University of Florida IRB-02
Protocol Template Guidelines

The “protocol” is similar in form to a brief research proposal. It should be as concise as possible. It should, however, contain all information relevant to the proposed research project not specifically covered in the SmartForms. (Not every item will be relevant for every project, of course, and you may limit responses as appropriate in such cases, but if you’re uncertain as to what to include, be “inclusive” as that makes it less likely we’ll have requests for additional information.)

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1. Background:

- **Colorectal cancer (CRC)** accounts for about 8% of new cancer cases in the US.[1] Alcohol and red/processed meat consumption are two diet-related risk factors for CRC.[2–4] Evaluating nutritional status is considered a key component of the patient care process[5] and when done effectively can help patients understand what foods increase CRC risk. Informing patients of personal nutrition risk factors for CRC may also help to stimulate accurate CRC risk perceptions and facilitate CRC prevention behaviors including screening. For some populations, including rural adults, technology can help address factors that contribute to CRC disparities such as low screening rates, poor diet, low literacy, and limited access to healthcare.

- Innovative technology can facilitate communication of dietary risk factors in a medical setting, which is often difficult due to measurement challenges and barriers related to patient and provider characteristics. Physicians own interest in nutrition, hours of nutrition education received, and personal fruit and vegetable intake impact frequency of nutrition counseling with patients.[7,8] **Virtual heath assistants (VHAs)** are human-like avatars that talk to and collect information from users in a web-based setting. There is growing evidence that using VHAs can facilitate discussions of stigmatized health information,[9] offer advantages over traditional patient-provider settings,[10] and integrate into existing healthcare systems.[11] Furthermore, racial minorities and rural adults can benefit from innovative nutrition interventions for CRC prevention as they experience poorer adherence to dietary guidelines,[12] higher incidence, morbidity, and mortality from CRC, and lower rates of screening compared to others.[13,14] Thus, a strategic nutrition communication intervention using VHT is a promising approach for enhancing nutrition communication for CRC prevention.

- This proposal is a subproject of a currently approved study (PI, Dr. Janice Krieger), titled “A Patient-centered Intervention Using Technology to Reduce Colorectal Cancer Disparities in Primary Care” (1R01CA207689-01A1) (IRB#201702765 and IRB#201601642). The goal of the parent project is to test the efficacy of a patient-centered, tailored message intervention for increasing CRC screening among racial minorities and rural patients. Given the challenges of discussing nutritional risk in a clinical setting, the objective of this proposed subproject is to test if tailored nutrition-risk information delivered in a web-based platform increases perceptions of CRC risk and CRC prevention behaviors.

2. Specific Aims:

- The goal of this proposed project is to adapt an existing CRC screening intervention to include a nutrition module that engages users with information about alcohol and red/processed meat consumption, and delivers tailored nutrition-risk messages to enhance CRC prevention outcomes.

- The objective of this proposed project is to pilot test the adapted VHT-delivered, tailored, nutrition-risk module to investigate mechanisms of efficacy for the adapted intervention including establishing preliminary estimates for CRC risk perceptions and CRC prevention behaviors. This information will be used to inform a larger trial.

- The hypothesis is reporting dietary intake and receiving personalized nutrition-risk factors for CRC via a VHA will increase perceptions of CRC risk, CRC screening intentions, and information seeking behaviors (e.g. reducing alcohol, red/processed meat, how to order at home screening kit).

- **Aim 1:** Modify an existing CRC intervention with a nutrition module where VHAs collect dietary intake information and give tailored visual feedback on nutrition risk factors for CRC**.** To increase patient engagement with nutrition-risk messages delivered in a virtual setting, we must first understand beliefs, experiences, and evaluations of nutrition-risk communication. We will engage in a cultural adaptation of an interactive nutrition module delivered by virtual health assistants (VHAs) to ensure acceptable social reactions to reporting dietary intake of alcohol and red/processed meat and receiving personalized feedback in the virtual setting. We will also conduct content adaptation of the module (tailoring language, visuals, and examples of food items).

- **Aim 2:** Pilot test the VHA intervention to assess if the tailored nutrition module increases (2a) accurate risk perceptions for CRC (2b) intentions to screen for CRC (2c) and information seeking behaviors (e.g. how to reduce alcohol and red/processed meat intake, how to order home screening kit).

3. Research Plan / Study Description:

Aim 1

Eligibility Criteria:

- Eligible adults will be between 50-73 years old, proficient in English and geographically rural areas of north central Florida. We will enroll black, white, male and female participants.

Focus Group Structure:

- Adults at risk for CRC will participate in focus groups with an estimated 6 groups comprised of approximately 6 people. (N=36)
- Focus groups will be conducted via an iterative cycle of adaptation based on participant feedback:

  -Cycle 1: FG 1 and 2 use storyboard exercise and discussion to inform initial content and message preferences for nutrition module→ PI meet with graphic designer/VH team to develop initial prototype

  -Cycle 2: FG 3 and 4 comment on developed first round stimuli from graphic designer/first prototype of module → PI meet with graphic designer/VH team to modify module

  -Cycle 3: FG 5 and 6 comment on module version 2→ PI meet with graphic designer/VH team to update

- Focus groups will take place in the community at an accessible location, take approximately two hours, and will be video and audio-recorded.
- Due to Covid-19, as of Fall 2020 we will be conducting focus groups via zoom.
- Trained researchers will conduct the focus groups using a semi-structured guide based on the Cultural Sensitivity Model (Resnicow, 2000).
- Participants will answer questions to inform acceptability of messages and graphics to be delivered in the virtual setting related to CRC risk. Participant responses will help adapt the VHT nutrition module for cultural appropriateness, content, and framing of nutrition communication.
- A questionnaire assessing participant characteristics, perceptions, and behaviors will also be administered.

Individual Think-aloud Interview Structure:

- A usability test of the nutrition module will be achieved by conducting individual, in audio and video-recorded think-aloud interviews (N=12) rooted in user-centered design principles.
- Due to Covid-19, as of Fall 2020 we will be conducting interviews via zoom.
- Think-aloud interviews will continue using the iterative process:

  -Cycle 4: TA 1-4 conducted on module version 3 → PI review data, make decision about content/functionality, etc., and continue agile design method as needed through TA 5-8 and TA 9-12

- Interviews will take place remotely, via zoom, take approximately one hour, and will be video and audio-recorded.
- Facilitated by trained researchers, participants will test the VHA delivered intervention on a web-enabled device and will be encouraged to verbalize thoughts, questions, opinions and concerns about the module.

- Results from think-aloud interviews will inform final adaptations needed for the nutrition module prior to pilot-testing.
- A questionnaire assessing participant characteristics, perceptions, and behaviors will be administered.

Data and analysis

- Focus group and interview data will be transcribed verbatim using secured transcription service DataGain, Inc. (reviewed by UF Integrated Risk Management and classified as low risk) and managed with qualitative data management software. The PI and trained members of the research team will analyze qualitative data using a constant comparative method and iterative process throughout data collection phase.
- Transcripts will be analyzed for a priori and emergent themes relevant to nutrition module adaptations needed including but not limited to a) surface culture adaptations, b) deep culture adaptations c) cognitive adaptations d) affective-motivational adaptations.
- Questionnaire data will be analyzed to summarize participant characteristics, perceptions, and behaviors. We will conduct descriptive statistics (e.g. Means, SDs) using quantitative data analysis software.
- A member of the research team will store electronic data files (i.e. transcripts, audio and video files, data spreadsheets) on a password protected and encrypted server.

Aim 2

Eligibility Criteria:

- Eligible rural (based on zip code) adults will be between age 45-73 years old, residents, who have not had CRC and who have not obtained CRC screening based on guidelines (i.e. <10 years for colonoscopy, <1 year for stool test, < 5 years for sigmoidoscopy). Participants should also answer "yes" to the question, do you have health insurance? We will enroll equal proportions of black, white, male and female participants.

Pilot Test Structure:

- We will enroll participants using Qualtrics Panels. Qualtrics Panels consist of U.S. adults who have agreed to participate in web administered surveys.
- We will pilot-test the module using a 3-group randomized design with 30 participants per group. Participants will be randomized to one of three groups: 1) high interactive VHA administered nutrition module, 2) low interactive VHA module, or 3) attention control module. Each module will be approximately 5-10 minutes.
- For group 1, the VHA will interactively collect nutrition information (alcohol, red meat, and processed meat intake) and report risk information back to users in visual and audio format. Group 2, will complete the current intervention module that includes items assessing alcohol and meat intake.

This module is consistent with Dr. Krieger's ongoing clinical trial work. Groups 1 and 2 will receive CRC prevention messages including information about how to use a home FIT screening test (delivered by the VHA).

- Group 3, the attention control group, will complete a non-CRC related module (e.g. recycling).
- All groups will complete a questionnaire assessing outcomes of interest and participant characteristics.
- All participants will access the intervention using an electronic link sent to them via email.
- Participants will have option to receive additional information (see outcome 3 below). Those participants will be directed to evidence-based cancer prevention resources housed on the secure web platform Wix.com.

Data and analysis:

- We will assess three main outcomes variables:
- **(1)** Accurate risk perceptions for CRC (e.g. items measured on a 7-point Likert scale, "My chance of getting CRC are high", "FIT screening decreases my chances of dying from cancer").[30]
- **(2)** Intentions to screen for CRC (e.g. items measured on a 7-point Likert scale "I want to get screened for colon cancer" or "I will talk to my doctor about colon cancer screening with FIT").[31]
- **(3)** Information-seeking behavior (e.g. assessed via clicks on links regarding "reducing alcohol/meat consumption", "how to order a FIT kit" (for intervention groups) or "tips for recycling" (for attention control group). We will use the Qualtrics "event tracking" feature to track clicks (yes/no).
- For outcomes (1) and (2) we will conduct one-way ANOVAS or Kruskal-Wallis test on the difference between baseline and post-test to obtain estimates to inform the larger trial.
- For outcome (3) we will use Pearson's chi-square test or Fisher exact test.
- Sample size was determined using a stepped rule of thumb based on an expected small effect size and 90% power for the future trial (Bell, Whitehead, & Julious, 2018). Based on this approach, if we expect a small effect size (.1-.3) at 90% power (for the larger trial) the pilot would require n=25 per arm to obtain estimates to inform larger trials sample size. Thus, n=30 per arm (N =90) is expected to give appropriate estimates to inform the larger trial.
- Data will be de-identified, stored with participant IDs on UF secure server accessible from PI's password protected computer, and analyzed using quantitative data analysis software for, preliminary estimates to plan a larger trial (e.g. confidence interval estimates, recruitment/response rates) and descriptive statistics to describe participant characteristics.
- Descriptive statistics will be calculated for all variables including mean, standard deviation, median, inter-quartile range, minimum and maximum for

continuous variables and frequency and proportion for categorical variables. Graphical illustration will be provided if applicable.

- Data analytics obtained from wix.com will be reviewed to understand use. Descriptive statistics on resources clicked and time spent on the site will be calculated.

4. Possible Discomforts and Risks:

- There are no potential risks of physical, psychological or economic harm associated with participant in this study.

5. Possible Benefits:

- While no direct benefits are expected, participants may benefit from learning about their health and ways to engage in health prevention behaviors relevant to nutrition and cancer screening.

- The risks to subjects are reasonable in relation to the anticipated benefits due to the importance of the knowledge that will be gained from this research to benefit future populations.

6. Conflict of Interest:

- There are no real or potential conflicts of interest with any investigators with regard to this specific research project.