CLINICAL STUDY PROTOCOL

VCU C. Kenneth and Dianne Wright Center for Clinical and Translational Research

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SUCCEED: Engaging Black Men in CRC Screening

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VCU Study Personnel

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Synopsis

Purpose

To determine the unmet needs, attitudes, barriers and facilitators of AA/Black men use of colorectal cancer screening and describe how community leaders such as barbers may act as Community Champions to educate and facilitate screening participation.

Objectives

Aim 1. Determine factors associated with self-reported CRC screening behaviors among (n=175) AA/Black men in Petersburg, VA.

Aim 2. Develop tailored S2S content for AA/Black men to be delivered using a combination of short video and text-based information optimized for delivery via QR codes for smartphones.

Aim 3. Test intervention on a sample of n=30 AA/Black men who are due for CRC screening. The primary aim is: completed CRC screening (any type) at 3months. Secondary aims are:

to collect process date to assess satisfaction and feasibility.

H1. Preliminary effectiveness of the intervention will be shown with >60% of men enrolled obtaining a CRC screen (any modality) by 12 weeks

H2. At Week 2 >80% of men enrolled will endorse an intention to be screened

H3. We will be able to recruit a sample of n=30 men into the intervention and maintain a retention rate (completion of baseline, 2 and 12 week surveys) >75%

Study Population

Survey Eligibility Criteria: Men aged 45-75 who reside in Petersburg and surrounding counties, and identify as AA/Black and have no personal history of cancer.

Intervention: For Aim 3 and additional criterion is that men have to be due for CRC screening upon study enrollment

Number of Participants

Survey: n=175

Intervention n=30

Study Design

Survey: Cross sectional; qualitative,

Intervention: single arm, pre-post Social behavioral intervention

Study Duration

Survey: 36 months total Intervention: Aim 3: 12 months (once enrolled men are on study for three months)
Outcome Variables Please see survey measures **Intervention: Aim 3:** Primary Outcome: CRC screening status at 3 months (>60%) Secondary Outcomes: • Intention to screen at 2 weeks (>80%) • Enrollment (target of n=30) • Maintain a retention rate (completion of baseline, 2 and 12 week surveys) >65% at 12 weeks • Viewing videos (# views, # repeat views) • Completion of baseline and follow up questionnaires (retention) • Responding to request to contact clinic/navigation services • Sharing any content with social network
Locations/Facilities Surveys will be completed online Recruitment for surveys will take place in-person, using social media, flyers in public spaces **Intervention: Aim 3:** Recruitment will take place with flyers, word or mouth and presentations to introduce the study at partner and CAB member places of business and worship. These include community health clinics, local gyms, barbershops, stores, churches. We will use social media, newsletters and text messaging avenues of communication as utilized by out community and clinic partners. We will also use radio announcements on local health focused radio shows.

1 - Background/Literature Review

1.1 Background

Colorectal Cancer Disparities. In the US, CRC is the third most commonly diagnosed cancer and the second most deadly cancer. The CRC incidence (45 vs 39 per 100,000) and mortality (16 vs 14 per 100,000) in the Virginia Commonwealth University (VCU) Massey Cancer Center (MCC) Catchment Area are slightly higher than the US. Compared to whites in the catchment, AA/Blacks experience higher incidence of colorectal (42 vs. 37 per 100,000). Notably, 26 of the 65 counties in the MCC catchment area are part of Southside VA and it is recognized as a national "hot spot" for CRC where Petersburg City, our

pilot site is located. Moreover, Petersburg has a large AA/Black population, many of whom experience poverty or lower socioeconomic status.

AA/Black Men's Barriers to CRC Screening. Factors associated with CRC screening include physician recommendation, social support, medical mistrust, perceived discrimination, and avoidance. While many of these factors (e.g., physician recommendation) are relevant for AA/Black men, several factors such as medical mistrust and discrimination may exacerbate screening behaviors. For AA/Black men, avoidance, fear, and perceived discrimination contribute to low screening and play a critical role in their healthcare utilization, health behaviors, and mortality. Though acknowledged, the extent to which cultural attitudes related to avoidance and medical mistrust dissuade participation in preventive CRC screening is unclear. Mistrust of the healthcare system and experiences of racial discrimination are associated with lower health services utilization among AA/Black patients and is a widely cited attitudinal barrier to CRC screening. AA/Black men expressed explicit fears of medical experimentation and uneasiness about the invasiveness of colorectal cancer screening procedures (e.g., colonoscopy). Therefore, CRC interventions tailored for AA/Black men must address concerns of medical mistrust and discrimination. Studies have indicated that social support is correlated with having a colonoscopy. Kinney et al., found that the association between social connection and CRC screening was stronger for AA/Blacks than for whites. Interventions promoting CRC screening exist but few addressed the unique needs of AA/Black men.

2 - Rationale/Significance/Problem Statement

2.1 Rationale

This project will address CRC screening among AA/Black men within the MCC catchment area. This is significant because AA/Black men remain a dramatically underserved group that has not equally benefited from existing colorectal cancer (CRC) education or screening interventions. Moreover, within the MCC catchment area is one of three enduring national CRC hotspots.

2.2 Significance

Clinically, this is significant because AA/Black men remain a dramatically underserved group that has not equally benefited from existing colorectal cancer (CRC) education or screening interventions. Moreover, as MCC is a member of the National Outreach Network (NON), an efficacious mHealth Screen to Save (S2S) for AA/Black men would have population-level impact through scalability to all NON CHEs. The proposed study will fill a gap in translational research by conducting qualitative and survey research pilot work to inform the tailoring of an existing screening intervention, Screen 2 Save, to develop and test an enhanced mHealth S2S intervention culturally tailored for African American (AA)/Black men. The testing of the intervention will be conducted as part 2 and will not begin until an amendment is approved by the IRB.

3.1 Purpose

While many factors associated with CRC screening (e.g., clinician recommendation) in the general population may also be relevant for AA/Black men, certain factors may be exacerbated and/or unique to

them. For example, medical mistrust and expectations of poor care due to perceived discrimination and racism, attitudes about the value of preventive care and concerns about test invasiveness and fear can dissuade screening, particularly for colonoscopies, as screening can be considered intrusive and embarrassing. Supportive social networks (e.g., friends, community leaders) may endorse and encourage the prioritization of personal preventive health behaviors while simultaneously attenuating fear and embarrassment that impede screening uptake. The lack of detailed empirical data about relationships among these factors and how they influence CRC in AA/Black men has hampered progress in the field. This study will collect in-depth information about AA/Black men's CRC screening practices and collect data necessary for the adaptation and development of a mHealth Screen 2 Save intervention to increase CRC screening among AA/Black men in Petersburg and Richmond, VA.

3.2 Hypothesis

H1.1. Lack of social support, higher medical mistrust, and perceived discrimination will be negatively associated with self-reported guideline concordant screening behaviors.

H2.2. Higher engagement in preventive care behaviors and greater perceived risk will be associated with higher completion of CRC screening. Subaim1a. Examine potential interactions between perceived discrimination, medical mistrust and engagement in preventive care behaviors.

H1.3. Increased perceptions of discrimination and greater medical mistrust will attenuate the relationship between preventive care and guideline concordant screening.

3.3 Objectives

Aim 1. Determine factors associated with self-reported CRC screening behaviors among (n=175) AA/Black men in Petersburg, VA.

Aim 2. Develop tailored S2S content for AA/Black men to be delivered using a combination of short video and text-based information optimized for delivery via smartphones.

Aim 3. Test intervention on a sample of n=30 AA/Black men who are due for CRC screening. The primary aim is completed CRC screening (any type) at 3months. Secondary aims are to collect process date to assess satisfaction and feasibility.

4 - Study Participants

4.1 Study Population

AA/Black men remain a dramatically underserved group that has not equally benefited from existing colorectal cancer (CRC) education or screening interventions. African American/Black men experience 20% higher incidence, 45% higher mortality, have the shortest CRC survival rates of all racial/ethnic groups. CRC screening participation rates among Black men are 10%-30% lower than other groups. The focus of this project is to: PART 1: identify risk factors associated with screening behaviors in Black men

and, PART 2 (not submitted yet): develop a scalable mobile Health (mHealth) tailored S2S intervention to address those factors that keep Black men from completing CRC screening. Therefore, we focus on recruiting Black men only.

4.2 Number of Participants

We require 8-10 men for the Community Advisory Board and we require n=175 Black or African American for survey in PART1. The intervention component will require n=30 men

Total study n=225

The survey component was powered on the interaction term "discrimination*preventive care engagement", both continuous, using a simulation study of 1000 runs of a logistic regression model, with the binary screening behavior response (1 = screened, 0 = not screened). A sample size of 175 subjects generates 80% power to detect a "small to moderate" effect size of 0.38 (corresponding odds ratio = 2.01, using R package "effect size") for the interaction term (continuous*continuous), at 5% level of significance, using a one-sided Z-test. To account for individuals who start but do not complete the survey we have added a buffer of 20% which gives a sample size of n=210 for the survey. The sample size has been chosen for the intervention to support an initial examination of intervention effectiveness using a one-arm design. This is a typical size that will generate pilot data on the feasibility of our approach.

4.3 Selection Criteria

Survey Eligibility Criteria: Men aged 45-75 who reside in Petersburg and identify as AA/Black and have no personal history of cancer.

CAB/Focus Group Criteria: adult men, identify as Black or African American, work or live in a Petersburg VA or surrounding counties and are interested in participating. They do not need to meet requirements for population based CRC screening.

Intervention Aim 3: adult men, identify as Black or African American, work or live in a Petersburg VA, aged 45-74, eligible for CRC screen at study enrollment

4.4 Recruitment Procedures

Recruitment Procedures Survey:

Recruitment will use a multipronged approach including community advertising, social media, word of mouth and leveraging of our community partners.

1.) Onsite at barbershops, Health Living and Learning Center (HLLC) and other community partner sites: Supervised by the research team, graduate and undergraduate students will be introduced to community partners and trained to introduce the study to potential participants who visit partnership businesses and organizations across the City of Petersburg. Project personnel will have a regular, weekly presence at each community partner site to build recognition and recruit to the survey.

2.) Additional recruitment pathways include distribution of study advertisements. These will be posted physically at various community locations and include a URL and QR code that enable access to the survey. We will also leave study information postcards (same URL and QR code) for distribution by community partners. We will also ask community partners with email lists, regular newsletters and other similar distribution lists to send out information about the study on their listservs.

3.) Social Media: distribution of study and survey advertising (including a link to the survey) using various social media platforms(e.g., direct recruitment via Facebook ads, posting information on VCU, VSU, and community partner social media accounts).

4.) Referral of friends (snowball) participants who complete the survey will have the option of completing a quick and seamless electronic recommendation for friends or family to consider participating.

5) Clinic partners. We have partnered with CVHS which has 4 clinics in the Petersburg city and surrounding counties. We will advertise in the clinic waiting rooms, staff at the clinics will hand out flyers for the study, and we will use any newsletters distributed by the clinic including playing our video on the television in the waiting rooms and sending invites to learn more via the text messaging system the clinic uses to distribute public health information, updates and health messages.

4.5 Risks

Subject confidentiality will be protected by storage of all data (survey data, focus group recordings) using a unique research identification number. Data will be stored in a VCU secure database with limited, monitored access by the research team only. Identifiable information will not be collected for survey participants. We believe that the unauthorized or accidental release of study data is extremely unlikely given the precautions that will be taken to minimize such an event.

Confidentiality with focus groups will be maintained using the VCU ZOOM account, storage of the recordings on VCU secure servers with limited access by study staff only on password protected and VCU owned computers. Participants will be asked to identify themselves using any made up name they choose.

Personal discomfort is a possibility given the subject matter. If someone is uncomfortable they do not have to continue to participate or answer any survey or focus group questions that they do not want to. They can also opt to obtain assistance with navigation to screening services without participating in the study.

4.6 Anticipated Benefits

No direct anticipated direct benefits beyond learning new information about CRC prevention and screening.

The screening intervention may identify previously unknown precancerous lesions or CRC that need to be treated.

4.7 Vulnerable Populations

NA

4.8 Consent/Assent Procedures

1. We will use an information form that covers all basic elements of consent. We are requesting waiver of all elements of consent for both the survey and the focus group. The survey collects non-identifiable information about attitudes, beliefs and behaviors related to cancer prevention and CRC cancer screening. This will be collected anonymously. The focus groups are small, completed using video conferencing (VCU ZOOM) and will use pseudonyms. The content of the focus groups will be to understand what barbers think the the training needs for becoming a CRC CHamP (i.e., a community resource for information), insights about program marketing and recruitment, how COVID-19 may affect their ability and interest in participating and recruiting. The focus group evaluating the initial QR code intervention will inform the research team on how to tailor the intervention to Black men age 45-75. These are not private information. The consent form would be the only identifying information being collected for the survey participants. The survey responses will be anonymous.
2. The intervention will use a self-administered consent form that participants will complete on their own through the mHealth application (the app).

5 - Study Design

5.1 Study Design

Cross sectional survey and focus groups

Aim 3: single arm, pre-post intervention

5.2 Study Duration

36 months

5.3 Outcome Variables

Please see the survey measures

Aim 3:

Primary Outcome: CRC screening status at 3 months

Secondary Outcomes:

- Enrolment
- Viewing videos (# views, # repeat views)
- Completion of baseline, 2 week and 12 week questionnaires (retention)
- Completing values elicitation activity

- Responding to request to contact clinic/navigation services
- Sharing any content with social network

5.4 Study Procedures

Survey

The survey will be a self-administered electronic survey (e-survey) expected to take 15-20 minutes to complete. Using a secure HIPAA compliant VCU Redcap survey housed on a VCU server, a unique survey link will be provided to interested participants (via email or QR code available on flyers and social media messaging). The secure, unique link will include a screener to determine eligibility, a self-administered information form with consent elements followed by the survey. Participants who complete surveys will receive an electronic gift card of $20 sent to an email provided by the respondent.

Focus Groups:

Local barbers currently working in a Petersburg or Richmond Barbershop; will be recruited for focus groups. Barbershops are an excellent way to gain intervention 'reach' among our target population, Black men. Barbers within the Petersburg area will be recruited from one of the four community partner barbershops that agree to participate in the study. Barbers will be approached in-person at the shop by a member of the research team) who will visit shops to introduce the study and ask permission to leave study information and/or come back to talk to the group. Focus groups will be conducted virtually using smartphone accessible VCU Zoom and will be video recorded, with permission. Participants will engage in a 60-90-minute discussion.

Aim 3 Intervention:

Men will be invited to participate using all methods outlined above. Men who are interested will be directed to download the app to their personal device. Once the app is downloaded participants are able to self-direct through the screening process. If requested, a study member can assist with downloading the app and navigating through to the study screener.

Potential participants will be asked to complete a screener to ensure all eligibility criteria are met. Those who do not meet eligibility will be thanked for their time and navigated to an exit screen. For those who are eligible, they will next be asked to complete the consent process. After they consent, they will be navigated to the baseline questionnaire. Once completed, they will be able to access all other content (videos, infographics, request link to receive a call from screening navigation, additional surveys for values elicitation).

One week after enrollment, men who have not engaged with the materials, completed the baseline questionnaire, or the navigation request will receive a text message aligned with the CRC risk perception and/or values elicitation that they shared with us at baseline. See table below.

Question: Which best describes your thoughts about colorectal cancer?

PARTICIPANT RESPONSE	AUTOMATED, TAILORED ANSWER
Never heard of it	Video # may interest you because it talk about CRC is and why screening can save your life!
Heard of it but not interested in screening	You might be interested to hear about the experiences of a CRC survivor. Video xx is "name" telling his story.
Heard of it and thinking about getting screened	You may want to check out video #, because it goes over the different types of screening options. The best one is the one that gets done!
Decided not to get screened	You might be interested to hear about the experiences of a CRC survivor. Video # is "name" telling his story. Video # also describes the many different screening options.
Decided to get screened	Inside the app there is a way to ask for a local clinic or screening navigator to call you directly. Check it out!
Have been screened in the past, but not recently	The best CRC screening test is the one that gets done! You may be interested in talking to a screening navigator. Inside there is a way to request a phone call from a local clinic.

Follow up: A three months after enrollment men will receive the final survey in their app and a text message notifying them that it is ready to be completed. Anyone who does not complete this survey within two weeks will be contacted by telephone by a study team member and given the option to complete it over the phone, have it emailed to them or to complete it in the app.

Table 2. Measures for intervention

Timing	CRC risk perception	Demographics	Health literacy (1 item)	Reg source of primary care (1 item)	Health status	Intention to screen	Screen status	CRC knowledge	Medical mistrust
Baseline	X	x	x	x	x	x		x	x
2 weeks	X					x		x	x
12 weeks	X					x	x	x	

5.5 Withdrawal Procedures

Participants can exit the browser at any time for both the survey and focus groups. Once the data has been collected participants will not be able to have their data erased (surveys are collected anonymously).

To withdraw from the intervention participants must contact one of the study PIs in writing.

5.6 Locations/Facilities

All study procedures will occur online

5.7 Data Collection

The survey will be a self-administered electronic survey (e-survey) expected to take 15-20 minutes to complete. Using a secure HIPAA compliant VCU Redcap survey housed on a VCU server, a unique survey link will be provided to interested participants (via email or QR code available on flyers and social media messaging).

Focus Groups: Participants (n=16) will be barbers employed at one of the four community partner barbershops. Two virtual focus groups of 6-8 barbers will be conducted. Focus groups will be conducted virtually using smartphone accessible VCU Zoom and will be video recorded, with permission. Participants will receive a $20 honorarium for the 60-90-minute discussion.

Intervention: Baseline, 2 and 12 week follow up surveys will be collected on the app. If men do not respond to the follow up survey on the app they will be contacted by a study team member and provided alternatives for completion (see study procedures above).

5.8 Data Collection Sources

Survey Measures. The survey has been designed to obtain key information while minimizing participant burden. *Demographics:* age, sex, highest attain ed education, annual household income, employment status, and marital status; health literacy (1 item); health status (1 item).

Medical Mistrust. measures (1) suspicion, (2) group (racial) disparities in health care, (3) lack of support from health care providers.

Perceived Racial Discrimination. Everyday Discrimination Scale reflect day-to-day experiences of unfair treatment. Higher scores corresponded to more frequent experiences of racial discrimination;

Preventive health care behaviors: The Good Health Practice Scale,[63] a 16-item scale that measures key preventive health behaviors. This scale has been shown to assess the avoidance of preventive health behaviors.

Social Support: MOS-SSS aims to assess the extent to which a person has the support of others to face stressful situations.

CRC Test fear and invasiveness and Cultural Attitudes about Masculinity: Males Role Norms Inventory-Short Form (MRNI-SF) is a 21-item questionnaire that assesses conformity to dominant cultural norms of masculinity (avoidance of femininity, negativity towards sexual minorities, self-reliance through mechanical skills, toughness, dominance, importance of sex, restrictive emotions). High total scores indicate greater conformity to traditional norms of masculinity

CRC Risk Perceptions. Lifetime risk of developing CRC will be asked on a 0-100% scale and a likert response adapted from the NIH HINTS.

Colorectal Cancer Screening Behaviors. Assessed using questions vetted by the national Behavioral Risk Factor Surveillance System we will measure those who have ever been screened and those who are up-to-date with screening

Focus Group: A focus group interview guide has been developed to inform how the barbers can be engaged to introduce the intervention, be empowered to have conversations about the need for CRC screening among Black men and encourage men to engage with the QR code and intervention materials.

Intervention.

1. Measures. See Table 2 above for all measures and timing of collection for the intervention.
    a. Outcomes measures
        i. CRC screening status (>60%) **OR**
        ii. Intention to screen (>80%): from S2S
    b. Covariates
        i. Perceived CRC risk: *CRC Risk Perceptions*. Lifetime risk of developing CRC will be asked on a 0-100% scale and a likert response adapted from the NIH HINTS
        ii. CRC knowledge: from S2S
        iii. Medical mistrust: *Medical Mistrust*. measures (1) suspicion, (2) group (racial) disparities in health care, (3) lack of support from health care providers.
        iv. Value elicitation
        v. Health Literacy-1 item
        vi. Regular source of primary care -1 item

vii. Health status -1 item

Demographic information: age, highest attained education, annual household income, employment status, and marital status; family history of cancer)

2. User engagement data collected from Pattern Health to determine the number times, number of minutes and which content pieces were interacted with in the app environment.
    a. Enrolment
    b. Videos viewed (# views, # repeat views)
    c. Completion of baseline and follow up questionnaires (retention)

       Completing values elicitation activity

    d. Responding to request to contact clinic/navigation services
    e. Sharing any content with social network

5.9 Standard Tools

See survey measures for complete list

6 - Statistical Analysis

6.1 Sample Size

The survey component was powered on the interaction term "discrimination*preventive care engagement", both continuous, using a simulation study of 1000 runs of a logistic regression model, with the binary screening behavior response (1 = screened, 0 = not screened). A sample size of 175 subjects generates 80% power to detect a "small to moderate" effect size of 0.38 (corresponding odds ratio = 2.01, using R package "effect size") for the interaction term (continuous*continuous), at 5% level of significance, using a one-sided Z-test. To account for individuals who start but do not complete the survey we have added a buffer of 20% which gives a sample size of n=210 for the survey.

We will also conduct focus groups with n=16 men.

Total project sample size n=226

Intervention Sample Size: To perform an initial test of efficacy, satisfaction and feasibility, we will test the intervention on 30 men.

6.2 Intervention Planned Analyses

Analysis. All variables will be described using standard methods for continuous and discrete variables and examined for completeness. An interaction effect of discrimination and engagement in preventive care will be assessed, controlling for other confounders, using a logistic regression model with the binary

response (cancer screening). Additional analysis will be conducted, controlling for demographics, via a random intercept logistic regression model. Parameter significance will be determined at the 5% level.

Research measures collected at baseline, exit and 12 weeks post are: CRC knowledge, risk perception, medical mistrust, preventive health behaviors. At 12 week only, CRC screening or intent to screen, and participant satisfaction with the intervention will be asked. Process evaluation will assess any change in CRC knowledge, risk perception, medical mistrust, and preventive health behaviors at 12 weeks.

Feasibility will be assessed using a priori benchmarks for recruitment and retention. The recruitment benchmark will be consenting 100% of the recruitment goal. Acceptance rates and reasons for declining participation will be tracked. Information on refusals will be used to modify recruitment methods as needed. Retention benchmarks will be supported if >=65% complete both weeks 2 and 12 follow up. Engagement benchmarks will be supported if >=65% of intervention completers who do not have a primary care provider chose to receive navigation services; 80% of those consented view intervention materials (e.g., click on text/graphical data, view videos, complete risk assessment).

Preliminary Efficacy. A signal for efficacy will be considered positive if among those who complete the intervention a) most (≥60%) complete CRC screening and b) >80% acknowledge their intent to get screened.

Follow-up interviews. Interviews will be conducted with all participants to collect in-depth, descriptive feedback on satisfaction with the intervention content, delivery modalities, ease of use and usefulness. We will also interview clinic staff and Community Champions to gain insight into facilitators and barriers to recruitment efforts and response of the community to the intervention. Suggestions for additions and alterations will be solicited from all interviews.

6.3 Data Relevance

Please see Section 2

6.4 Data Coding

Data analysis plan for focus groups. Video recorded focus groups will be analyzed using Max QDA, a qualitative data analysis software that enables seamless coding of text, video and picture based media. Qualitative analysis will proceed using Corbin and Strauss' constant comparative method. This method involves several coders (n=3), breaking down the data into discrete units and coding them to categories that reflect the language and concepts of the study participants. Weekly coding meetings will occur to discuss coding progress. Disagreements will be discussed until resolved.

6.5 Data Analysis Tools

MaxQDA for Focus groups

Statistical packages for survey and intervention (e.g., SAS, SPSS, R)

6.6 Data Monitoring

Redcap will be enabled to allow participants to skip questions (non-response option available) but they cannot advance through unless a choice is made. This will eliminate missing data while ensuring participants the ability to skip questions they do not want to answer. Incomplete surveys will be mitigated by survey creation to keep the survey short, use known presentation methods to ensure usability, comprehension and comfort reading. Missing data will be assessed and managed using standard procedures.

Verbatim transcripts will be produced form the focus groups.

7 - Data Handling and Record Keeping

7.1 Subject Data Confidentiality

Survey: Will be completed without collection of identifying information (names, contact, IP address). Electronic gift cards will be issued after completion of the survey to an email address provided by the participant and will not be linked to the data collected.

Focus group: we will use pseudonyms for the recorded VCU ZOOM focus groups

No link between the focus group participant PHI and data will be made. We will not keep a key that links the pseudonym with the demographic data collected.

7.2 Data Quality Assurance

See above

7.3 Data Storage/Security

The survey will be a self-administered electronic survey (e-survey) expected to take 15-20 minutes to complete. Using a secure HIPAA compliant VCU Redcap survey housed on a VCU server, a unique survey link will be provided to interested participants (via email or QR code available on flyers and social media messaging). The secure, unique link will include a screener to determine eligibility, a self-administered information letter outlining consent items followed by the survey.

7.4 Study Records

VCU Redcap and VCU secure servers will be used to store all study data. Only study personnel will have access to the study data.

7.5 Retention of Records

The records will be kept secured and for the length of time necessitated by funder/sponsor.

8 - Study Considerations

8.1 Research Personnel Training

All personnel will maintain CITI training and records will be kept by study coordinator.

Dr. Thomson will oversee training of the focus group moderators.

8.2 Unanticipated Problems and Protocol Deviations

Will be reported to the IRB according to regulations.