Study Title:	**Advancing People of Color in Clinical Trials Now Using a Patient Centered Website: A Community-Engaged Approach (ACTNOW)**
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PROTOCOL Title: Advancing People of Color in Clinical Trials Now Using a Patient Centered Website: A Community-Engaged Approach (ACTNow) (S17-00170)

1. BACKGROUND AND SIGNIFICANCE

Compelling evidence demonstrates racial/ethnic disparities in health and healthcare in the United States.[1-4] These disparities arise from various factors including unequal access to adequate medical care, perceived racial discrimination, and poor health literacy.[1-4] The Center for Healthful Behavior Change (CHBC) has been involved in numerous initiatives to eradicate health disparities and have implemented NIH-funded interventions to address inequities in health. While our initiatives to reduce disparities have been successful, interventions targeting patient-centered outcomes have been suboptimal because of inadequate infrastructure to support equitable contributions from stakeholders (patients, providers, and community leaders) in all aspects of the research process. This is crucial to promote sustainable effects regarding minority patients' ability to make informed decisions about participating in existing clinical trials. This study will address this gap, bringing together academic investigators and important stakeholders to develop a website providing access to culturally tailored videos to enhance awareness of clinical trial, health literacy, thus promoting participation in existing clinical trials.

Supporting Evidence and Purpose of the Study

Minorities are under-represented in clinical trials, therefore limiting the evidence base for what works and does not work for racial/ethnic minority and health disparity populations. A systematic review of the factors influencing minorities participation in clinical trials revealed that though medical mistrust is often cited as a barrier to participation, other barriers such as poor understanding of clinical trials, low health literacy, pre-existing disease co-morbidities resulting in study exclusion, structural barriers related to access, and social barriers such as lack of social support have also been cited as barriers for racial/ethnic minorities.[5-6] Health literacy levels are lower among members of racial/ethnic minority groups and individuals with lower levels of educational attainment, traits are also linked with very low clinical trial participation.[7-8] The proposed pilot study will address associations of poor health literacy with low participation among racial/ethnic minorities in clinical trials and will ascertain effects of a culturally-tailored clinical trial literacy website on increased likelihood of participation in existing clinical trials.

Objective 1: To evaluate the comparative effectiveness of patient-centered messages to enhance clinical trial participation, through a culturally tailored website, accessed using iPads, versus NYU's standard clinical trial participation website.

Hypothesis 1: Participants exposed to tailored messages about clinical trial literacy will exhibit greater likelihood in participating in clinical trials than those exposed to NYU's standard website.

Objective 2: To determine whether psychosocial factors (awareness of clinical trial, intrinsic motivation, health literacy, and self-efficacy) and medical factors (risk behavior, history of preventive behavior, and clinical diagnoses) mediate greater likelihood of participating in clinical trials among individuals exposed to the intervention.

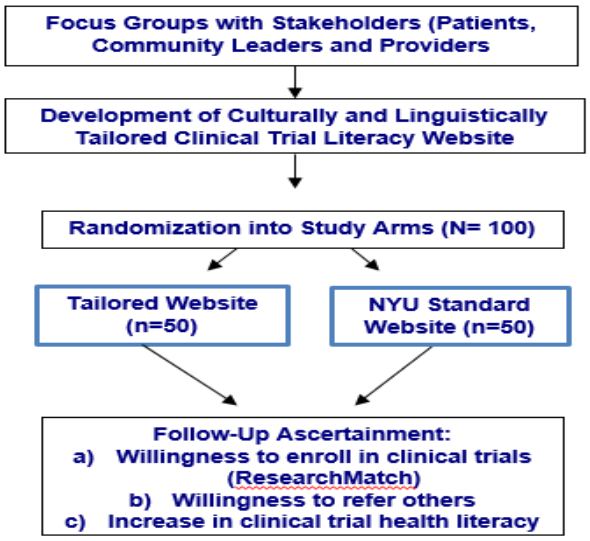
Hypothesis 2: Greater likelihood of participating in clinical trials will be mediated by greater health literacy and self-efficacy independent of other individual-level factors (medical, knowledge, attitude/beliefs, and intrinsic motivation) and contextual-level factors (social support and socio-economic position).

Study Design

Objective 1: To evaluate the comparative effectiveness of a culturally and linguistically tailored clinical trial literacy website in increasing likelihood of participating in clinical trials. To achieve this objective, we will use a randomized group design, assessing the following patient-centered outcomes: willingness to enroll in clinical trials and behavioral intent as well as likelihood of referring others to enroll in such trials) before and after exposure to a culturally-tailored clinical trial literacy website. Health literacy will be measured both before and post exposure to tailored messages.

Participants will be randomized into two groups. The intervention group (n=50) will have access to culturally tailored website. Participants in the control group (n=50) will have access to NYU 's standard trial participation website.

Study Flowchart



***Flow chart for participants in the ACTNOW trial; focus group data will be derived from previous RCTs.**

ACTNOW Project Timeline	Year 1		Year 2	
Tasks	**1-3**	**4-12**	**1-6**	**7-12**
Train Staff & Formalize Procedures	■			
Engage the CAB	■	■	■	■
Heuristic Testing and Endorsement		■		
Recruitment/Data collection		■	■	
Intervention/Follow-Up Assessment		■	■	
Information Diffusion		■		■
Data Entry/Analysis		■	■	■
Report Writing/Dissemination				■

The ACTNOW conceptual framework was developed according to best practices and recommendations from the NIH Behavior Change Consortium (BCC) and was informed by CONSORT statements. Adherence to these recommendations ensures program implementation fidelity, thus enhancing the internal validity and generalizability of its findings. During the formative period, we will refine our strategies to ensure that all components are feasible and acceptable to potential participants and stakeholders (patients, leaders, and providers) comprising the Community Advisory Board. We will assemble and meet with a Community Advisory Board to seek endorsement of our implementation plan. We will also meet with leaders in representative communities to discuss plans for participant selection and enrollment to achieve our study objectives.

Study Duration

We estimate 4 months to assemble the Community Advisory Board, building consensus for project aims and materials, contracting all enrollment sites, and recruit participants. We estimate 3 months for initial meetings with stakeholders to discuss and endorse the implementation plan (Phase 1); 6 months for development and heuristic testing of the tailored website (Phase 2); 9 months for data collection and analysis in Phase 3, and 6 months for debriefing at the end of Year 2 and optimizing the website before dissemination (Phase 4).

II. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

1. Recruitment

We will use several recruitment strategies. First, we will utilize a recruitment funnel that we have developed from several studies (MetSo: IRB#S13-00897, Grant# NCT01946659; Multi-Site: IRB# v i13-00182, Grant# R01 HL095799-01A2; PEERS-ED: IRB# i14-01028, Grant# 5R01MD007716-02).

During the consent phase, all participants in these IRB approved studies are asked if they would like to be contacted for future studies. We have a recruitment pool of approximately 400 participants (who have completed studies) from which to draw upon who meet the eligibility criteria and who indicated that they would like to be contacted for future studies.

In addition, we will also obtain participants from research match, an online tool used to bridge individuals who are seeking out research studies and researchers who are looking for participants. Participants will be contacted via phone to ascertain their level of interest and eligibility. If participants express interest, they will be invited to come to our project office. Then, a member of the research team will provide detailed information about the study protocol, and read the consent form. Participants will have time to answer questions. No study procedures are conducted without written consent.

Second, in addition to this existing pool of potential participants, others will be recruited who meet the study criteria through community steering committee members, health fairs, and community events. At this time, recruitment will be conducted on site at the requisite health fair or community event. Study fliers will be available for participants who are interested in the study. Participants will have the opportunity to ask the study personnel questions about the study. Those who express interest will be scheduled for an enrollment session to join the study at the Center for Healthful Behavior Change to begin the enrollment process.

For the eligible participants contacted via telephone, the trained research assistant placing these calls will 1) provide detailed information about the study protocol 2) discuss requirements and expectations of participants, and 3) ascertain interest in moving forward with the study. Participants who are interested will be scheduled into an enrollment session. Participants will have time over the phone with the trained research assistant, and also during their assigned enrollment session, to answer questions of the investigative team.

Study Intervention
Participants randomized to the intervention arm will have free access to a password protected interactive culturally and linguistically tailored website via a tablet device. No private identifiable data about you will be collected. Participants will receive a brief 10-

minute tutorial by a trained research assistant on login procedures and use of the website.

Control Condition
Participants randomized to the control condition will have free access to the NYU standard clinical trials website. Currently, there is no specific comparative effectiveness data evidencing superiority of any website or other format for increasing clinical trials literacy. Furthermore, there has been previous research to suggest the overall difficulty that patients have in using generic, versus tailored clinical trial materials. This, our study will ascertain effectiveness of a tailored website compared to the standard website. Participants in the control condition will have access to the tailored website at the date of study completion (no later than 6 months' post-date of enrollment).

2. Process of Consent
We will explain to participants that the purpose of the study is to understand barriers pertaining to why blacks do not participate in clinical trials, assess their willingness to enroll in clinical trials, and ascertain whether or not they will refer others to participate in such trials. We will obtain participants consent to audio-record the debriefing session. The screening team will comprise ethnically concordant investigator: Dr. Jean-Louis. All participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such action will in no way affect their future interactions with their health care provider, or with New York University Medical Center. To ensure confidentiality, data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a locked drawer that only the study investigators will have access to.

3. Number of subjects.
The proposed study expects to recruit a total of 100 participants from all recruitment strategies over a period of 9 months.

4. Gender of Subjects.
The study will include black men and women

5. Age of Subjects.
The sample frame will include black men and women 18 years old and older.

6. Racial and Ethnic Origin.
Our emphasis on blacks is justified by the low participation in clinical trials in this group.

7. Inclusion Criteria.
Self-reported race/ethnicity as African American, African, Caribbean American or black men and women; ages ≥18 years; accessible by telephone; no plans to move away from the region within the year following enrollment; consent to participate.

8. Exclusion Criteria.

Progressive medical illness in which disability or death is expected within one year; impaired cognitive or functional ability, which would preclude meaningful participation in the study; stated intention to move within the same year of enrollment.

9. Vulnerable Subjects.
This study does not involve vulnerable subjects

10. Subject/Representative Comprehension.
Participants will be asked to repeat back to the research assistant the salient points of the consent form to make sure that they understand the study they are agreeing to participate in. Children and/or decisionally impaired adults will not be subjects in this study.

11. Debriefing Procedures.
Information will not be purposely withheld from the subject. Participants will be asked to sign the audio-consent form. An audio-recording will be obtained for an accurate summary of the debriefing process. At the three-month follow-up visit, participants will be asked to provide overall feedback and experience about the study to encapture content that may not otherwise be received through the survey measures. The audio-recording will be held in perpetuity to evaluate after the study is closed. Participants will be given the opportunity to ask questions, and provide comments on the study importance.

12. Consent Forms.
We will use consent forms approved by the IRB. All participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such action will in no way affect their future interactions with their health care provider, or with New York University Medical Center. To ensure confidentiality, data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a locked drawer.

13. Costs to the Subject.
There will be no costs to study subjects.

14. Payment for Participation.
Participants in Phase I Heuristic Testing will receive $50 for providing baseline data. Participants in Phase II (Intervention/Control) will receive $25 at baseline, $50 at the 1 month follow up period and $25 at 3 months.

III.STUDY DESIGN/METHODS

Using data from previous RCTs (R25H116378, R01MD004113, and R01MD007716, we will use previously gathered data on barriers and facilitators to clinical trial participation

among minorities in partnering communities. Barriers and facilitators have been elicited through focus groups using standard OBSSR-recommended approaches. These data will be used to develop a culturally-tailored website, to assess participants knowledge of clinical trials and to promote increased clinical trial health literacy, leading to enhanced in rates of participation. Our team has considerable experience translating qualitative data into relevant interventions. Previously, we developed and tested the TASHE website (Tailored sleep health education: a community-engaged approach-R25H116378). The objective was to develop a web-based sleep education program for blacks with metabolic syndrome and who were at risk for sleep-related CVD. We will utilize a similar approach to develop and test the proposed ACTNOW website www.nyulmc.org/sleephealtheducationwww.nyulmc.org/sleephealtheducation

The proposed ACTNOW website will use an existing health education and social networking website initially developed by the Harlem Health Promotion Center (HHPC), one of 37 Prevention Research Centers in the Centers for Disease Control and Prevention (CDC) network (U48DP000030). This will be a world-class clinical trial literacy program describing in lay terms the rationale for clinical trials, importance of participation, and knowledge to be gained by participating. The parent website (GetHealthyHarlem.org) was built by *Woven Web Digital Design* in collaboration with community stakeholders, serving minority communities in New York. Currently, it provides health advice regarding physical activity, nutrition, the built and social environment, psychosocial concerns, and other topics of interest to the health and well-being of New Yorkers. Online formats include interviews with community health experts, health testimonials based on interviews with community members and short informative articles on various health topics. Additionally, it provides a forum for community members to connect, engage, and network. On a monthly basis, more than 6,000 users access the website.

The platform will be incorporated in the getHealthyHarlem.org portal. Initially, this portal was created using Drupal, a popular, highly flexible, sophisticated, and scalable content management system. It allows easy creation of different types of content including video vignettes, animations, and RSS feeds. Drupal has fine-grained user permissions, allows for “plug and play” added functionality, provides mechanisms for easy customization, and has active development support from the technical community. This allows community stakeholders and visitors to rate various website elements, use communication and collaboration tools such as the discussion boards. Web tools allow sharing of research and educational materials among researchers. The platform will be designed so that project staff can easily configure it in accordance with community preferences and needs as gleaned from the final debriefing sessions in year 2.

Specific content of the site will assist users in understanding the basics of clinical trial using previously developed educational materials, customized at the 5-6th grade

reading level. The site will be password-protected, accessible only by participants in the exposure arm. By providing a specific password to each participant, we will be able to track their activity on the site (e.g., frequency and time spent on the site) using Google Analytics log file data and relate it to other participant characteristics. The site will be designed for use by individuals with low literacy and computer experience, in consultation with an experienced linguist.

Data acquisition for objective 1: We will use a randomized group design, assessing patient-centered outcomes (health literacy, willingness to participate in a clinical trial, willingness to refer others), contrasting participants who were exposed to health messages via NYU's standard clinical trial website (http://www.med.nyu.edu/oct/home) [control arm] and those exposed to the newly created culturally and linguistically tailored website [intervention arm]. They will all complete measures at baseline assessing demographics, general health status (Medical Outcomes Study Short Form), baseline health literacy measures (National Assessment of Adult Literacy), and willingness to participate in a clinical trial ("On a scale from 1 to 5, with 1 being 'not at all willing' and 5 being 'very willing', how willing would you be to participate in a clinical trial in the future?" Response anchors will be; not at all willing, somewhat unwilling, neutral, somewhat willing, and very willing).

At the 1-month debriefing, we will reassess participants' willingness to participate in a clinical trial, and ask whether or not they opted to register with ResearchMatch; an online volunteer clinical research registry. These data will help establish a model for future translational and dissemination research. At the end of the 2-year project, we expect to have developed a culturally-tailored clinical trial literacy website that could be widely accessed. There are over 31,000 racial/ethnic minority barbershops, beauty salons, and faith-based organizations across the United States that could use this non-traditional model promoting participation in clinical trials. The long-term goal is to use this infrastructure for dissemination of evidence-based clinical trial health literacy and participation at the community level.

Schedule of Events

The primary aim of this study is to compare the tailored materials to control information only materials that are not tailored to the population being studied. However, before the Intervention/Control study, all messages and online resources will be assessed using cognitive heuristic testing to ensure the website is user friendly and culturally and linguistically tailored to the population. Heuristic testing to ensure cultural and linguistic appropriateness of the resource will be conducted, followed by the Intervention/Control study.

Our collaborator from SUNY Downstate, Dr. Senathirajah, will conduct heuristic evaluation and cognitive walkthroughs of all web materials, and then perform standard formative usability testing onsite with 10 representative participants to ensure the site is well-suited to the needs of the intended community. These participants will be recruited from the existing pool of participants from previous RCT's mentioned above..
Participants will be contacted, and recruited for this portion of the study via telephone. Participants will be scheduled into time slots of approximately 40 minutes in duration. Participants will come to CHBC at their assigned timeslot, read and sign the consent form, and then begin the heuristic testing. She will ascertain whether health materials are acceptable and whether they capture daily experiences of potential patients whose lives vignettes intend to portray. She will recommend necessary changes based on log-file analysis that captures computer activity while the participant uses the website. In addition, Dr. Senathirajah will ask participants several debriefing questions, such as their experience with the Internet, their willingness to use the resource in the future, and their overall user experience. This will ensure that messages are credible and understandable to the partner community.
Materials will also be presented to stakeholders in our Community Advisory Board for final approval. Once approved, materials will be available for use in the Intervention/Control Study.

Intervention/Control Study
Participants in the Intervention/Control study will be asked to come to the Center for Healthful Behavior Change for three discrete visits, including baseline, 1-month follow up, and 3-month follow up.

Baseline:

I. Participants will be contacted from our prior IRB approved studies. Potential participants recruited through community locations and events like health fairs will also be contacted. All potential participants will be scheduled into an enrollment slot at which time they arrive at the CHBC (227 East 30th Street, 6th Floor, New York, NY) to fill out baseline surveys and receive study instructions.
II. When participants arrive, they will be invited to go to either the intervention or control enrolment sessions. These groups will remain separate so as not to cross-contaminate instructions or materials.
III. Participants will receive the consent forms, and will be asked to read the documents carefully. Participants will be provided time to call any family or friends, and given the time they need to make an informed decision about participation. The consent forms will be approved by the IRB, and include a request for participant cell phone number and email address. Cell phone is collected so that participants may be sent study reminders, and email is

requested so that the study personnel might share the intervention resource with participants in the control condition at the end of the study. Participants will also be asked if the study team can record the debriefing session. If so, consent will be obtained.

IV. Participants will take baseline surveys; this will take approximately 25 minute. Next, participants will receive their experimental materials, which include a Wi-Fi enabled tablet that has been pre-loaded with either intervention or control materials on the browser. Participants will receive verbal and paper-based instructions from the research assistant on how to log into the online, tailored website (intervention condition) or how to access the generic informational website (control condition). Participants will be debriefed, thanked for their time, and scheduled for a slot for their 1-month follow up visit. Participants will receive $25 for their participation.

One-month follow up:

- Participants will return to the Center for healthful Behavior Change at their 1-month follow up appointment. At this time, participants will be instructed to bring their tablets with them to return the device, and take a follow up survey. The survey will take approximately 25 minutes.
- Participants will be thanked for their time, and scheduled for a slot for their for their 3-month follow up visit. Participants will receive $50 for their participation.

Three-month follow up:

- Participants will arrive at the CHBC for their 3-month follow up to simply take on last, follow up survey. Participants in the intervention condition will receive $25 for their participation, debriefed, and released from the study.
- Participants in the control condition will also receive $25 for their participation, debriefed, and instructed that they will receive access to the intervention resources via email after no later than 3 months.

All outcome measures are located in Table 1.

Table 1 Outcome Measures	**Baseline**	**1 months**	**3 months**
Demographic and Clinical Variables	X		
Medical Outcomes Study Short Form 36	X		
Internet Self-efficacy Scale	X	X	X
Clinical Trials Literacy	X	X	X

Message Effectiveness Scale		X	X
Clinical Vignette			X

IV.DATA ANALYSIS AND DATA MONITORING

Throughout the study, Dr. Jean-Louis will oversee data entry and verification, ensure adherence to coding, clean and edit protocols. Data will be maintained on a password-protected PC with backup copies kept on external disks in a secured location. Participant-identifying information will be kept in a locked file cabinet with only numerical identifiers in computer files.

Hypothesis 1: Participants exposed to tailored messages about clinical trial literacy will exhibit greater likelihood in participating in clinical trials than those exposed to NYU's standard website. Secondarily, we expect them to show greater likelihood to refer others to clinical trials as well.

Analysis: While the primary goal of the study is to develop and test effectiveness of tailored messages to overcome identified to participating in clinical trials, the secondary goal is to examine factors likely to facilitate adoption of such messages. All participants in the intervention arm will have been exposed to all tailored web-based messages. To compare participants who exhibited improvement in health literacy and those who did not 2-months post-enrollment, t-tests and chi-squared tests will be used. Baseline subjective factors will be entered in a logistic regression model in order to determine which factors are associated with higher likelihood of (a) registering to participate in clinical trials, contrasting individuals in the two study arms and (b) referring others to participate as well. Multivariate analysis of covariance will be used to assess effects of messages on the secondary outcome: health literacy scores; effects of sociodemographic confounders will be adjusted.

Hypothesis 2: Greater likelihood of participating in clinical trials will be mediated by greater health literacy and/or self-efficacy independent of other individual-level factors (medical, knowledge, attitude/beliefs, and intrinsic motivation) and contextual-level factors (social support and socio-economic position).

Analysis: We will examine the path toward greater participation in clinical trials using Structural Equation Modeling (SEM). SEM will determine influences of mediating/moderating factors on the role of tailored messages in improving participation rates in existing clinical trials. Specifically, we will use moderated path analysis from Baron and Kenny's model. We chose these factors based on research showing acceptable effect size in predicting likelihood of increased participation. Alternatively, we will employ probabilistic modeling methods (e.g., Bayesian Belief Network) to investigate interactions (omni-directionality) among predictors and different pathways to the desired study outcomes, determining which factors best differentiate cases and controls. Thus, we will ascertain patient characteristics most likely to show improvement in rates of participation.

V. STATISTICAL PLAN

Power Calculations: Primary Objective: Assuming a medium effect size (d = 0.32), as derived from Cohen, and a sample size of 100, the study will be adequately powered (> 80%) to detect significant differences between participants likely to show improvement in health literacy scores and those who are not using Fisher's Exact tests (critical X^2 = 6.58). This will also permit detection of a significant increase in the number of participants in the intervention arm opting to register for clinical trials. In a previous pilot study, we found that 45% of minority patients in the community adopted recommendations for medical treatments after exposure to tailored health messages, which compares to 25% who did without such exposure. Assuming a 20% increase in the likelihood of adopting health messages and a sample size of 100, the proposed study will have adequate power for a preliminary test of the hypothesis that exposure to health messages will foster greater update of tailored health messages and improvement in clinical trial health literacy level. Achieving the goal of a 20% increase would have an important public health impact regarding adoption of messages about clinical trials. A two-tailed test, with 80% power and α= 0.05 comparing 25% to 45% requires 50 participants per arm. The study is powered to assess differences in participation rates between the two arms as well as the mediating effect of individual and contextual factors between tailored clinical trial messages and participation rates, considering a 23% attrition rate.

VI. DATA HANDLING

Confidentiality

Steps will be thoughtfully taken throughout the execution of this study to maintain confidentiality of participant data. First, consent forms will be retained in locked cabinet. Only the PI and lead administrative assistant to the CHBC will have access to the key. In addition, all participant data will be made anonymous.

All personal identifiers will be removed and replaced with a pseudonym. In addition, any comments that could potentially identify a participant will be removed and discarded. All participant data collected in Phase III Intervention/Control activities will be assigned a user ID, only the consent form will link a participant with their responses, and consent forms will be retained in locked cabinet described above.

Furthermore, all spreadsheets with participant information will be retained in password protected computer, with Firewall and security software in compliance with the latest guidelines of the Medical Center Information Technology (MCIT) department.

VII. Data Safety and Monitoring

In compliance with Merck Pharmaceuticals requirements, we will establish a Data Safety Monitoring Plan (DSMP). The purpose of the DSMP is to ensure the safety of participants and the validity and integrity of the data. The DSMP will be tasked to develop its data sharing plan in consultation with representative(s) from the research office at NYU Langone Medical Center. Data will be made available from the medical center's website once the main findings of the project will have been published. The plan will incorporate language to ensure that the rights and privacy of people who participate in Merck Pharmaceuticals-sponsored research are protected at all times. Thus, data will be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of individual participants. All requests for data will be reviewed by the DSMP internal committee before access to the data is granted.

Personnel involved in the monitoring activities will include:

- The Principal Investigator, Dr. Girardin Jean-Louis
- The Co-Investigators: Drs. Alicia Chung, Rebecca Robbins, Azizi Seixas

- Study Coordinator: Shannique Richards

The data and safety monitoring plan will comprise the following elements: Reporting of adverse events to the NYU Langone Medical Center's IRB, as well as the study sponsor, Merck Pharmaceuticals. Summaries of adverse events reports will be made to Merck Pharmaceuticals in the yearly progress report or, at the end of year 2, in the final report, unless the nature of a particular event is such that it bears reporting to Merck Pharmaceuticals immediately.

VIII. RISK/BENEFIT ASSESSMENT

Risks/Discomfort :

1). Psychological Discomfort answering questions

The physical and psychological risks of the study are minimal, as no invasive procedures are proposed. No PHI will be collected by accessing the website; access to such sites will be restricted. As part of the process involved in obtaining written consent, all participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation.

2). Potential loss of confidentiality

To protect confidentiality, consent forms will be stored in locked files, with data coded so that identification of an individual's data can only be made with a master list. This list will also be kept in a locked file and will be available only to the PI or the research assistant. While we do not anticipate any adverse events, we will comply with reporting requirements as required by the Institutional Review Board.

Potential Benefits to the Subjects

The dissemination procedures are designed to be practical so that, if efficacy is demonstrated, they can be widely adopted. By evaluating the intervention in the context of a community-based setting, we can evidence to other organizations how tailored health messages can promote uptake of healthful messages. There are other populations in the country, with similar settings that might adapt this type of health information diffusion in their communities. It will also evidence that partnership between academic investigators and community providers and stakeholders is a proven approach to establish a strong infrastructure to enable translational and dissemination research.

IX. INVESTIGATOR'S QUALIFICATIONS AND EXPERIENCE

See attached CVs.

X. Publication Plan

We anticipate developing 2 manuscripts in each year of the proposed study. We plan to submit these manuscripts to journals such as American Journal of Public Health and Trials. We will plan to submit the first manuscript by December 1, 2017. These manuscripts will emanate from abstracts that will be developed for scientific meetings, including American Public Health Association, Society for Behavioral Medicine, and Society of Clinical Research Associates (SOCRA).

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