CLINICAL STUDY PROTOCOL

Assessing Social Determinants of

Health to Increase Cancer Screening

SD-CAN: **S**ocial **D**eterminants for **C**ancer screening **A**ccess & **N**avigation

Protocol Version

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Study Personnel

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Name and information of sponsor: Hackensack Meridian *Health*

Research Locations (all non-HMH locations): N/A

Abbreviations

Abbreviation	Explanation
SDOH	Social Determinants of Health
LCS	Lung Cancer Screening

Revision History

Revision #	Version Date	Summary of Changes	Consent Change?
1	02.16.2024	Changes to recruitment. Changes to study design to include a waitlist control arm.	

Summary

Study Title	**Assessing Social Determinants of Health to Increase Cancer Screening**

Study Design	Pilot randomized controlled trial with a waitlist control arm to compare lung cancer screening uptake among individuals who undergo SDOH assessment and referral (n=50) compared to those who do not (n=50)
Primary Objective	Lung cancer screening uptake
Secondary Objective(s)	Health literacy, Medical Mistrust, Perceived Stigma, Cancer Fatalism, Knowledge: Lung Cancer and Screening, Lung Cancer Screening Health Beliefs (perceived risk, perceived benefits, perceived barriers, self-efficacy)
Research Intervention(s)	SDOH Assessment and Referral using SDOH screening survey and UniteUs (*formerly NowPow*) website to link to resources to address identified SDOH needs
Study Population	Men and women who are eligible for lung cancer screening (aged 50-80 years, currently smoke or quit smoking within the past 15 years, 20 pack-year tobacco smoking history)
Sample Size	N=100
Study Duration for individual participants	3 months

1 – Introduction

The **goal** of this study is to compare the effectiveness of a community-based lung screening educational tool paired with a social determinants of health (SDoH) screening assessment and referral process compared to a community-based lung cancer screening (LCS) educational tool alone

as part of outreach activities to improve (a) LCS rates (primary outcome); (b) intention to screen; and (c) individual-level potential drivers of LCS (*health literacy, mistrust, stigma, fatalism, knowledge, health beliefs*). We **hypothesize** that providing SDOH screening and referral will result in higher levels of LCS, forward movement of intention to screen, and improved individual-level drivers of LCS.

2 – Background

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

Lung cancer kills more people than colorectal, breast, prostate and cervical cancers combined.[1] Despite lung cancer mortality rates being lower in NJ compared to nationally, lung cancer remains the leading cause of NJ cancer death regardless of race, ethnicity or gender. Although LCS is recommended by the USPSTF, has the potential to detect lung cancer at earlier, more treatable stages, has a 20% lung cancer-related mortality reduction in those at risk and is covered by insurance, *population uptake has been abysmal*.[2] Even though it has been a decade since the USPSTF released its recommendation, only **5.8%** of screening-eligible Americans have been screened, and in NJ that rate is only **3.7%**. Screening-eligible individuals are generally unaware of LCS. Our team's prior work revealed that in addition to lack of awareness, screening-eligible individuals do not screen – *when they are aware* – because of perceived and actual barriers to LCS.[3–5] One of the most significant barriers is needs related to the social determinants of health (SDoH).[6] Engaging screening-eligible individuals is challenged by unmet needs related to SDoH. If an individual is dealing with financial strain, housing instability, transportation needs, food insecurity or beyond, cancer screening is not a priority. Those most vulnerable tend to be those also at high-risk for the development of disease and infirmity. Therefore, if the public health benefit of LCS is to be realized, we must first realize that we need to address the most basic needs of those most vulnerable. Screening for the SDOH is also documented with improving the ability to engage underserved individuals with the healthcare system at an entry level and maintaining their engagement over time.[6] LCS efforts cannot be performed in a silo; LCS efforts cannot stay confined to the health system alone. We must assess and connect resources addressing basic needs before we can focus on early detection of cancer to have the broadest and most meaningful impact. SDOH screening and referral paired with LCS education has the potential to address basic needs while increasing awareness about the importance of early detection of lung cancer when more treatment options exist and is associated with better outcomes. Improving SDOH has been supported as an evidence-based strategy to promote health equity by leveraging SDOH to increase breast, cervical, and colorectal cancer screenings.[6] Assessing SDOH and intervening with appropriate SDOH referral has the potential to increase LCS in at risk New Jerseyans.

Impact. A multilevel lung screening intervention that pairs SDoH screening and referral with a tailored health communication and decision support tool for lung screening has the potential to significantly impact lung screening uptake among at-risk individuals in the community, particularly among those who face barriers related to SDOH. In addition, findings will advance our understanding of effective strategies for improving lung screening and prevention efforts in non-traditional settings, with the ultimate goal of reducing the burden of lung cancer. As we consider ways to support the realization of the public health benefit of lung cancer screening, multiple strategies and venues to reach, and intervene, with screening-eligible is key.

References

1. *Cancer Facts & Figures 2023*. American Cancer Society, Inc.; 2022. https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html

2. Pettit N, Ceppa D, Monahan P. Low Rates of Lung and Colorectal Cancer Screening Uptake Among a Safety-net Emergency Department Population. *West J Emerg Med*. 2022;23(5):739-745. doi:10.5811/westjem.2022.5.55351

3. Carter-Harris L, Ceppa DP, Hanna N, Rawl SM. Lung cancer screening: what do long-term smokers know and believe? *Health Expect*. 2017;20(1):59-68. doi:10.1111/hex.12433

4. Carter-Harris L, Brandzel S, Wernli KJ, Roth JA, Buist DSM. A qualitative study exploring why individuals opt out of lung cancer screening. *Fam Pract*. Published online January 24, 2017:cmw146. doi:10.1093/fampra/cmw146

5. Carter-Harris L, Slaven JE, Monahan PO, Draucker CB, Vode E, Rawl SM. Understanding lung cancer screening behaviour using path analysis. *J Med Screen*. 2020;27(2):105-112. doi:10.1177/0969141319876961

6. Mohan G, Chattopadhyay S. Cost-effectiveness of Leveraging Social Determinants of Health to Improve Breast, Cervical, and Colorectal Cancer Screening: A Systematic Review. *JAMA Oncol*. 2020;6(9):1434-1444. doi:10.1001/jamaoncol.2020.1460

7. Weinstein D. The Precaution Adoption Process Model. In: *Health Behavior and Health Education: Theory, Researchm and Practice*. 4th Ed. Jossey-Bass; 2008:123-147.

8. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Fam Med*. 2004;36(8):588-594.

9. Thompson HS, Valdimarsdottir HB, Winkel G, Jandorf L, Redd W. The Group-Based Medical Mistrust Scale: psychometric properties and association with breast cancer screening. *Prev Med*. 2004;38(2):209-218. doi:10.1016/j.ypmed.2003.09.041

10.Cataldo JK, Slaughter R, Jahan TM, Pongquan VL, Hwang WJ. Measuring stigma in people with lung cancer: psychometric testing of the cataldo lung cancer stigma scale. *Oncol Nurs Forum*. 2011;38(1):E46-54. doi:10.1188/11.ONF.E46-E54

11.Mayo RM, Ureda JR, Parker VG. Importance of fatalism in understanding mammography screening in rural elderly women. *J Women Aging*. 2001;13(1):57-72. doi:10.1300/J074v13n01_05

12.Carter-Harris L, Slaven JE, Monohan P, Rawl SM. Development and Psychometric Evaluation of the Lung Cancer Screening Health Belief Scales. *Cancer Nurs*. 2017;40(3):237-244. doi:10.1097/NCC.0000000000000386

13.Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform*. 2019;95:103208. doi:10.1016/j.jbi.2019.103208

3 – Rationale, Objectives and Hypothesis

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

The **goal** of this study is to compare the effectiveness of a community-based lung screening educational tool paired with a social determinants of health (SDOH) screening assessment and referral process compared to a community-based lung cancer screening (LCS) educational tool alone as part of community outreach activities to improve (a) LCS rates (primary outcome); (b) intention to screen; and (c) individual-level potential drivers of LCS (*health literacy, mistrust, stigma, fatalism, knowledge, health beliefs*).

3.2. Hypothesis (if applicable)

We **hypothesize** that providing SDOH screening and referral prior to lung cancer screening education among screening-eligible individuals will result in higher levels of lung cancer screening, forward movement of intention to screen, and improved individual-level drivers of lung cancer screening.

3.3. Primary and Secondary Objectives

3.4. Primary Outcome Variable(s)

1. Lung cancer screening uptake

3.5. Secondary Outcome Variable(s)

1. Intention to screen for lung cancer
2. Health Literacy
3. Medical Mistrust
4. Perceived Stigma
5. Cancer Fatalism

6. Knowledge: Lung Cancer and Screening
7. Lung Cancer Screening Health Beliefs

4 - Study Design

4.1 General Design

We will conduct a pilot randomized controlled trial (RCT) to compare primary (*LCS uptake*) and secondary outcomes (*intent to screen, literacy, mistrust, stigma, fatalism, health beliefs*) among LCS-eligible men and women in NJ community- and health system-based settings who receive a LCS educational tool (*LungTalk*) paired with a social determinants of health (SDOH) screening assessment and referral process (n=50) compared to the LCS educational tool alone (n=50) as part of lung screening uptake outreach activities. All individuals who attend a CCOE event are normally assessed for cancer risks and appropriate cancer screening education is provided. **For those who screen eligible for lung cancer screening, the standard of care for the JTCC Cancer Community Outreach & Engagement Program for lung screening is *LungTalk*.** For those who are eligible for LCS, they will also be invited to participate in this study. In addition, we will identify lung screening eligible patients within Hackensack Meridian Health (HMH) system using the electronic health record with the assistance of HMH Business Intelligence to create a list of lung screening eligible patients for telephone outreach about the study. LCS eligibility includes being aged 50 to 80 years, currently smoke cigarettes or quit within the past 15 years, and has a 20 pack-year smoking history. Pack-years are calculated by multiplying the total number of packs smoked daily and the total number of years smoked.

Potential Participants Identified in the Community: Informed consent will be provided to everyone participating prior to study enrollment with emphasis of the voluntary nature of participation as well as time to ask questions. Preferred contact information including telephone, mailing, and email addresses will be obtained during enrollment. Participants will then complete the baseline survey via REDCap using a study-provided iPad followed by the intervention according to the arm to which the participant is randomized (SDoH screening and referral + LCS education versus LCS education alone). *If the participant does not have time to complete the full intervention component (SDOH screening and referral + LCS education or LCS education alone), a follow-up telephone appointment with study staff will be made for subsequent outreach.* Immediately after the intervention, the participant will complete the post-intervention survey on the iPad using REDCap and receive a $25 gift card for their time. The primary outcome (screening uptake) will be assessed by telephone 1-month

post-intervention; participants will receive a $25 gift card after completing the 1-month follow-up survey.

Potential Participants Identified through BI-generated HMH Patient List: Informed consent will be provided to all participants by telephone with a copy of the informed consent emailed prior to study enrollment with emphasis of the voluntary nature of participation as well as time to ask questions. Preferred contact information including alternative telephone number, mailing, and email addresses will be obtained during enrollment. Participants will then receive a link to complete the baseline survey via REDCap to their preferred email address followed by the intervention according to the arm to which the participant is randomized (SDoH screening and referral + LCS education versus LCS education alone). Immediately after the intervention, the participant will receive a link to complete the post-intervention survey via REDCap. The participant will receive a $25 gift card for their time. The primary outcome (screening uptake) will be assessed by telephone 1-month post-intervention and receive a $25 gift card after completing the 1-month follow-up survey.

4.1.1 Study Duration (if applicable)

Total study duration = 1 month

4.1.2 Number of Study Sites

1 (HMH)

4.2 Study Population

Men and women eligible for lung cancer screening

4.2.1. Number of Participants

100

4.2.2. Eligibility Criteria

Inclusion Criteria:

- Aged 50 years to 80 years
- Currently smoke cigarettes or quit smoking cigarettes within the past 15 years
- 20 pack-year smoking history
- Has never had lung cancer screening
- Able to provide informed consent
- Able to speak and understand English

Exclusion Criteria:

- Diagnosed with lung cancer

- Has a history of having a lung cancer screening scan
- Unable to speak and understand English

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

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. *There is also the potential for discomfort in answering survey questions about lung cancer risk. Participants may choose to skip any question they do not feel comfortable answering with no repercussions.*

4.4.2. Benefits

Potential benefits are related to lung cancer screening and early detection and addressing health-related social needs.

5 – Methods

5.1. Screening

We will identify potential participants during community-based outreach efforts using current standard practices at these events in which we screen individuals who attend Cancer Community Outreach & Engagement (CCOE) programming for eligibility for various types of cancer screening. For those eligible for lung cancer screening, we will share the study opportunity with them. We will also identify potential participants by enlisting HMH Business Intelligence (BI) to identify current patients who are eligible for lung cancer screening, have not been screened, and do not have a diagnosis of lung cancer.

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

We will recruit eligible study participants in two ways: (1) community-based outreach efforts, and (2) from the lung screening-eligible patient population at Hackensack Meridian Health (HMH).

Community-based Recruitment/Enrollment. Recruitment will occur at CCOE programming events in Bergen, Hudson, and Passaic Counties to recruit LCS-eligible individuals. All individuals who attend a CCOE event are assessed for cancer risks and appropriate cancer screening education is provided to

them. For those who are LCS eligible, they will also be invited to participate in this study. A study brochure will be shared with the potential participant, the study explained and time given to ask and have questions answered. If the participant agrees to enroll in the study, a signed informed consent document will be obtained prior to study enrollment. Each community-based setting is unique and offers different levels of ability to provide privacy in a community outreach setting. We provide the *LungTalk* educational program on an iPad and a headset so that privacy to what is being listened to is provided. If the participant is unable to complete the intervention at the CCOE event venue, arrangements will be made to follow-up by telephone and provide a weblink to the participants preferred email address to send the link to *LungTalk* and to all surveys for completion.

Health System-based Recruitment/Enrollment. Potential participants will be identified from 2 sources: (1) lung cancer screening-eligible patients of the HMH Tobacco Quit Center, and (2) lung cancer screening-eligible primary care patients of HMH.

Lung Cancer Screening-Eligible Patients of the HMH Tobacco Quit Center: For lung screening-eligible patients of the HMH Tobacco Quit Center, the Quit Center routinely screens patients for lung cancer screening eligibility during their intake process for tobacco treatment. For individuals who are lung cancer screening eligible, a list will be shared with the CCOE team for outreach related to lung cancer screening education. During the outreach telephone call, patients will be informed about the study opportunity. If they are interested, study details will be shared during the outreach telephone call, time allotted for the patient to ask questions, verbal informed consent obtained, and enrolled in the study. A link will then be emailed to the participant to the informed consent document and electronic signature requested on the informed consent. The research study staff member will then schedule them for a telephone appointment with the CCOE Patient Navigator.

Lung Cancer Screening-Eligible Primary Care Patients of HMH: HMH lung screening-eligible primary care patients will be identified with the assistance of HMHN Business Intelligence (BI). Using parameters of age (50-80 years), smoking status (current or former), and lack of a lung cancer diagnosis, BI will generate a patient list of potential participants that can be used for telephone outreach by IRB-approved research study staff. We will email a study information sheet to the potential participant to their email on record in the EHR. Twenty-four (24) hours to one week post email, the research study team will reach out to potential participants by telephone. For individuals without an email on record in their EHR, we will mail the recruitment letter with study information sheet. One week post mailing, the research study team will reach out to potential participants by telephone. We will attempt to contact the potential participant up to 5 times by telephone in a 30

day time period. After the 5th attempt, we will document on the study recruitment sheet that the participant is a passive decline and we will not re-contact.

When reached by telephone, the research study staff member will clearly introduce themselves, confirm they are speaking with the intended individual (see Box A for Plan to Identify and Confirm Contact below), briefly explain how the researcher obtained the potential participants' contact information and clearly state the purpose of the call. The research study staff member will then offer an explicit opt-out option here at the beginning of the call, allowing individuals to decline participation without pressure while maintaining a respectful and courteous tone throughout the conversation. If the potential participant would like to continue the conversation to learn more, the research study staff member will share the study opportunity, share study details, answer questions about the study, and if interested, confirm eligibility, obtain verbal informed consent, and enroll into the study. A link will then be emailed to the participant to the informed consent document and electronic signature requested on the informed consent. The research study staff member will then schedule them for a telephone appointment with the CCOE Patient Navigator.

Box A. Plan for Study Staff to Identify Themselves & Confirm Contact)

1. Introduction and Affiliation:

- **We will start by politely greeting the individual.** "Hello, this is [Research TM's Name] calling."
- **Clearly state our affiliation with the research project.** "I'm calling from Hackensack Meridian Health on behalf of a research study about lung health and screening."
- **We will mention the recruitment email sent.** "You may have received an email invitation from us in the past couple of days regarding this research project."

2. Confirmation of Contact:

- **We will ask for their name.** "May I please confirm I'm speaking with [Name on recruitment list]?"
- **If there's a slight discrepancy:** (e.g., nickname used in email)
    - We will acknowledge the difference politely. "I see the email went to [name on list]. Is this [participant's preferred name]?"
    - If unsure, clarify. "Our records show [name on list]. Apologies if there's a mistake."
- **If it's the wrong person:**
    - We will thank them for their time. "Thank you for answering. I apologize for the inconvenience. I'm looking for [name on list]."
    - We will offer to remove them from the call list if desired. "Would you like me to remove you from our contact list?"
    - We will politely end the conversation.

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

Interventions. *Unite Us* is an electronic SDoH screening and referral tool assessing: (1) financial resource strain; (2) housing stability; (3) transportation needs; and (4) food insecurity. Upon completion, the Unite Us platform identifies a list of geographically-tailored resources to connect the individual in need. A CCOE staff member will administer the SDoH screening and referral tool, review the results with the participant, and use the geographically-tailored resources to make SDoH-related

referrals. ***LungTalk*** is a novel theoretically grounded health educational tool that will be delivered via iPad and is an interactive computer-based program that includes audio, video and animation segments with scripts presented from a master content library in consideration of different ways people like to learn. Informed by our prior research, *LungTalk* tailors its content based on smoking status and perceived barriers. In prior work, *LungTalk* more than doubled LCS knowledge and health beliefs ($p < 0.01$), and was associated with a significant increase in deciding to screen for lung cancer compared to control group; OR 1.99; 95% CI, 1.03, 3.85, $p = 0.03$.

5.4. Assignment / Randomization (if applicable)

Participants in the study will be randomly assigned to one of two groups: intervention (n=50) or waitlist control (n=50). For those randomized into the intervention arm, they will complete SDOH screening assessment with the CCOE Patient Navigator and receive referral to local resources based upon identified needs followed by viewing the *LungTalk* educational program. For those randomized into the waitlist control group, they will view the *LungTalk* educational program. One month following viewing the *LungTalk* educational program, participants in the waitlist control group will receive an outreach call for SDOH screening assessment and referral to local resources based upon identified needs.

5.5. Section of instruments.

Table 1. Data Collection Timeline / Measurement Tools	***in person via iPad or by phone***		***by phone***
Measure (Cronbach's α, if applicable) (# of items)	**Pre**	**Post**	**1 mo.**
Sociodemographic & Health Status Characteristic Survey (11 items)	X		
PRIMARY OUTCOME			
LCS Uptake (self-report) (1 item) and verification of lung cancer screening (LDCT of the chest) via EHR			X
SECONDARY OUTCOMES			
Stage of Adoption for LCS (algorithm allows assessment of intent)[7]	X	X	X
Health Literacy (0.80) (3 items)[8]	X	X	X
Medical Mistrust Scale (0.84) (5 items)[9]	X	X	X
Perceived Stigma Scale (0.89) (5 items)[10]	X	X	X
Lung Cancer Fatalism (0.89) (8 items)[11]	X	X	X

Knowledge: Lung Cancer and LCS Scale (7 items)	X	X	X
Perceived Risk of Lung Cancer Scale (0.88) (3 items)[12]	X	X	X
Perceived Benefits of LCS Scale (0.76) (6 items)[12]	X	X	X
Perceived Barriers to LCS Scale (0.87) (17 items)[12]	X	X	X
Self-Efficacy for LCS Scale (0.92) (9 items)[12]	X	X	X

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

All data collected (baseline and follow-up) will be collected via REDCap (Research Electronic Data Capture) which 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.[13]

5.7. Follow-up and end-of study (if applicable)

One follow-up survey will be conducted at 1-month post-intervention and will be collected by phone and entered into REDCap.

5.8. Statistical Method

Baseline characteristics of the two study arms will be compared using descriptive statistics. Continuous variables will be summarized using means and standard deviations, while categorical variables will be summarized using frequencies and percentages. To assess feasibility, we will assess the study procedures (recruitment and retention rates), adherence to the intervention, and completion rates for the study measures.

5.8.1. Sample size calculation and justification

As a pilot study, the primary analytic purpose is feasibility analysis and descriptive analysis to inform a larger, fully powered trial. At least 12 subjects per arm are required to obtain reasonable effect size estimates to design a larger well-powered trial. We will recruit 100 participants (50 per arm). This sample size is also sufficient for providing a precise attrition rate estimate.

5.8.2. Statistical Analysis Plan

The primary analysis will use an intention-to-treat approach, with all randomized participants included in the analysis. The proportion of participants whose follow-up assessment indicate 'intention to screen' will be compared between the intervention and enhanced control arms using a chi-squared test. Because we will be enrolling all screening-eligible individuals at CCOE programming events, we will perform subgroup post-hoc analyses to compare the primary outcomes by race. Logistic regression will be used to adjust for any baseline differences between the two arms that may

have influenced the primary outcome. Secondary outcomes will be analyzed using appropriate statistical tests, such as t-tests for continuous variables and chi-squared tests for categorical variables. We will also use regression analysis to identify factors associated with intention to screen and lung cancer screening uptake.

6 - Trial Administration

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

This 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 an 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

Written informed consent will be provided to everyone enrolled in the study. During the recruitment process, potential participants will be screened for inclusion and exclusion criteria. During the screening process, 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 written informed consent to enroll in the study, or to decline to participate. If the

individual provides written informed consent, a copy of the consent form will be provided to the participant for their records.

6.5. Data Quality Assurance (if applicable)

The REDCap survey 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.)

Study 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 **and in a manner in which no identifiable information can be linked back to the study**.

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:

Both the **Cancer Prevention Precision Control Institute** and the **John Theurer Cancer Center Cancer Community Outreach & Engagement Program** are led by the principal investigator. There is primary office space for both programs at the Center for Discovery & Innovation on the Nutley campus. The space is well equipped with individual offices, cubicles, and several multipurpose rooms for conducting interviews and convening research team meetings.

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.

Administrative Support: The PI has full time administrative support who provide administrative 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