Increasing African Immigrant's Breast Cancer Screening
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Principal Investigator*: Jamilia R. Sly, PhD

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CONFIDENTIALITY STATEMENT

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 03/9/2023

Name*: Jamilia Sly, PhD

Title*: Assistant Professor

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1 PROTOCOL SUMMARY

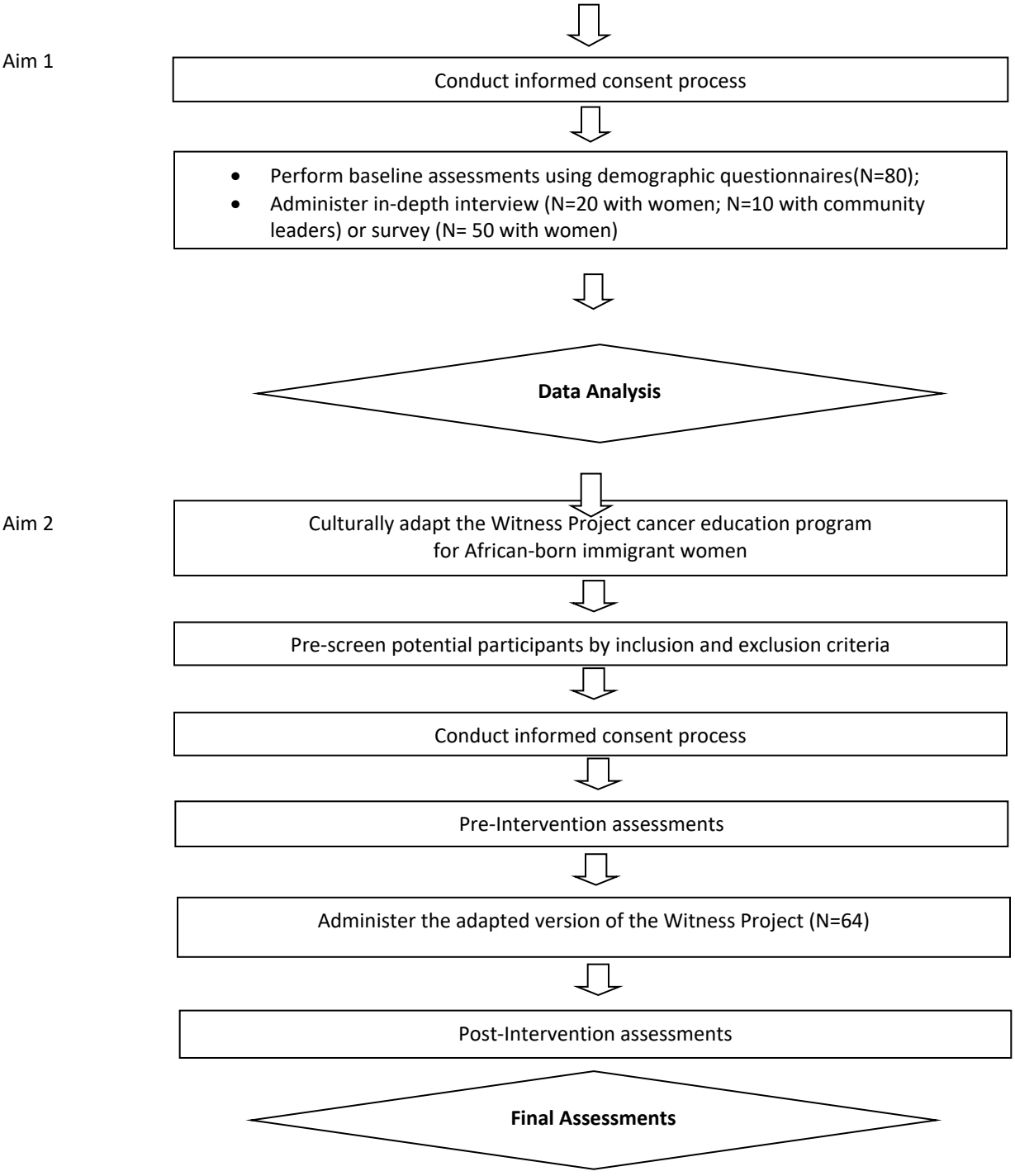
1.1 SYNOPSIS

Title:	Increasing African Immigrants' Breast Cancer Screening
Grant Number:	R21MN012863
Study Description:	The barriers and facilitators to breast cancer screening for other minority groups from underserved populations, such as African Americans and Latina women have been studied. Less is known about these for African immigrant women and how to most effectively engage their participation in regular screening. The long term goal of the proposed project is to conduct a clinical trial that tests the feasibility of an adapted intervention to increase breast cancer screening rates for African-born immigrants. The study team plans to pursue the following specific aims: (1) Identify barriers and facilitators to breast cancer screening among African-born immigrants and (2) Culturally adapt and pilot test the Witness Project breast cancer education program for African-born women.
Objectives*:	Primary Objective: Adapt and pilot the Witness Project breast cancer education program. Secondary Objectives: Identify barriers and facilitators of breast cancer screening
Endpoints*:	Primary Endpoint: change from baseline assessment of mammogram screening intention and mammogram location and appointment. Secondary Endpoints: change from baseline assessment of perceived breast cancer risk and self-efficacy for mammography.
Study Population:	Men or women 18 and older; stakeholder or leader in African immigrant community; English or French speaking (Aim 1) African-born women 40 years and older; English or French speaking (Aim 1) African-born women 38 years and older; English or French speaking (Aim 2)
Phase* or Stage:	Not Applicable
Description of Sites/Facilities Enrolling Participants:	Participants will be enrolled at one site (Icahn School of Medicine at Mount Sinai) in collaboration with African immigrant-serving community organizations.
Description of Study Intervention/Experimental Manipulation:	African immigrant women are at significant risk for not participating in preventive screening, such as for breast cancer. Thus, this project will culturally adapt an existing evidenced-based intervention, the Witness Project, by identifying barriers and facilitators to screening for African-born women and, guided by the Health Belief Model, incorporate those findings into a group-based narrative education program for English and French-speaking African immigrant women. The program content will include: (1) information about the benefits of early detection of breast cancer screening, (2) education about disparities in breast cancer, (3) education about disparities in breast cancer screening among African immigrant women, and (4) will address the unique barriers and facilitators of African immigrant women identified in Aim 1 of this study.
Study Duration*:	18 months
Participant Duration:	60 min (Aim1); 90 mins (Aim 2)

1.2 SCHEMA

Pre-Intervention Assessment

- Pre-screen potential participants by inclusion and exclusion criteria;
- Schedule in-depth interview or survey



1.3 SCHEDULE OF ACTIVITIES

	Pre-consent	Time 1
AIM 1		
Review Eligibility	X	
Schedule in-depth interview or survey	X	
Informed Consent		X
Demographics		X
In-Depth Interview/Survey		X
Data Analysis		
AIM 2		
Cultural adaptation of the Witness Project cancer education program for African-born immigrant women	X	N/A
Pre-screening of potential participants by inclusion and exclusion criteria	X	N/A
Informed Consent	N/A	X
Pre-Intervention assessments	N/A	X
Administration of the adapted version of the Witness Project	N/A	X
Post-Intervention assessments	N/A	X
Outcome Evaluation		

2 INTRODUCTION

2.1 STUDY RATIONALE

New York City (NYC) is home to a large and diverse immigrant population. Specifically, African immigration has increased over 750% in the past 20 years with a high concentration living in NYC.[1,2] African immigrants are a very heterogeneous population with no individual country accounting for more than 14% of the total; most are likely to live below the poverty line, less likely to have health insurance, more likely to have low health literacy, and less likely to visit a doctor particularly for primary/preventive care.[3,4,5] While overall screening rates for breast cancer have increased significantly in NYC in the last decade[6,7], many immigrant groups still face significant barriers to preventive health care, including lack of insurance, poor health care access and language difficulties. Without access to primary care, many preventive services, like breast cancer screening, go unattended. For example, annual mammography exams and timely follow-ups after abnormal findings are crucial for the early detection of breast cancer, which has been shown to be one of the most important factors of increased survival.

Health disparities plague the health care system and arise from a complex interplay of economic, social and cultural factors. The Health Belief Model (HBM) provides a framework for addressing cultural health disparities related to preventive health care and cancer screening by positing that making a decision to engage in a health behavior (e.g., cancer screening) is determined by weighing perceived threats (susceptibility, barriers) versus benefits.[11] Traditionally, health information has been presented in didactic forms (i.e., statistical evidence/facts) to educate, persuade, and engage target communities.[12,13] Narrative communication (i.e., storytelling, personal testimonials) has emerged as a method for supporting and motivating behavioral change including personal experiences with cancer or screening. The appeal and success of narrative communication stem from its familiarity as a basic mode of human interaction.[14,15] Our own work in minority and immigrant communities has shown that narrative communication can increase participation in cancer screening. Thus group-based narrative educational programs could play a significant role in promoting healthy preventive engagement including breast cancer screening among African immigrants.[16,17,18,19]

The proposed project is innovative in several important ways. First, to our knowledge, this study is the first to examine barriers and facilitators regarding the uptake of breast cancer screenings among eligible African-born women immigrants in NYC. A community-based intervention is one that entails a strategy for education and behavior change by increasing awareness and knowledge through public service announcements, education, written manuals, etc. Research on breast and cervical cancer screenings has targeted African Americans and Latinas [20,4,21,22,23]; but few have targeted African-born populations. Second, a community-based recruitment strategy for the cancer screening education intervention is proposed. Adopting this approach will allow us to reach African-born immigrant women at places they frequent and provide new information about the barriers and facilitators to breast cancer screenings, particularly among those who are currently unable to access health care. Third, to our knowledge, this is the first study to obtain the perspectives of African-born community leaders about how African immigrant women's participation in breast cancer screening can be improved. Fourth, this project will represent the first approach to pilot test the feasibility and acceptability of a narrative approach in educating African-born immigrants about breast cancer screening. While education programs can improve cancer and

cancer screening knowledge[20,24] and increase intent to get screened for other underserved populations, it remains to be seen if a theory-informed and evidence-based education program can be similarly effective among African-born immigrants. By incorporating an understanding of the barriers and facilitators to breast cancer screenings, we will target important facilitators and potential barriers to address in future interventions.

The long term goal of the proposed project is to conduct a randomized clinical trial that tests the adapted intervention to increase breast cancer screening rates for African-born immigrants. In the short term, we plan to pursue the following specific aims: (1) Identify barriers and facilitators to breast cancer screening among African-born immigrants and (2) Culturally adapt and pilot test the Witness Project breast cancer education program for African-born women. Thus, we will culturally adapt an effective, innovative intervention to address this significant health disparity in African-born immigrant communities. Once we have pilot tested the feasibility and acceptability of the intervention, we will apply for R01 funding.

2.2 BACKGROUND

Minimal research has been conducted specifically on the needs of African immigrant groups. Though African immigrants and African Americans/blacks share a common ancestral history, they are distinct cultural groups with differing values, perceptions, experiences and languages.[8] Available research studies often erroneously classify each culture as one homogenous group (i.e., African American/Black), which limits our understanding of the specific needs of African immigrants. Most research on the cancer control needs of African immigrants has focused on individuals from Nigeria, Somalia and Ghana[9], furthering limiting our understanding of individuals who are not from these countries. Immigrants from Africa come from many different countries that have distinct languages.[10] Lack of knowledge of the US healthcare system is a persistent problem for African immigrants and addressing language access and health literacy may be one approach to improving healthcare engagement in this population.

Our breast cancer screening data in this population of African-born immigrants, when corrected for age, shows that only 56% have ever had a mammography for breast cancer screening. *This finding demonstrates the need for breast cancer screening awareness and education within this population.* We have conducted robust culturally targeted outreach into several minority communities. The Witness Project (WP) is a community-based cervical and breast cancer education program that is designed to meet educational and cultural levels of underserved African American women. The WP model is a belief and theory-based intervention incorporating the Health Belief Model, locus of control beliefs, social learning theory, transtheoretical model of change and the 4MAT System.[43] The program begins with a narrative presentation by a breast cancer survivor who briefly shares her personal experience of breast cancer, from diagnosis to treatment and survivorship. Lay volunteers present educational information about breast cancer risks and protective factors, demonstrate how to perform a breast self-examination and a question and answer session concludes the program. Research by Jandorf (Co-I) and Erwin successfully replicated the Witness Project in 22 states at 40 unique sites including NYC. Replication was achieved using an Implementation Guide, locally produced, award winning video (now on CancerControl PLANET RTIPs) and training curriculum developed by Erwin and Jandorf (National Cancer Institute Cancer Control Planet). In NYC, we conducted hundreds of programs at a variety of community sites and have educated over 3,000

participants.[44,20,45,12] *This research demonstrates our ability to reach culturally targeted members in the community and over 15 years of community-based research experience.*

Development of *Esperanza y Vida*: A unique aspect of the Witness Project is the ability to adapt the program to another culture as evidenced by Esperanza y Vida (EyV). In 2003, Jandorf and colleagues initiated EyV to expand this breast educational program among Hispanic populations in a culturally and linguistically congruent, community-based approach.[4,12] EyV development was conducted with members of the target group, including qualitative studies, to ensure the adaptation would be culturally appropriate and meaningful.[46,47] The social network characteristics and language preferences (Spanish) assessed and integrated into the intervention to include such factors of where to present the programs (e.g. both community and faith-based locations) and the need to educate men about issues related to women's health.[22,4] *This successful replication and adaptation demonstrates our ability to adapt education programs through vigorous qualitative methods and pilot testing as well as to address linguistic needs of different cultural groups.*

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Physical risks in this study are minimal. The surveys include questions that are not different from those that might be asked or presented by a health care provider and thus do not pose greater than minimal risk. Although the chances of psychological distress are minimal, any psychological distress will be monitored by the staff and reported to the Principal Investigator.

2.3.2 KNOWN POTENTIAL BENEFITS

Although we cannot guarantee that participants may benefit directly from study participation, prior study participants have reported that they enjoyed providing researchers with greater knowledge of their experience in hopes of aiding the design of cancer prevention programs and materials and in possibly benefiting others. It is possible that for patients, participating may raise awareness of their need to uptake cancer screening and their decision to undergo screening. There are minimal physical risks posed by this study. Risk of psychological distress is possible as a reaction to some study questions about cancer. Research staff will monitor participants' reactions. Through the ongoing monitoring process of the study (e.g., regular meetings with research staff), the PI will be informed of any concerns/distress that occur at any point in the study. Given the potential gains to participants, the ratio of risk to benefits is quite low and reasonable.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The knowledge gained by conducting this research will help us to potentially develop interventions to increase the uptake of breast cancer screening among African-born immigrant women at high risk for breast cancer. There is minimal physical risk and minimal risk of psychological distress as a reaction to some study questions about cancer and screening; however these risks are overpowered by the

potentially life-saving benefits of cancer screening to prevent the onset of breast cancer in African born immigrant women.

Given the potential gains to participants, the ratio of risk to benefits is quite low and reasonable. There are no effective alternative procedures for collecting these data

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Adapt and pilot the Witness Project breast cancer education program	**Primary Outcome Measure:** 1. Mammogram intention: Participants' intentions to complete breast cancer screening by responding to: **A.** *For women who had a mammogram in the past:* **Do you think you will have another one?** *Yes, later this year (2023)* *Yes, next year (2024)* *Yes, in two years (2025)* *No* *Not sure/don't know* **B.** *For women who never had a mammogram in the past:* **Do you think you will have one?** *Yes, later this year (2023)* *Yes, next year (2024)* *Yes, in two years (2025)* *No* *Not sure/don't know* 2. Mammogram location and appointment: **Do you know where you could go to get a mammogram?** *Yes* *No* *Not sure* **Secondary Outcome Measures:** 3. Perceived Risk: Participants' perceived risk of developing breast cancer: What do you think are the chances that you will have breast cancer at some point in your life? (1. Very low 2. Somewhat low 3. Moderate	*Intention to screen is hypothesized to be a dependent variable.* *Perceived risk is hypothesized to be mediator variable that could explain the causal mechanisms of the intervention.*

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	4. Somewhat high 5. Very high) [Time Frame: Immediate] 4. <u>Comparison Perceived Risk:</u> Participants' perceived risk of developing breast cancer: Compared to the average person your age and gender, would you say that you are (1. Less likely to get breast cancer 2. About as likely to get breast cancer 3. More likely) to get breast cancer [Time Frame: Immediate] 5. <u>Self-Efficacy for Mammography:</u> Ten items will be used to examine participants' self-efficacy for undergoing mammography using a 5-point Likert-type scale. (Full scale from 1 to 5, with higher score indicating greater self-efficacy) [Time Frame: Immediate]	*Self efficacy is hypothesized to be a mediator variable that could explain the causal mechanisms of the intervention.*
Secondary		
Identify barriers and facilitators of breast cancer screening	N/A - survey/interview completion	N/A
Tertiary/Exploratory		
N/A	N/A	N/A

4 STUDY DESIGN

4.1 OVERALL DESIGN

The goal of Aim 1 is to collect formative data via a mixed methods approach and use those results to culturally adapt the Witness Project for African immigrant populations. Cultural adaptation will follow the stage model outlined by Barrera et al.[48] The model includes five stages: 1) information gathering to determine which intervention components to modify; 2) preliminary adaptation design that integrates information from stage 1 to inform preliminary modification of the original intervention; 3) preliminary adaptation tests to pilot the intervention for feasibility and acceptability, 4) adaptation refinement with decisions informed a leadership team/advisory board; and 5) cultural adaptation trial to test the effectiveness of the intervention in changing health outcomes. As this is the first step in this line of research, the proposed study will only follow stages 1-4.

The Witness Project has three main components that will be culturally adapted: 1) educational presentation addressing myths, barriers and values related to breast cancer and mammography, 2) culturally matched, peer led narrative about breast cancer experience, 3) experiential education about breast anatomy and self-examination.

The "point of interface" (i.e., merging quantitative and qualitative data) will be associations between mammography screening and HBM constructs (e.g., perceived risk, self-efficacy) and any socio-demographic characteristics (i.e., preferred language, health literacy level). The quantitative results will inform the refinement of the qualitative questions. For example, if an association is found between self-efficacy and screening, we will ask in-depth questions about self-efficacy and suggestions for how it could be improved in this population.

The design chosen for the pilot-test is a one-group pretest –posttest. All of the enrolled participants will receive the same intervention in their preferred language (English or French). To measure the impact of the intervention, will conduct a pre-post assessment of key variables around perceived risk for breast cancer, the intention to complete a mammogram, and self-efficacy related to seeking and completing breast cancer screening. This trial will also assess the feasibility and acceptability of the intervention.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Aim 1. Although there are multiple social/environmental determinants of cancer screening, screening involves an individual deciding whether to engage in the screening behavior or not.[26,27] The HBM asserts that an individual's attitudes and beliefs (e.g., perceived benefits, perceived barriers) will determine their behavioral intentions.[11] Therefore, improving breast cancer screening rates in African-born immigrant women requires a deep understanding of the factors that influence decisions about breast cancer screening uptake. Most existing health decision-making models assume that decisions about a behavior are a function of an individual's perceptions of the expected utility (benefit-cost ratio) of the behavior and of other cognitive factors (e.g., self-efficacy, perceived risk).[28,29,30] Expected utility and other cognitive constructs have been shown to predict engagement in cancer screening behaviors.[31,32,33,34] Specifically, several of our own studies in colorectal cancer screening have provided data on attitudes and barriers regarding colorectal cancer screening including fear, fatalism, less perceived disease risk, medical mistrust, lack of knowledge and insurance access.[35,36,37,38,39,40,41] Importantly, many existing screening educational interventions are based on these cognitively-focused models.[62] However, to our understanding, there are sparse data on attitudes and beliefs regarding breast cancer screening tests among African-born immigrants. To our knowledge, only one intervention to improve breast cancer among African immigrant women has been published. A linguistically targeted DVD-based intervention that provided information about health care services related to mammography, pap smears, and mental health services to Somali and Congolese women and increased knowledge and intent to undertake screening.[42] Culturally specific barriers and facilitators were not addressed which could have more a beneficial impact on intention than presenting information to participants in their language.

Aim 2. Narrative communication methods are a widely recognized tool for mitigating barriers and effectively increasing a variety of health behaviors including cancer screening.[14,53] Transporting narratives, or immersion into a story, can successfully change beliefs and motivate action.[15] Narrative communication is a comfortable way of presenting information because people communicate with each other and learn in everyday life primarily through stories.[14] By creating a feeling of similarity to and identification with the communicator, narrative communication can increase an individual's perceived risk regarding a particular health related behavior.[54] People with personal experiences make credible, believable messengers.

Additionally, narratives can be particularly useful for conveying cancer information because they reduce counterarguments which can help individuals overcome barriers to seeking treatment.[15] Narratives also diminish negative feelings towards unknown, difficult, or frightening procedures (e.g., screening), provide role models for behavior change and create new attitudes that are based on cognition and emotion.[15] Four distinct capabilities of narrative health communication are: "overcoming resistance, facilitating information processing, providing surrogate social connections, and representing emotional and existential issues."[14] Narrative means of communication have been shown to lead to significant emotional responses[55,56] which subsequently have a large impact on behavioral decisions. This feature is a major strength of the narrative approach.[14] Additionally, people are more likely to remember information that has an emotional impact on them or elicits an emotional response.[57] Embedding important information into personal stories accomplish this more effectively than simply conveying facts.[55,56]

There is substantial evidence that community-based group narrative education cancer screening programs can be effective in fostering positive health behavior change.[53,58,24,59] However, to our knowledge, no studies have examined the influence of these programs on barriers and facilitators on health care engagement among African-born immigrants. It is anticipated that, like with other cancer screenings, African-born immigrants' eligible for screenings face unique barriers to these procedures that can be successfully targeted in community-based group narrative education cancer screening interventions. One study showed that narrative communications about certain cancers (e.g., breast cancer) reduced message counterarguments, increased positive affect, fostered identification with the communicator and led to better engagement with the message. These outcomes thereby reduced perceived barriers, increased message recall and promoted discussion with family members.[53] Another study examining the effect of narrative and non-narrative skin cancer messages found that participants exposed to the narrative message were two to four times more likely to engage in health promoting actions and information-seeking behavior.[19] Furthermore, Dillard et al. found that participants who received a narrative message reported that colorectal cancer screening barriers would not have as much of an impact on screening decisions and the narrative message increased interest in colorectal cancer screening.[17] While numerous studies have illustrated the success of narrative communication over didactic communication in terms of various types of behavior change, neither narrative *or* didactic education formats have been developed within the context of African-born immigrants.

4.3 JUSTIFICATION FOR INTERVENTION

We have described the scientific premise and discussed the strengths of weaknesses of both the published research and our preliminary data. This careful consideration of the prior research and our preliminary data has been critical in: 1) identifying the gaps apparent in research and public health practice with respect to the unknown barriers and facilitators that African immigrant women face when attempting to undergo breast cancer screening; and 2) adaptation of the narrative group-based cancer screening education program that we propose to pilot test. We will identify cultural barriers and facilitators to engagement in breast cancer screening and develop a culturally targeted breast cancer education program for African immigrant women. The community-based education program will be the first its kind to specifically target barriers and reinforce facilitators to breast cancer screening faced by African-born

immigrant women. Aim 1 results will also provide information about specific intervention components to refine and adapt our existing community based narrative group education cancer screening programs on breast cancer. Results will detail the specific needs of the target population to inform the execution of Aim 2.

The results of this proposal are in direct alignment with the objectives of PA-17-043 and will lead to the development of a culturally-targeted theory-informed, group-based breast cancer screening education program. The successful completion of the study aims will make a novel and transformative contribution to the field of cancer screening, especially for this underserved and understudied population.

The mode of delivery of the intervention (a culturally-adapted education program on breast cancer screening) will be determined together with the target population and key informants form the community. Aim 1 of the study is precisely oriented to gathering relevant information to inform the adaptation of an existing program (Witness Project). Participants in Aim 1 of the study will be asked to suggest the ideal length of the intervention and the frequency of intervention contacts.

The intervention will be adapted for women born in Africa who currently live in New York City. The research team will explore the needs for a cultural adaptation of the existing intervention with the participants in Aim 1 of the study. The results of Aim 1 will inform the justification for the cultural adaptation.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed an interview or survey in Aim 1, or a baseline pre-program assessment and the post-program assessment in Aim 2.

The end of the study is defined as completion of the post program assessment shown in the Schedule of Activities (SoA), **Section 1.3**.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

- Eligibility criteria for Aim 1 include (n=80):

  i. Eligible individuals for Aim 1 in-depth interviews with leaders (N=10) will be:
     1) 18 years or older;
     2) stakeholder/gatekeeper in the African immigrant community;
     3) speak English or French.

  ii. Eligible individuals (n=70) for Aim 1 In-depth Interviews and Quantitative Surveys will be:
     1) women who are 40 years or older;
     2) have been born in Africa;
     3) speak English or French.

- Eligibility criteria for Aim 2 include (n=64):
    1) women who are 38 years or older;
    2) have been born in Africa;
    3) speak English or French.
    4) Smartphone or computer with zoom (for virtual programs)

5.2 EXCLUSION CRITERIA

Exclusion criteria include: 1) do not agree to audio record their interview.

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or entered in the study.

Individuals who do not meet the criteria for participation in this trial (screen failure) because of failing to meeting one or more inclusion criteria that are likely to change over time may be rescreened (e.g. age). Rescreened participants will be assigned the same participant number as for the initial screening.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

As indicated in the proposal, human subjects will be recruited for in-depth interviews (N=30) and surveys (N=50), in Aim 1 to understand preferred language, cultural beliefs, access to health care; healthcare engagement, knowledge of breast cancer screening guidelines and predictors of screening behavior. Recruitment will take place within African immigrant communities in New York City.

After incorporating the Aim 1 findings to our existing breast cancer educational program, 64 (n = 32 for English and n = 32 for French speaking) eligible African-born women will be recruited to pilot test the adapted educational program. Participants will be recruited from African immigrant communities in New York City.

Aim 1: Participants will be recruited from the community with the help of our community partner – African Services Committee. Our community partners will help us with our recruitment efforts by advertising the study within their organizations and at events and meetings they may hold for their consumers. Participants will be compensated $30 to a local store for participating in the research study. In addition, we will promote our study on social media (e.g. WhatsApp groups, Facebook pages) using flyers and video advertisements adapted for online sharing.

Aim 2: Experienced outreach coordinators, assisted by our community partners, will recruit local community, faith-based, and other social organizations to host breast cancer educational programs as we

have successfully done for previous studies. Moreover, our outreach team has a database of more than 100 faith- and community-based organizations with which we have developed relationships with and provided outreach and education for other studies. With the assistance of our partners, we will approach the leaders and gatekeepers of these organizations to present a breast cancer screening education program to their members. Research staff will focus on sites that include African-born immigrant women. A program will be scheduled by the coordinator and individuals at the community sites will be approached to participate in a breast cancer educational program. Some programs will also be held virtually. Some programs will be held in English and some in French; we will recruit participants who speak either English and/or French. Participants will receive an incentive for their time ($60 gift card to a local store).

The study team has significant experience recruiting participants and have well-trained culturally competent research staff. We have well-established collaborative relationships with gatekeepers in the African immigrant community and have successfully recruited African-born immigrants into other studies. Our prior recruitment has demonstrated response rates of 70%-90%.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

Aim 1 of the study is formative research for a cultural adaptation of the Witness Project. Aim 2 is a pilot test of the adapted program that will inform a larger trial to test the efficacy of the intervention.

The educational aspect of the program will be modeled after our current community based programs, as noted above, using narrative formats. The programs will disseminate relevant, up-to-date information for breast cancer to eligible African-born immigrant women. Trained staff will conduct the educational programs. Trained staff will enroll and collect data from English- and French- speaking African-born immigrants working with our consultants. Eligible individuals will be: 1) women who are 38 years or older; 2) born in Africa; 3) read and speak English and/or French; 4) smartphone or computer with Zoom for virtual program participants. Information and resources about breast cancer and existing primary care clinical services, including the mobile mammography van operated by our institution as well as external mobile mammography van programs, will be available to all participants. We will inform both insured and uninsured participants about the Cancer Services Program and local clinical service resources for those without primary care physicians (PCPs) as well as questions to guide them about asking clinicians about breast cancer screenings when they have medical appointments.

The educational intervention program will include: a) reviewing of the IRB Research Information Sheet, b) confirmation of eligibility for the study, c) completion of a brief demographic survey and pre-program survey, d) narrative presentation with topics addressing the benefits of early detection of breast cancer through screening; education about disparities in breast cancer; education about disparities in breast cancer screening among African immigrant women; and the unique barriers and facilitators to screening for African immigrant women identified in Aim 1 of this study, e) interactive discussion / question/answers

session and f) completion of the post-program survey including feasibility questionnaire and feedback discussion. After the completion of the question and answer session, participants will be given breast cancer resource guides with local information about how and where to obtain screening. The program will take approximately 90 minutes to complete. Participants will receive an incentive ($60 gift card) for their participation. Participants will complete a pre-program survey and a post-program survey to assess changes in HBM constructs. The post-program survey will also include a feasibility questionnaire. [62,63,64,65] The programs will be evaluated using a program summary template that Jandorf and colleagues have used in previous studies. The summary collects information about the length of the program, number of participants attending the program, gender of program participants, location and site of the program, number of staff and volunteers present, and type of site (faith-based or community-based).

For both in person and virtual educational programs, demographic and pre-post surveys will be primarily collected via RedCap. For virtual programs, participants will be provided with RedCap survey links via chat. For in person programs, participants will be able to complete surveys through RedCap on their own devices or on devices provided by the study team. Hard copies of the surveys will also be available for completion for in person educational programs. All pre and post assessments, collected via RedCap or hard copy of surveys, will be linked only via participant study ID. Assessments will not collect any PHI. They will be anonymous as participant names will not be collected.

6.1.2 ADMINISTRATION AND/OR DOSING

For Aim 1 of the study, interested individuals will be invited to perform the study activities in a single session, in which they will express informed consent, provide demographic data and complete an in-depth interview or an interviewer-administered survey. Once consented, participants may also complete the demographic questionnaire and/or the interview or survey on another time and/or day of their choice, if so they prefer (i.e., because they feel fatigued; if they have limited continuous availability of time).

For Aim 2 of the study, research staff will focus on sites that include African-born immigrant women 38 years of age and older. A program will be scheduled by the coordinator and individuals at the community sites will be approached to participate in a breast cancer educational program. Some programs will also be held virtually. We will conduct a total of eight programs in English (N=4) and French (N=4). We will recruit a total of 64 eligible women at each program. When recruiting program sites, the Research Assistant will emphasize the language in which the program will be conducted.

The administration of the intervention – including frequency, schedule, setting, and required personnel – will be determined using the input of individuals taking part in Aim 1 of the study.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

N/A

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

N/A

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

N/A

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

N/A

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded on the Case Report Form (CRF).

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to complete an interview or survey and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to complete the study requirements:

- The site will attempt to contact the participant, reschedule the missed interview or program within 2 weeks of the initial date, counsel the participant on the importance of their participation and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Table 1 below summarizes the measure collected for this study.

Table 1. Study Measures

Measure	Source	Study Aim	Number of Items	Reliability
Demographics	Study team	1,2	18	N/A
Breast Cancer Knowledge	Study team	1,2	6	N/A
Self-Efficacy for Mammography	Champion, Skinner & Menon, 2005	1,2	10	α = 0.91
Breast Cancer Fear	Champion, Menon, Rawl & Skinner, 2004	1,2	8	α = 0.91
Medical Mistrust	Thompson, et al., 2004	1,2	12	α = 0.80
Perceived Risk/Susceptibility	Health Information National Trends Survey, 2005	1,2	2	α = 0.79
Perceived Benefits/Barriers to Mammography	Adapted from Champion, Skinner & Menon, 2005	1,2	23	α = 0.73, α = 0.89
Fatalism	Powe et al., 1997	1,2	5	α = 0.88
Screening Behavior/Intentions	Adapted from O'Neill et al., 2008	1,2	4	N/A
Health Literacy	Chew et al., 2004	2	3	α = 0.76-0.887
Acculturation	Johnson-Agbakwu et al., 2014	2	38	α = 0.87
Feasibility and Acceptability	Vandelanotte & De Bourdeaudhuij, 2003	2	5	α = 0.79

After the completion of the interviews and surveys in Aim 1, a 3×3 table of themes categorized using the PEN-3 model [25] will be produced for each of the three components of the Witness Project: 1) addressing myths, barriers and values, 2) culturally relevant breast cancer narrative, 3) experiential breast education. Themes will be categorized in the following domains: cultural empowerment and relationships and expectations. These themes will inform *how* the intervention components for the educational narrative program should be adapted for an African immigrant audience. The themes will first be categorized according to barriers and facilitators to screening and then our team will decide which themes are appropriate. For example, barriers and facilitators from the cultural empowerment domain may include concerns about deportation, modesty, religiosity and healthcare screenings and will be addressed in the Witness Project component 1. Another example might be that barriers and facilitators from the

relationships domain could include concerns about the role of patriarchy in women's healthcare decision making – such as having a mammogram. This could potentially be addressed in the culturally relevant narrative (component 2). The cultural facilitators to screening identified in the interviews will be incorporated into the program by highlighting them as reasons to participate in screening. Cultural barriers identified will also be addressed in the culturally relevant narrative by providing examples and suggestions for coping with these perceived risks.

8.2 SAFETY ASSESSMENTS

Monitoring the progress of trials and the safety of participants. The proposed research is a low-risk behavioral trial. Research staff will carefully monitor each participant's emotional reaction during interviews and offer a referral when appropriate. As per ISMMS IRB policies, the PIs are required to notify the IRB promptly of any unanticipated problems involving risks to study participants or others that occur. The PIs and study investigators will monitor the progress of the trial and safety of participants on an ongoing basis. The procedures of this study, such as regular meetings with research staff, will ensure discussion and reporting of all possible outcomes including adverse events. If the adverse event is due to the study and is unexpected, the PIs will draft a safety report and send a copy to the ISMMS IRBs. The IRB committees will serve as an objective review mechanism. This policy/procedure means that any potential conflict of interest inherent in the PIs being the sole reviewers of serious adverse advents is avoided. The Data and Safety Monitoring Board (DSMB) meets at least quarterly to review the results of adverse event reporting, protocol deviations, protocol audits and the conduct of the study. Each ISMMS study not otherwise overseen by an external DSMB is reviewed at least annually. The DSMB reports the analysis of their review to Sr. Vice President for Research and to the IRB. To avoid conflicts of interest, members of the DSMB are not involved in the oversight of studies for which they serve as Principal Investigator or Co-Investigator/ biostatistician.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

Plans for assuring adherence with requirements regarding the reporting of adverse events (AEs) All serious adverse events (AEs) (e.g., medical occurrences resulting in death) that occur during the study defined by the given protocol, regardless of the relation to the research, must be reported to the IRB by telephone, e-mail or fax within 24 hours of the investigator's awareness of the occurrence of the event. The PIs will report AEs to the ISMMS IRB and will disseminate information to other agencies as necessary. These initial reports are followed by a safety report which is a written account of a serious AE determined by a sponsor/investigator to be both related to the treatment under investigation and unexpected in nature. Serious AEs will be summarized annually in the IRB application for continuation or termination of research. All expected non-serious AEs that occur at a greater frequency or severity than anticipated and all unexpected non-serious AEs will be reported to the IRB within 15 working days of the Investigators becoming aware of the event. These AEs are also summarized annually in the IRB application for continuation or termination of the research. Plans for assuring that any action resulting in a temporary or permanent suspension of an NCI funded clinical trial is reported to the NCI grant program director responsible for the grant. Jessica Moise, Director, Grants and Contracts Office at ISMMS, will provide

prompt written notification of any action resulting in a temporary or permanent suspension of this protocol to the NCI grant program director responsible for the grant.

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the Data Coordinating Center (DCC)/lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the DCC/study sponsor/funding agency within <insert timeline in accordance with policy> of the investigator becoming aware of the event

- Any other UP will be reported to the IRB and to the DCC/study sponsor/funding agency within <insert timeline in accordance with policy> of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within <insert timeline in accordance with policy> of the IRB's receipt of the report of the problem from the investigator

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Descriptive statistics will provide summary information about the feasibility of recruitment, acceptability and cultural sensitivity of the program and satisfaction with the program. An arbitrary cutoff value of 80% acceptance will determine the interventions' feasibility for the study. Some parameters include the proportion of eligible participants who are contacted, enrolled, agree, and disagree with the acceptability and cultural sensitivity of the program. Thus, if at least 80% of the participants exceed the previous parameters, the developed program will be determined to be feasible.

- Primary Endpoints:

We hypothesize that we will observe a change in the assessment of mammogram screening intention and knowledge of places where it is possible to obtain a mammogram appointment in the participants who will take part in the pilot test of the culturally adapted intervention (posttest), compared to baseline (pretest).

- Secondary Endpoints:

We hypothesize that we will observe a change in assessment of perceived breast cancer risk and self-efficacy for mammography in the participants who will take part in the pilot test of the culturally adapted intervention (posttest), compared to baseline (pretest).

9.2 SAMPLE SIZE DETERMINATION

We estimate that our sample size of 64 participants will generate a +/- 12% margin of error at a 95% confidence level.

9.3 POPULATIONS FOR ANALYSES

Per-Protocol Analysis Dataset

Descriptive statistics will provide summary information about the feasibility of recruitment, acceptability and cultural sensitivity of the program and satisfaction with the program. An arbitrary cutoff value of 80% acceptance will determine the interventions' feasibility for the study. Some parameters include the proportion of eligible participants who are enrolled, agree, and disagree with the acceptability and cultural relevance of the program. Thus, if at least 80% of the participants exceed the previous parameters, the adapted program will be determined to be feasible and acceptable. To determine program efficacy and sample size estimates for a future intervention, we will use a repeated measures ANOVA to analyze differences in the primary outcomes: screening intentions and HBM constructs (e.g., self-efficacy and perceived risk) immediately before viewing the educational program and immediately after viewing the program. We will conduct univariate and bivariate analyses of the data to provide descriptive summaries of the data, including demographics and responses to primary outcome measures.

We expect only minor amounts of missing data from the surveys and feasibility questionnaires. However, we will examine any patterns of missing data and if needed, consider using missing data imputation methods.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

For Aim 1 demographic characteristics of the participants will be reported. Data from the quantitative surveys will be analyzed to identify predictors of non-adherence to breast cancer screening. We will conduct univariate and bivariate analyses of the data to provide descriptive summaries of the data, including demographics and responses to primary outcome measures. Data from the audio-recorded in-depth interviews will be transcribed verbatim from audio recordings (using a transcription service). Analyses of the qualitative data will be conducted using the PEN-3 model, which is a method of analyzing data focusing on social processes and actions. The goal of our qualitative research is to identify the unique barriers and facilitators African immigrant women encounter with breast cancer screening. In line with this approach, the coding steps of open coding, axial coding, and selective coding will be used to identify categories and develop properties. Memoing will be conducted throughout the process. A constant comparative method will be used to generate theoretical categories and refine concepts.

For Aim 2, we will conduct univariate and bivariate analyses of the data to provide descriptive summaries of the data, including demographics and responses to primary outcome measures. Independent samples t tests will be used to compare changes in the primary outcomes measures pre-education and post-education. Using a pre-post test design, we will analyze differences in the three primary outcomes: screening intentions, self-efficacy and perceived risk immediately before viewing the educational program and immediately after viewing the program.

To determine program efficacy and sample size estimates for a future intervention, a generalized linear modelling approach will be used with logistic regression. We will use a repeated measures ANOVA to analyze differences in the primary outcomes: screening intentions and HBM constructs (e.g., self-efficacy and perceived risk) immediately before viewing the educational program and immediately after viewing the program. We will conduct univariate and bivariate analyses of the data to provide descriptive summaries of the data, including demographics and responses to primary outcome measures.

9.4.2 ANALYSIS OF THE ENDPOINT(S)

Quantitative Data Analysis: As the assessment will be administered as an interview, we do not anticipate much missing data. As needed, missing data will be imputed and then be used to estimate the parameter values for each of scales. We estimate that our sample size of 64 participants will generate a +/- 12% margin of error at a 95% confidence level. The primary outcomes are screening status (up-to-date with for mammography screening) and HBM constructs. As screening status is dichotomous, a logistic regression analysis will be conducted using socio-demographics and HBM constructs (e.g., self-efficacy, perceived risk, perceived benefits) as explanatory variables. Since Aim 1 is designed to provide information to inform the adaptation of the subsequent intervention and education, we shall adopt a less conservative criterion for statistical significance using a *p*-value equal to or less than 0.15.

Qualitative Data Analysis. The PEN-3 model[25] will guide the interpretation and analysis of the in-depth interviews. Using this model as a framework, the analysis approach will identify the unique barriers and facilitators related to African-born immigrants' health care engagement. Transcripts will be reviewed using a qualitative data management software. [50] Analysis will use a content analysis approach – which includes examining transcripts for salient categories of information supported by the text (e.g., barriers and facilitators to uptake of cancer screening in African immigrants). Themes that are extensively discussed by participants will be coded. Using a constant comparative approach, categories will be saturated until new information is no longer added. The research team will meet prior to conducting analysis to define coding labels and definitions. Potential labels and definitions will be drawn from identified barriers and facilitators for other preventive cancer screening exams (e.g., pap test, colonoscopy). All transcripts (including those translated from French to English) will be independently coded by PI Sly and research coordinators using the same framework to ensure consistency. They will meet multiple times to discuss the coding strategy for the first half of the interviews and discuss and resolve any coding discrepancies prior to coding of the remaining interviews, and again to resolve any remaining discrepancies by consensus. When there is disagreement on coding labels, the research team will meet to discuss reasons for disagreement and modify coding labels appropriately. Analyses will also examine subgroup differences (i.e., country of origin), age, and language. Our proposed sample size of 30 in-depth interview participants will be stratified by language and we anticipate achieving saturation with these sample sizes. If saturation is not achieved with the 30 participants, we will recruit more participants with collaborators and community partners.

9.4.3 SAFETY ANALYSES

N/A

9.4.4 BASELINE DESCRIPTIVE STATISTICS

Descriptive statistics will provide summary information about the feasibility of recruitment, acceptability and cultural sensitivity of the program and satisfaction with the program.

9.4.5 PLANNED INTERIM ANALYSES

N/A

9.4.6 SUB-GROUP ANALYSES

Subgroup analyses are not warranted because the intervention is intended for a specific population – African immigrant women over the age of 38. Additionally, because of the small sample size, subgroup analyses will not be adequately powered to detect differences in endpoints. A future, large-scale trial will have the ability examine sub-group differences.

9.4.7 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will be listed by measure and time point (e.g. pre-post program assessments)

9.4.8 EXPLORATORY ANALYSES

N/A

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS.

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

For Aim 1, consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention. The following consent materials are submitted with this protocol:

- In-depth interview consent form (English and French)
- Survey consent form (English and French)

For Aim 2, we have requested a waiver of written consent due to the extremely low risk of this research as no PHI will be collected from participants. We are unable to consent participants prior to the program because we will not have their contact information (as we are not collecting any PHI) – participants will be recruited and invited to the programs by community partners. We anticipate having up to 10 participants in each program and we will have limited staff available to consent participants. Based on past experience, doing a full consent process with each individual participant is not feasible (for example, consenting procedures for Aim 1 have taken up to 45 minutes for some participants). Since participants will be part of group sessions, the time and study personnel needed to individually consent each participant would become an undue burden for the participants. Each individual will be informed of study procedures and will give informed consent through reviewing a Research Information Sheet and verbally confirming their willingness to participate before engaging in the research. This also allows participants to become anonymous since we are not collecting their names or signatures, and privacy is a demonstrated concern for this population. Individuals will review, either via RedCap or hard copy, the

Research Information Sheet that will provide details about the research study. If individuals agree to participate in the study, they will confirm their eligibility for the study. The following materials are submitted with this protocol:

- Pilot intervention research information material based on waiver of written documentation of consent: Research Information Sheet (English and French)

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Aim 1: Participants will be recruited from African immigrant communities in New York City. We have a well-established collaborative relationship with gatekeepers in the African immigrant community and have successfully recruited African-born persons into prior studies and therefore anticipate successful recruitment for this proposed research. Participants will be recruited for in-depth interviews and surveys through IRB approved flyers at community sites and via social media platforms. Advertisements for recruitment will be in English and French and identical for both languages. A bilingual Research Assistant (English and French) will administer the in-depth interviews (n=30), which will take 60 minutes to complete and administer the surveys (N=50) which will take about 20 minutes to complete.

Aims 2: Similar to recruitment for Aim 1, participant recruitment for Aim 2 will occur in African immigrant communities in New York City. After refining the education programs using the findings from Aim 1, 64 new participants (n=32 per language) will view the culturally-adapted education breast cancer screening program, after reviewing the Research Information Sheet and confirming their eligibility.

On the day of the program, participants will review, either via RedCap or with a hard copy, the Research Information Sheet that will provide details about the research study.

In person programs:

After participants arrive at the program, but before study procedures begin, study team members will distribute to each participant hard copies of the Research Information sheet and/or online versions via RedCap link that participants can access on their own or study team provided devices. Study team members will review the Research Information Sheet with each participant, privately and one on one, and answer any questions. Participants will also have the ability to read through the Research Information Sheet. Study team members will tell participants that participation is voluntary and will not impact their ability to seek medical care at Mount Sinai, discuss the expectations of participation (participating in an educational program, completing surveys, giving feedback on the educational program), discuss compensation ($60 giftcard), communicate that no PHI will be collected (all information will be anonymous), and explain risks and benefits.

Virtual programs:

After participants arrive to the program Zoom Room, but before study procedures begin, study team members will put participants into breakout rooms, one by one, and provide copies of the Research Information sheet to each participant via RedCap link sent through Zoom chat. Within the zoom room, study team members will review the Research Information Sheet with each participant, privately and one

on one, and answer any questions. Participants will also have the ability to read through the Research Information Sheet. Study team members will tell participants that participation is voluntary and will not impact their ability to seek medical care at Mount Sinai, discuss the expectations of participation (participating in an educational program, completing surveys, giving feedback on the educational program), discuss compensation ($60 giftcard), communicate that no PHI will be collected (all information will be anonymous), and explain risks and benefits.

If individuals agree to participate in the study, they will confirm their eligibility for the study before being considered fully enrolled.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (ie, significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or

organizations supplying the product, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Icahn School of Medicine at Mount Sinai. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by Icahn School of Medicine at Mount Sinai research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Icahn School of Medicine at Mount Sinai.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

N/A

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator
Jamilia Sly, PhD, Assistant Professor
Icahn School of Medicine at Mount Sinai
One Gustave L Levy Place, Box 1077, New York, NY 10029
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10.1.6 SAFETY OVERSIGHT

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of individuals with the appropriate expertise, including psychology and psychiatry. Members of the DSBM will be independent from the study conduct and free of conflict of interest. The DSMB will meet at least

semiannually to assess safety and efficacy data from each arm of the study. The DSMB will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. The DSMB will provide its input to the study sponsor.

10.1.7 CLINICAL MONITORING

N/A

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

Each clinical site will perform internal quality management of study conduct, data and biological specimen collection, documentation and completion. All sites will follow a common quality management plan.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on source documents (see **Section 10.1.9, Data Handling and Record Keeping**) and will ultimately be entered into the study database. To ensure accuracy site staff will compare a representative sample of source data against the database, targeting key data points in that review.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant consented/enrolled in the study. Data recorded in the electronic case

report form (eCRF) derived from source documents will be consistent with the data recorded on the source documents.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 5 years after the last approval of a marketing application in an International Council on Harmonisation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

10.1.9.3 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents, reported to NIMHD Program Official and Icahn School of Medicine at Mount Sinai. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

10.1.9.4 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

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 5 years after the completion of the primary endpoint by contacting Jamilia Sly, PI. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

10.1.10 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIMHD has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
Co-I	Coinvestigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
EyV	Esperanza y Vida
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
HBM	Health Belief Model
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation

ICMJE	International Committee of Medical Journal Editors
ISMMS	Icahn School of Medicine at Mount Sinai
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
NIMHD	National Institute for Minority Health and Health Disparities
NYC	New York City
OHRP	Office for Human Research Protections
PCP	Primary Care Physicians
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

This is the first submission to IRB.

Version	Date	Description of Change	Brief Rationale
1.1	02/12/2021	1) Recruitment for Aim 1 decreased from 94 to 80 participants; 2) Focus groups with community leaders replaced by in-depth interviews; 3) Recruitment strategy updated to include social media (e.g. WhatsApp and Facebook) as a new channel	Conducting individual interviews (up to 10 individual interviews) instead of 3 focus groups will better help the study team adhere to social distancing guidelines amid the COVID-19 pandemic. Using social media to recruit potential participants is expected to help us better dealing with the challenges to enroll individuals when the access to the community and community events is restricted.
1.2	4/22/21	A mistake in the protocol title was corrected.	A mistake in the protocol title was identified and corrected.
1.3	3/9/23	1) Aim 2 age eligibility changed to 38 years of age or older. 2) Having had a mammogram in the previous 12 months was removed as an exclusion criteria for Aim 2.	1) Women should be given the option to start screening for breast cancer at the age of 40 and our primary endpoint outcome is intention to be screened within 2 years, so it is

		3) The length of the Aim 2 intervention increased from 60 to 90 minutes. 4) Aim 2 compensation increased to $60. 5) The measures for primary endpoints have been refined. 6) Mention of research information material for Aim 2 was included. 7) Approach to qualitative data analysis was updated.	sound to include women under 40. This is also based on the request a few participants have made about the inclusion of younger women in the educational program. 2) Our primary endpoint is intention to have a screening mammogram within 2 years, so it is sound to include women who have been screened recently. 3) We have also increased the length of the intervention from 60 to 90 minutes to account for the assessments that participants will complete for research purposes. 4) Since the time of the intervention increased, the compensation amount has also increased in order to accurately reflect their time and effort. 5) Primary Endpoint: change from baseline assessment of mammogram screening intention and mammogram location and appointment. Secondary Endpoints: change from baseline assessment of perceived breast cancer risk and self-efficacy for mammography. 6) Aim 2. We have requested a waiver of written consent due to the extremely low risk of this research as no PHI will be collected from participants. We are unable to consent participants prior to the program because we will not have their contact information (as we are not collecting any PHI) – participants will be recruited and invited to the programs by community partners. We anticipate having up to 10 participants in each program and we will have limited staff available to consent participants. On the day of the program, participants will

			review, either via RedCap or in person with a hard copy, the Research Information Sheet that will provide details about the research study. If individuals agree to participate in the study, they will confirm their eligibility for the study. 7) The study team decided to adopt a different, leaner approach to coding.

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