UNIVERSITY OF ILLINOIS
CANCER CENTER
Bench to Community

UI CAAN (Cancer Screening; Access; Awareness; Navigation)

Assessing the Effectiveness of a Community-Based Colorectal Cancer Screening Intervention

Version: 4

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Study Location(s):
University of Illinois at Chicago, including the University of Illinois Cancer Center and Mile Square Health Centers; Cut It Out Curt (a barber shop);

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LIST OF ABBREVIATIONS

ACS	American Cancer Society
COE	Community Outreach and Engagement
CPC	Cancer Prevention and Control Program
CRC	Colorectal Cancer
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
FITs	Fecal immunochemical tests
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Queer
MSHC	Mile Square Health Center
OCERIS	Office of Community Engaged Research and Implementation Science
OHRP	Office of Human Research Protections
OPRS	Office for the Protection of Research Subjects
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
UIC	University of Illinois at Chicago
UICC	University of Illinois Cancer Center
UI CAAN	Cancer Screening; Access; Awareness; Navigation
USPSTF	U.S. Preventive Services Task Force

1.0 Project Summary/Abstract

The UI CAAN (**C**ancer Screening; **A**ccess; **A**wareness; **N**avigation) Project is a community focused cancer education, prevention, screening and navigation program aimed at addressing the elevated burden of cancer among marginalized communities in the UI Cancer Center (UICC) catchment area. Cook County is populated by some of the most diverse racial/ethnic groups in the US; 2017 census data showed that almost 50% of the Cook County population is Hispanic/Latino (25%) and African American (24%). The top five cancers with the highest incidence rates in the UICC catchment area include Lung, Prostate, Colorectal (CRC), Breast and Cervical cancers. Within the UICC catchment, under-represented racial/ethnic minorities carry the greatest burden of cancer disparities, which is further impacted by social determinants of health. Cancer disparities in racial/ethnic minorities are further impacted by intersecting identities such as being a sexual and gender minority (LGBTQ) or by being differently abled.

UI CAAN advances health equity by addressing barriers to care; mobilizing community assets and partners; coordinating comprehensive prevention; screening and navigating patients to healthcare services and resources; and engaging community members as a vital part of the health care workforce. By employing community health workers and navigators *from* communities that are most impacted by cancer inequities, the UI CAAN addresses community inequities from an asset-based model. Creating a cancer screening/navigation workforce representative of the diversity of the UICC communities also addresses workforce needs of underserved communities. The overall goal of this project is to evaluate the feasibility of conducting community-based colorectal cancer screening in an urban environment. We will study the efficacy of the community-based intervention on improving CRC screening rates. A controlled trial will be conducted to achieve these objectives. Additionally, we will characterize factors that inhibit and/or facilitate colorectal cancer screening among people in the UICC catchment area.

2.0 Background/Scientific Rationale

Population health can be improved by implementing effective screening programs for CRC. CRC is the second-leading cause of cancer death in the United States. The USPSTF recommends screening for CRC starting at age 50 years and continuing until age 75 years. The American Cancer Society (ACS) recommends screening starting at age 45. Fecal immunochemical tests (FITs), which identify intact human hemoglobin in stool, are FDA approved tests for detecting CRC (Lin et al. 2016). Screening strategies that employ annual screening with FIT have been shown to reduce CRC deaths (Lin et al. 2016). A 2015 community health needs assessment in the South Shore area (*http://www.southshorehospital.com/wp-content/uploads/2014/07/Community-Health-Needs-Assessment-2013.pdf*) showed that CRC deaths are an area of opportunity for health improvement in the South Shore community area.

The CRC screening process is complex, particularly for those that screen positive and require diagnostic evaluation, treatment, and/or repeat screening following an abnormal test. Furthermore, screening for CRC is not a one-time activity and instead requires annual screening to be most effective. The UI Cancer Center Community Outreach and Engagement (COE) program is housed within the Office of Community Engaged Research and Implementation Science (OCERIS) of the UI Cancer Center. OCERIS is the community engagement and health disparities research arm of the Community Outreach and Engagement Program of the UI Cancer Center's Cancer Prevention and Control Program (CPC). Established in 2014, OCERIS has led the mission of the UI Cancer Center to ensure the community is at the center of research, screening, prevention, and supporting the training of a diverse and inclusive biomedical and population health workforce. Mission: The mission of OCERIS is to lead the UI Cancer Center in integrating the community in everything it does through fostering community based screening, prevention, education, building community-academic partnerships, to conduct transdisciplinary research, training and education to reduce the burden of cancer health disparities and inequities.

This study is a direct results of OCERIS' involvement in ongoing community based screening and navigation programs, and will go beyond quality improvement in screening to extend to answer the important research questions about engagement within a healthcare system and lack of follow-up.

3.0 Objectives/Aims

We propose to address the multiple determinants of health that impact CRC screening in the South Shore community in the UI Cancer Center's catchment area by conducting a quasi-experimental intervention to test the effectiveness of FIT tests dispensed by community stakeholders (community-dispensed) versus FIT tests dispensed using standard of care procedures by a clinic (clinic-dispensed) on FIT test return rates. This study will follow ACS guidelines for FIT testing, with the South Shore community area assigned to the intervention group (community-dispensed). CRC screening within the Mile Square Englewood Health Center, using standard of care, will serve as our control group to use for comparison (clinic-dispensed). The intervention will include a multifaceted approach to health education and community engagement focused on CRC led by a team of trusted health champions (community leaders, a barber, a hair salon, and community health workers) in the South Shore community area. We specifically propose to investigate the following three specific aims to be achieved over the three-year project period:

Aim 1: To assess the feasibility and efficacy of the community-based CRC screening intervention in increasing CRC screening rates;

Aim 2: To evaluate individual-level knowledge related to CRC screening and risk factors;

Aim 3: To characterize individual -level facilitators and barriers to engaging in CRC screening and related diagnostic tests and treatment when applicable.

4.1 Eligibility

Community Intervention Group/Arm

Eligibility to participate in this community intervention will primarily be driven by location of residence and age, since screening CRC have established age criteria for screening initiation. A total of four community health navigators will be deployed in the South Shore community area. Each navigator will be trained to understand the eligibility criteria and determine subject eligibility. For those that consent to take the FIT kit and return it, the navigator will document the participants' eligibility in the appropriate REDCap participant information form (attached). .

Standard of Care Comparison Group/Control Arm

Within the Mile Square Health Center system, lay navigators already work to do colorectal cancer screening in the Mile Square Health Center setting. It is standard of care for these navigators to engage patients in health education and awareness regarding the need for colorectal cancer screening. As such, each navigator is familiar with eligibility criteria for screening under standard of care. For the purposes of this study, we will use deidentified aggregate data from the CRC screening navigation program at the Mile Square Health Center in Englewood as a comparison group to evaluate the value of the community intervention relative to standard of care. As general practice, each navigator at MSHC keeps a running tally of the number of patients approached, deemed eligible, and who opt to participate in colorectal cancer screening during each day the navigator works in the health center setting.

4.2 Inclusion Criteria

- Male or female adults ages 45 to 74, who speak English and reside in or near the South Shore community area or utilize the Mile Square Englewood Health Center. Must not have had CRC screening in the previous 12 months.

4.3 Exclusion Criteria

- Adults ages <45 or >74, those that do not speak English, do not reside in or near the South Shore community area, do not utilize the Mile Square Englewood Health Center, or have had CRC screening in the previous 12 months.

Table 1. Inclusion and Exclusion Criteria

Cancer Screening	***4.1 Inclusion Criteria***	***4.2 Exclusion Criteria***
Colorectal	Male or Female Age ≥45 and < 75 years Resides in or near the South Shore community area (within UI Health MSHC-South Shore Clinic Service Area) Utilizes the Mile Square Englewood Health Center	Age <45 or >75 years Does not reside in or near the South Shore community area (within UI Health MSHC- South Shore Clinic Service Area) Does not utilize the Mile Square Englewood Health Center Does not speak English Has received CRC screening in past 12 months

5.0 Subject Recruitment and Enrollment

Participants will have an opportunity to enroll in this project at multiple points as summarized in Table 2. We will enroll at least 600 men and women across a three-year period for CRC screening in the South Shore community area, and acquire deidentified aggregate comparison data for the men and women who engage in CRC screening in the Mile Square Englewood Health Center across the same three-year period.

Community Intervention Group/Arm

For the intervention arm, the team of community navigators will recruit participants from multiple venues. We will work with local business owners who are actively engaged in health advocacy and will use their local businesses as sites of participant recruitment (Cut It Out Curt, a barber shop and a hair salon (Location TBD)) to identify and inform eligible community members within or near the South Shore community area about CRC screening. These partners will post the attached CRC screening flyer, and engage with each potential participant to provide information and education about CRC screening using the attached script. If the participant is interested, the partner will inform one of our trained community navigators who will connect with the interested participant to review the study information sheet and ask the participant to provide written consent to participate. Once the participant agrees to participate, the navigator will document the participant's contact information, and assist the participant in obtaining and understanding how to use and return their FIT via mail. The navigator will also give the participant a short survey (attached) to complete. The FIT test, instructions, survey, and mailing envelope will be contained in a “FIT Kit,” a labeled plastic bag, that will be dispensed to participant by the community navigator. The FIT and survey will be returned to the UICC via mail or dropped off at the barber or hair salon using a drop box (to be picked up regularly by research personnel), where it will be processed by key research personnel following the manufacturer's instructions. Participants who receive their FIT from the barber or hair salon will be offered a $25 gift certificate to the barber or hair salon for use towards a future service. Each community navigator will keep a tally of the number of participants who are approached, eligible, and who decline to participate in screening for evaluation purposes. All potential participants will be informed that declining participation will not influence their ability to participate in any future activities at either business or with the UICC.

In addition to recruitment efforts in the barber shop and beauty salon, our community navigators who are trained on the study protocol will attend community events in the South Shore and surrounding communities such as the annual African Festival of The Arts (*https://www.aihusa.org/african-fesitval-of-the-arts*) where UICC hosts an informational table each year. These navigators will use the attached CRC screening flyer, and engage with each potential participant to provide information and education about CRC screening using the attached script. If the participant is interested, the navigator will review the study information sheet and ask the participant to provide written consent to participate. Once the participant agrees to participate, the navigator will document the participant's contact information, and assist the participant in obtaining and understanding how to use and return their FIT. The navigator will also give the participant a short survey (attached) to complete. The FIT and survey will be returned to the UICC via mail or dropped off at the barber or hair salon using a drop box, where it will be processed following the manufacturer's instructions. Any positive FIT will be promptly reported (within 48 hours) to the MSHC clinical navigator, who will follow standard practices to register the participant as a patient, and navigate the participant through standard medical care if clinical follow-up is needed due to a positive screening and need for a diagnostic examination within the MSHC System. Participants who receive their FIT from a community navigator outside of the barber or hail salon setting will be offered a $25 incentive (Walgreens store gift card or cash) to be paid upon receipt of the FIT to UICC. Each navigator will keep a tally of the number of participants who are approached, eligible, and who decline to participate in screening for evaluation purposes.

Standard of Care Comparison Group/Control Arm

For the standard of care control arm, we will obtain deidentified aggregate data from the Mile Square Englewood patients that are approached following standard practice utilizing clinic schedules, walk-ins, etc. to identify potentially eligible participants for CRC screening during the intervention period. This aggregate data will include the number approached, the number eligible, the number that take and return the FIT kit, and the number of FITs returned. Among those that return the FIT, aggregate data will be provided detailing the proportion of positive FITs, the proportion of positive FIT participants who return for diagnostic services, and the proportion of detected cancers.

Table 2. Subject Enrollment Plan

Screening Target	***Community-Based (Intervention Arm)***
Colorectal	- *Community navigators will work with local businesses (barber shop, hair salon) to identify and screen eligible community members within or near the South Shore community area. The navigator will engage with each potential participant using the attached script. If the participant is interested, the navigator will document the participant's contact information, and assist the participant in obtaining and returning their FIT.* - *Community navigators will attend community events to post the informational flyer and provide education about CRC to community members. At these events, they will identify and screen eligible community members within or near the South Shore community area. The navigator will engage with each potential participant using the attached script. If the participant is interested, the navigator will document the participant's contact information, and assist the participant in obtaining and returning their FIT.*
Screening Target	- ***Standard of Care Clinic-Based Comparision Group (Control Arm)***
Colorectal	- *These procedures are a detailed summary of the existing lay navigation program at MSHC. These procedures are unrelated to our research, except to demonstrate how the existing navigation program from which we will obtain deidentified data works.* - *Lay clinic navigator use clinic schedules and walk-ins to identify and screen eligible participants within the Englewood MSHC. The navigator engages with each potential participant using standard scripted language. For interested patients, the navigator documents interest and FIT dispensing as appropriate, and assists the patient in obtaining and returning their FIT.* - *Lay clinic navigators attend community events as normally scheduled to provide community-based health education and referral to the MSHC. At these events, they identify and screen eligible community members within the Englewood community area.*

6.1 Study Design and Procedures

6.2 Dimensions of the RE-AIM framework

The overall aim of this study is to assess the feasibility and efficacy of the community-based CRC screening intervention in increasing CRC screening rates. We have designed this controlled trial in an effort to improve the quality of CRC screening that people receive and to assess whether or not implementing a community-based intervention where FIT tests are dispensed by community stakeholder will increase screening rates for CRC in specific community areas in

Chicago. If we find evidence supporting the efficacy of our intervention, that will demonstrate that community-based CRC screening interventions that actively involve community stakeholders in screening education and implementation may be a potential tool to improve health outcomes among the people that live in medically underserved communities. The RE-AIM framework will be used to evaluate both process and outcomes of the intervention program (Gaglio et al. 2013; Glasgow et al. 1999; Glasgow et al. 2019). The RE-AIM framework has proven utility in assessing program impact. Through the RE-AIM Framework we will be able to assess Reach, Effectiveness, Adoption, Implementation and Maintenance.

Data will be collected to evaluate our ability to “reach” targeted community members, hard to reach community members and the targeted number of participants. This is defined as the absolute number, proportion, and representativeness of individuals who are willing to participate in screening within our target community area. The clinical outcomes proposed through this project include improved screening of high risk populations for CRC screening and improved early detection of cancer through improved screening. To disseminate the findings to key stakeholders and community members, we will hold town hall forums to inform community members of findings from the project and produce infographics that clearly and succinctly communicate study findings.

6.3 Study Procedures

The expected flow of participants through the study is depicted in Figure 1.

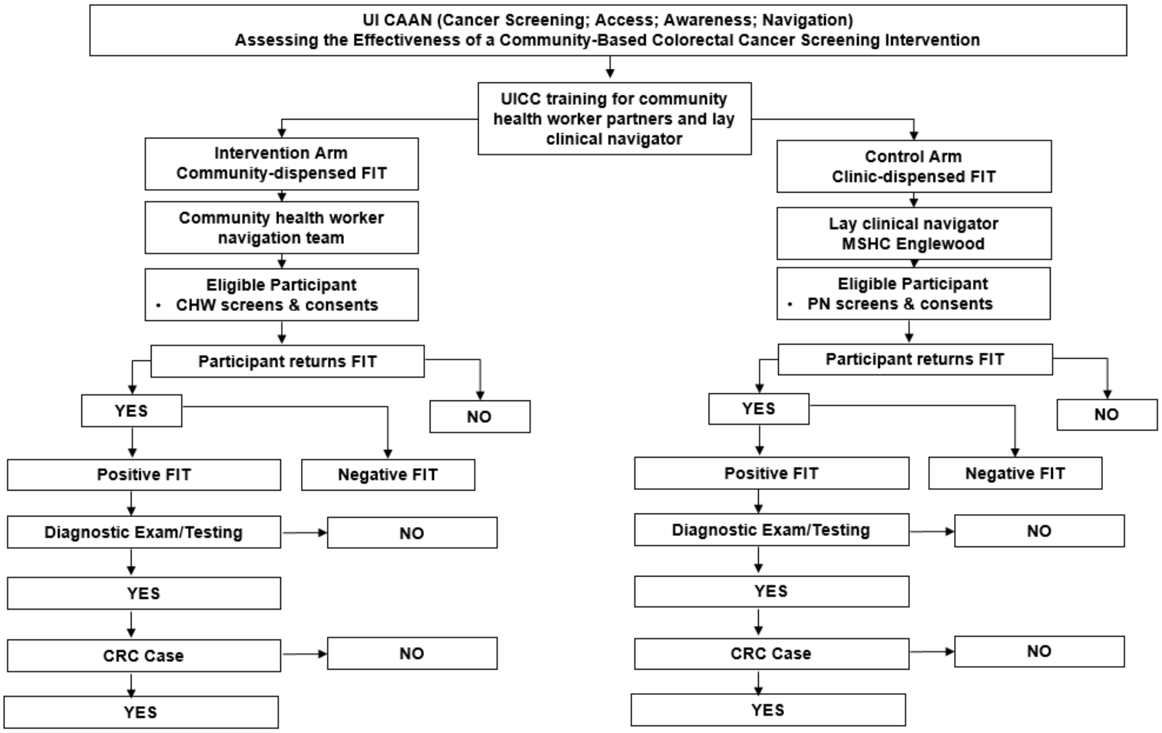

Figure 1. Study Design Schematic

Community Intervention Group/Arm

For the intervention arm, community navigators will work with local businesses (barber shops, nail/hair salons, restaurants, etc.) to identify and screen eligible community members within the South Shore community area. In an effort to increase screening among the LGBTQ community, navigators will work with local entertainment venues to post the study flyer in order to provide information to patrons, and identify eligible participants for screening. The navigator will engage with each potential participant using the attached script. If the participant is interested, the navigator will review the study information sheet and ask the participant to provide written consent to participate. Once the participant agrees to participate, the navigator will collect contact information from the participant (see Participant Information Form), and provide the participant with a FIT, a short survey to complete and return with their FIT, and a postage paid envelope addressed for delivery to the UICC. The participant will also have the option to return the FIT at the barber or hair salon using a drop box. If the FIT is not returned within two weeks, the navigator will call the participant to remind them to return the FIT.

FITs will be returned via mail directly to the UICC, where they will be processed following the manufacturer's guidelines. Navigators will call back each participant to let them know about the results of their FIT using the attached script. If a participant screens positive, the participant will be informed by the navigator, who will direct the participant to the MSHC- South Shore Clinic, and connect the participant to the MSHC- South Shore clinical patient navigator. We will track the time between FIT dispensing and return, and the time between FIT processing and participant agreement to engage in diagnostic testing with the clinical navigator at MSHC as indicated (for those that screen positive). Once the FIT is returned, participation in the study will end. However, for those that have a positive/abnormal FIT, the community navigator will refer the person to MSHC for clinical follow-up. This is not part of the research, but to ensure a continuum of care among those that screen positive. The clinical navigator will follow the standard clinical flow and standard clinical care practices used at the MSHC- South Shore Clinic to schedule the participant for a diagnostic test, and any further procedures or treatments necessary. This will include, but is not limited to, helping the participant enroll in a health insurance program if the participant is uninsured, and/or obtaining a voucher to pay for the diagnostic/further screening examinations and tests. For CRC screening, we have partnered with administrative and clinical staff at the MSHC- South Shore clinic in the South Shore community area to facilitate this transition when needed.

Standard of Care Comparison Group/Control Arm

For the standard of care control arm, the lay patient navigator at Mile Square Englewood Health Center will provide deidentified aggregate data from the Mile Square Englewood patients that are approached following standard practice utilizing clinic schedules, walk-ins, etc. to identify potentially eligible participants for CRC screening during the intervention period. This aggregate data will include the number approached, the number eligible, the number that take and return the FIT kit, and the number of FITs returned. Among those that return the FIT, aggregate data will be provided detailing the proportion of positive FITs, the proportion of positive FIT participants who return for diagnostic services, and the proportion of detected cancer.

For project evaluation purposes and to compare to the intervention arm, the deidentified aggregate data will include the number of participants who receive the FIT, return the FIT, screen positive, have a positive diagnostic, and receive a diagnosis. We will track the time between FIT dispensing and return, and the time between FIT processing and participant engagement in diagnostic testing as indicated (for those that screen positive).

7.1 Expected Risks/Benefits

Potential Risks:

- Participants who engage in colorectal cancer screening by completing and returning the FIT may require diagnostic testing to evaluate if they have colorectal cancer. Some of the participants identified for diagnostic testing may or may not have colorectal cancer. Engaging in subsequent diagnostic testing and/or receiving a cancer diagnosis may cause these participants to feel psychological discomfort. All diagnostic and subsequent testing (as necessary) will be conducted within the MSHC system under standard of care, which has resources and trained staff to answer questions that participants may have during this time.
- Breach of confidentiality is another risk to individuals. To minimize the loss of confidentiality, the PHI collected for the participants will be kept on a password-protected UICC secure server network. No published data or public reports will have any identifiable information.
- We do not foresee any other physical, psychological, social, or legal risks to subjects.

Potential Benefits to Subjects and Society:

- An individual may benefit from participation in this study by having an existing cancer identified and diagnosed and being navigated to a source of treatment.
- Friends and family members of individual participants may benefit from increased awareness about colorectal cancer and the recommendations for screening.
- The potential benefit to society is that this study could have important public health implications future community based screening programs of adults. The information learned from this evaluation may aid future intervention or prevention studies.

8.1 Data Collection and Management Procedures

- Navigators will collect participant contact information for tracking and follow-up using REDCap.
- Survey data will be collected via a paper survey, which will be entered into REDCap. Following data entry, paper copies will be destroyed.
- All participant Protected Health Information (PHI), including contact

information, and full street address, unique participant ID numbers, demographic, the date a FIT was returned or diagnostic completed [colonoscopy]), navigation and follow-up data is stored on the University of UICC's password-protected secure server (K drive) in an encrypted Excel data entry workbook. Only the Principal Investigator (PI), Co-Investigators (Co-I), and key research personnel have access to the password-protected data entry workbook.

- Data will be harmonized and cleaned prior to analyses by the statistical team at the UICC and stored on the UICC secured server. All individual workstations at UIC that access data with PHI will be encrypted. PIs will have access to all data collected. Overall data management will be overseen by the PI and Research team.

9.1 Data Analysis

- Prior to any analyses, all data sources (tracking, demographic, and questionnaire) will be cleaned and linked using the participant unique study identifier. We will summarize the data using frequencies and percentages for categorical variables, and means and standard deviations for continuous variables.

Aim 1: To assess the feasibility and efficacy of conducting a community-based CRC screening intervention in increasing CRC screening rates. We aim to evaluate the feasibility and efficacy of conducting a community- based navigation program for colorectal cancer screening. In both arms of the study, we will examine the number of participants who were provided with health education about colorectal cancer, the number of FITs distributed, and the number of FITs returned. We will summarize the number of persons screened positive and negative, and determine the proportion of positive screening participants who are referred to clinical care overall, and at the Mile Square South Shore and Englewood sites through our community navigation program (intervention) and existing MSHC lay clinical navigation program. We will compare the FIT return rate and average return time at the South Shore and Englewood sites to determine if the rates and times are similar. We will also determine return rates and times for participants who screen positive and are navigated to return the MSHC for diagnostic testing, and make comparisons across the intervention and control arms.

Aim 2: To evaluate individual-level knowledge related to CRC screening and risk factors. We aim to assess knowledge related to CRC screening and risk factors as measured by our short survey that participants will return with their FIT. We will summarize the frequency and percentage of respondents who have had a prior CRC screening, in addition to the frequency and percentage of respondents who select the correct answers on knowledge questions.

Aim 3: To characterize individual -level facilitators and barriers to engaging in CRC screening and related diagnostic tests and treatment when

applicable. We aim to evaluate facilitators and barriers people living in or near the South Shore communities experience related to CRC screening and related follow-up. We will summarize the respondent responses to survey questions about barriers and facilitators.

10.1 Quality Control and Quality Assurance

- The program evaluator (Jessica Madrigal) will monitoring the data entry in REDCap weekly, and follow up with the navigation team as appropriate for continued quality control and improvements.
- The PIs will supervise and review the results of the FIT.

11.0 Data and Safety Monitoring

All participant information, including survey questionnaires and contact information will be kept secure with strict confidentiality. All key research personnel and clinical collaborators are or will be aware of HIPAA rules and will adhere to its policies when necessitated by science, before they initiate contact with participants. Risk of access to participant information will require simultaneous knowledge of data format, file name, password, and computer language. No individuals will be identified in any reports from the study. Confidentiality of participants will be protected in this project through assignment of a study identification number. Information linking the participant name and study ID number will be kept in a separate password-protected computer file that has no data concerning survey or other study-related data. Survey questionnaires, screening results, and details regarding engagement with the MSHC (among those with positive screening) will be coded and managed as separate files in a protected part of the computer network. Personal health identifying (PHI) information will be saved in XML files. De-identified survey questionnaire will be kept in standard statistical packages, including SSPS, SAS, or Stata. Data will be regularly backed up and securely stored. No information will be released that could lead to identification of any participating individual. All files will be encrypted/password-protected. We will log dates when the data are handled. We will have regular study team meetings to discuss data handling issues. Any breaches in confidentiality or privacy as well as any possible adverse effects that are unanticipated will be immediately reported to the UIC IRB for review and action. The study PIs will keep a log of the outcome of IRB decisions regarding these events and ensure study staff are aware of changes made as a result of IRB decisions.

Adverse Event Monitoring and Reporting. Participants will be asked to report each adverse health event in person at study visits or via telephone/email to Dr. Watson or University of Illinois at Chicago Institutional Review Board (IRB). The investigative team will monitor adverse health events related to the study procedures, respectively. The PI and his team will consult and determine the severity and appropriate response or action to the reported adverse health event. All serious unanticipated problems or serious adverse health events will be reported to the UIC IRB within 24 hours. Serious adverse health events are extremely unlikely to occur in this study; however, if such an event occurs, Dr. Watson will immediately inform the UIC Office for the Protection of Research Subjects and IRB within 24 hours. Any adverse event of a nature serious enough to warrant withdrawal from the study will also be reported to the UIC IRB in a timely manner. UIC Office for the Protection of Research Subjects requires that all other problems (non-serious adverse events) be reported within five days of discovery and provide sufficient information to gauge severity and to complete the mandatory Office for the Protection of Research Subjects report form. UIC Office for the Protection of Research Subjects has procedures in place to review the report form, and the PI is notified if further review, changes to research protocol or consent form, or other action is required.

12.1 Statistical Considerations

- The primary aim of this project is to evaluate the feasibility and efficacy of a community-based cancer screening intervention. The projected sample size will allow us to determine if the intervention is feasible, and we anticipate the sample size will be sufficient to make comparisons across the intervention and control arms of the study. The purpose of any analyses conducted is to understand the needs of the community being served and to inform future interventions in this area as they relate to cancer control and prevention.

13.1 Regulatory Requirements

13.2 Informed Consent

This research presents no more than minimal risk of harm to the participants. Written informed consent will be obtained by the community navigator prior to dispensing the FIT in the community. During the recruitment process, the community navigator team members will describe the study and screen potentially eligible participants. The community navigator team will use the attached script and informed consent document to inform all potential participants of the study procedures. Interested participants will provide written documentation of consent if they decide to enroll in the study. In addition to training on health education and colorectal cancer screening content, informed consent training for the navigators will include consent simulations in which the trainee will read the consent script and respond to various questions about the purpose and procedures of the project. All navigators will practice explaining the study and obtaining informed consent with the study staff prior to engaging in recruitment and enrollment. All adult participants will provide written informed consent for participation.

13.3 Subject Confidentiality

As described in section 11.0, no protected health information will be stored with the electronic datasets, and research datasets will be stored on a secure data server in the UI Cancer Center (maintained by the UIC College of Medicine IT department), accessible only by password, and backed up every night. For the purposes of enrollment and follow-up reminders for return of the FIT, some PHI will be collected, including name and address. This data is collected only because it is necessary to complete the research objectives. This information will be entered into a secure REDCap database. Identifying information for the study participants will be kept separately from the analytic dataset and will only be accessed by the PIs. These precautions are expected to be completely effective in eliminating risks to confidentiality. pIdentifiers will be kept separate from the study data. At the conclusion of the study, the research data with be stored without any PHI on a secure server in the UI Cancer Center (maintained by the UIC College of Medicine IT department).

13.4 Unanticipated Problems

Although unlikely, should any unanticipated problems or deviations from the protocol occur, the IRB will be promptly notified. When appropriate, the protocol would be amended to prevent further unanticipated problems or deviations from the protocol.

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