Increasing Uptake of Evidence-Based Screening Services through CHW-led Multi-modality Intervention: South Florida Center for Reducing Health Disparities

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1) **Protocol Title**
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5) **IRB Review History**
N/A

6) **Objectives**

In this proposal we seek to develop a CHW led multi-modality strategy for the early detection and/or prevention of the following four health priority conditions: Human Immunodeficiency Virus (HIV); Hepatitis C Virus (HCV); colorectal cancer (CRC) and cervical cancer (only women). To our knowledge, this proposal would be the first attempt to conduct a multi- pronged screening strategy that tests for four distinct diseases in a community based setting.

7) **Background***

For nearly decade, the University of Miami's South Florida Center for Reducing Health Disparities (SUCCESS) has led interventions to improve health and reduce health disparities among the most vulnerable and medically-underserved individuals throughout the Miami metropolitan area. Since inception, our approach has been guided by the principles Community-Based Participatory Research (CBPR), involving community stakeholders in all aspects of the interventions design and delivery, including, but not limited to: needs assessments, program planning, implementation, evaluation, and dissemination of findings. To date, the bulk of such work has focused on increasing prevention and early detection of diseases that disproportionately affect communities disenfranchised from the formal healthcare system.

Specifically, we have tested the uptake of innovative screening modalities, such as cervical self-sampling, that circumvent known access and structural barriers to healthcare delivery through their portability and ease of use. Such modalities can be delivered by Community Health Workers (CHWs) in non-clinical settings, including the privacy of one's home, and therefore, provide prevention opportunity to even the hardest to reach minority population sub-groups.
A major limitation of all such projects is that each has existed as distinct, stand-alone initiative targeting a specific community and/or individuals who meet narrow eligibility criteria. In this proposal we seek to develop a CHW led multi-modality strategy for the early detection and/or prevention of the following four health priority conditions: Human Immunodeficiency Virus (HIV); Hepatitis C Virus (HCV); colorectal cancer (CRC) and cervical cancer (only women). To our knowledge, this proposal would be the first attempt to conduct a multi- pronged screening strategy that tests for four distinct diseases in a community based setting.

Our partners in this application will be the Health Choice Network- a consortium of Federally Qualified health Centers (FQHCs), and the Center for Haitian Studies- a health care and social advocacy organization predominantly serving Haitians- both longstanding CBPR collaborators. Geographically our study will be based in three South Florida communities with very active Community Advisory Boards: Little Haiti (Haitians); Hialeah (Hispanics); and South Dade (approximately 50% Hispanic, 25% Haitian and 25% non-Haitian black).

We propose a pragmatic trial of 900 persons aged 50-65 who have not been appropriately screened for one or more of the above four conditions. In each of the three communities we plan to recruit 300 residents from community based venues (not health care facilities) using strategies and approaches guided by our community partners and CABs. Persons will be randomized to one of two active CHW led intervention arms. The first will be CHW education and navigation to partnering health centers for appropriate screening. The other will be a CHW conducted multi-modality screening approach using some of the latest technologies for home based screening for these conditions as follows 1) HIV (oral buccal swab testing); 2) Hepatitis C (finger stick testing);, cervical cancer (using self-sampling for Humana Papilloma Virus [HPV], the virus responsible for most cervical cancer), and CRC screening (through home fecal Immunochemical testing [FIT] kits). The proposal incorporates important feedback from our existing community partners, namely that a) health interventions should not be limited to one health condition; b) patient-centered pragmatic trials should use a comparative effectiveness design, rather than a “control” group; and c) data collection should be simpler and less intensive.

Our specific aim is to determine if a strategy in which CHWs themselves conduct the multi-modality screenings results in an increase in the proportion of participants whom have been screened for all four conditions as compared to a strategy in which patients are actively linked to primary care at one of our participating health centers. Our study will have over 95% power to examine our primary hypothesis that the CHW led multi-modality screening strategy will result in a fifteen percentage point increase in participants who are up to date in screening for these four conditions (3 for men) as compared to a strategy of linkage to primary care. Secondary analysis will examine increases in screening for each of the four conditions individually. Subgroups analysis will include data within each community, by race/ethnicity and by gender. We will also calculate the costs and cost effectiveness of having persons screened in each arm. Demonstrating that a CHW led multi-modality home based screening approach leads to increases testing rates among minority populations in non-clinical settings will provide important information for health systems undertaking population health management approaches to improving the health of minority communities.

8) Inclusion and Exclusion Criteria

Rational for inclusion/exclusion criteria: our target population are individuals ages 50-64 living in one of the three target communities who have not been screened for HIV, Hepatitis C, colorectal cancer, and/or cervical cancer per USPTF guidelines.

To be eligible men or women must:

- 1) live in one of the three target communities
- 2) self-identify as Haitian, Hispanic and/or Black.
- 3) be 50-65 years old

- 4) need at least one of the four recommended screening services as per USPSTF121 guidelines as follows: never having had a HIV test b) never having had a HCV test c) not having a Pap smear in the last three years d) not having had a colonoscopy in last 10 years and/or stool-based test in the last year.

EXCLUSION CRITERIA:

Men or women will not be included in the study if they:

- 1) plan to move out of the community during the next six months;
- 2) current or prior enrollment (5 five years) in any research study that involved screening for these conditions.
- 3) Are adults unable to consent
- 4) Are individuals who are not yet adults (infants, children, teenagers)
- 5) Pregnant women
- 6) Prisoners

9) **Number of Subjects**

900

10) **Study-Wide Recruitment Methods**

Participants will be recruited to participate in the study primarily through the efforts of Community Health Workers (CHWs), who are indigenous to the area, employed by our community partners and certified to conduct research by the University of Miami (UM) Institutional Review Board (IRB). The CHWs are not UM employees but are CITI-certified and are from both the Health Choice Network, which includes the Citrus Health Network and Community Health of South Florida, Inc. (CHI), and the Center for Haitian Studies (CHS).

The CHWs will be trained by the Principal Investigator and community partners about how to approach potentially eligible individuals and encourage their participation in the study. They will recruit participants from various community settings in Little Haiti, Hialeah, and South Dade, such as laundromats, flea markets, health clinics, local botanicas, and church gatherings, that have been identified through ethnographic community mapping as regularly frequented by the target population. The CHWs will also rely heavily on their own social networks and those of the community leaders, to identify potentially eligible participants.

Although we recognize the inherent limitations in such non-probability approaches to sampling, our preliminary research in Little Haiti and Hialeah indicates that more random recruitment strategies engender suspicion and compromise overall participation. As a result, we must employ a non-probability, purposive quota-based sampling strategy to recruit participants. However, we will attempt to introduce randomness into this sample by using recruitment protocols that direct the CHWs to approach every Nth person in socially salient community settings. We will compare study samples with data abstracted from the US census to better understand whether our sample is, in fact, representative of our target communities.

Community Advisory Group members will also promote our research agenda through culturally-appropriate communication channels, such as radio print media, and flyers. Radio is the primary

news source for a majority of residents in our target communities, and can help generate community interest in, and support for the proposed research.

11) Study Timelines

An individual will participate in the study for six months (baseline interview at intake and a six-month follow-up interview). We estimate the time necessary to enroll all study subjects will be 35 months.

12) Withdrawal of Subjects

Participation in study is completely voluntary where participants can elect not to answer any specific question on the questionnaire. It is also voluntary to complete the FIT test and can elect to not participate at all in the study.

13) Study Endpoints*

Our primary study outcome measure will be proportion of the persons fully up to date on all their needed screenings for these four health conditions (three for men). This will be a binary (yes/no) variable which is the proportion of participants receiving all the appropriate screening for the conditions they were eligible at the time they enrolled into the study (three for men and four for women) and had not completed at six months. Although our primary outcome is based on self-report, for all participants who received care through the health centers as well as those who chose to undergo HBT we will have access to the electronic medical records and our own lab records (FIT, HPV, HCV) to validate the 6 month self-reported data. These can be used in sensitivity analyses (in our HPV study 70% received care at the health centers). As per CONOSORT guidelines we propose an intent-to-treat analysis. Participants who were lost to follow-up will be assumed not to have the screening(s) that had not been done before the enrollment into the study. However, through electronic records and our lab records we may be able to obtain data for some of those who were lost-to-follow-up which can also be used in sensitivity analyses. As a secondary study outcome measure, we will examine each screening individually as a binary variable and look at the change from baseline to 6-month of participants having each screening done in each arm of the study. For example, change in proportion of people up to date in screening for HVC in each arm. Another secondary outcome we will consider is the increase in median number of screenings done. For this endpoint, the possible ranges will be 0 to 4 for women (HIV, HVC, HPV, FIT) and 0 to 3 for men (HIV, HVC, FIT). For example, at baseline one group may be up to date for a median of 2.3 screenings and at study conclusion in may be 3.1. Screening completion for study participants is documented at the 6 month exit interview. All screening for Arm 1 participants will occur at a primary care clinic and screening procedures will be based on clinical standard of care for the relevant health condition. Confirmation of screening completion for Arm 1 participants will be based on self-report. All screening for Arm 2 participants will be home-based. Screening will be confirmed by study team member and documented upon completion. Participants in both study arms will receive opportunity for screening prior to study completion at 6 month exit interview if screening has not previously been reported (Arm 1) or completed (Arm 2). Additionally, please note that we

are testing the feasibility of two screening approaches (clinic based vs. home based) so those participants that do not complete screening are not considered screening failures.

14) **Procedures Involved***

Determination of eligibility The CHWs will screen potential participants for eligibility by asking whether they are 1) Haitian, Hispanic orBlack, 2) 50-65years of age or older, 3) have not hadscreening for one of the four health priorities, 5) has not been enrolled in a similar study (e.g. SUCCESS, HIYA, FIT), 6) is not pregnant, 7) will not move in the next 6 months.. For those persons who screen potentially eligible, the CHW will further describe the study. Potential participants will be told that we are conducting a research study to determine the best method to increase rates of cervical cancer, colorectal cancer, HIV and Hepatitis C screening among persons in their community. They will be told that the study will involve a brief education session about prevention and treatment, as well as instructions on how to use the relevant screening test we will be providing them with.

- **Persons who decline participation**: For persons who are potentially eligible but were not interested in participating, the brief demographic information collected during the eligibility screen (age, ethnicity) will be kept without any identifiable information. This data will be used to compare responders versus non-responders.
- **Persons who agree to participate**: The study research associate (RA) will obtain signed informed consent from the persons who are interested in participating.

Informed Consent and Intake Survey:
The CHWs will follow up with potentially eligible participants, verify inclusion criteria, discus the study in detail, and if interested in participating, schedule a study intake visit. The intake visit will take place in an area of mutual agreement, e.g. home or the local health center. During intake RAs verify that the person meets the study criteria, explains the study in detail, answers any questions, and obtains written informed consent. The RA will then proceed with the study intake. Based on input from community partners, CABs, CHWs and our RAs, we try to limit the entire intake process to less than 45 minutes (including consent process) which requires some very thoughtful prioritization of items to include in our questionnaires. Most importantly is self-reported data on the four health screenings. In addition we also collect basic socio-demographics (age, gender, race, education, ethnicity (including country of birth, immigration, marital status, acculturation122) and information regarding access to care.123 At the conclusion of the visit, the RA thanks the subject for participation and gives them a $20 gift card for their time and effort (Publix supermarket cards are most popular). All participants will also receive a culturally tailored (Spanish, English or Kreyol) brochure on preventive services outlining the USPSTF guidelines for screening for these four health conditions. The RA then tells participants to expect a call within a week from the CHW. The RA also reminds them of the six months follow-up interview.

Randomization: Participant tracking and reporting will occur per CONSORT guidelines. Once subjects are identified as potentially eligible they are assigned a tracking ID number. Data on age, race, ethnicity and need for each preventive service obtained from the eligibility screen will be tracked from the time they are identified as potentially eligible until they are ultimately recruited, without any patient identifiers. After signed informed consent is obtained, subjects will be assigned study subject specific IDs and randomization will then be performed in a 1:1 ratio by

block (site, gender) using SAS Procedure PLAN. The 900 subjects will be randomized into one of the interventions 1)Navigation to Primary Care or 2)Home Testing. The CHW will call participants within a week, using the randomization phone script, to inform them of 1) randomization group allocation, and then 2) navigate to primary care (Group 1) or schedule a screening visit for home-based screening (Group 2).

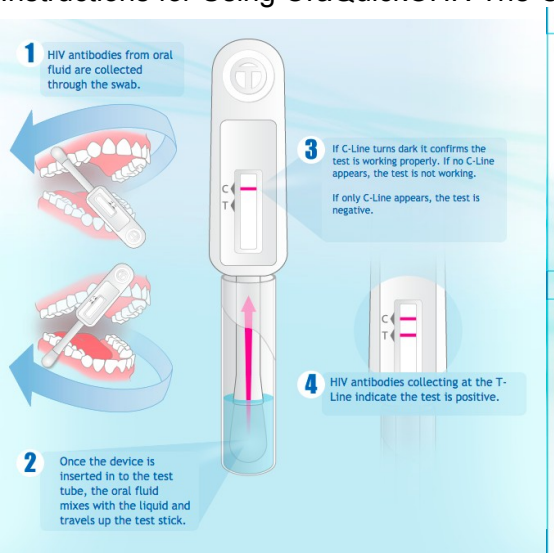
Group 1: Navigation to Primary Care - CHWs will contact participants, assess which preventive services they are eligible for and work closely with their FQHC supervisor develop tailored approaches appropriate for each person (consistent with the pragmatic trial design). The preferred approach will be to navigate subjects to primary care services at the health centers where PCPs as part of routine care evaluate patients for needed preventive services. EMR data from HCN shows that in 2014-15, CHI and Citrus performed a combined total of 15,532 CRC screenings, 3,443 HCV and 3,861 HIV. As health centers outreach workers, CHWs will not limit the scope of work to the four screening services. They will also to help link study subjects with other services offered by the centers (e.g. facilitated enrollment in health insurance plans, immigrant and refugee programs, behavioral health, and programs for person with diabetes, as needed. CHWs will have flexibility in how and where to navigate subjects for preventive services. In some cases persons may already have PCPs and appropriately choose to go to them for care. Subjects may also prefer to obtain these services from other locations such as Project Screen (free cervical cancer screening for women age $\geq$50), locations providing anonymous HIV and Hepatitis C testing, or health fairs sponsored by health centers or even UM.

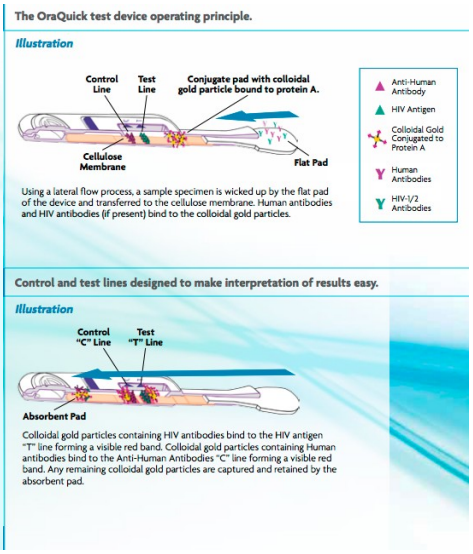
Group 2: Home-based Screening: The CHWs will develop tailored approaches appropriate for each person in this arm. Some persons may prefer navigation to primary care. But in this arm CHWs will have the ability to conduct the interventions themselves using the home-based kits. There are various strategies CHWs may use. The approach likely be acceptable for many subjects will be selecting a place of mutual agreement to conduct the needed testings. Most typically it will be at the person's home, though it can be at another location such as the FQHC. However, some subjects may prefer we mail kits they can conduct themselves (HIV) or mail back to us for analysis (FIT, HPV). For mailed kits, CHWs would conduct follow-up phone calls encouraging mailing the kits back (FIT, HPV) or that testing has been performed (HIV). One potential limitation of this approach is for HCV where only blood finger stick tests have been approved. Although there are no saliva tests, there is an FDA approved HCV home blood test. But as per Dr. Thomas (study team expert on HCV) most participants prefer the CHW to do the test because few people are willing to do their own fingerpick (our CABs also agreed with this). However, based on patient preference we will also explore the possibility of mailing the approved HCV home test to select patients. All persons who chose home based testing options will receive a letter signed by Dr. Carrasquillo explaining their results which they can provide PCPs. CHWs will emphasize that while they are following a broad set of screening guidelines, only a PCP will know which preventive services are needed for each person based on their unique circumstance and risk profiles. An example being that persons engaged in sexually risky behaviors may need annual testing for HIV. Thus, all persons who chose the CHW facilitated home based testing option will still be urged to follow-up with a PCP who can more exactly review any preventive and screening tests subjects may they may need (including other conditions like diabetes, cholesterol or breast cancer).

Screening Devices:

All screenings for Group 1 will utilize standard of care screening devices (e.g. Pap smear, HIV PCR, Hepatitis C PCR, and colonoscopy and/or FOBT) and will occur at a primary care clinic. Below we list the home-based screening devices for Group 2.

HIV1 (1/2) using oral swab testing: OraQuick®HIV (OraSure Technologies, Bethlehem, PA) OraQuick Test detects these HIV antibodies in the oral fluid. The test uses an oral swab to collect mucosal transudate is by swabbing the gums. Persons can perform the test themselves or have the CHW (using appropriate bloodborne pathogens precautions) collect the swab for them. The CHWs will be trained in all HIV testing procedures, pre and post-test counseling by Dr. Sonjia Kenya who has trained several CHWs for her prior HIV studies. Clients who test positive can have confirmatory test done at either one of the participating health centers of the South Florida AIDS network.
Instructions for Using OraQuick®HIVThe OraQuick®HIV Test Device





Hepatitis C: Patients will be tested for HCV infection using a fingerstick blood test. The OraQuick® HCV Rapid Antibody Test HCV (OraSure Technologies Inc, Bethlehem, PA). The test which has been shown to have a specificity of 99.6-99.9%. Sensitivity is practically identical for venous blood, fingerstick blood, serum, and plasma (99.7-99.9%). If a patient tests positive for HCV using this point-of-care test they will have the option of going to the FQHC for confirmatory blood testing or can have the testing done at the Schiff Center for Liver disease. At Schiff sera are tested using the VITROS Anti-HCV Reagent Pack on the VITROS 3600 Immunodiagnostic System (Ortho-Clinical Diagnostic, Rochester, NY, USA). Specimens with a signal-to-cut- off ratio > 1.0 will be considered to be positive. (specimens with a signal-to-cut-off ratio >8.0 by the VITROS Anti HCV assay do not require anti-HCV RIBA 3.0 confirmatory testing). Those samples with positive anti- HCV will undergo further testing for HCV RNA quantification with Roche Cobas/Ampliprep (Roche, Indianapolis, IN, USA). CHWs will be trained the procedures for HCV testing as well as pre-post test counseling by Dr. Thomas who has trained other CHWs involved in Schiff Center HCV screening initiatives. For patients with positive confirmatory testing the CHWs will explain and discuss in great detail the serology results in relation and the potential for complications to individuals who have HIV. The importance of screening for their family members will also be emphasized. As the cost of medications for HCV are considerable (over $80,000) through a unique partnership brokered by the UM Schiff Center, involving the Gilead Patient Assistance program, AcariaHealth Specialty Pharmacy, and

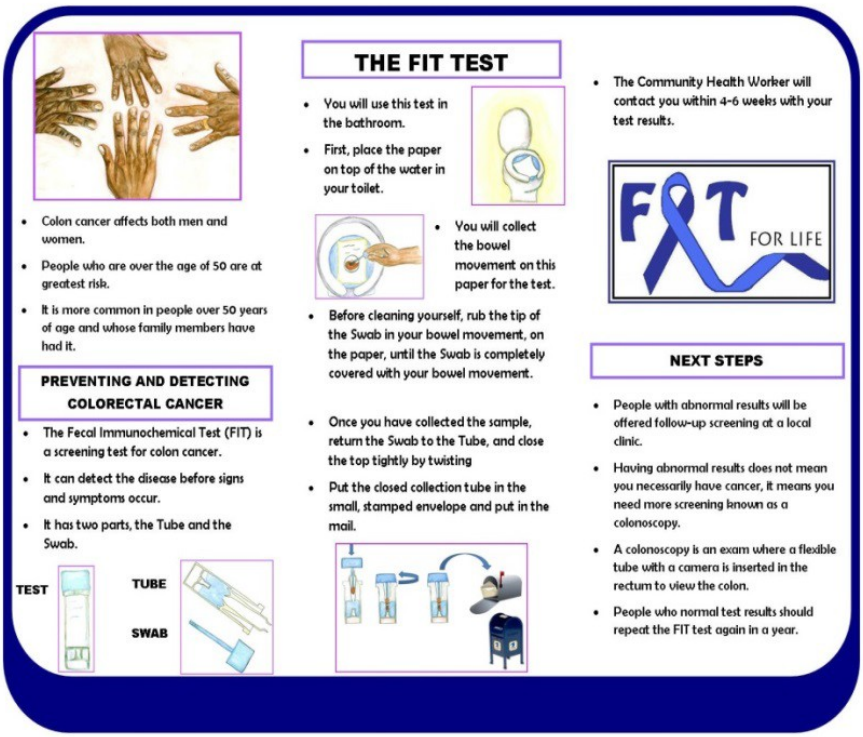
SkyeMed Infusion Services, they are able to provide treatment in our UM affiliated public hospital (Jackson) for all patients who screen positive in their HCV screening programs.

OraQuick Rapid point-of-care HCV test Procedures for HCV Testing

CRC: Subjects will receive education on the importance of CRC testing as well as how to properly perform the FIT at home using materials from the American Cancer Society and the manufacturer of the FIT product which we have translated and tailored to our population. CHWs will subsequently make follow up calls to reinforce education on proper collection and ensure return of FIT specimens. We use a CLIA-approved FIT
(OC-Auto Micro 80, Polymedco/Eiken, Cortlandt Manor, NY). This FIT is a quantitative test with a cutoff for a positive, abnormal result of 100 ng hemoglobin/mL stool. Patients receive education on how to properly perform the stool collection at home from a spontaneously passed bowel movement, and will be provided a FIT collection kit, consisting of the collection device, instructions, and a mailer so that the sample may bedelivered to UM Pathology by a Research Assistant. Patient samples will be mailed to a PO Box using the mailers and self-addressed, stamped envelopes provided in the FIT kit. Individuals will be asked to record the date of stool collection on the mailers, and the date of sample receipt by the laboratory will also be recorded. Samples may be stored in the laboratory in a refrigerator (4-8 degrees Celsius) for up to 7 days

from specimen collection, within proven manufacturer specifications. If specimens are not received and analyzed within 7 days of collection, the laboratory staff will inform the study team that the patient sample will need to be re-collected. Samples will be analyzed using the OC-AUTO Micro 80 (Eiken/Polymedco), a fully automated device providing objective results, using the manufacturer's recommended cut-off of 100ng/mL of hemoglobin or higher as a "positive" or "abnormal" result. This machine is calibrated on a weekly basis, or more frequently if the power is lost. Our team has participated in a calibration using reference standards from Eiken to ensure the fidelity of the results from our pilot investigation described above. Patient results will be reviewed by Dr. Sussman from gastroenterology (investigator) and stored in a password-protected file. CHWs will be disseminate test results to participants. If FIT results are normal, these patients will be instructed by the CHW to return for repeat FIT in their primary care clinic in one year. If FIT is abnormal/positive for blood in the stool, patients will be scheduled for colonoscopy within ninety days with the assistance of the CHW including navigation through the financial classification program for the medically indigent at Jackson Memorial Hospital. Prior to colonoscopy, CHWs will contact patients for a total of three times to provide education and reminders to ensure proper preparation for colonoscopy.. Colonoscopy preparation will consist of 1 gallon PEG-3350 (e.g., GoLytely) ingested as a split dose. All three of our CHWs participated in the FIT study led by Dr. Sussman and Kobetz and trained in study procedures including post test counseling and system to navigate patients for colonoscopy.

Instructional Brochure we use for FIT Testing



Cervical Cancer Screening: We are using the HPV self-sampling device developed by Preventive Oncology International (POI) and the National Institutes of Health (NIH). (Preventive Oncology International Inc., Ohio, USA). The POI/NIH self-sampler is a nylon swab that is 2cm in

diameter and 15cm length. Based on prior feedback on comfort and ease of use from earlier study participants, we are using the sampler without the outer sheath. After the woman collects the sample using the swab, she removes the swab out of her vagina and gives it to the CHW. The CHW puts the swab in a pre-labeled liquid media vial (ThinPrep, Holigic Inc, Bedford, MA) stirs the sample, caps the bottle, and stores the sample in a re-sealable plastic bag in a locked cabinet. Once a week, the CHW delivers the samples to the University of Miami's Department of Pathology for processing. The sample is then sent to an outside CLIA approved laboratory (Quest Diagnostics Inc.) for HPV testing. Initially our specimens were being processed by Quest using the Cervista HPV Invader Assay (Holigic Inc). This was later changed to APTIMA HPV Assay (GenProbe Inc). The former tests for HPV using a DNA based two-step signal amplification method and the latter tests for mRNA using a three step transcription-mediated amplification assay. Both assays test for the fourteen HPV strains which have been identified as high risk HPV by the International Agency for Research on Cancer163 (i.e. 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). They have similar sensitivitiesfor detection of cervical Intra-epithelial neoplasia (CIN2+). All three of our CHWs participated in the HPV study led by Dr. Carrasquillo and Kobetz and are trained in study procedures including post test counseling and system to navigate patients Pap smears if they screen positive and colposcopy if they have an abnormal smear. All three participating FQHCs have on site gynecology services providing colposcopy.

Report of Lab Results

For Group 1, participants will receive their test results and follow-up from their primary care provider. For Group 2, it will be the CHW whom communicate the results, provide post-test counseling and referrals. For those whom choose mailing kit options for HIV/HCV the CHW will give her cell phone number and also follow-up with phone calls to ensure post test counseling and referrals are done.

Confirmatory blood testing for HIV and HCV positive tests as well as Pap smears (for HPV positive samples) can be done at the FQHCs. If needed they can be done at no cost to the subject through the South Florida AIDS Network (SFAN) for HIV, Schiff Center for HCV and Project Screen for HPV. SFAN and Project Screen also cover follow-up costs of treatments when needed. The expected 1-3% of persons having positive FIT tests will need to have colonoscopies. Our CHWs have become very adept at helping participants navigate our public hospital's financial classification requirements to obtain colonoscopies. Referrals are also facilitated by Dr. Sussman who is an attending gastroenterologist for these clinics.

Exit Survey at 6 months: At 6 months RA's (blinded to study allocation status) will reach out to all subjects to conduct an exit interview. She will make up to 15 attempts, including evening and weekend calls. This limited interview will ask about having each of the preventive services, where the service was received (using the EMR we can validate if received at the FQHC), if home based testing was used (we can also validate), and questions on access to care in last six months (PCP visits). This follow-up can be done in person or by phone. Our CHWs are very creative in helping RA's find subjects "lost to follow-up". Once the subject exits the study, if they are missing any preventive service the RA will encourage them to contact the CHW whom can provide a home based kit regardless of what arm they were in during the study (CABs made this important ethical recommendation).

15) Data and Specimen Banking

HPV specimens will be banked for future use. The self-sample specimens will be taken to the Oncogenomic Core Facility at UM Sylvester Comprehensive Cancer Center (SCCC). FIT specimens will not be banked. Specimens will be mailed by participants or taken to UM/JMH laboratories by study staff. Specimens will be labeled with a number that matches the number assigned to the participant during the study intake. Results will be reported back to Study Manager within 2 weeks, who will obtain signature from Dr. Carrasquillo. He will sign and date lab result sheet. Copies of results will be filed and kept in locked cabinet.

16) Data Management

All study data will be captured by REDCap (http://project-redcap.org/), and Velos (velos.med.miami.edu), which provides both secure data capture for clinical research studies. The REDCap (Research Electronic Data Capture) system (project-redcap.org/) is a web-based clinical research management application that is designed specifically for investigators and their research teams. It supports processes for patient recruitment, patient scheduling, budgeting, invoicing, and milestone management, data safety monitoring, adverse event reporting, system integration, data collection and study execution. Data safety checks, redundancy, and skip patterns can all be easily programmed. A major strength for our proposal is that REDCAp allows all study related information to be centralized yet be accessed through the internet from anywhere through encrypted and password protected access granted only to authorized personnel as designated by the study PIs. It is easy to use, reliable, fully HIPPAA complaint and completely secure. A major advantage of using this system is that UM provides this important resource to UM and associates (such as non-UM community research partners) at no cost. This includes technical support and effort of REDCap team staff who assists investigators in uploading all their surveys and questionnaires into REDCap. In this study, all of the data collected at the time of the home visit by the CHW will be uploaded in real time into REDCap system. However, the CHWs will also have paper versions of the instrument for the anticipated but hopefully rare occasions when technological glitches occur. In these cases the CHW would input the data at a later time. Through REDCap we also have the ability to integrate data from various distinct sources including several EMRs platforms including those of in the community.

In compliance with HIPAA, individual subject confidentiality is assured through the use of ID codes throughout the processing and analyses maintained through our REDCAP system. Additionally, none of the analyses will permit identification of any individual. At the central office level, individual subjects will be “known” only by their ID numbers, which will be used as the basis for communication with the RA in the event of data anomalies.

Generally speaking, the clinical/ research barrier will remain intact, in that it will not be necessary for any of the data-processing staff to be familiar with the identity of any of the patient-subjects. Off site, electronic back-up of REDCAP data occurs daily. In addition, all computers are password protected and use encryption algorithms to upload data.

For UM based computers, a hardware-based firewall separation will protect against hackers and unauthorized access to all electronic data. This will provide protection against viruses, worms and Trojan horses transmitted over the Internet. Spam and email filtering is also built-in within the firewall device. The firewall contains anti- virus software (MacAfee Anti-Virus) to protect the network from threats of viruses contained in email attachments. This anti-virus software is automatically updated for all virus definitions. .

For data entry, we will be using computer assisted entry using REDCAP and Velos. The first 20 subjects enrolled will have date entry and quality checks for outlying variables missingness and proposer use of skip patters will done by Koru-Segul's team initially every week and after the first 30 subjects are enrolled will be moved to monthly.

DATA & SAFETY MONITORING COMMITTEE OVERSIGHT
The Sylvester Comprehensive Cancer Center (SCCC) Data and Safety Monitoring Committee (DSMC) will monitor this study research according to the Cancer Center's Data and Safety Monitoring Plan (DSMP). In its oversight capacity, the DSMC bears responsibility for suspending or terminating this study.

DSMC oversight of the conduct of this study includes ongoing review of adverse event data, and periodic review of **the proportion of persons fully up to date on all their needed screenings for the four relevant health conditions (three for men)**. The guidelines appearing in Section **Study Endpoints** are offered for DSMC consideration in assessing adverse events and **the proportion of persons fully up to date on all their needed screenings for the four relevant health conditions**. In addition, the DSMC will review reports from all audits, site visits, or study reviews pertaining to this research study and take appropriate action.

The SCCC DSMP to which this study is subject can be found at www.sccc.org.

Trial Monitoring, Auditing, and Inspecting

The investigator will permit trial-related monitoring, quality audits, and inspections by, government regulatory authorities, of all trial-related documents (e.g., source documents, regulatory documents, data collection instruments, case report forms). The investigator will ensure the capability for inspections of applicable trial-related facilities. The investigator will ensure that the trial monitor or any other compliance or QA reviewer is given access to all trial-related documents and trial-related facilities.

Participation as an investigator in this trial implies the acceptance of potential inspection by government regulatory authorities.

Quality Assurance and Quality Control

In addition to the Clinical Monitoring component of this protocol, Quality Assurance will be implemented (QA) to assess compliance with GCP and applicable regulatory requirements. Data or documentation audited shall be assessed for compliance to the protocol, accuracy in relation to source documents and compliance to applicable regulations.

Statistics

17) Risks to Subjects

HCV: Fingerstick testing has minimal risk but may result in residual risk. For both HCV and HIV the follow-up confirmatory testing may result in some bruising of the skin, some bleeding or swelling at the site of blood draw.
HPV: The POI/NIH self-sampler is considered a non-significant risk device and has been approved for research conducted by NIH faculty throughout the United States and in various

international settings. POI/NIH has conducted a thorough review and assessment of the potential hazards associated with the device. In testing over 300 women we had no major hazards causing serious injury and only a few instances where minimal patient discomfort resulted.

Screening: As will all screening tests, anxiety will result from having a positive result until confirmatory testing is done. Training CHWs in pre-post test counseling is essential to minimize this risk. In addition, those who test negative may believe that since they had negative result they are no longer needed to be seen by a provider for a routine check-up by a PCP. In all parts of the study, CHWs will stress to subjects that regardless of test results, they will still need to see a PCP to do a comprehensive annual evaluation including any preventives test they may need including ,any not covered by this intervention such as cholesterol.

Breach of personal health information is also an additional risk.

Adverse Experience Reporting: If any participant who chose to use the screening tests to CHW that a discomfort is persistent or something else has occurred, CHW should contact directly the Principal Investigators of the study.

18) Potential Benefits to Subjects

1. There may be direct benefits to the participants. All persons will receive health education as part of the process and those in the navigation group will receive assistance to see a PCP for needed health services.
2. Those, in the home based testing group, may receive screening services they were on need of and in cases be linked to needed health care. ion our cervical cancer of 600 women we ultimately identified two women who were ultimately diagnoses with early stage cervical cancer.
3. At the conclusion of the study (6 months), and after the follow-up visit is completed, the CHW will attempt to contact all persons in need of any screening and offer them home based tests in person or by mail.

19) Vulnerable Populations

N/A

20) Multi-Site Research

N/A

21) Community-Based Participatory Research

Grant funding from the NIH enabled the creation of a University institute to address health disparities. The institute, known as South Florida Center for Reducing Health Disparities or SUCCESS, is focused on attenuating the excess burden of cervical cancer observed in Little Haiti, Hialeah, and South Dade. For the past decade, our team, comprised of diverse academic and community stakeholders, has been working to increase screening opportunity through outreach and education that reflects the unique cultural and linguistic needs of our target communities, and builds upon the assets of our extensive network of community partners. With the support and active participation of such partners, we have played a critical role in over 100 events held throughout Hialeah, Little Haiti, and South Dade this year alone. This study provides an opportunity to extend our impact, and continue our work in our targeted communities.

Publication policy/Results Reporting/Progress and Final Reports:

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers x years after the completion of the primary endpoint by contacting <specify person or awardee institution, or name of data repository>.

22) Setting

The CHWs will identify and recruit potential subjects at various community venues that they deem appropriate and at which our target populations tend to congregate. These may include, but are not limited to laundromats, churches, health clinics, and flea markets in Little Haiti, Hialeah, and South Dade.

23) Resources Available

The current research study uses SUCCESS' infrastructure to accomplish study aims and build necessary capacity to support future large scale, community-based interventions to address other areas of cancer disparity. SUCCESS has established Community Advisory Groups (CAGs) in Little Haiti and a steering Community Leadership Board (CLB). The CLB involves representation from members of all CAGs as well as other local experts in cancer prevention and control. The CLB meets quarterly to maximize information exchange between CAGs and also to ensure that key findings are disseminated to the community in a timely and appropriate manner. Additionally, SUCCESS is an active member of the Southeast Florida Cancer Control Collaborative, a group of more than 50 local organizations that collaborate on cancer prevention, education, and patient services, and may provide future opportunities for dissemination and expansion of the pilot intervention.

24) Confidentiality

Multiple steps will be taken to guarantee confidentiality. All paper-based surveys and forms will be entered and uploaded using Research Electronic Data Capture (REDCap) and Velos. All REDCap data is securely hosted by the University of Miami's IT Department. Research IT administers project creation, user account management, and movement of projects from development to production. Authentication is performed via CaneID Authentication Service (CAS), the same institution-wide system used for a variety of applications such as myUM. Other electronic data will be stored in password-protected files that only Dr. Carrasquillo and the Study Manager and study staff will be able to access. There are multiple levels of security once placed on the local network. Paper copies will similarly be stored in a locked file drawer that only Study Manager and the Data Manager will be able to access. **All human participants enrolled in the research study conducted at the University of Miami Miller School of Medicine (including any University of Miami facility, all affiliated and satellite locations will also be registered in the Velos clinical trial management system. Velos is a web-based clinical research management application that is designed specifically for investigators and their research teams. Velos supports processes for patient recruitment, patient scheduling, budgeting, invoicing, and milestone management, data safety monitoring, adverse event reporting, system integration, data collection and study execution. All study-related information is**

centralized and can be accessed from anywhere. Password-protected, the account is accessible only to authorized personnel.

All study personnel will be certified to conduct human subjects' research by the University of Miami Institutional Review Board.

All data will be inspected for quality assurance prior to analysis. Prior to performing statistical analyses on quantitative data, the data will be checked, screened and verified. Data checking is critical to ensure the integrity of the database. Range checks will be routinely performed, and random items from the raw data will be checked against the entered data so that mistakes can be identified.

The study investigators and their staff will consider all records confidential to the extent permitted by law. The U.S. Department of Health and Human Services (DHHS) may request to review and obtain copies of any records. Records may also be reviewed for audit purposes by authorized University employees or other agents who are bound by the provisions of confidentiality

25) Consent Process

Written Informed consent will be obtained by the RA at the intake visit. We will be following the SOP HRP-090 Informed Consent Process for Research when obtaining consent. Consent will be obtained in a private area from individuals who are eligible and agree to participate after the RA describes the study. Potential participants will be told that we are conducting a research study to determine the best method to increase rates of cervical cancer, colorectal cancer, HIV, and Hepatitis C screening among individuals in their community. Informed Consent will be provided in English, Spanish, and Creole, based on the participant's language preference.

26) Waiver of Signed Consent

A waiver of signed consent is requested for screening activities. This research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.