

# CLINICAL STUDY PROTOCOL



## Quit & Fit 2.0: Feasibility and Usability Testing

**Protocol Version**

05.02.2023

Study Number: Pro2022-0894	05.02.2023
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## Study Personnel

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**Sub-I(s):** N/A

**Statistical support:** N/A

**Protocol Development support (if applicable):** N/A

Name and information of sponsor: Hackensack Meridian *Health*

**Research Locations (all non-HMH locations):**

Georgetown Lombardi Comprehensive Cancer Center, Washington, D.C.

### Abbreviations

Abbreviation	Explanation
NCCN	National Comprehensive Cancer Network
NRT	Nicotine Replacement Therapy

### Revision History

Revision #	Version Date	Summary of Changes	Consent Change?
1	05.02.2023		

## Summary

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<b>Study Title</b>	<b>Quit &amp; Fit 2.0: Feasibility and Usability Testing</b>
<b>Study Design</b>	Pilot randomized controlled trial to compare tobacco cessation rates of two arms: a 6-week culturally tailored tobacco cessation intervention versus a 6-week personalized culturally-tailored tobacco cessation intervention among African American women (N=20).
<b>Primary Objective</b>	Examine feasibility, acceptability and satisfaction of a 6-week community-based tobacco treatment intervention.
<b>Secondary Objective(s)</b>	Examine self-reported stage of change for tobacco cessation.
<b>Research Intervention(s)</b>	community-based tobacco treatment intervention
<b>Study Population</b>	African American women who currently smoke tobacco in Washington, D.C. and New Jersey (Lombardi-Hackensack consortium)
<b>Sample Size</b>	N=20
<b>Study Duration for individual participants</b>	6 weeks

## 1 – Introduction

Despite lower overall smoking rates, African American women have comparable lung cancer rates to higher rate smoking groups. Smoking is the leading cause of preventable morbidity and mortality in African American women. Disparities exist in disease and death from smoking-related diseases regardless of gender. Because African American women carry a disproportionate tobacco-related disease burden, research that focuses on intervening in tobacco treatment among African American women is critical.

Tobacco treatment is the single most important preventive health behavior African American women can engage in to significantly reduce their chances of morbidity and premature mortality related to smoking-related illnesses. Although more African American men smoke compared to African American women, data show that African American women may be less successful at quitting than men. Interventions are most effective when they are paired with other lifestyle behavior interventions. Specifically, exercise has been used successfully as an adjunct to tobacco treatment interventions because exercise has the potential to reduce cigarette cravings, withdrawal symptoms and weight gain, all of which are barriers to tobacco treatment among women. Therefore, an intensive tobacco treatment program paired with a fitness component is a promising intervention to promote smoking abstinence in women who have difficulty quitting. Further, culturally tailored comprehensive interventions that address tobacco treatment among African American women are needed if we are to address the current disparities that exist in disease and death from smoking-related diseases among African American women.

## 2 – Background

### 2.1. Background/literature review (make sure you provide references)

#### **Tobacco use remains the single most preventable cause of disease and death in the United States.**

<sup>1-2</sup> Smoking creates well-known risks for conditions such as cancer, stroke, and heart disease. Blacks are 13% more likely to die from all types of cancer than Whites, adjusting for age.<sup>3</sup> Even when controlling for differences in socioeconomic status and age, Blacks have higher all-cancer mortality across all but the highest socioeconomic decile, as compared to Whites.<sup>4</sup> For lung cancer, Blacks have 2 to 3 times more risk than do any other ethnic group.<sup>5</sup>

#### **Blacks face a significantly higher disease burden as a result of modifiable health behaviors as compared to their White counterparts.**

They have a higher incidence of mortality attributed to coronary heart disease, stroke, heart failure, and high blood pressure as compared to non-Hispanic Whites.<sup>6</sup> The prevalence of high blood pressure (a major risk factor for coronary heart disease, stroke, heart failure, and kidney disease) is 40% higher among Blacks than in Whites, with even greater disparities seen between women.<sup>7</sup> Blacks are also more likely to consume fewer servings of fruits and vegetables<sup>8</sup> and have lower rates of physical activity,<sup>9-10</sup> which are all modifiable risk factors for cancer and cardiovascular disease.<sup>11</sup> Reports illustrate that Black adult females across all age groups are more likely to be overweight or obese compared to White females, and also exhibit greater disparities than between Black and White men.<sup>6</sup> Consequently, Black women are in particular need of *effective targeted interventions*.<sup>7</sup> Given the prevalence of smoking among women in the U.S., evidence-based tobacco treatment programs need to be translated from the research setting into community settings that are accessible to the large population of women who smoke.<sup>12</sup> Women, in general, are four times more likely than men to report fear of weight gain as a reason for smoking cessation relapse<sup>13</sup> and they gain significantly more weight than men who smoke following tobacco treatment.<sup>14</sup> Black women are more likely to be satisfied with their body shape compared to White women; however, they report less tolerance for post-cessation weight gain and are less likely to exercise as a means of weight control.<sup>15</sup>

#### **There is emerging evidence that positive changes in one's health behavior may be accompanied by other constructive health behavior changes.**

Berg et al. determined that among 539 Blacks who smoked lightly, those who reduced or quit using tobacco were more likely to walk for exercise at follow-up, after controlling for baseline walking status.<sup>16</sup> Regular physical activity may be an effective means of not only promoting one's health directly but it has been associated with improved smoking cessation rates and improved mood. A recent review of 15 clinical trials demonstrated that exercise interventions combined with tobacco treatment can provide additional benefit compared to interventions that do not incorporate exercise.<sup>17</sup> Commit to Quit is a smoking cessation intervention<sup>18-22</sup> that has shown women who received cognitive-behavioral treatment (CBT) combined with an exercise intervention achieved significantly higher levels of continuous abstinence

relative to CBT plus a contact control condition.<sup>20</sup> However, Commit to Quit was validated over a decade ago<sup>22</sup> and advances in tobacco treatment in general have shown the importance of combined treatment and inclusion of nicotine replacement therapy (NRT) in cessation programs.<sup>22</sup>

Although pilot work has attempted to translate Commit to Quit into a community setting,<sup>23</sup> the studies were primarily conducted among White women and little work has been done to examine the efficacy of the approach in diverse samples. Previous research has highlighted the importance of cultural relevance in health risk communications, including tobacco interventions. Webb et al<sup>24</sup> demonstrated that the culturally tailored tobacco treatment messaging produced greater culturally specific risk perceptions, readiness to quit smoking, and smoking-related knowledge.<sup>24</sup> Findings support the roles of message content and culturally specific framing in the efficacy of brief written interventions for tobacco treatment in this population.

**When individuals quit smoking, they tend to gain weight.** Potential weight gain is a significant barrier to tobacco treatment; weight maintenance strategies should be included in early tobacco treatment support.<sup>25</sup> Further, tobacco treatment is associated with hyperphagia and weight gain in over 70% of those individuals who attempt to quit smoking. Nicotine, which is the known main addictive component of tobacco, has anorexigenic properties and promotes body weight reductions.<sup>26-29</sup> Thus, the idea of weight gain has acted as an incentive for the continued smoking habits and the effects of nicotine on energy homeostasis demonstrates that smoking leads to negative energy balance.

**Phone-based Interventions have the potential to drive behavior change.** Health professionals use cell phones to monitor chronic diseases, improve medication adherence,<sup>30</sup> and to help individuals who smoke to quit.<sup>31</sup> Telephone quit lines enhance cessation rates by over 50%.<sup>31</sup> A recent cell phone cessation intervention in a low income, largely Black urban HIV clinic sample indicated that patients who received 8 phone sessions were significantly more likely at 3 months follow-up to be abstinent.<sup>32</sup> A recent review concluded that text message interventions are efficacious for tobacco treatment.<sup>30</sup> Recent trials are emerging that suggest mobile phones are a feasible delivery method to promote energy balance.<sup>33</sup> For example, a randomized trial with 337 urban Blacks received 8 months of either weekly automated, tailored, interactive phone calls, or standard care education.<sup>33</sup> The phone calls were arranged in three modules addressing hypertension medication adherence, physical activity, and diet. The intervention was associated with improvements in a measure of overall diet quality and in energy expenditure. The study suggests that diet and energy balance messages delivered by phone have promise given their convenience, scalability, and ability to deliver tailored messages for urban Blacks. Cell phones have a high penetration among underserved minority populations, and researchers have explored the use of cellular phones as a disparity-reducing advancement.<sup>6</sup> Black and Hispanic groups have become the largest per capita users of basic cell phone functions.<sup>6</sup> In 2014, 90% of African Americans reported cellphone ownership and 81% of all cellphone users reported sending and receiving text messages.<sup>34</sup> Cellular phones do not present the digital divide -- the perceived gap between those who have access to the latest information technologies and those who

do not.<sup>6</sup>

**Impact.** To date, researchers have focused on tobacco treatment interventions individually as opposed to combining positive changes in one health behavior as synergistic for another constructive health behavior change. **This application challenges the current status quo by transforming tobacco treatment in the community among Black women to address not only tobacco treatment but to proactively address the fear of weight gain with cessation using a culturally framed, targeted approach.** Ultimately, using a novel community-based tobacco treatment and exercise intervention to target community-based Black women is innovative and has the potential to engage women with individualized content that is personally relevant to foster engagement in improving their health.

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## 3 – Rationale, Objectives and Hypothesis

### 3.1. Study Rationale/Problem Statement/Research question or Study significance

The rationale of the overarching study that this pilot feasibility and usability study will support is to compare the effectiveness of a 6-week community-based tobacco treatment and exercise intervention – Quit & Fit to the control (tobacco treatment intervention) targeted to African American women on tobacco cessation rates via 7-day cotinine confirmed point-prevalence abstinence (primary outcome) and secondary outcomes (caloric intake, weight changes, health beliefs).

For this study, the rationale is to pilot the feasibility, acceptability and satisfaction of the study procedures of a shortened intervention protocol that compares a culturally-tailored tobacco treatment intervention to a preference driven culturally-tailored tobacco treatment intervention.

### 3.2. Hypothesis (if applicable)

- 1) Participants will report the 6-week tobacco treatment intervention is acceptable and they are satisfied with the intervention.
- 2) Participants who complete the preference driven culturally-tailored tobacco treatment intervention will have higher rates of tobacco abstinence compared to participants in the control arm.

### 3.3. Primary Objective

**Aim 1.** Examine the feasibility, acceptability and satisfaction (primary outcome) of a 6-week community-based culturally-tailored tobacco treatment intervention to a preference driven culturally-tailored tobacco treatment intervention targeted to African American women.

**Aim 2.** Compare the effectiveness of a 6-week community-based culturally-tailored tobacco treatment intervention to a preference driven culturally-tailored tobacco treatment intervention targeted to African American women on self-reported stage of change for tobacco cessation (secondary outcome).

### 3.4. Primary Outcome Variable(s)

Feasibility, acceptability and satisfaction with the content of the educational content and the tobacco treatment intervention.

## 4 - Study Design

### 4.1 General Design



The overall study design is a 6-week community-based tobacco treatment intervention to address tobacco use in the African American female community. This pilot study is testing the feasibility, acceptability and satisfaction of a 6-week community-based culturally-tailored tobacco treatment intervention to a preference driven culturally-tailored tobacco treatment intervention targeted to African American women in New Jersey with 20 African American women; 10 participants will receive the culturally-tailored tobacco treatment intervention and 10 participants will complete the one-item Control Preference Scale and receive preference driven culturally-tailored tobacco treatment intervention based upon their control preference.

#### **4.1.1 Study Duration (if applicable)**

Total study duration = 6 months

#### **4.1.2 Number of Study Sites**

1 (HMH)

#### **4.2 Study Population**

African American women

##### **4.2.1. Number of Participants**

20

##### **4.2.2. Eligibility Criteria**

###### Inclusion Criteria:

- Self-identify as an African American woman
- Aged 18 years to 69 years
- Currently smoke 5 cigarettes per day or more
- Has smoked daily for the past one year
- Able to provide informed consent
- Generally good health as determined by medical history

###### Exclusion Criteria:

- Currently pregnant
- Diagnosis of cardiovascular disease
- Diagnosis of lung disease
- Diagnosis of mental illness
- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Prisoners

**4.2.3. Vulnerable populations (if applicable). Vulnerable populations include children, prisoners, cognitively impaired individuals, economically or educationally disadvantaged individuals, employees, students. When vulnerable populations are**

**included, indicate what safeguards are in place to minimize coercion or undue influence to participate.**

n/a

#### **4.2.4. Withdrawal criteria (as applicable)**

n/a

#### **4.3. Study procedures**

We will recruit participants using informal recruitment through advertisements/media (e.g. advertisements, neighborhood flyers) in New Jersey.

After a participant is consented and enrolled into the study, they will complete a baseline survey, receive the home CO monitor and instructions on how to use, and be scheduled for weekly telephone calls with a certified tobacco treatment specialist (CTTS). The culturally-tailored tobacco intervention content by week via telephone call with the CTTS is listed in the table below:

<b>Week</b>	<b>Tobacco Intervention Content</b>
1	Reasons and Motivations for Quitting, Nicotine as an Addiction, Coping Response Training, Tracking Your Triggers, Education about Nicotine Replacement Therapy
2	Benefits of Quitting; Reinforce Prior Education about NRT
3	Discussion about Creating a Buddy System for Cessation and Discussion with Participant about Decreasing Daily Cigarette Use by an Additional 20% (total 40%) (CTTS will assess current cigarettes per day and ask participant to decrease cigarettes by 20% using Table 1)
4	Stress Management
5	Stress Management
6	Discussion about Environmental Influences, Stress Management, Life in your neighborhood, Gaining freedom from smoking

This intervention will address practical and logistical barriers associated with engaging patients. The intervention will integrate motivational interviewing and evidence-based tobacco treatment (i.e., cessation counseling and nicotine replacement therapy medication).

#### Intervention Content

#### **Culturally-tailored Tobacco Treatment Intervention (Arm 1) vs. Preference-Driven Culturally-tailored Tobacco Treatment Intervention (Arm 2)**

In addition to weekly cessation counseling by a CTTS for 6 weeks covering the Tobacco Intervention Content outlined above in Table 1, participants will receive weekly Content Newsletters emailed after their weekly cessation counseling session.

Participants randomized to Arm 1 will receive the Culturally-tailored Content Newsletters and participants randomized to Arm 2 will complete the one-item Control Preference Scale and receive either an Active Content Newsletter or Passive Content Newsletter. The Control Preference Scale question is:

*In terms of making decisions about your health care with your provider, which ONE of the following best describes how you would like to make these decisions?*

- <sup>1</sup> *Make the final selection about which treatment I will receive.*
- <sup>2</sup> *Make the final selection after seriously considering my provider's opinion.*
- <sup>3</sup> *Have my provider and I share responsibility for deciding what treatment is best.*
- <sup>4</sup> *Have my provider make the final decision but consider my opinion.*
- <sup>5</sup> *Leave all decisions regarding treatment to my provider.*

Individuals will be classified as follows:

1 or 2 = Active Control Preference

3 or 4 = Collaborative Control Preference

5 = Passive Control Preference

Participants will receive weekly cessation counseling by a CTTS for 6 weeks covering the Tobacco Intervention Content outlined above in Table 1. Participants will receive variations (active vs. passive control preference) of the weekly Content Newsletters emailed after their weekly cessation counseling session:

#	Active Content Newsletter	Passive Content Newsletter
1	Addresses Race and Smoking, History of Research Distrust, and Concerns about Nicotine Replacement Therapy (NRT)	Concerns about Nicotine Replacement Therapy (NRT)
2	Addresses Reasons and Motivations for Quitting, Nicotine as an Addiction, Coping Response Training, Tracking Your Triggers	Nicotine as an Addiction, Coping Response Training, Tracking Your Triggers
3	Addresses Benefits of Quitting, Stressors Unique to African Americans, Discrimination & Racism, Ways to Cope	Addresses Benefits of Quitting, Ways to Cope
4	Addresses Mood and Depression Among African Americans, Buddy System	Buddy System
5	Addresses Stress Management (same)	Addresses Stress Management (same)

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6	Addresses Weight and African Americans, Smoking and Weight Concerns, Minimizing Weight Gain, Healthy Eating within a Soul Food Diet including Recipes	Minimizing Weight Gain
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During the Week 1 telephone call with the CTTS, the participant will be educated about combination nicotine replacement therapy over-the-counter medication and the Nicotine Replacement Therapy (NRT) patch kit + NRT lozenge kit will be mailed to the participant's home.

**4.3.1. Study discontinuation (if applicable) n/a**

**4.3.2. Concomitant medication (if applicable) n/a**

**4.4. Risks and Benefits**

**4.4.1. Risks**

As this study proposes tobacco cessation, risks to participants are deemed minimal. There is a potential risk of loss of confidentiality but that is protected against by coding all data with study IDs only, presenting results of statistical analyses only in aggregate form, and limiting the use of the data to research staff who are IRB approved to participate in the research, have been trained in methods of maintaining confidentiality, and have completed training in the protection of human subjects and research integrity at regular intervals.

**4.4.2. Benefits**

Potential benefits are tobacco cessation for participants.

## 5 – Methods

**5.1. Screening**

This is a community-based feasibility and usability study. As such, recruitment procedures will be community-based and described below.

**5.2. Recruitment, enrollment, and retention (including screen failures as applicable)**

We will recruit participants using informal recruitment through social networks and community-based advertisements/media (advertisements, neighborhood flyers) in New Jersey.

The weekly intervention calls with the CTTS will assist with retention in this 6-week study. In addition, the weekly content newsletter will assist with retention secondary to actively engaging participants during the course of the study.

**5.3. Study intervention (including schedule of events and study visits)**

The study intervention includes a combination of tobacco treatment counseling sessions using motivational interviewing by certified tobacco treatment specialists, randomization to either (a) culturally-tailored tobacco treatment intervention or (b) preference driven culturally-tailored tobacco treatment intervention, home CO monitoring, and combination

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nicotine replacement therapy over-the-counter medication and the Nicotine Replacement Therapy (NRT) patch kit + NRT lozenge kit.

After a participant is consented and enrolled into the study, they will complete a baseline survey and be scheduled for weekly telephone calls with a certified tobacco treatment specialist. After the baseline survey is completed, a personal home CO monitor will be ordered for the patient and shipped directly to their home. Instructions on how to use will be emailed to the participant and reviewed in the 1<sup>st</sup> weekly counseling session with the CTTS.

The tobacco intervention content will be delivered by telephone by a CTTS weekly. The weekly activities including plan to reduce total cigarette intake, and dosing chart for the nicotine replacement (based upon the National Comprehensive Cancer Network's Evidence-Based Tobacco Treatment Guidelines (2022) is listed below by week:

Week	Tobacco Intervention Content	Nicotine Replacement Therapy
Orientation (Baseline)	<ul style="list-style-type: none"> <li>Overview of Study</li> <li>Informed Consent</li> <li>Baseline Surveys</li> </ul>	<p><b><u>Dosing Chart</u></b></p> <p>&gt;10cigarettes/day: Initially one 21mg patch daily for 6 weeks; then one 14mg patch daily for 2 weeks, then one 7mg patch daily for 2 weeks, then stop.</p> <p>≤10cigarettes/day: initially one 14mg patch daily for 6 weeks then one 7mg patch daily for 2 weeks, then stop.</p>
Session 1	<ul style="list-style-type: none"> <li>Review Quit Plan</li> <li>Baseline CO Level</li> </ul>	
Session 2	<ul style="list-style-type: none"> <li>Behavior Target: Decrease # of Cigarettes Daily by 20%</li> </ul>	<ul style="list-style-type: none"> <li>Start NRT: Nicotine Patch (see dosing chart) + 2mg NRT lozenges prn</li> </ul>
Session 3	<ul style="list-style-type: none"> <li>Behavior Target: Decrease # of Cigarettes Daily by additional 20% (total = 40%)</li> </ul>	<ul style="list-style-type: none"> <li>Continue NRT: Nicotine Patch (see dosing chart) + 2mg NRT lozenges prn</li> </ul>
Session 4	<ul style="list-style-type: none"> <li>Behavior Target: Decrease # of Cigarettes Daily by additional 20% (total = 60%)</li> </ul>	<ul style="list-style-type: none"> <li>Continue NRT: Nicotine Patch (see dosing chart) + 2mg NRT lozenges prn</li> </ul>
Session 5	<ul style="list-style-type: none"> <li>Behavior Target: Decrease # of Cigarettes Daily by additional 20% (total = 80%)</li> </ul>	<ul style="list-style-type: none"> <li>Continue NRT: Nicotine Patch (see dosing chart) + 2mg NRT lozenges prn</li> </ul>
Session 6	<ul style="list-style-type: none"> <li>Behavior Target: Decrease # of Cigarettes Daily by additional 20% (total = 100% = QUIT)</li> </ul>	<ul style="list-style-type: none"> <li>Continue NRT: Nicotine Patch (see dosing chart) + 2mg NRT lozenges prn</li> </ul>
Final Session	<ul style="list-style-type: none"> <li>Assess how participant is doing. How many cigarettes (if any) smoking per day. Answer any questions including questions about NRT tapering schedule</li> <li>Assess NRT use, response, issues</li> </ul>	<ul style="list-style-type: none"> <li>Taper NRT per protocol</li> </ul>

During the Week 1 telephone call with the CTTS, the participant will be educated about combination nicotine replacement therapy over-the-counter medication and the Nicotine Replacement Therapy (NRT) patch kit + NRT lozenge kit will be mailed to the participant's home.

The 6 tobacco treatment counseling sessions will use motivational interviewing by a CTTS to address quitting motivations, benefits of tobacco treatment, overcoming nicotine dependence and practical ways to handle triggers, nicotine withdrawal management, stress management, healthy eating and activity, and relapse prevention.

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#### 5.4. Assignment / randomization (if applicable) n/a

#### 5.5. Section of instruments.

The primary outcome of this feasibility and usability pilot study is satisfaction with the processes of the study. A Satisfaction and Usability Questionnaire will be used that assesses participant thoughts and opinions about the intervention components, duration, outreach, and methods.

In addition, we will assess sociodemographic data including gender, race, marital status, education, and employment status will be gathered along with data on health status, history of chronic disease, and height and weight. Nicotine addiction will be measured by the Fagerström Questionnaire. Stage of change for smoking will be assessed uses the processes of change, self-efficacy for behavior change, and decisional balance (pros and cons of change). *Biochemical Validation*. Expired carbon monoxide measures will be used to confirm smoking status. CO levels < 9 ppm will be used as the cutoff.

Timing of Assessments	Baseline	Weekly	6 weeks post study start
Sociodemographic & Health Status Questionnaire	X		
Fagerstrom Test for Nicotine Dependence	X	X	X
CO Monitor	X	X	X
Stage of Change for Tobacco Cessation	X		X
Usability			X
Acceptance & Satisfaction			X

#### 5.6. Data management (data collection, source and storage)

Data at baseline and end of study (6 weeks post study start for each participant) will be collected by phone. Self-report data will be gathered via a standardized interview using REDCap (Research Electronic Data Capture). REDCap is a secure web-based application for building and managing online surveys and databases. REDCap provides audit trails for tracking data manipulation and user activity as well as export procedures for secure data downloads to common statistical packages.

#### 5.7. Follow-up and end-of study (if applicable) n/a

#### 5.8. Statistical Method

**5.8.1. Sample size calculation and justification** N/A (this is a feasibility and usability pilot study with 20 participants)

#### 5.8.2. Statistical Analysis Plan

This is a feasibility and usability pilot study; all analysis will be descriptive.

## 6 - Trial Administration

### 6.1. Ethical Considerations - Institutional Review Board (IRB) Review

The study will be conducted according to the International Conference on Harmonization (ICH), Good Clinical Practice (GCP), the Declaration of Helsinki, Institutional Review Boards (IRB) and in accordance with the U.S. Code of Federal Regulations on Protection of Human Rights (21 CFR 50).

### **6.2. Institutional Review Board (IRB) Review (list the IRB of record)**

The final study (ICF, HIPAA form as applicable) and data collection tools will be approved by the Institutional Review Board (IRB) at HMH. Approval will be received in writing before study initiation.

Any changes to the study design will be formally documented in amendments and be approved by the IRB prior to implementation.

### **6.3. Confidentiality**

A unique identifier (study ID number) will be assigned to each participant. The study ID number will be included in the data collection tools and analysis software while the list with direct identifiers and ID numbers will be stored separately in a HMH-password protected computer and locked office.

If results of the study are published, individual names or other identifying information will not be used, and findings will be reported in aggregate data only.

### **6.4. Informed consent**

Participants are invited via community-based recruitment flyers and advertisements. Participants who contact the study office will be screened by telephone for inclusion and exclusion criteria. During the telephone screening, the study personnel will speak with the individual to determine that they can give informed consent for themselves. At that time, the study personnel will read through and discuss the informed consent with the individual. Once they have finished discussing the informed consent, the individual will be given an opportunity to ask any questions they may have. The study personnel will stress that the individual can withdraw from the study at any time with no penalty. The individual will then be asked to provide verbal informed consent and enroll in the study, or to decline to participate. If the individual provides verbal informed consent, a copy of the consent form will either be emailed or mailed to their home for their records.

### **6.5. Data Quality Assurance (if applicable)**

Online processes and platform (REDCap) will be monitored by the study team to assess survey/data collection issues and any unusual events. Modifications will be made as necessary and recorded to ensure maintenance of protocol integrity. In addition, any problems identified will be discussed at team meetings and corrected.

### **6.6. Study Records (retention etc.)**

Records will be retained in accordance with regulatory and organizational requirements, but for no less than six (6) years following the completion of the study. Disposal of records will be performed according to regulations.

**6.7. Compensation for Research-Related Injury (if applicable)**

N/A

**6.8. Economic Burden to Subjects (if applicable)**

N/A

**6.9. Credentials, Training**

All research personnel will be up to date with required CITI training.

**6.10. Financing and Insurance (if applicable)**

N/A

**6.11. Publication Plan (if applicable)**

N/A

## 7- Resources Available

**7.1. Describe the resources available to conduct the research:**

The **Cancer Prevention Precision Control Institute** is led by the applicant. The primary office space for senior investigators, fellows, data managers and research support staff consists of 10,000 sq feet. Access to the research office, which houses study data, is limited to study personnel and is kept locked at all times. The space is well equipped with individual offices, cubicles, and several multipurpose rooms for conducting interviews and convening research team meetings, journal clubs, and didactic seminars. Faculty all have office space, computer workstations, locked filing cabinets, and onsite access to videoconference facilities.

**Computer** The PI and research team have designated computer workstations that are networked to the various secure campus-wide hospital systems. CDI has a well-maintained computing environment that includes frequent software updates, proper hardware maintenance schedules, and 24/7/365 help desk and network administration support. CDI has an institutional site license for many software programs including Microsoft Office Suite, Adobe Acrobat, SAS, and SPSS. The computers are also equipped with the statistical program R, and bibliographic manager software (EndNote). The CDI has its own web and database servers based on Microsoft platform to streamline data collection and maintain data integrities. The department also has full-time in-house software developers and project managers to build and manage all the research IT related activities.

**Administrative Support:** The CDI and HMH provide full supportive services for all research projects including a full time Sponsored Programs Manager to help investigators comply with all relevant regulations and policies and managing grants. A financial analyst supports financial needs in sponsored research, cost analysis, procurement, and budgeting. The Research Department also has comprehensive administrative support for all researchers.



## Appendices

Appendix #	Name
1	Measures
2	Content Newsletters (Active)
3	Content Newsletters (Passive)