improvement project, online focus groups, surveys and message testing, and implementation/evaluation of a social media campaign about HPV vaccination. The key informant interviews (STUDY00030641), healthcare provider surveys (STUDY00030641), and quality improvement project (STUDY00030771) have been submitted to CPHS in separate applications. This application includes the online focus groups (Phase 1- IRB approved), message testing (Phase 2), and social media campaign (Phase 3- we will submit a modification before starting the campaign).

2. Objectives and Hypotheses

Related to the online focus groups, message testing, and social media components:

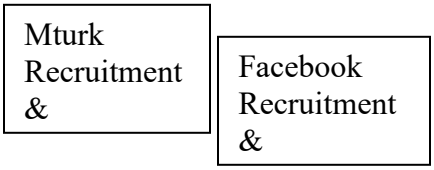
1) Identify HPV vaccine themes/messages/materials and measure their effectiveness to change parent attitudes and intentions to vaccinate their adolescent children;
2) Describe any differences in message/material effectiveness for parents residing in rural areas versus parents residing in urban areas
3) Launch a social media campaign with the most effective messages to improve parent attitudes.

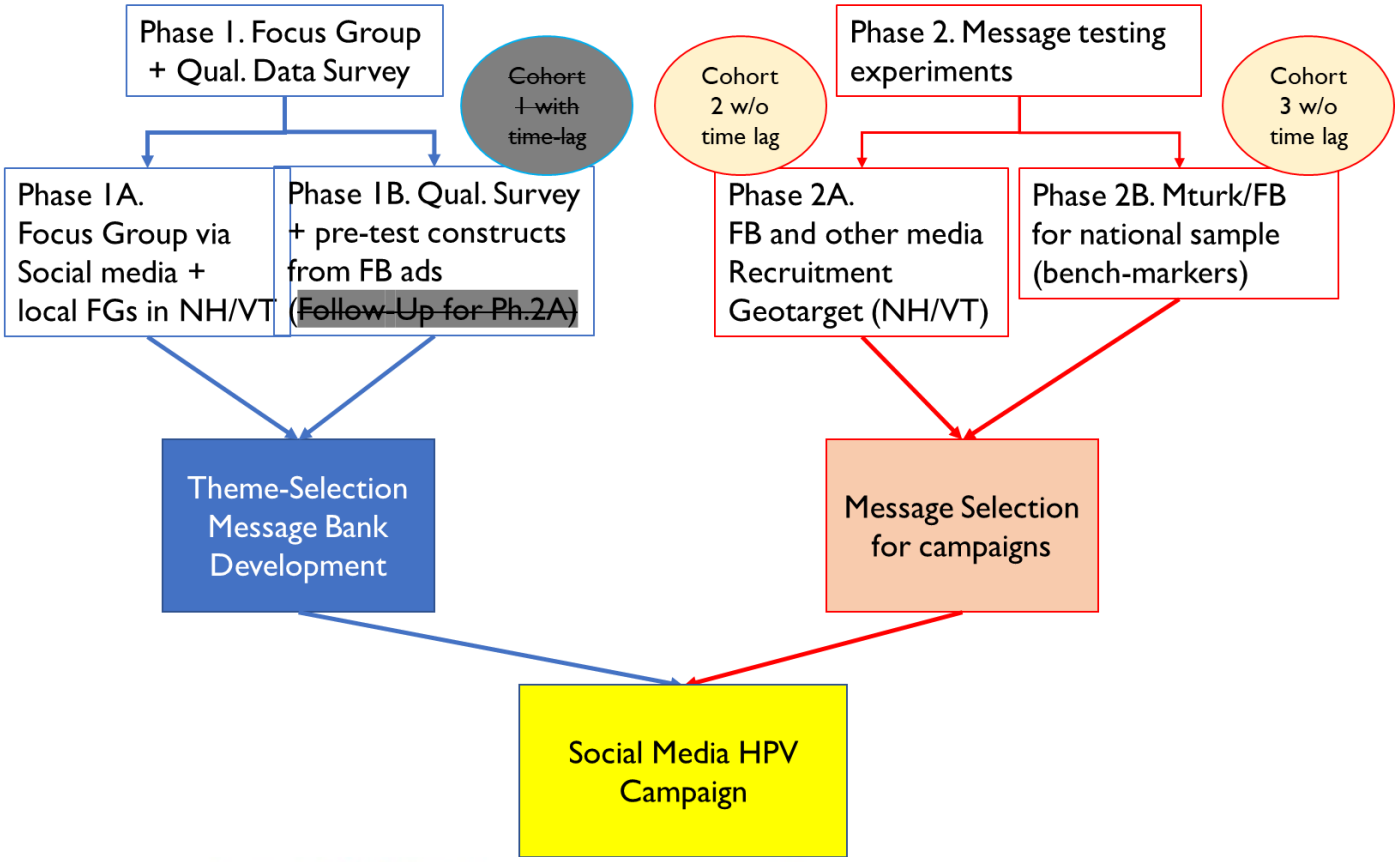
3. Study Design

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

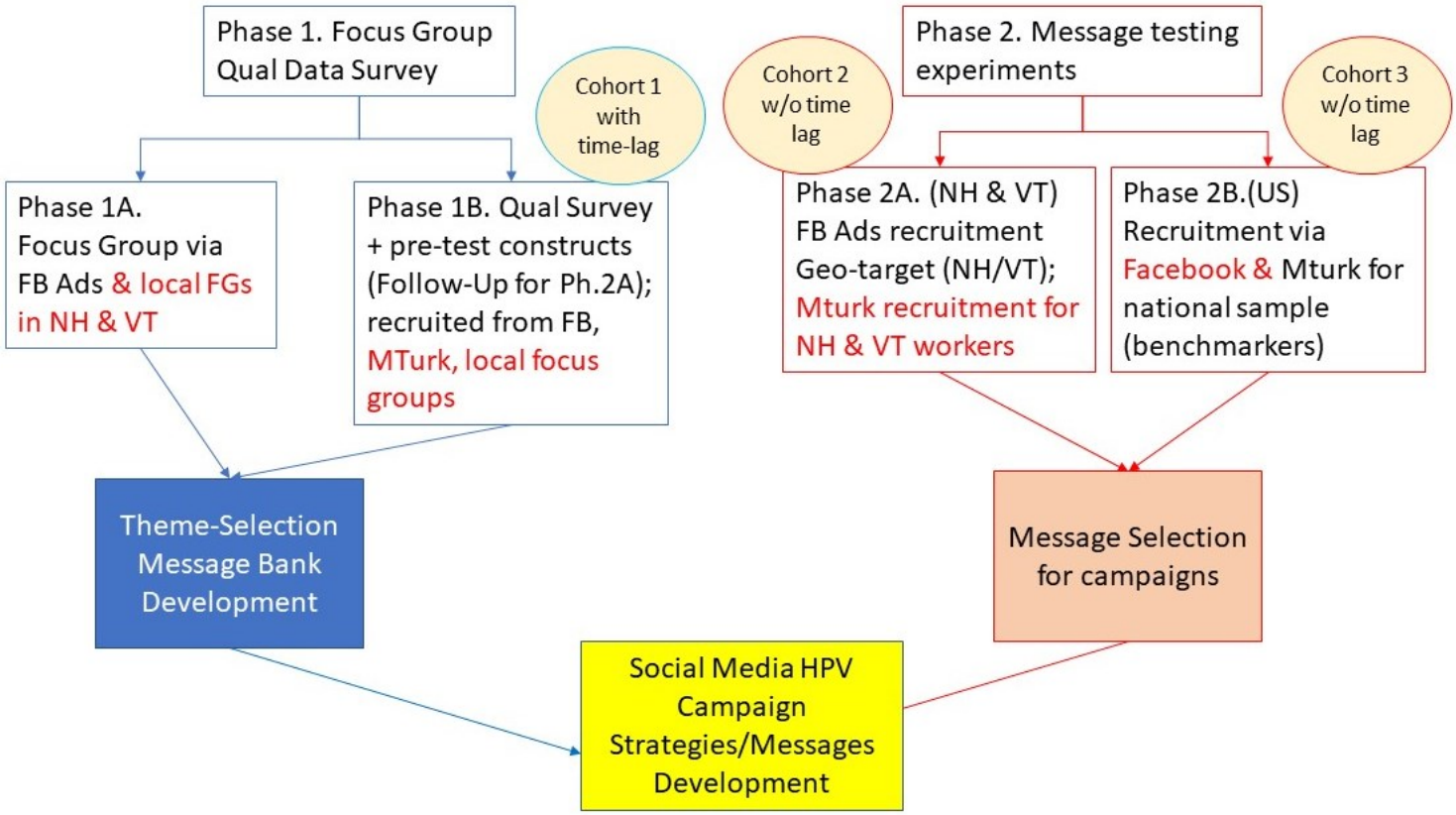
Our project includes several components, as depicted in the following research project diagrams:

Figure 1.





Revised 7/19/2018 (New components in red)



1. **Focus groups (Online & Local) & Survey (Phase 1)**

Online Focus Groups- The research team will develop HPV vaccine themes/messages/campaign materials intended for parents of children 9-14 years old, based on literature review of common parent attitudes toward the HPV vaccine (e.g., it's not necessary, it's not safe, it's only for sexually-active people)—See enclosed recruitment messaging that addressing the themes/messages we'd like to consider for message-testing in Phase 2 (pictures with the messages will vary based on bank of images available through Facebook at time of recruitment). In Phase 1A, the research team will facilitate discussions on the themes via Facebook ads and comment features to identify messages for testing in Phase 2 and develop candidate message/campaign materials in Phase 3. The questions asked in the Facebook ads for discussion have been formed by integrative health behavior model by Fishbein and Yzer (See enclosed recruitment messaging for questions). Using Facebook ads and anonymous survey feedback data for campaign themes, we will collect up to 2,000 comments about the themes/questions. Messages that elicit strong emotional disturbance, negative affect, and negative feedback will be removed from the comments list. A similar set of discussion questions will be used to facilitate traditional, in-person focus groups in New Hampshire and Vermont (described below), for determining reliability of the Facebook discussion method and to help shape the messages for testing in Phase 2.

Survey (Online)- In addition to the public form of focus group discussions available via comments under Facebook ads, we will also have an external survey (Phase 1B, through Qualtrics—See enclosed survey questions) embedded on the Facebook ads to allow participants to privately share their written feedback. For those who are interested in participating in further survey questions may continue after they provide comments responding to the questions posed in the Facebook ads. Previously approved methods using MTurk for this phase has been removed from the study design. *Sample size and recruitment:*

i. Facebook: We will recruit using stratified sampling by geo-targeting the Facebook ads to recruit from predominantly-rural ZIP codes and predominantly-urban ZIP codes (as defined by Rural-Urban Commuting Area (RUCA) Codes) from New Hampshire and Vermont. We will also work with Facebooks ad features to have the ad primarily presented to parents with 9-14 year old children. With six different themes/sets of questions to test, we will have up to 12 ads/strata (one urban and one rural for each of the six themes). There is an eligibility screener at the beginning of the survey.

b) *Data collection methods:* See enclosed recruitment messages to review the focus group questions that people will provide public comments on. See enclosed survey to review all possible questions we may ask; we expect to reduce the number of questions, but have provided all possible questions for CPHS review. The survey will be administered via Qualtrics for those recruited from Facebook Any contact information will be collected via a link to a separate Qualtrics survey to ensure contact information is maintained separate from survey responses. Participants will be debriefed with factual information about the HPV vaccine (e.g., from the Centers for Disease Control and Prevention or American Cancer Society).

c) *Participant compensation:* Survey participants recruited through Facebook (Phase 1B) will have the opportunity to enter a prize drawing for up to 80, $5 gift cards/online gift codes. As of 7/19/2018, only four people have provided their contact information for prize drawing entry; we will award all four of them a $5 gift card and will then reduce the number eligible to win to 80 (rather than 120). This will be updated in our information sheet for any new study participants.

d) *Eligibility:* For Facebook recruitment, we will geo-target the Facebook ads to recruit from predominantly-rural ZIP codes and predominantly-urban ZIP codes (as defined by Rural-Urban Commuting Area (RUCA) Codes). Anyone viewing the ad will be eligible to leave comments. Those people interested in answering the private survey (whether recruited through Facebook) will need to confirm their ZIP code, state of residence, and that they have a child 9-14 years old for inclusion, as eligibility will be limited to parents with children 9-14 years old living in New Hampshire or Vermont. In addition to our actual screening questions to ensure the prospective participant meets our eligibility criteria, we will ask some dummy questions, to avoid deception.

As needed, we may post additional advertisements to Facebook just to recruit for survey completion (without inviting people to leave public comments).

e) *Confidentiality and Protections:* For the online focus group comments, Facebook users viewing the ad will receive a disclaimer that any comments will be publicly-available and viewable by others (See enclosed recruitment messaging). For the private surveys, data will be collected online through Qualtrics and on paper for people participating in the local focus groups (described below). Any electronic survey data will be stored on password-protected computers and will only be viewable to CITI-trained research team members through Qualtrics portal and/or through this project's Dartmouth-hosted SharePoint site that is only accessible to the research team members via password. After data are no longer needed, they will be destroyed by the research team, and destruction will be confirmed by the information technology team at the Norris Cotton Cancer Center/Geisel School of Medicine. Further, participants who provide their contact information will do so via a separate survey link to ensure their contact information is collected and maintained separate from their survey data. We will ask demographic information, but these self-reported responses will be anonymized and paired with a random Study ID number. Responses will never be linked to any identifying information.

Local Focus Groups with Surveys- In addition to online focus groups and surveys, we will conduct traditional in-person focus groups with parents of children 9-14 years old living in New Hampshire and Vermont. This will enable us to validate the information received during the online focus groups and compare methodologies.

a) *Sample size and recruitment:* We will recruit through advertisements in New Hampshire and Vermont communities (see recruitment messaging), including but not limited to newspaper advertisements, social media advertisements, flyers in primary care/medical practices, announcements in community listservs, in-person recruitment at community venues, and bulletin board postings.

b) *Data collection methods:* Prospective participants may complete a telephone screening call and, if eligible, will receive a brief description of the study verbally from a CITI-trained research team member, and the participant will have the opportunity to ask questions. The eligibility screening will consist of the following questions:

   a. Are you a parent?
   b. Do you have at least one child between the ages of 9 and 14 years old?
   c. Are you a resident of New Hampshire or Vermont?

   At the time of the focus group, a consent form will be reviewed, participants will again have the opportunity to ask questions, and signatures will be obtained. See enclosed consent form.

   Focus groups are expected to take approximately 75 minutes (60-90 minutes) and will take place at local sites throughout New Hampshire and Vermont (e.g., at the YMCA, schools, libraries, community centers). We will recruit through advertisements in the communities (see recruitment messaging), including but not limited to newspaper advertisements, social media advertisements, flyers in primary care/medical practices, in-person recruitment at community venues, and bulletin board postings.

   Notes will be taken during the focus groups, and the sessions will be audio recorded; we may consider using a free or paid service for audio transcriptions.

   We will also ask participants to complete an anonymous survey to provide more of their attitudes and beliefs about the HPV vaccine in a more private way, as we have done with the online focus groups. We will use the same survey/questionnaire that we are using for the online focus groups' survey (previously approved by CPHS), with minor edits (see enclosed with tracked changes); depending on timing, we may reduce the number of questions presented in the survey.

At the end of the focus groups, we will also ask participants if they have interest in providing future input to the cancer center as part of the cancer center's Community Advisory Board and/or if they have an interest in being contacted about future research opportunities—including a follow-up survey about this project (Cohort 1). Information about the Community Advisory Board will be provided, and contact information will be obtained from anyone interested in learning more about the Community Advisory Board and/or research opportunities.

c) *Participant Compensation:* Participants will be compensated $20-$40 depending on the level of participation/time involved. Meals or snacks may also be provided.

d) Eligibility: Eligibility will be based on verbal screening of the following three questions:
    a. Are you a parent?
    b. Do you have at least one child between the ages of 9 and 14 years old?
    c. Are you a resident of New Hampshire or Vermont?

e) *Confidentiality & Protections:*
    a. *Administrative:* Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. Any data that are made publicly available will be presented in aggregate so that no one participant can be identified through the data. Additionally, participants will have the opportunity to use a pseudonym during the focus groups, and the transcript will not include any names; rather, we will refer to the participants more generally such as "Mother 1" and "Father 1."
    b. *Physical:* All paper records, such as signed consent forms, will be stored in a locked cabinet in a locked office at DHMC.
    c. *Technical:* Access to all electronic files will be limited to CITI-trained research team members. Audio recordings of the focus groups will be destroyed after transcription. Electronic data will be stored on secure servers housed at DHMC with appropriate backup and will be shared across the research team using the research team's password-protected SharePoint site hosted by Dartmouth.

2. **Online message testing (Phase 2) -** Once the list of strong candidate themes is finalized, we will test the effects of those theme-relevant messages/materials on changing knowledge, attitudes, beliefs, and behavioral intentions of parents of children 9-14 years old living in New Hampshire and Vermont; (parents of any age child are invited to complete the survey as well, excluding questions related to vaccination history and intention to vaccinate). The message testing phase will involve pre/post-test designs. Prior to the message-testing phase (Phase 2), if needed, we will conduct anonymous online pilot surveys through Qualtrics. Prior to the message testing, this pilot test is to check the validity of each message (e.g., ensuring that the stimulus materials -campaign messages- are presented and perceived by audiences as we intended for positive effects).
   To test the persuasion effects of candidate messages, we will measure an array of constructs in the pre-test stage (before exposure to materials/messages). A list of the candidate constructs that are critical in understanding message effectiveness include: prior knowledge, pre-existing attitudes, normative beliefs, response efficacy, and issue involvement. After finishing pre-test assessments, participants will be randomly assigned to one of the conditions and asked to read/review the stimulus material/message while experimentally controlling for high elaboration likelihood. After the message exposure step, participants will be asked to answer post-test survey measures, including: persuasiveness of the viewed message/material, attitude toward behavior promoted, response efficacy, behavioral intention, and normative belief assessment. A full list of finalized survey questionnaires and messages will be submitted in a future modification to this study, before the online message testing commences.

   a) *Sample size and recruitment:* We expect to test a finalized set of messages, up to approximately 40 messages, with up to 30 people evaluating each message; as such, we will recruit maximum 1,200 people to complete message testing via various media recruitment and platforms (including Amazon Mechanical Turk and social media advertisements). For message testing

experiments, we implement two different cohort studies (Cohort 2A and 2B in Figure 1). Additional people will be screened for eligibility.

Cohort Phase 1B: Previously IRB-approved Cohort 1B is no longer part of this study design. We did not have large enough sample size to conduct a time-lag follow-up study, thus this Cohort 1B is removed from the project.

Cohort Phase 2A: We use paid advertisements on social media and MTurk to recruit residents in VT and NH. An external link to Qualtrics surveys will be embedded in the ads and in the MTurk posting. The message testing study will be held on Qualtrics. We will measure same constructs and examine an identical set of candidate messages across two cohorts. This cohort will not have a time-lag between pre- and post-assessments.

Cohort Phase 2B: We will implement the same message testing study and recruit participants in the US via Mturk and social media advertisements (e.g., Facebook ads). MTurk is an online labor market with more than 500,000 active members where requesters distribute small tasks, and workers complete the tasks for compensation as low as 1 cent in US dollars. More than 345,000 tasks are available on MTurk to anonymous workers to complete. The cohort will be invited to the same message-testing experiments with identical pre- and post-assessments used in Cohort 1B and Cohort 2A. The data from this national pool of participants will be used as reference points. This cohort does not have a time-lag between pre- and post-assessments.

b) *Data collection methods*: After recruitment, we will screen participants for eligibility (criteria described below) with a Qualtrics-administered survey that asks the participant a series of questions that include the eligibility criteria as well as some dummy questions, to avoid deception on part of the prospective participant (see enclosed pre/post test survey). They will be asked to read the information sheet to proceed. Once they click the NEXT button to provide implicit consent to participate in the study, they will be asked to click on a link to the survey hosted on Qualtrics. They will be asked to answer pre-test questions. Cohort 1B will end survey and will be followed-up later for a random assignment for message exposure and post-assessments (for those who provide email address or MTurk worker ID number). After finishing pre-test, (without any time-lag), participants in Cohort 2A and 2B will be randomly assigned to one of the advertisement/message conditions in the following page. For message exposure, participants will be asked to carefully view the assigned message/material, and then answer a series of post-test questions. When participants finish the entire questionnaires, they will be debriefed and provided with useful resources about HPV. MTurk participants (Cohort 2B) will be asked to enter their worker ID (to verify their participation for compensation on Amazon Mechanical Turk). Eligible participants recruited from social media (Cohort 2A and 2B) who want to receive study compensation will have a chance to enter their contact email address for one of e-gift cards (to be sent to randomly selected participants). Eligible participants recruited from MTurk (Cohort 2A, and 2B) will be asked to provide their MTurk Worker ID number before being paid (amount described below). See enclosed document with examples of messages that participants could be exposed to/randomized to.

c) *Participant compensation:* Participants recruited from social media platforms (Cohort 2A and 2B) will have a chance to receive one of 50 e-gift cards worth up to $10. Participants recruited through MTurk will be compensated as MTurk workers using their worker ID numbers. We estimate the screening questionnaire to take approximately up to 5 minutes and will compensate

people up to $0.50 for completing the screener. We estimate the actual survey/message testing to take about 15 minutes per participant. For those recruited through MTurk, based on typical MTurk payment amounts and based on Dr. Kim's extensive experience with MTurk, we estimate each MTurk worker to receive up to $1.50 for 15 minutes of message testing. This payment amount is in-line with typical payment amounts expected on MTurk ($0.10/minute).

d) *Eligibility:* Participants must be parents with at least one child who is 9-14 year old child living in New Hampshire or Vermont to complete the entire survey as part of Cohort 2A and in the US for Cohort 2B (parents with any age children are invited to complete the survey, excluding questions related to vaccination history and intention to vaccinate their 9-14 year old child/ren). The survey will contain a set of screening questions (as described earlier) to determine eligibility; geographic eligibility will be determined based on self-reported zip code/state and geo-targeting tools available on social media platforms.

e) *Confidentiality and Protections:* Data will be collected online through Qualtrics. Any electronic data will be stored on password-protected computers and will only be viewable to CITI-trained research team members through Qualtrics portal and/or through this project's Dartmouth-hosted SharePoint site that is only accessible to the research team members via password. After data are no longer needed, they will be destroyed by the research team, and destruction will be confirmed by the information technology team at the Norris Cotton Cancer Center/Geisel School of Medicine. Further, participants will not be asked to reveal their names or social security numbers. We will ask demographic information, but these self-reported responses will be anonymized and paired with a random Study ID number. Responses will never be linked to any identifying information.

3. **Social media campaign (Phase 3):** The purpose of Phase 3 is to implement and evaluate an educational social media campaign for the public. Based on the results of Phase 1 and 2 studies to-date, we have identified a set of strong messages that improve parent attitudes and increase parents' intent to vaccinate their 9-14 year old child/ren for HPV. We will use these tested messages to launch a social media-based campaign via the Norris Cotton Cancer Center's Facebook page. We will deploy up to six campaign messages (see enclosed document with messages) to two groups of parents using Facebook's geo-targeting features, based on users' zip codes: 1) Parents in rural NH and VT and 2) Parents in urban NH and VT. We will measure each message's effectiveness by analyzing engagement data (provided by social media campaign metrics—all aggregate data with no individual identifiers), and attitudes and intent to vaccinate (to be assessed via online survey embedded in the social media campaign messages). See enclosed survey; parents with children of any age are invited to complete all questions except for questions related to their intention to vaccinate, which are limited to parents with 9-14 year old children. We will compare the differences between the two audience segments (rural vs. urban) and other subgroups that emerge from the data..

4. Analysis

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

1. **Online and local focus groups and message testing (Phases 1 & 2)-** Facebook comments, survey comments, and transcripts/audio files of the focus groups will be reviewed by the research team and coded for themes. We will also perform content and linguistic analyses. The self-reported survey measures will be examined for outliers and data skewness. Recording, transformation, or standardization will be made when necessary. We will conduct chi-square statistics for categorical variables and employ repeated GLM, ANOVA, ANCOVA, or regression statistics for continuous multivariate variables while controlling for relevant covariates. We will take structural equation modeling or path analyses to model persuasion pathways from message/ad exposure to changes in behavioral intentions to vaccinate. Based on persuasiveness scored rated for the HPV vaccine messages/ads, we will statistically test and select the

most highly-ranked messages/ads (best candidate messages/ads). These selected messages/ads will be used for the social media campaign.

2. **Social media campaign (Phase 3)-** We will measure message effectiveness by analyzing each message's effectiveness by assessing engagement data (provided by social media campaign metrics), and key constructs, including attitudes and intent to vaccinate (to be assessed via online survey embedded in the social media campaign messages).See enclosed survey; parents with children of any age are invited to complete all questions except for questions related to vaccination history and intention to vaccinate their 9-14 year old child/ren, which are limited to parents with 9-14 year old children. We will compare the differences between the two audience segments (rural vs. urban) or other subgroups of interest that emerge from the data. Although we do not solicit comments on Facebook, we expect that some Facebook users may leave comments/questions anyway; we will analyze the comments for themes and linguistic characteristics and compare between rural and urban audiences or by campaign themes (research team will de-identify all comments prior to analyses). .

5. Study Progress Monitoring

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

- data quality
- timelines
- recruitment and enrollment

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

The overall project timeline will be reviewed at our research team's weekly meetings, and adjustments will be made as needed to keep on schedule.

1. **Online focus groups/surveys (Phase 1)-** We will monitor the focus group comments under Facebook ads and review the number and themes of the comments in our research team's weekly meetings. Once we achieve either 2,000 comments or sufficient comments to identify strong candidate themes, we will discontinue online focus groups and proceed to message-testing. We will remove comments that are irrelevant or could be unpleasant or emotionally disturbing to others. We will also monitor survey recruitment in our weekly meetings and adjust Facebook ad budget (to increase visibility of the ad among Facebook users) and number of MTurk HIT postings as needed.

2. **Local focus groups/surveys (Phase 2)-** Our team will create a study timeline at the start of any participant recruitment, and we will review the study's progress/timeline at least biweekly. If we are struggling to recruit a sufficient number of participants, we will identify other communication channels to distribute the recruitment messaging.

3. **Online message testing (Phase 2)-** We will monitor the enrollment status on Amazon Mechanical Turk and social media (e.g., Twitter, Facebook), and open more HIT's (Human Intelligence Tasks on MTurk) or Ads (or increase the ad budget). During the data collection period, we will screen the collected data saved in the hosting survey server, and if data are missing at non-random (e.g., missing a whole block of measures), we will follow-up with the subject via Amazon Mechanical Turk, which does not reveal personal information of the individual, to see if s/he wants to drop from the study.

   We will compensate participants via the Amazon Mechanical Turk payment system daily. We will also monitor the recruitment status on MTurk while preventing duplicate participation. As needed, we will post additional ads on social media to help with recruitment and compensate participants who expressed their interest in receiving an e-gift card when the survey quota is met.

Social media campaign (Phase 3)- Our team will monitor the Facebook ads daily throughout the duration of the campaign; the daily monitoring will include an assessment of number of people reached by the ads, number of people completing the campaign evaluation survey, and number and content of comments left by Facebook users. Depending on the campaign reach and engagement, we will increase or decrease the amount of money allocated to each ad within Facebook. If a Facebook user leaves a comment or question on the ad, we will respond using the guidelines developed for our team (see enclosed document); the idea of generating user interaction guidelines was conceived by Dr. Kim as part of the research protocol section, and the guidelines were developed in consultation with the Marketing/Communications teams at Dartmouth-Hitchcock and at the Norris Cotton Cancer Center and have been developed using evidence-based information. Because the ads are being deployed using the Norris Cotton Cancer Center's Facebook page, the team will continue to consult with the Marketing/Communications teams as needed.

6. Risks & Benefits

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

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

The risks involved with this study are minimal, and there is no direct harm to the participants.
1. **Online and local focus groups and message testing (Phases 1 & 2)-** It is unlikely but possible that some of the HPV messages/materials could be emotionally disturbing or sensitive for some participants. However, the HPV messages/materials to be used in the current project are based on scientific fact and are designed to help participants consider vaccinating their children. Also, the level of risks in the messages/materials is not stronger than any vaccine messages/materials or Public Service Announcements (PSAs) participants may encounter in their everyday life. We will also put measures in place to minimize any potential privacy or confidentiality issues, as described in the sections below.
2. **Social media campaign (Phase 3)-** It is unlikely but possible that some of the HPV messages/materials could be emotionally disturbing or sensitive for some participants. However, the messages we are using in Phase 3 have already been tested using a national sample of parents (Phase 2) and found to improve their attitudes toward HPV vaccination, as well as increase their intention to vaccinate their children (if they have children 9-14 years old). Also, the level of risks in the messages/materials is not any stronger than any vaccine messages/materials or Public Service Announcements (PSAs) participants may encounter in their everyday life. Therefore, we feel the risks to viewers of the ads are fairly low. We have also developed guidelines for our team to follow in handling comments and questions from Facebook users. See enclosed guidelines.

We will also put measures in place to minimize any potential privacy or confidentiality issues (private/confidential survey), as described in the sections below.

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

We will take steps to minimize the likelihood of risk to human subjects in all activities and to ensure that any potential risks are offset by the potential gains, both for participants themselves and for the population more broadly. We will ensure that all individuals are able to provide voluntary informed consent prior to participating in survey data collection and that all data collected are stored securely with a restricted access, thereby minimizing risks to the privacy of individuals.

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

Participants will learn about the benefits of HPV vaccination, which is a method of preventing certain types of cancer. The knowledge gained from this study will also be disseminated to local and regional partners (e.g., health departments, non-profits) to build collaborations and to guide work to improve HPV vaccination rates, which will help decrease cancer incidence.

7. Unexpected Events or Incidental Findings

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

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

Describe potential events and provide a plan of action:

1. **Online and local focus groups and message testing (Phases 1 & 2)-** It is possible that some messages or comments will have the unintended effects in some audiences (e.g., vaccine-hesitant parents may be even less trusting of the HPV vaccine after viewing other messages or comments). We will debrief parents by providing them with links and/or handouts to learn more about the HPV vaccination (e.g., through the Centers for Disease Control and Prevention or the American Cancer Society) and will suggest that they talk further with their child's physician.
2. **Social media campaign (Phase 3)-** The messages we are using in Phase 3 have already been tested in a national sample of parents and found to improve their attitudes toward HPV vaccination, as well as increase their intention to vaccinate their children (if they have children 9-14 years old). The evaluation survey will include 'debriefing' at the end, including links where they can go to find scientifically-based information about HPV vaccination (e.g., CDC). While we are not soliciting Facebook users to leave any comments or questions on the ad, we expect that some Facebook users will leave comments and questions anyway. If a Facebook user leaves a comment or question, we will respond using the guidelines developed for our team; the idea of generating user interaction guidelines was conceived by Dr. Kim as part of the research protocol section, and the guidelines were developed in consultation with the Marketing/Communications teams at Dartmouth-Hitchcock and at the Norris Cotton Cancer Center.

8. Deception

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

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

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

N/A

9. Equitable Participant Selection

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

1. Online focus groups and survey (Phase 1)- We will seek up to 2,000 comments from parents (which could come from up to 2,000 parents) to identify salient themes for the top 40 candidate messages/materials for online message testing. We are seeking 200-300 pre-survey completions, with 200 people providing contact information for follow-up survey.

2. Local focus groups and survey (Phase 1)- We plan to conduct up to ten focus groups in all- up to five in rural communities and up to five in urban communities of New Hampshire and Vermont. We aim to have 8-12 participants in each group for ideal discussion facilitation. We will need to screen additional people for eligibility.
3. Online message testing (Phase 2)- We will enroll up to 1200 parents in the message testing (40 messages, 30 parents each). However, to achieve this, we expect that we may need to screen 2000+ parents.
4. Social media campaign (Phase 3)- The number of people who view the ads is difficult to estimate because of Facebook's algorithm in displaying ads to users. We would expect the ads to be displayed to tens of thousands of people throughout New Hampshire and Vermont, covering more than 75% of the target audience in the two states. For the evaluation survey, we will enroll everyone who is eligible and who consents to complete the survey, without setting an upper limit.

b. Provide a justification of the proposed sample size

1. Online focus groups (Phase 1)- Given the possible number of messages to present to parents and the possible themes than may emerge in the comments, we feel up to 2,000 comments may be necessary to identify common themes in the comments.
2. Local focus groups (Phase 1)- In our experience, 8-12 people per group is reasonable to facilitate and meaningful for discussion. Given the different themes we are exploring, we expect that we may need as many as ten focus groups- five in rural areas and five in urban areas. **3. Online message testing (Phase 2)-** We expect to evaluate a finalized set of up to 40 messages/materials. Based on our Co-PI's experience (Sunny Kim), we need at least 30 people to evaluate each message in order to determine its persuasiveness. Further, based on her experience, we also expect that about 40% of people screened will be eligible for the study, so we expect to screen at least 2000 people.
4. Social media campaign (Phase 3)- Our primary goal with the social media campaign is educating parents on this topic. As such, we are hoping to get as large of a reach as feasible across the Norris Cotton Cancer Center's catchment area of Vermont and New Hampshire. Because we are evaluating the effectiveness and acceptability of the campaign in a 'real world' setting across six messages and two sets of audiences, we are not setting an upper limit for the number of people who enroll and consent to complete the evaluation survey. Based on our experience with similar surveys, however, we do not expect more than 2,000 people to complete the survey.

c. Define the target population:

1. **Online focus groups/surveys (Phase 1)-** We will geo-target the Facebook ads to recruit from predominantly-rural ZIP codes and predominantly-urban ZIP codes (as defined by Rural-Urban Commuting Area (RUCA) Codes). Anyone viewing the ad will be eligible to leave comments. Those people interested in answering the private survey will need to confirm their ZIP code and that they have a child 9-14 years old for inclusion, as eligibility will be limited to parents with children 9-14 years old living in New Hampshire or Vermont.
2. **Local focus groups/surveys (Phase 1)-** Using the same RUCA definition as described above, we will identify several rural and urban communities in NH and VT for hosting the focus groups and recruiting the participants. Participants need to be parents of 9-14 year old children and live in VT or NH. We will screen prospective participants before the focus groups, asking:

Are you a parent?
Do you have at least one child between the ages of 9 and 14 years old?
Are you a resident of New Hampshire or Vermont?

2. **Online message testing (Phase 2)-** Participants must be parents with at least one child between the ages of 9-14 years old to complete all questions. They will be recruited from social media ads by targeting residents of NH or VT for eligibility (as determined by zip code), or via MTurk workers registered as parents in the US. For social media recruitment, we will only target our ads for

residents of New Hampshire and Vermont and will use Facebook ad targeting to target parents. The survey team will use a screening questionnaire to ensure eligibility (e.g., parents of 9-14 year-olds) for the full survey (parents of other age children are invited to complete the survey, with an exception of questions related to vaccination history and intent to vaccinate their 9-14 year old child/ren)
3. **Social media campaign (Phase 3)-** We will use Facebook's advertising targeting to display the campaign ads to two groups: 1) Parents living in rural areas of NH and VT and 2) Parents living in urban areas of NH and VT. Parents of 9-14 year old children will be invited to complete the entire evaluation survey (including questions about vaccination history and intention to vaccinate their 9-14 year old child/ren), and parents of any age child will be invited to complete most of the survey (including attitude questions but excluding vaccination history and intention to vaccinate 9-14 year old child/ren).

d. Vulnerable populations

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

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

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

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

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

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

N/A

10. Recruitment

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

1. **Online focus groups/survey and message testing (Phases 1 & 2) -** Participants will be recruited from Amazon Mechanical Turk and social media platforms such as Facebook and Twitter to discuss the topics and to evaluate messages/ads. See enclosed recruitment messaging.
2. **Social media campaign (Phase 3)-** Ads, messaging content, and/or posts will be presented to social media (e.g., Facebook) users. Those users who click on the content for more information will be invited to participate in the evaluation survey (same process as used during Phase 2). We are not soliciting Facebook comments but some Facebook users may leave comments anyway..

11. Informed Consent, Assent, and Authorization

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

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

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

1. **Online focus groups and survey (Phase 1)-** For the Facebook ad comments-based online discussions, the comments are publicly-available and, thus, no information sheet will be presented; rather, viewers of the ad will receive a disclaimer that their comments are publicly-available and readily viewable (see recruitment messaging enclosed). The disclaimer will explain that their comments will be used for us to learn about important themes for campaign development but without using any of their Facebook profile information (i.e., their publicly shared comments will remain not-identifiable). For the participants who want to further participate in the survey (either from Facebook or from MTurk), the information sheet will be displayed on the external survey page (on the first page of the Qualtrics survey). Participants who want to participate in the online survey will be asked to carefully read the overview of the study described in the information sheet before answering survey questions and click "NEXT" to complete the implicit consent process. See enclosed information sheet and waiver for documentation of signature.
2. **Local focus groups and survey (Phase 1)-** Focus group participants who pass the telephone screening and meet eligibility criteria will receive a brief description of the study verbally from a CITI-trained research team member, and the participant will have the opportunity to ask questions. At the time of the focus group, a consent form will be reviewed, participants will again have the opportunity to ask questions, and signatures will be obtained. See enclosed consent form.
3. **Online message testing (Phase 2) -** The information sheet will be displayed on the first page of the online survey implemented on Qualtrics (for participants recruited from MTurk and social media) before the web-based survey starts. Participants who want to participate in the study will be asked to carefully read the overview of the study described in the information sheet (provide their anonymous MTurk worker ID for MTurk workers), and click "NEXT" to complete the implicit consent process. See enclosed information sheet.
4. **Social media campaign (Phase 3)-** Social media users who click on the ad will be presented with an opportunity to participate in the evaluation survey. The information sheet will be displayed on the first page of the online survey implemented on Qualtrics before the web-based survey starts. Participants who want to participate in the study will be asked to carefully read the overview of the study described in the information sheet and click "NEXT" to complete the implicit consent process. See enclosed information sheet (which is slightly modified from the previously approved information sheet used in Phase 2). Because the ads offer a platform where users can leave comments and interact with others, some users may leave comments; we will provide a similar disclaimer to what we used during Phase 1 (previously approved by IRB; only edit is addition of Virginia Commonwealth University to the text). The disclaimer will be part of the ad, the first comment under the ad, or the 2nd image in the carousel ad setting for high visibility. The disclaimer text will read:

    a) "Please Note: Regarding comments on this post, researchers at Dartmouth College and Virginia Commonwealth University will use your comments below for RESEARCH purposes to learn about people's views on the HPV vaccine. Leaving comments and participating is completely voluntary, and we will NOT collect your name or any other identifying information. Please note: your comments on this post may be publicly available.

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

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

12. Compensation or Gifts

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

1. **Online focus groups/survey (Phase 1) -** Participants who click on the link in the Facebook Ad (to then go to the Qualtrics survey) will be eligible to enter a drawing for up to 120, $5 gift cards/online gift codes (up to 10, $5 gift cards/codes per ad x 12 ads).
2. **Local focus groups/surveys (Phase 1)-** Focus group participants will receive up to $40 cash, depending on the level of participation/time involved (range of $20-40). Meals or snacks may also be provided during the focus groups.
3. **Online message testing (Phase 2)-** MTurk workers who complete the screening questionnaire will be paid up to $0.50 for their time, which is in-line with typical payment amounts on MTurk (~$0.10/minute). MTurk workers who then complete the message testing/survey will be paid up to $1.50 for their time (about 15 minutes, $0.10/minute). Participants recruited from social media platforms will have a chance to receive one of 50 e-gift cards worth up to $10.
4. **Social media campaign (Phase 3)-** People who complete the survey will have a chance to receive one of 100 e-gift cards worth up to $10.

13. Privacy of Participants

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

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

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

1. **Online focus groups/surveys (Phase 1)-** Social media platforms (e.g., Twitter, Facebook) will be used to recruit for the online focus groups. People may leave comments to participate in publicly open discussions on Facebook Ads. For further participation, a link to the online survey will be embedded in the Facebook Ads for those who want to take part in our online survey through Qualtrics. Online survey participants will not be asked to reveal their names or social security numbers. Only emails will be requested for e-card drawing purposes. The email addresses will be collected through a separate Qualtrics survey link and will be managed and stored separately from the study data.
2. **Local focus groups/surveys (Phase 1)-** Participants will provide their names but not social security numbers. Focus groups will be audio recorded. Focus groups participants will be asked to only use their first name and will be offered the opportunity to use a pseudonym to further protect their privacy if they would like. Audio recordings will be transcribed and any identifying information will not be included in the transcripts or in any presentations or publications. Audio recordings will be destroyed after

transcription. All records will be kept in locked file cabinets at DHMC, on password-protected computers, and on the research team's password-protected Dartmouth Sharepoint site.

3. **Online message testing (Phase 2)-** MTurk and social media platforms will be used to recruit for the message testing. Participants will not be asked to reveal their names, social security numbers, or any other identification information. We will ask demographic information, their attitudes, risk perception, issue involvement, and other constructs related to HPV vaccination in the survey. In order to protect the privacy of participants, these self-reported responses will be anonymized. Only emails will be requested for prize drawing purposes (from social media users) and they will be obtained, managed, and stored separately from the study data.
4. **Social media campaign (Phase 3)-** Social media ad services don't provide individual personal information but provide summary of data metrics reporting how many people were reached through ads and demographic features (e.g., gender, age group), and number of clicks. People who click on the ad for more information, consent to participate in the survey, and complete the survey will be offered the opportunity to enter a prize drawing by providing their email address (no other identifying information will be collected); all email addresses will be stripped from the data prior to analyses and won't be used for research purposes. Any comments left by Facebook users will also be de-identified by the research team before analyses, and no direct quotes will be used for research purposes.

14. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

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

☒ **No** ☐ **Yes**

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

N/A

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

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

Administrative: Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. All data collected under this application will be collected electronically via Qualtrics/MTurk and social media platforms or as hard-copies in locked filing cabinets. Participants will not be asked to provide their names or social security numbers. Only social media users will be asked for their email addresses for purposes of the gift card drawing and follow-up, and the emails will be collected, handled and stored separately from the study data during Phase 2. During Phase 3, emails will be collected in the same survey for participant ease and to minimize technical errors experienced by users in the past; the email information will be stripped from the data before analyses and won't be used for research purposes. The names/contact information will not be used in any publications or papers about this study and

will only be viewable by authorized, CITI-trained research team members. Further, we are applying to waive the documented signature on the consent form, as that is the only identifying information for parents (e.g., MTurk, social media).

Physical: Any paper copies of the data will be kept in locked filing cabinets at Dartmouth-Hitchcock Medical Center and/or Geisel School of Medicine offices at Centerra.

Technical: All electronic data will be password-protected through Qualtrics, MTurk, social media, and/or the research team's Sharepoint site (administered by Dartmouth College). Only research team members will be able to access these data. Further, electronic files will be saved on password-protected computers.

Please note: One of our research team members—Dr. Sun Jung ("Sunny") Kim no longer works at Dartmouth and is now at Virginia Commonwealth University (VCU). Sunny plans to remain engaged with this project, and Dartmouth has a sub-contract in place with VCU to compensate them for her time. We have an established reliance agreement with VCU. We will follow the steps outlined by CPHS in the "Responsibilities and Communications Plan" document.

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

Data will be maintained by the Dartmouth research team members. After data are no longer needed, they will be destroyed by the research team and destruction will be confirmed by the information technology team at the Norris Cotton Cancer Center/Geisel School of Medicine.