FULL PROTOCOL TITLE: Podcasting HIV Prevention within African American Communities to Decrease New Infection.

Podcasting HIV Prevention within African American Communities to Decrease New Infection.
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PRINCIPAL INVESTIGATOR:

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1.0 Objectives

1.1 Aim 1 (Phase 1): To conduct 5 focus groups for the development of two theory-based, video podcast-delivered, HIV prevention interventions for self-identified heterosexual African American males and females.
Aim 2 (Phase 2): To evaluate the effectiveness of the two theory-based, video podcast-delivered, HIV prevention interventions for self-identified heterosexual African American males and females.

2.0 Background

2.1 There is a need to implement more evidence-based HIV prevention messaging in the African American community in order to mitigate HIV incidence and prevalence disparities. However, the resource expenditure associated with implementing evidence-based HIV prevention interventions may not coalesce with community resources and expertise available to successfully implement such interventions. Thus, the scientific premise for this mixed-methods study is grounded in 1) progressing the field of HIV prevention to create accessible and acceptable modes of science-driven interventions for behavior change; and 2) engaging the community as participants in the development of, as well as, recipients of HIV prevention science.

2.2 NA

2.3 African Americans in the U.S. continue to experience the highest rates of HIV incidence. African Americans are one of the most affected populations in the U.S., and HIV is among the top 10 causes of death among African Americans between 20 – 54 years old.[1] Of the 37,968 newly HIV-infected persons in 2018, 42% were African American.[2] The latest available data shows that HIV testing has decreased and HIV prevalence has increased in the state of Texas between 2015 and 2019.[3] Likewise in Harris County, TX, the estimated HIV incidence rate has increased from 2018 to 2019, while HIV testing has showed a decrease during that time.[3] HIV incidence has seen an increase among African Americans, ages 25 to 34, in particular. While men who have sex with men (MSM) comprise the majority of new HIV cases in 2018, heterosexual sexual contact comprised 34% of new cases among African Americans.[2] Systems dynamics methodology has illustrated causal loops that suggest how heterosexual individuals may directly spread infection through heterosexual contact, but can also be directly infected by bi-sexual sexual contact and/or indirectly through homosexual sexual contact[4]; indicating that, in a community system, the spread of HIV does not occur within a group-specific vacuum. Thus tackling HIV prevention among heterosexual African American individuals is also important.

1. Heron M, Centers for Disease Control and Prevention. Deaths: Leading Causes for 2018, National Vital Statistics Reports, Vol 70(4).

https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-04-508.pdf. Published May 17, 2021. Retrieved June 28, 2021.

2. Centers for Disease Control. HIV and African American People. https://www.cdc.gov/hiv/group/racialethnic/africanamericans/index.html. Published January 21, 2021. Retrieved June 11, 2021.

3. Centers for Disease Control. NCHHSTP AtlasPlus. http://www.cdc.gov/nchhstp/atlas/. Updated April 29, 2021. Accessed June 17, 2021.

4. Waring A. Practical System Thinking. Hampshire, UK: Cengage Learning EMEA; 1996.

3.0 Inclusion and Exclusion Criteria

3.1 Phase 1 & 2: Individuals eligible to participate will: (1) self-identify as African American; (2) reside in a low SES predominantly African American super neighborhood; (3) speak and read English; (4) be 18 years old or older; and (5) not previously diagnosed with HIV. The screening questionnaire will assess these eligibility criteria (attached in the smartforms).

3.2 Phase 1 & 2: Potential participants will call dedicated university phoneline or email study team email account. Flyers will be distributed at African American-based community events; contact information will be displayed on the flyers.

3.3 The following groups will be excluded. The research may possibly involve economically and/or disadvantaged persons.

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Students for whom you have direct access to/influence on grades

4.0 Vulnerable Populations

4.1 Additional safeguards to protect their rights and welfare of economically and/or educationally disadvantaged persons.

- Phase 1 (focus groups): Individuals who are economically/educationally disadvantaged: Participants' incentives for research participation are proportionate with the risks. Participants will be paid $45 for their participation. Discomforts and inconveniences involved in the research, and financial or other gains are not overly compelling. Consent documents are written in language that is easily understandable to participant. Research team will read consent document out loud for each participant and participant will

have the ability to ask questions. Eligibility criteria includes the ability to read and speak English.

- Phase 2 (effectiveness phase): Individuals who are economically/educationally disadvantaged: Participants' incentives for research participation are proportionate with the risks. Upon pre-test completion, participants will be emailed (or pick up in person) a $20 Walmart, Target, or Amazon gift card; $80 Walmart, Target, or Amazon gift card upon post-test completion; and $25 Walmart, Target, or Amazon gift card upon 3 month follow-up completion; for an opportunity to receive $125 for complete participation. (For participants who do not have email addresses, research assistants will assist them in obtaining one; alternately, participants will be able to schedule a time to meet at one of the community centers in order to complete pre- and post-test surveys in person, (and/or to pick up gift card) if needed.) Discomforts and inconveniences involved in the research, and financial or other gains are not overly compelling. Consent documents are written in language that is easily understandable to participant. Participants will email or call a dedicated study email/phone line, where research assistants will screen them, answer any questions they may have, and get them formally consented and enrolled, if applicable. Eligibility criteria includes the ability to read and speak English.

5.0 Number of Subjects

LOCAL:

5.1 Phase 1: Total number of subjects to be accrued locally = 35; Phase 2: Total number of subjects to be accrued locally = 128

5.2 NA - The participant procedures involve no more than minimal risk.

5.3 Phase 1: We are seeking to conduct 5 focus groups with 7 people each. Phase 2: We are seeking to assess 128 African American adults (64 male; 64 female).

6.0 Recruitment Methods

LOCAL:

6.1 When and Where: Phase 1 - Rolling recruitment and focus group facilitation will occur over 3 months (Year 1). Participants will be recruited through postings on community bulletin boards in African American communities and churches, at public community events within African American communities, and at events held by UH HEALTH Research Institute (HRI). Flyers and email list serves will be used to recruit participants. Community based service organizations that serve many

predominantly African American communities will assist in the active recruitment of participants as well (see letters of support). Dr. Ezemenari Obasi, an established investigator, faculty mentor, and collaborator for the associated grant proposal submission, currently serves as director at the HRI and will assist in recruitment efforts via the center's community engagement core.

Phase 2: Participants will be recruited on a rolling basis with the assistance of community partners, through postings on community bulletin boards, and flyers at public community events within African American communities; as well as at events held by HRI (virtually or in-person), and the center's RCMI websites; as well as with the assistance of community partners (see letters of support).

Appropriate permissions for recruitment at the above-mentioned locations are ensured: Community partner support for recruitment at their local events is evidenced through the community partner letters of support (attached in the smartforms), the funded project will be conducted through the HRI which lend their recruitment support for all projects funded within their center (i.e., the HRI community engagement core), and community bulletin postings are free for public use.

6.2 Participants will be sourced from community events (market gatherings, various local festivals, events held by community partners) and through HRI events throughout the African American community.

6.3 Methods and materials for recruitment:

Phase 1: Flyers will be distributed as indicated above. Inclusion criteria will be printed on flyers. Potential participants who presumably fit the study criteria and are interested will call the study phone or send correspondence via the study email and will be screened for eligibility. For phone screening: the potential participant will call the study hotline and be asked a series of short screening questions estimated to take approximately 3 minutes. If eligible, the research team member will inquire on the preferred participation day/time (during one of the evening or weekend focus group sessions). If ineligible, the research team member will notify the potential participant that s/he is not eligible and thank him/her for interest as indicated in the screening script. For email screening: interested participants will email the study using the email provided on the recruitment flyer. A research team member will reply to them, asking all eligibility questions via email and ask that the potential participant send an email reply, responding to each screening question. If eligible, the research team member will reply with a list of available study day/times and ask the participant to reply with the most convenient time she wishes to participate. After confirming her preferred time, s/he will be sent a confirmation email to participate in the scheduled focus group. This constitutes a total of three email exchanges. If ineligible (via email screening), the research team member will send a follow-up email notifying the potential participant that she is not eligible

and thank the participant for their interest as indicated in the screening script.

Phase 2: Flyers will be distributed as indicated above. Inclusion criteria will be printed on flyers. Potential participants who presumably fit the study criteria and are interested will call the study phone or send correspondence via the study email and will be screened for eligibility. For phone screening: the potential participant will call the study hotline and be asked a series of short screening questions estimated to take approximately 3 minutes and answer any questions they may have, and get them formally enrolled, if applicable. If ineligible, the research team member will notify the potential participant that s/he is not eligible and thank him/her for interest as indicated in the screening script. For email screening: interested participants will email the study using the email provided on the recruitment flyer. A research team member will reply to them, asking all eligibility questions via email and ask that the potential participant send an email reply, responding to each screening question. If eligible, the research team member will enroll participant, assign a unique ID to participant, and email them the secure link which will include the consent form and pre-test. If ineligible (via email screening), the research team member will send a follow-up email notifying the potential participant that she is not eligible and thank the participant for their interest as indicated in the screening script.

6.4 Phase 1 & 2: Materials for recruitment include a study flyer indicating the abbreviated purpose of the study, solicitation for participation, eligibility criteria, incentives offered, and study contact information (phone and email). Phase 1 & 2 flyers are attached to the SmartForm.

7.0 Multisite – N/A

8.0 Study Timelines

- Phase 1: The total duration of an individual's participation in the study is no more than 1.5 hours. The number of study visits is 1 per participant. No follow-up is included in the study. It is anticipated that it will take approximately 10 minutes to consent each participant. The estimated date of completion for this phase of the study (focus group phase) and primary analyses is March 30, 2022.
- Phase 2: The total composite time duration of an individual's participation in the study is estimated to be about 60 minutes. The number of study visits is 3 per participant. All study "visits" are in the form of online survey and video viewing. The first study visit will consist of consenting via cover letter and pre-test. The second study visit will consist of a 1 month-follow-up survey video podcast viewing. The third study visit will consist of a short follow-up survey 3 months following post-test completion. It is anticipated that it will

take approximately 5 minutes to recruit/enroll each participant; 15 minutes to complete the pre-test; 20 minutes to watch draft podcast video; 15 minutes to complete the posttest; and 5 minutes to complete the 3-month follow-up. The estimated date of completion for this phase of the study and primary analyses is August 30, 2023.

9.0 Study Endpoints

9.1 The primary study endpoint for the proposed study shall be 3 months following the last participant's post-test in Phase 2 and been analyzed.

9.2 There are no primary or secondary safety endpoints to be described.

9.3 "There are no safety endpoints given that there are no safety risks associated with the study."

10.0 Procedures Involved

10.1 Study Design:

Phase 1: The study design is focus group methodology, a qualitative research design in which participants are guided through a freeform discussion of a particular issue. The results of will reflect perceptions about HIV that are validated directly from the participants themselves. Five focus groups will be conducted.

Phase 2: The study design is quantitative repeated measures methodology. Participant data will be de-identified and used aggregately in repeated measures analyses (N=128).

10.2 Phase 1: Participants will be introduced to the study and given written informed consent, with an opportunity to ask any study related questions. Participants will be notified that they will be digitally audio recorded throughout the duration of the focus group session. The moderator will introduce herself and instruct the participants to identify themselves with a pseudonym of their choice, and not to use their real names. The moderator will begin by asking the first question. Once discussion has begun, the moderator will guide the focus group discussion with a series of questions using the focus group script. [The focus group script of questions can be found in the SmartForms.] The moderator will take notes throughout the focus group sessions that will provide context, if needed, throughout the discussion. The moderator will carefully watch the time, making sure that all questions are asked during discussion within the 1.5-hour time allotted for participation. Participants will be thanked for their participation, provided light refreshments, and will be given a Target, Amazon, or Wal-mart gift card of $45 for participation.

Phase 2: Participants will email or call a dedicated study email/phone line, where research assistants will screen them, answer any questions they may have, and get them formally enrolled, if applicable. Participants will be given a unique ID number. Participants will be emailed a secure unique link to the pre-test survey (which will include cover letter consent information – See Section 22.1). Participants will complete the pre-test measure. One month after pre-test survey completion, participants will be emailed a secure unique line to the post-test survey in which they will view the podcast video and complete the post-test measures. Participants will be emailed a secure unique link 3 months later to complete a brief behavioral outcome questionnaire. The research team will be knowledgeable about the podcasting software in order to assist participants in trouble-shooting, if necessary. Dark Light Studios will also provide consulting throughout the entire research process, if needed. Upon pre-test completion, participants will be emailed (or pick up in person) a $20 Walmart, Target, or Amazon gift card; $80 Walmart, Target, or Amazon gift card upon post-test completion; and $25 Walmart, Target, or Amazon gift card upon 3 month follow-up completion; for an opportunity to receive $125 for complete participation. For participants who do not have email addresses, research assistants will assist them in obtaining one, within the recruitment procedures, if desired; alternately, participants will be able to schedule a time to meet at one of the community centers in order to complete pre- and post-test surveys in person, and/or to pick up gift card, if needed.

10.3

There will be no drugs, devices, or biologics used in the research.

Eligibility Screening Form/Script: For Phase 1 and 2, the eligibility screening form/script will indicate age, race, preferred language, and Houston residence status (i.e., “Do you currently reside in Houston MSA?”).

Phase 1 - Focus Group Script: The focus group script will contain questions that ask about condom use and perceptions of HIV and other STIs. The first part of the discussion will ask about familial and media messages concerning safer sex (35 minutes); the second part will ask about safe sex curriculum materials (25 minutes); and the third part will discuss perceptions about condom use (20 minutes). 10 minutes is allotted for “anything else” participants would like to share.

[Eligibility Screening Script and Focus Group Script are attached in SmartForms]

Phase 2 – Survey Data: Demographics will include age, biological sex, education, and income. Based upon the behavioral outcomes we expect participants to adopt from the HIV prevention podcasts, we will inquire (pre, 1 mo post, & 3mo): (1) frequency of penetrative sexual intercourse acts in the past month, (2) unprotected penetrative sexual intercourse in the past month, (3) number of sexual partners in

the past month, (4) PhenXToolkit Self-reported HIV Results, and (5) condom use during the last act of penetrative sexual intercourse. Based on the knowledge and psychosocial cognitions we expect to influence, measures (pre & post) will consist of (1) Motivations to use condoms scale, (2) HIV knowledge, (3) attitudes toward condom use, (4) condom use self-efficacy, and (5) condom use communication, (6) perceived social and subjective norms, (7) feedback concerning HIV prevention video content and presentation (1 mo post only), and (8) Marlowe-Crowne social desirability scale(1 mo post only). [A copy of the survey measures is attached in the SmartForm section]

10.4 1 month and 3 month follow-up data will be collected from Phase 2 participants. No follow-up data will be collected form Phase 1 participants.

11.0 Setting

11.1 Phase 1: Research procedures will be performed within a closed-door conference room at a community center in the evenings and/or on Saturdays. Letter of support is attached in Smartforms. Phase 2: Procedures will be performed on participants' individual personal computing device (computer, smart phone, etc.) Participants will have the opportunity to arrange to complete study procedure (survey data collection and podcast viewing) in person, at a designated community center, if needed.

- There will be no involvement of a community advisory board.
- The Blacklist Association, MMOA, Action One Media group, and research team will recruit primarily through word-of-mouth and directing community members to check out the IRB-approved study flyers that will posted on community bulletin boards within the Houston MSA. Community bulletin boards at community centers are free to the public. Community centers are available for scheduling usage of closed-door conference areas. [Letters of Support are attached in Smartforms.]

12.0 Drugs or Devices – N/A

13.0 Risks to Subjects

13.1 The focus group questions ask about attitudes, efficacy, and perceptions of sexual behaviors. This may be minimally uncomfortable psychologically for more conservative participants. Participants may decline participation at any time while in the study. Participants may also elect not to participate in discussing any question that they are not comfortable talking about. No procedures are in place by the PI personally to reduce the potential minimal psychological discomfort, other than encouraging and allowing participants

to self-select out of the study if they are experiencing significant psychological discomfort.

13.2 Phase 2: The survey questions ask about sexual behaviors and prevention behavior. This may be minimally uncomfortable psychologically for more conservative participants. Participants may decline and stop participation at any time while in the study. Participants may also elect not to answer any question that they are not comfortable answering. No procedures are in place by the PI personally to reduce the potential minimal psychological discomfort, other than encouraging participants to self-select out of the study if they are experiencing significant psychological discomfort.

14.0 Potential Benefits to Subjects

There are no direct benefits for participation.

15.0 Provisions to Monitor Data to Ensure the Safety of Subjects – N/A

16.0 Withdrawal of Subjects

16.1 There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

16.2 If a participant wishes to withdraw from the research during the focus group procedure (phase 1), they will be free to leave, the moderator will note this in her notes, and their audio data thus far will not be used during transcription and analysis. No further contact will be initiated by the researcher. If a participant wishes to withdraw from the research during the effectiveness phase (phase 2), they will be free to stop all study procedures at that time. As stated in the Cover Letter (consent information), they can call or email the study contact information and request that they be withdrawn from the study, so that no other follow up will be initiated. No further contact will be initiated by the researcher.

17.0 Costs/Payments to Subjects

17.1 There are no costs that subjects may be responsible for due to their participation in the described research.

17.2 Describe the amount and timing of any payments or inducements to subjects.

Phase 1: Participants will receive a Target, Wal-mart, or Amazon gift card in the amount of $45 upon completion of the study procedures. Participants

will need to remain in the focus group throughout the duration prior to receiving any remuneration; the payment will not be pro-rated.

Phase 2: Upon pre-test completion, participants will be emailed (or pick up in person) a $20 Walmart, Target, or Amazon gift card; $80 Walmart, Target, or Amazon gift card upon post-test completion; and $25 Walmart, Target, or Amazon gift card upon 3 month follow-up completion; for an opportunity to receive $125 for complete participation. For participants who do not have email addresses, research assistants will assist them in obtaining one, if they wish, within the recruitment procedures; alternately, participants will be able to schedule a time to meet at one of the community centers in order to complete pre- and post-test surveys in person (on a university laptop), and/or to pick up gift card, if needed. At each survey activity (pre-test, post-test 3mo follow up), participants will need to electronically submit the survey prior to receiving any remuneration; the payments will not be pro-rated.

18.0 Compensation for Research-Related Injury – N/A

Research involves no more than minimal risk

19.0 Confidentiality

19.1 Phase 1: The PI will not be able to identify any individual's real identity during playback of the audio recordings, only their pseudonym. The PI will physically take digital audio data to the university and it will be downloaded with encryption immediately after each focus group on the PI's university office computer, stored there, transcribed, and analyzed on the PI's UH office computer. There will be nothing to connect the participant to any transcribed statement.

Phase 2: The PI will assign each enrolled and consented individual a unique ID number that will be matched to their email address via a study key code. Email addresses are needed in order to email each participant their e-gift card for participation, should they wish to receive it electronically. The study key code will be a spreadsheet and will be encrypted and located on the PI's secure university computer.

Phase 1: Study participation will collect consent forms that will not be linked to any audio file data and will be kept stored and locked in researcher's on-campus office. The consent form will include participant signatures which are direct identifiers. However, the consent form will not be linked to audio file data.

Phase 2: ID numbers will be linked to their pre, post, and follow-up assessment. Email addresses will be collected in the pre-test. This will be the only identifying information for study participation. An encrypted

spreadsheet will identify participant's email address and study ID number (study key code); stored on the PI's secure university computer. Email addresses are needed for the distribution of electronic gift cards. Gift cards will be emailed with encryption. If participants do not wish to provide an email address, they will be given the option to pick-up their gift card at a designated community center at each point of study participation (pre, post, and follow-up).

A certificate of confidentiality will be used in this research. The following language is documented in the consent form and cover letter:

*"*This research is covered by a Certificate of Confidentiality. The researchers with this Certificate may not disclose or use information, documents, or email addresses that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena. Information, documents, responses, and/or email addresses protected by this Certificate cannot be shared with anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Heath which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it."

19.2 No one outside the research team will have access to any identifiers.

19.3 The key to the study code will be destroyed following completion of all data collection procedures or at the end of study completion.

19.4 Phase 1: The recordings will be destroyed upon transcription.

20.0 Provisions to Protect the Privacy Interests of Subjects

Phase 1: Participants will be told that they are not required to interact with anyone they do not wish during the group discussion. They will not have to give any written personal information except for signature on consent form. Participants will be told that they do not have to participate in discussion that they do not want to. Participants will also be told that if they feel uncomfortable or if any question is too intrusive, they can discontinue participation and help themselves to light refreshments upon leaving, without incidence or penalty.

Phase 2: Participants will be told that they are not required to answer any question that they do not feel comfortable answering. They will not have to give any written personal information except for email address, should they wish to have their gift card emailed.

Participants will be told that they can discontinue participation at any time, and/or withdraw themselves through emailing the study team (information found on Cover Letter – See Section 22.1).

21.0 Informed Consent Process

21.1 The researcher will be obtaining consent:

- Phase 1: Consent will take place in a closed-door conference room at Jacob's Group Home conference room on the day of anticipated study participation. Phase 2: Consent will take place via the "accept" button on the electronic survey (See Section 22.1).
- There is no waiting period between informing the prospective subject and obtaining the consent.
- Phase 1: There will be no ongoing consent. Participation is cross-sectional, meaning no other participation is required upon completion of their focus group. Additionally, participants who were a part of a previous focus group will not be allowed to attend or participate in a subsequent focus group.

  Phase 2: There will be no ongoing consent. Consent to the initial pre-test (in the form of electronic cover letter – See Section 22.1) will consent participants for the current data collection and follow-ups. Participants are able to leave any question blank they do not wish to answer, or withdraw from the study any time, via email, and no further contact will be initiated (-as stated in the Cover Letter consent information document).

- I will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects: N/A
Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A
Subjects who are not yet adults (infants, children, teenagers): N/A
Cognitively Impaired Adults: N/A
Adults Unable to Consent: N/A

22.0 Process to Document Consent in Writing

22.1 Phase 1: I will be following "SOP: Written Documentation of Consent (HRP-091)."

Phase 2: We are requesting a Waiver of Written Consent because survey data collection will be obtained online through a secure survey portal. This research presents no more than minimal risk of harm to subjects; and the

research procedures include activities that would not require written consent outside of the research context. Consent information will appear as a cover letter on the first page of the online survey, followed by confirmation (click "accept" button) that the participant has read the consent information and agrees to take part in the research. If a participant disagrees, the survey is closed. If a participant agrees, their response is recorded as a part of their survey data.

22.2 Written Consent form for phase 1 is attached in SmartForm

22.3 Cover letter (consent information) for phase 2 is attached in SmartForm

23.0 HIPAA- N/A

24.0 FERPA – N/A

25.0 Data Management

25.1 Phase 1: Data Analysis will include transcribing the focus group data, examining all the transcriptions aggregately and analyzing the qualitative data for common themes, as thematic analysis will constitute the analysis procedure.

Phase 2: Data analysis will include aggregating the data, eliminating any identifiers, and performing repeated measures t-tests on the study variables of interest.

25.2 Phase 1: Electronic data (audio files and transcripts) will be secured and encrypted on my on-campus university computer in my office. Consent forms, will be stored in separate folders in a locked file cabinet.

Phase 2: Electronic data will be secured and encrypted on my on-campus university computer in my office. Study key code spreadsheet (linking participant ID number with email address) will be encrypted and stored securely on my office computer.

25.3 Data will be stored for seven years

25.4 Only the PI (researcher) and approved student research team members will have access to the raw data.

25.5 The PI (researcher) will be responsible for receipt of the data (Both Phases).

25.6 Phase 1: One approved student research team member will have access to the audio files and will be responsible for all audio transcription. Transcription will take place only on the PI's university-issued laptop within the researchers' office during student researcher's work hours. Audio transcription files will be password protected on the UH secure server.

Phase 2: Approved student researchers will have access to the de-identified data. All data analyses will take place only on the PI's university-issued laptop within the researchers' office during student researcher work hours.

25.7 Data will not be banked for future use.

26.0 Specimen Use and Banking – N/A

27.0 Community-Based Participatory Research – N/A

28.0 Sharing of Results with Subjects

28.1 Study results will be shared with participants only through public article publication only if participant contacts researcher about the study, post-study.

29.0 Resources

29.1 I am an associate professor in the college of education. The proposed research consists of cross-sectional qualitative study data. The researcher has previous training in the facilitation of focus groups and extensive training in collecting and analyzing focus group data. The PI has completed a post-doctoral appointment at The Pennsylvania State University's The Methodology Center and learned cutting-edge statistical procedures (quantitative and qualitative) involved in health and prevention research. The PI also currently instructs the research and methodology course within her department program, authors and co-authors manuscripts on sexual risk behavior, and often serves as qualitative (and quantitative) methodologist on student dissertation committees and research papers.

29.2 Resources

There are approximately 50-100 people to come out to various community service events (neighborhood cleanups, cultural fairs, other special events, etc.). With the assistance of a trusted community organization, the Blacklist Association, I anticipate that finding five groups of seven African American adults willing to participate is feasible.

- I intend to devote my academic and summer months to the data collection period and data analysis.
- Facilities include university office, university computer, and department access to schedule a classroom in Farish Hall for research team meetings.

- There is no anticipated medical or psychological resource that subjects might need as a result of a consequence of the human research.
- Any persons assisting with the research data analysis will be adequately informed about this protocol, the research procedures, and their duties and functions. All research team assistants who will potentially participate in either phase of the research will have been personally trained by the PI and are/will be added to the IRB before their human subjects interactions. The student research team member who will have access to the raw data for transcription will be added to the IRB.

30.0 Additional Approvals – N/A