A Culturally Tailored Web-Based Cognitive Behavioral Stress Management for Latino Sexual Minority Men living with HIV and Cancer

Principal Investigator	Sara St. George, PhD
Funding Agency	National Institute on Minority Health and Health Disparities
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Funding Agency	National Institute on Minority Health and Health Disparities
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Confidentiality Statement

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PROTOCOL REVISION HISTORY

Version Number	Version Date	Summary of Revisions Made:
1.0	10-09-2020	Initial Submission
2.0	02-01-2022	Inclusion and exclusion criteria
3.0	05-17-2022	Procedures schema and timeframes Inclusion and exclusion criteria
4.0	12-02-2022	Inclusion and exclusion criteria
5.0	12-07-2022	Updated recruitment and compensation procedures
6.0	04-20-2023	Added a new recruitment location
7.0	07-21-2023	Added secondary avenues for participant recruitment (i.e., online recruitment platforms)
8.0	08-25-2023	Update for procedure of withdrawal of subjects
9.0	10-26-2023	Updated Jackson Health System recruitment procedures
10.0	02-22-2024	Included MyChart Research Recruitment Tool
11.0	04/25/2024	Removed Jackson Health System as a site
12.0	05/21/2024	Added a final interview

STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with International Council on Harmonization Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the National Institute on Minority Health and Health Disparities Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), and the Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor, if applicable, except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

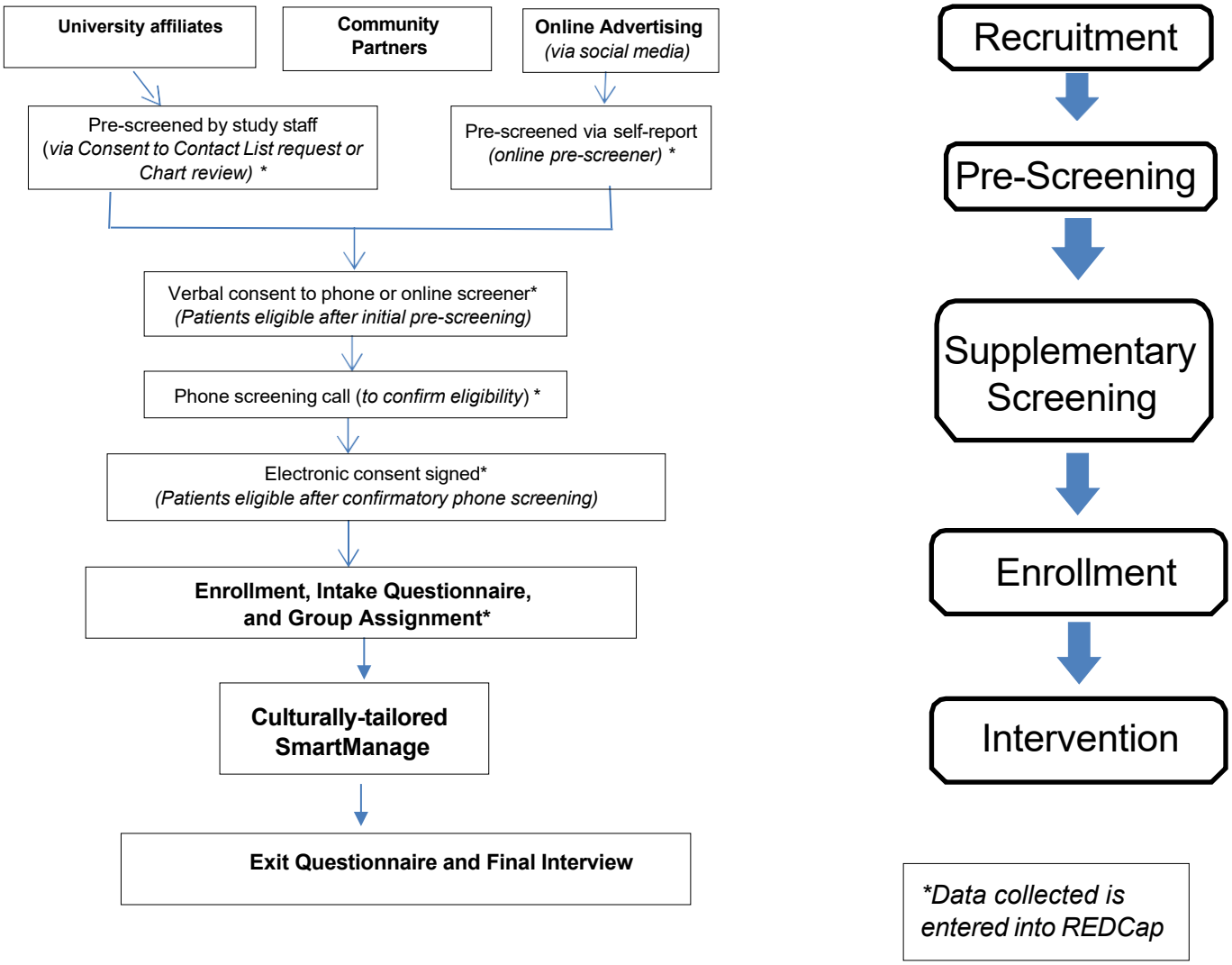
The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review 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.

TABLE OF CONTENTS

1 PROTOCOL SUMMARY

Title	A Culturally-Tailored Web-Based Cognitive Behavioral Stress Management for Latino Sexual Minority Men living with HIV and Cancer	
Background	HIV infection is associated with increased risk for several types of cancer, including but not limited to Kaposi's sarcoma, non-Hodgkin lymphoma, and anal cancer. With an increasing aging HIV-positive (HIV+) population, which includes large proportions of ethnic and sexual minority individuals, there has also been a substantial increase in the proportion of these individuals who develop and survive cancer. Living with a dual-diagnosis of HIV and cancer can increase distress, as well as affect multiple aspects of health-related quality of life (HRQoL). Moreover, among dually-diagnosed individuals, those who are ethnic and sexual minorities may experience more substantial cancer survivorship disparities. For example, prior research indicated sexual minority cancer survivors experience higher distress and poorer self-rated health than their heterosexual counterparts. Our prior research demonstrated the efficacy of a cognitive behavioral stress management (CBSM) intervention in improving psychosocial and health outcomes for individuals living with HIV or cancer. Thus, we propose a single-arm feasibility trial of a culturally-tailored web-based CBSM intervention for dually-diagnosed (HIV/cancer) Latino sexual minority men (SMM).	
Objectives/Endpoints	**Objectives**	**Endpoints**
	Primary: To examine the feasibility and acceptability of the culturally-tailored web-based SmartManage intervention among dually-diagnosed Latino SMM. Secondary: To evaluate the preliminary efficacy of the culturally-tailored web-based SmartManage intervention among dually-diagnosed Latino SMM.	Feasibility will be examined via retention (> 85%) and attendance (> 70%) rates. We will evaluate acceptability via quantitative assessment as well as open-ended feedback. Intended effects will be evaluated via examining pre-post changes in health-related quality of life, general stress, and disease/dual-diagnosis related distress using the following measures: Functional Assessment of Cancer Therapy Scale-General, Medical Outcomes Study HIV Survey, Perceived Stress Scale, and Impact of Event Scale.
Study Design	Single-arm feasibility trial	
Number of Patients/ Target Study Population	30 Latino sexual minority men living with both HIV and cancer	
Description of Sites Enrolling Participants	University of Miami Health System	
Study duration	1 year	
Statistical Analysis	The analyses will be primarily descriptive. A paired t test statistic and linear regression model will be used to compare outcome variables pre- to post-intervention. We will also estimate effect sizes for the outcome variables, which will be selected depending on which statistical test was performed and variance assumptions.	

1.0 Schema


University affiliates
Community Partners
Online Advertising (via social media)
Pre-screened by study staff (via Consent to Contact List request or Chart review) *
Pre-screened via self-report (online pre-screener) *
Verbal consent to phone or online screener* (Patients eligible after initial pre-screening)
Phone screening call (to confirm eligibility) *
Electronic consent signed* (Patients eligible after confirmatory phone screening)
Enrollment, Intake Questionnaire, and Group Assignment*
Culturally-tailored SmartManage
Exit Questionnaire and Final Interview
Recruitment
Pre-Screening
Supplementary Screening
Enrollment
Intervention
*Data collected is entered into REDCap

2 BACKGROUND

2.0 Study Rationale

Given the health disparities Latino SMM living with HIV and cancer experience, interventions to improve health and psychosocial outcomes are warranted. Cognitive behavioral stress management (CBSM) intervention is efficacious in reducing distress, as well as in improving overall quality of life. Prior studies have demonstrated the efficacy of CBSM in Latino men living with prostate cancer or Latino SMM living with HIV but have not included content specific to dually-diagnosed (cancer & HIV) SMM. The co-management of HIV and cancer presents a series of challenges that (a) critically impact health related quality of life and (b) have not been adequately addressed in evidence-based psychosocial interventions. The availability of culturally-tailored, evidence-based interventions that include techniques to enhance cognitive restructuring, emotion regulation, and communication, with favorable effects on psychosocial and physiological adjustment, and overall quality of life have been documented. Given that these prior intervention components have demonstrated efficacy, the current study will examine the feasibility, acceptability, and preliminary efficacy of content that has not been specifically tailored to this unique, yet growing subgroup, of Latino HIV+ SMM cancer survivors. Thus, our proposed work involves the development and testing of content that is of clinical and cultural relevance to this group: co-management of HIV and cancer, strategies for self-advocacy, partnering with the health system and health providers, intimacy and disclosure concerns regarding both conditions, assertiveness and communication skills, and self-efficacy in care coordination. This content will be grouped into 10 weekly sessions, which will be culturally-tailored to Latino SMM.

2.1 Background

With the advent of highly active antiretroviral therapy (HAART), HIV-infected individuals in the US are living substantially longer and have a life expectancy that now approximates that of the uninfected population. As such, an increasing number of individuals living with HIV, as they age, are being diagnosed with cancer.[1-3] Moreover, HIV infection may increase the risk for certain types of cancer, such as non-Hodgkins lymphoma and Kaposi's sarcoma.[1-3] Unfortunately, medical management of individuals dually-diagnosed with both HIV and cancer may be more complex, which may also increase potential for significant stress and its sequelae.[1-3] For example, medications used for HIV and cancer treatment may interact, increasing possibility for toxicity and detrimental side effects.[1, 2] Moreover, it may be difficult to distinguish whether a drop in CD4 count and/or constitutional symptoms among those dually-diagnosed are due to HIV infection or cancer treatment, further complicating medical management.[1, 2] All in all, dually-diagnosed individuals are at greater risk of experiencing stress due to the complex medical management of these diseases, as well as to the uncertainty associated with living with two life-threatening conditions. ***Furthermore, the stress of living with a dual diagnosis of HIV and cancer is likely compounded for ethnic and sexual minorities, who experience disparities in both HIV and cancer outcomes.*** HIV is disproportionately represented among ethnic and sexual minority men (SMM).[4, 5] The CDC estimates approximately 1 in 4 Latino SMM will be diagnosed with HIV in their lifetime.[5] Thus, while current estimates of dually-diagnosed individuals are forthcoming, Latino SMM are likely to make up a substantial proportion of individuals living with both HIV and cancer. This is particularly alarming, given that, as described in detail below, Latino SMM experience a variety of health disparities, including those associated with the negative impact of stress, in the experience of living with each of these diseases.[1] While there has been little to no research examining health outcomes among dually-diagnosed Latino SMM, there are studies indicating Latino SMM experience disparities in both HIV and cancer-related outcomes, outlined below.

In addition to being more likely to be diagnosed with HIV than non-Latino white SMM, Latino SMM experience poorer HIV-related health outcomes once infected. For example, Latino SMM demonstrate poorer access to care than their non-Latino white counterparts.[6] Moreover, Latino SMM may experience higher levels of HIV-associated stigma than their non-Latino counterparts.[7] HIV stigma, in turn, has been associated with increased depression, lower levels of social support, and poorer physical health.[8]

Relative to heterosexual men, SMM living with cancer generally report heightened symptom bother as well as poorer sexual functioning, greater psychological distress, and worse health related quality of life (HRQoL).[9-14] Evidence also suggests that SMM are more likely to engage in risky health behaviors, including inadequate exercise and greater rates of smoking and alcohol use, which may persist following a cancer diagnosis.[9] SMM also report lower satisfaction with their cancer-related medical care and poor treatment satisfaction has been associated with fear of recurrence.[15, 16] This of particular importance since fear of recurrence is one of the most common and distressing concerns reported by cancer survivors and a prior study found SMM with prostate cancer generally report greater fear of recurrence than heterosexual men.[10-17] Additionally, Latino men experience poorer quality of life than their non-Latino white counterparts following a cancer diagnosis.[18] Latino SMM may have less access to healthcare and resources for coping, *which may be exacerbated by multiple minority status*.[6] Moreover, while prior research has shown that cultural values play a significant role in health and wellness among Latino populations living with HIV and cancer, no interventions have been tailored for Latino SMM.

3 OBJECTIVES AND ENDPOINTS

3.0 Objectives

Primary objective: To examine the feasibility and acceptability of the culturally-tailored web- based SmartManage intervention among dually-diagnosed Latino SMM.

Secondary objective: To evaluate the preliminary efficacy of the culturally-tailored web-based SmartManage intervention among dually-diagnosed Latino SMM.

3.1 Endpoints

Feasibility will be examined via retention (> 85%) and attendance (> 70%) rates. Acceptability will be evaluated via quantitative assessment as well as open-ended feedback. These assessments will measure standard dimensions of acceptability including relative advantage, compatibility, and complexity.

Intended effects will be evaluated via examining between-group pre-post changes in health- related quality of life, general stress, and disease/dual-diagnosis related distress.

4 STUDY DESIGN

4.0 Overall Design

This is a single-arm feasibility trial of a culturally-tailored web-based ***SmartManage*** *(**S**tress **M**anagement **a**nd **R**elaxation **T**raining **Manage**ment)* intervention. For this study, staff will utilize these primary avenues for participant recruitment: 1) the University of Miami Medicine system and its University of Miami affiliates (e.g., Sylvester

Comprehensive Cancer Center, consent to contact lists from other University of Miami investigators), 2) online advertising, via social media, and 3) collaboration with external partnering community-based organizations.

Culturally-Tailored Web-Based SmartManage Intervention: Through our prior work with cancer survivors and HIV+ SMM, we have developed, implemented, published and disseminated evidence-based manuals to managing prostate cancer survivorship or HIV infection in sexual minority men. CBSM is and evidence based, chronic disease management program, from which we derived content for the web-based SmartManage intervention for HIV+ SMM cancer survivors. The web-based SmartManage intervention includes ten 90-minute weekly therapist delivered group sessions (4-6 participants) via video conference. In the first 30 minutes, participants are taught/discuss a new stress reduction technique whereas the latter 60 minutes focus on stress- and self-management. Disease course, symptom burden, communication with intimate partner and/or family members and health care provider, impact of stress on physical and mental health and symptoms, and management of symptom burden and decrements in HRQoL are used for educational purposes and as catalysts for CBSM techniques. Participants describe stressors with an emphasis on symptoms and disruption, HRQoL and their coping responses for in-session role-plays. The SmartManage web platform has all intervention material, resources, and exercises.

We will adapt each of the SmartManage intervention components to be compatible with our participants' cultural beliefs and context by including culturally-relevant content and examples within both the didactic (website) and interactive (session) portions of the SmartManage intervention. Specifically, our intervention will be adapted to reflect the values of familism, allocentrism, health stigma, power distance, external locus of control, and male gender roles. Our adaptation will be guided by previous cultural concepts and adaptations used to inform similar CBSM studies.

4.1 Study timelines

The study will last approximately 16-20 weeks for all participants (factoring in time for recruitment, enrollment, assessment, and intervention). We anticipate it will take approximately 6 months to recruit our full sample, and study will last no more than 1 year in total.

5 STUDY POPULATION

This pilot study will include a total of 30 sexual minority Latino men who are HIV+ and survivors of cancer.

5.0 Inclusion Criteria

Participants must:

a) Be ≥ 18 years of age.
b) Be fluent in English.
c) Have evidence of at least one form of metastatic or non-metastatic solid tumor cancer and/or hematologic malignancy, including, but not limited to, the following types:
   i. Oral cavity and pharynx (i.e. tongue, mouth, pharynx, etc.)
   ii. Digestive system (i.e. esophagus, stomach, small intestine, colon, etc.)
   iii. Respiratory system (i.e. larynx, lung, bronchus, etc.)

iv. Urinary system (i.e. kidneys, bladder, urethra, ureters)
v. Bone and joint
vi. Soft tissue (including heart)
vii. Breast (male)
viii. Genital system (male, i.e. prostate, testis, penis, etc.)
ix. Endocrine (i.e. thyroid, adrenal glands, pancreas, etc.)
x. Melanoma skin cancer

d) Be ≥ 30 days post active primary treatment (i.e. surgery, radiation, and/or chemotherapy*) for their cancer. *(Note: Adjuvant therapies, such as hormone therapy for prostate cancer, etc. are not considered exclusionary).*
e) Self-identify as a cisgender male
f) Self-identify as Hispanic or Latino
g) Have been diagnosed with HIV.
h) Have reliable access to a computer/device with internet accessibility.

5.1 Exclusion Criteria

Participants must *not*:

a) Have had one of the following exclusionary cancer types:
   i. Non-melanoma skin cancer *only (not in combination with another type listed in the inclusion criteria above)*
   ii. Brain cancer
   iii. Eye cancer
   iv. Any form of pediatric cancer *(if the pediatric cancer is the only cancer diagnosis the patient has had)*
b) Currently be undergoing primary treatment for their cancer
c) Have had inpatient treatment for severe mental illness in the past 12 months or have overt signs of psychopathology (i.e. psychosis) and/or suicidality at the time of screening.
d) Be experiencing active alcohol dependence or have had inpatient treatment for alcohol abuse within the past 12 months.
e) Be experiencing active substance dependence or have had inpatient treatment for substance abuse within the past 12 months.
f) Have any other medical conditions resulting in a predicted life expectancy <12 months.

5.2 Recruitment and Retention Methods

For this 1-year pilot, we plan to recruit 30 Latino HIV+ cancer survivors who are sexual minority men. By working with a variety of UM and UM-affiliated groups, including Sylvester Comprehensive Cancer Center as well as our external partners we hope to enroll HIV+ cancer survivors of diverse backgrounds, in terms of age, education, and socioeconomic status. We acknowledge that recruiting this many patients from such a unique population and within the proposed timeframe may present several challenges. However, study staff will capitalize on their working relationships with University of Miami Medicine affiliates and their connections to community partners.

Screening and Recruitment: Participants for this pilot will be recruited remotely (online or by phone). For this study, staff will utilize these primary avenues for participant recruitment: 1) the University of Miami Medicine system and its University of Miami affiliates (e.g., Sylvester Comprehensive Cancer Center, consent to contact lists from other University of Miami investigators), 2) online advertising via social media, and 3) collaboration with external partnering community-based organizations.

University of Miami Medicine and its UM affiliates (UHealth Clinics, UM Consent to Contact Database, or Other UM Investigators' Consent to Contact Lists)

A partial HIPAA waiver is requested for screening and recruitment purposes (See section 12.1.3 for HIPPA Waiver). Such a waiver is appropriate for the following reasons:

a) This study is of no more than minimal risk to prospective patient/participants, as their participation simply involves undergoing a psychosocial intervention and providing questionnaires and does not utilize drugs, medical devices, or medical procedures of any kind.
b) Personal identifiers obtained via the report will be used to determine patients' eligibility for enrollment only and will be destroyed as soon as possible after the determination of eligibility is made.
c) All other personal health information (PHI) collected from patients will be obtained by self-report only. For the purpose of this pilot, study staff is *not* requesting access to enter patients' electronic medical records beyond the pre-screening.
d) Given the timeline of the recruitment for the project (less than 1 year), it would be impracticable for the study team to rely solely on direct referrals from healthcare providers to enroll the desired number of patients for the pilot (50). Conducting a chart review will enable the study team to obtain a larger number of patient names in a shorter amount of time, thus rendering the recruitment timeline feasible.

A limited amount of PHI will be reviewed from patient charts in order to pre-screen patients. Patients to be pre-screened will be determined from the scheduled list of patients on a given day within the study period in the appropriate disease teams (i.e., Infectious Diseases, AIDS Clinical Research Unit, etc.). The research personnel will review charts for the following information: whether the person is male, 18 years or older, Hispanic, speaks English, has a metastatic or non-metastatic solid tumor cancer, and is ≥ 30 days post active primary treatment. Patients who are identified through UChart review will be approached through their treating physician. We will advise their treating physician and direct medical staff of the possible eligibility to our study, and further request for them to introduce our study to the patient. If the patient is interested, they will be instructed to either call us or provide their verbal consent to be contacted by the study team for screening.

We will also obtain a list of potentially eligible participants from the UM Consent to Contact Database. The following criteria will be used to generate the patient contact list: male, 18 years or older, Hispanic, speaks English, a metastatic or non-metastatic solid tumor cancer (by ICD-10/ICD-9 codes), and not receiving active treatment (by CPT codes). Additionally, we will be utilizing MyChart Research Recruitment as a tool to identify and safely communicate with participants who agreed to be contacted if they meet the initial study eligibility criteria from the EMR.

In addition, our research team will partner with other UM investigators doing work in HIV and/or cancer who have obtained informed consent from prior or current study participants to be contacted for future studies. Requesting these lists from other investigators will enable the study team to obtain a larger number of patient names in a shorter amount of time, thus rendering the recruitment timeline feasible.

After receiving the lists of potentially eligible participants, study staff will contact individuals via phone using the Consent to Contact Script. If the prospective participant declines to provide verbal consent for screening, the study team member will thank them for their time and end the call. However, if the prospective participant does provide

verbal consent, the study team member will proceed with the screening process, giving the individual the option of completing the full screener either by phone or online. *For those screened by phone*, study staff will enter patient's responses into REDCap and confirm the prospective participants' eligibility (or lack thereof) for the study. *For those who complete the online eligibility screener* (also REDCap), study staff will confirm eligibility during a follow-up phone call.

Online Advertising via Social Media

As most individuals are now using social media, such as Facebook, Instagram, and Twitter to stay connected with friends and family, it makes sense for the study team to advertise this potential research opportunity in this manner. Those who learn of the study via Facebook advertisements or other social media, will be directed to a brief online eligibility pre-screener, the responses to which will be captured in REDCap. On other similar studies utilizing Facebook ads, staff have noted that a number of people have clicked on the pilot's Facebook ads and either "liked" them or shared them on their personal pages. However, these same individuals have not then proceeded to complete the online pre-screener.

Moving forward, study staff will send a brief message to those individuals who comment explicitly on their Facebook pages that they are interested in taking part, but who have been unsuccessful in finishing the online pre-screener. If an individual simply shares or "likes" an ad for the pilot, study staff will not message them. Same procedures will be utilized for the other social media channels. Study staff will review all completed online pre- screeners and determine whether respondents appear to meet preliminary eligibility criteria. If respondents do meet these preliminary criteria, UM study staff will call these respondents to complete the screening process by phone or online.

Partnership with External Collaborator

Potential participants may also be recruited remotely via the study team's collaboration with local community-based organizations serving LGBT individuals. These community-based organizations provide social services specifically for sexual minority men living with HIV and have longstanding relationships with university investigators. These organizations may advertise the study to their patrons. If someone who is not currently a UM patient, or who is a UM patient that has not been identified by the staff as a potential participant, calls our external community partners to inquire about general research opportunities, they will be redirected to our staff who will provide them with information about the study and ask for their verbal consent to complete the screening process by phone or online. In addition, we will recruit participants through referrals from enrolled participants. Enrolled participants will receive $20 for every referral of a potentially eligible person (i.e., adult male with HIV and cancer).

Other avenues for participant recruitment

We will advertise this trial in online recruitment platforms (e.g., ResearchMatch) that help connect researchers with individuals interested in learning about research study opportunities. First, we will enter our inclusion criteria to generate a list of potentially eligible participants. Then, we will send a contact message to these individuals (See *ResearchMatch message*). Once the individual has authorized to release their contact information to our study team, we will call these respondents to complete the screening process by phone or online.

Financial Compensation:

Participants will receive a $75 electronic payment (e.g., Zelle, digital gift card) at each of two assessments (baseline, post-intervention), and additional $25 for participating in a

final interview (A total of $175 for study participation).

6 STUDY PROCEDURES

Study staff will follow guidelines from the CTSI on e-consenting using REDCap. After consent has been obtained, study staff will instruct the participant to complete the intake questionnaire.

Intake questionnaire:

a) **Demographics and Disease Information:** Participants will complete: a demographic survey which will include factors such as age, race, education, employment status, income, nativity, years in the US, and relationship status. Participants will also complete a disease information form, which will collect medical history relevant to their cancer and HIV diagnoses. Finally, participants will complete ACTG HIV medication Adherence measure,[19] and the Barriers to HIV Care survey.[20]

b) **Psychosocial Factors:** Participants will complete the Coping Self-Efficacy scale,[21] Interpersonal Support Evaluation List (ISEL),[22] the Bidimensional Acculturation Scale for Hispanics,[23] and the Computer Proficiency Questionnaire (CPQ).[24]

c) **Intervention Outcomes:** Participants will complete: the Perceived Stress Scale (General Stress),[25] the Impact of Event Scale (Disease/Dual-diagnosis-related Distress),[26] and The Functional Assessment of Cancer Therapy scale-General (FACT-G; HRQoL)),[27] and Medical Outcomes Study HIV Survey (MOS-HIV; HRQoL).[19]

d) **COVID-19 Questions:** Participants will complete the COVID-19 Impact of the Pandemic and HRQOL in Cancer Patients and Survivors measure.

e) **Computer Proficiency:** Measured with the Computer Proficiency Questionnaire.

Once participants complete the intake questionnaire, they will be prompted to register on the culturally-tailored SmartManage intervention website. Study staff members who have previous experience and expertise in delivering CBSM interventions to Latino populations will conduct the study intervention interactive sessions. Following the intervention, participants will be prompted to complete their exit questionnaire in REDCap.

Exit Questionnaire. For the exit questionnaire, the participants will complete all intake measures (excluding the Demographics and Disease Information) and will also complete a measure of acceptability. As standard acceptability constructs include relative advantage, compatibility, and complexity, the acceptability evaluation measure will cover ease of use of the culturally-tailored web-based SmartManage intervention, including participants' confidence in their ability to successfully complete the intervention, as well as general comfort with the intervention process.[28] Additionally the acceptability evaluation measure will gauge preference web-based vs. in-person interventions, as well as willingness to complete the culturally-tailored web-based SmartManage intervention again or refer a friend to the intervention. The acceptability evaluation measure will also allow participants to give open- ended comments/feedback about the intervention.

Final Interview. Participants will be asked to participate in a final interview to discuss the challenges or factors that influenced their participation in the program, the impact of the program on their health, and suggestions for improvement. The interview will be conducted by phone or videoconference, will last about 30 minutes, and will be video or

audio-recorded and then transcribed by study team members (See Final Interview Guide).

7 PARTICIPANT WITHDRAWAL

7.0 Participant Withdrawal from the Study

Although we will seek to minimize participant withdrawal, participants will be told that this study is completely voluntary and that they have the right not to participate in any intervention procedure. They also can completely withdraw from the study at any time without any negative consequences.

If, for some unforeseen reason, a situation arises in which a participant experiences more harm than good during the study, the PI may choose to withdraw this participant. Though highly unlikely, such situations could include excessive physical, psychological, or emotional suffering. Other circumstances under which participants will be withdrawn from the study may include: the participant no longer meet the eligibility criteria, providing fraudulent data, or other reasons deemed appropriate by the Primary Investigator. If a participant is arrested, reports suicidal ideation, or some other extreme adverse event, a qualified study staff member (i.e., Dr. Sara St. George, a licensed psychologist) may ask them to withdraw from the study, and if appropriate, refer them to necessary services. According to IRB, if a participant becomes incarcerated while enrolled in a study, all research interactions and interventions with that participant, and the obtaining of identifiable private information about the participant must cease. When participants withdraw from the research, study staff will update their data set to reflect this change. Study team members will no longer contact participants to schedule future study activities, depending on the time point at which the participants withdraw.

Unless participants expressly request the destruction of whatever data that has already been collected, and unless participants request no further data be collected about them whatsoever, study staff may continue to gather certain information at the other time points at which the participants would have been seen had they remained active in the study. Unless otherwise instructed by these participants, study staff may also continue using their previously collected data for analysis purposes.

7.1 Lost to follow up

Participants will be considered lost to follow-up after five failed attempts to contact them. To minimize loss to follow-up and missing data, we will contact participants by phone if they miss intervention sessions. We will ask about barriers to participation and brainstorm ways to facilitate their participation and accommodate their unique circumstances so they can fulfill their participation in the study.

8 RISKS AND BENEFITS

8.0 Risks

Though we regard the risks of participating in this pilot project to be low, we will take care that every member of the research study team is trained to handle all situations with sensitivity and empathy. All research staff is required to complete UM-mandated training on the Protection of Human Research Participants, which must be renewed on a yearly basis. Certificates for all research staff will be kept on file. Since the anticipated risks associated with this pilot are relatively low, and since the potential benefits for participants are significant, the balance of risks-to-benefits seems reasonable to us.

While taking part in this project, participants may be exposed to information related to cancer survivorship and HIV, and they may be asked to discuss sensitive topics, both of which may lead some participants to experience transient, mild anxiety. In these cases, every attempt will be made to provide relief to participants and to ameliorate the source of their discomfort. Should participants experience extreme acute or persisting affective reactions at any point during the study, they will be referred to a psychiatrist or clinical psychologist associated with the study site in question.

In the event that a participant reports symptoms or concerns of extreme distress (i.e., severe symptoms of depression and/or anxiety, suicidality, etc.), the PI will assess the severity of such distress by meeting individually with the participant at an appropriate juncture either after completion of the study activities scheduled for that time point, or potentially immediately, in emergencies. If it is then determined that the participant needs individual care, our research staff will be prepared to refer the patient to an additional source of clinical intervention. Participants may be referred to the appropriate channels within University of Miami health system. They will also be provided with a list of community resources in the Miami area that serve individuals experiencing extreme distress.

In addition, group sessions provide a particular challenge to confidentiality because it is possible that participants may repeat comments outside the group. Research staff will remind participants not to talk to people outside the group about what was said in the group sessions and to keep it confidential. Research staff will ask participants to attend the group sessions alone from a quiet, private, confidential room with no background noise.

There is the potential for participants to be bothered by the questions asked during the final individual interviews, which may make them feel uncomfortable, angry, sad, embarrassed or fatigued.

Lastly, confidentiality during internet communication activities cannot be guaranteed. The study team will provide participants with internet privacy tips and show them how to log in to and use the program. Also, participants will be completing all questionnaires online using a secure and unique log in REDCap (See section 12.6 for Data Handling and Record Keeping).

8.1 Potential for Benefits

There may not be any direct benefit. However, participants taking part in this pilot may benefit from exposure to information about cancer and HIV with which they were previously unfamiliar. They may also get exposed to basic cognitive-behavioral stress management techniques while reviewing the web-based platform. As mentioned earlier, our culturally-tailored SmartManage platform will be specifically designed to ameliorate the distress, general stress, and health-related quality of life challenges experienced among HIV+ sexual minority male cancer patients. Thus, participants may absorb information about ways to decrease distress, cope with challenges related to symptom management, and improve their HRQoL, all through exposure to an innovative new online tool.

9 UNANTICIPATED PROBLEMS

9.0 Definition of Unanticipated Problems

The Office for Human Research Protections (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 Institutional Review Board (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.

9.1 Unanticipated Problem Reporting

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) as per institutional guidelines.

9.2 Reporting Unanticipated Problems to Participants

Not Applicable

10 DATA REPORTING

10.0 Data submission

Electronic case report forms for study data entry will be developed by staff at the University of Miami using Velos and REDCap, a HIPAA AND 21 CFR part 11 compliant database. Only investigators and assigned research staff will have access to study data. The electronic case report forms will be available to the sponsor, IRB or regulatory authorities in event of an audit

10.1 Data and Safety Monitoring

The Sylvester Comprehensive Cancer Center (SCCC) Data and Safety Monitoring Committee (DSMC) will monitor this clinical trial according to the Cancer Center's data and safety monitoring (DSM) plan to assure the well-being of patients enrolled on Investigator-Initiated Trials that do not have an outside monitoring review. In its oversight capacity, the DSMC bears responsibility for suspending or terminating this study. The activities of this committee include ongoing review of accrual, periodic review of response adverse events including SAEs, important medical events, significant revisions or amendments to the protocol, and approval of cohort/dose escalations. The DSMC also reviews reports from internal audits of protocol compliance and data integrity conducted by the University of Miami, Office of Research Compliance Assessment. If the DSMC and/or the PI have concerns about unexpected safety issues, the study will be stopped and will not resume until the issues are resolved. The DSMC will review reports from all audits, site visits, or study reviews pertaining to this clinical trial and take appropriate action. The guidelines appearing in this section are offered for DSMC consideration in assessing adverse events and response to study treatment. The SCCC DSM Plan to which this study is subject can also be found at www.sylvester.org.

11 STATISTICAL METHODS

11.0 Statistical Hypothesis

Primary research question: To examine the feasibility and acceptability of the culturally-tailored web-based SmartManage intervention among dually-diagnosed Latino SMM.

Primary Hypothesis: The culturally-tailored web-based SmartManage intervention will be feasible and acceptable to dually-diagnosed Latino SMM.

Secondary research question: To evaluate the preliminary efficacy of the culturally-tailored, web-based SmartManage intervention among dually-diagnosed Latino SMM.

Secondary Hypothesis: The culturally-tailored web-based SmartManage will show preliminary reductions in stress and disease-related distress and improvements quality of life among dually-diagnosed Latino SMM.

11.1 Sample Size Determination

We expect that, within this subgroup of HIV+ sexual minority men, rates of prevalence of cancer will likely be greater or equal to 30% (i.e. the rate of prevalence observed in the general older male population). This estimate, along with consultations with our co-investigators and community partners has informed our recruitment goals. Based on our institution accrual capacity, we are able to enroll 30 subjects in the study. In accordance with Leon et al. 2011,[29] we assert that the main goal of our pilot study is to examine the feasibility and acceptability of a culturally-tailored SmartManage intervention and based our sample size on the number of participants that could feasibly be recruited within our time frame. Thirty participants will be assessed for retention and attendance rates. As detailed here, 30 participants provide reasonable precision for estimating the above rates. Table 1 illustrates study precision for estimating the true attendance rate. If we observe 21 participants among 30 who attend all intervention sessions, the estimated attendance rate will be 70% and the corresponding 95% confidence interval will be 50.6% to 85.3%. If the number of participants who attend all intervention sessions is 27, then the estimated attendance rate will be 90% with a corresponding 95% confidence interval of 73.5% and 97.9%. Furthermore, with 30 participants, a one-sided binomial test with 5% significance will have power >80% to detect improvement to 18.6% attendance relative to a null rate of 70%.

Table 1. Possible study findings for attendance rate with 30 subjects

Number (%) of attended subjects	95% CI*
21 (70%)	50.6% - 85.3%
24 (80%)	61.4% - 92.3%
27 (90%)	73.5% - 97.9%

* CI: confidence interval, binomial method.

11.2 Statistical Analyses

11.2.1 General Approach

All data will be inspected for quality assurance prior to analysis. Data screening will focus on: (a) Missing data: we will determine the amount, the pattern, and randomness; (b) Outliers: we will identify observations that appear to be very high or very low and decide how to proceed based on the presumed cause; and (c) Inconsistencies: we will identify inconsistencies within a single variable and between variables. Initially, we will perform an exploratory data analysis and calculate descriptive statistics. Transformations of the data in order to meet statistical assumptions will be undertaken when indicated. Type-1 error will be set to 5% ($\alpha = .05$) for calculating confidence intervals and performing hypothesis testing and all tests will be two-sided. If needed,

alphas will be adjusted accordingly for multiple comparisons using Bonferroni correction. Standard statistical goodness-of-fit measures will be used assessing any of the model fittings. Missing values will be handled with appropriate statistical methods. Last observation carried forward (LOCF) and multiple imputation will be considered for missing values.

Demographic and disease characteristic variables will be summarized using descriptive statistics. Counts and percentages will be used to summarize the distribution of categorical variables. Median, range, mean, and standard deviation will be used for continuous variables. Categorical variables will be tested using Fisher's exact test. Continuous variables will be tested using Student's t-test and/or Mann-Whitney U test. For correlation coefficients, Pearson's correlation coefficients and Spearman's correlation coefficients will be estimated along with corresponding 95% confidence interval. All statistical analyses will be carried out using SAS or SPSS, all of which are available to investigators through the University of Miami.

11.2.2 Analysis of the Primary Endpoint(s)

Feasibility will be analyzed using attendance and retention rates. For the proposed study to be considered feasible, we will need to uphold all the following criteria: 70% of participants attend all intervention sessions and 85% of participants are retained throughout the study (from pre-intervention to post-intervention assessment). These proportions are based on previously successful CBSM trials in other populations.

We will also perform descriptive analyses to better understand the feasibility of our future R01 trial, including:

1) Personnel time: This will include personnel time that is devoted to assessing eligibility, managing contacts, and recruiting, conducting the intervention, and administrative time.
2) Space: We will collect information on any space used that is needed to conduct the intervention, including administrative space.
3) Supplies: We will collect information on all supplies that are needed and any costs associated with maintaining the SmartManage website.

Acceptability will be analyzed using the proportion of the number of participants who agree to participate in the intervention. We will evaluate the acceptability of the intervention two ways:
1) via the proportion of eligible SMM who agree to participate vs. decline and 2) via the exit survey that will measure acceptability of the intervention.

We will explore whether feasibility and acceptability differ by sociodemographic, medical, and psychosocial factors via Fisher's exact tests. These analyses will be primarily descriptive and will provide the basis for future randomized trials to formally evaluate the efficacy of the culturally-tailored web-based SmartManage intervention among dually-diagnosed Latino SMM.

11.2.3 Analysis of the Secondary Endpoint(s)

Preliminary Efficacy: The main outcomes will be health-related quality of life, general stress, and disease/dual-diagnosis related distress all of which will be continuous total scores. We will examine descriptive statistics (e.g., means, medians, standard deviations) among study variables. Based on the distribution of the data, we will select either paired t- tests or the Wilcoxon signed-rank test for paired samples to examine whether the following variables improve significantly following the intervention using total

scores and scores from subdomains. Linear regression will be used to examine study variables and the following change of endpoints between pre- and post-intervention:

- **The Functional Assessment of Cancer Therapy Scale-General:** This instrument will used to assess HRQOL. This 5-point Likert scale instrument includes 27 items and yields four subscales (physical, social, emotional, and functional well-being) and a total score, with higher scores indicating better HRQOL (Cronbach's α from .85 to .92)[27].
- **The Medical Outcomes Study HIV Survey:** This is a widely accepted instrument to assess HRQOL in individuals living with HIV. The instrument includes 35 items that assess the ten dimensions of health, including mental health, quality of life, health distress, cognitive function, energy/fatigue, overall health, role function, physical function, pain, and social function. The subscales are scored as summated rating scales on a 0–100 scale where higher scores indicate better health (all Cronbach's α > .75)[19].
- **Perceived Stress Scale:** This instrument will be used to assess the degree to which participants appraise their lives as stressful. It consists of 14 items, with seven positive items and seven negative items rated on a 5-point Likert scale. Positive items will be reversed coded and all items will be summed to generate a total score, with higher scores indicating greater stress (Cronbach's α =.86)[25].
- **The Impact of Event Scale:** This instrument will be used to measure dual-diagnosis- related distress. This 5-point Likert scale instrument includes 22 items and it was developed to assess post-traumatic stress disorder symptom clusters associated to a life-threatening event. It yields 3 subscales (intrusion, avoidance, and hyperarousal) and a total score. Higher scores indicate greater distress (Cronbach's α from .79 to .97)[26].

11.2.4 Planned Interim Analyses

We do not plan to do interim analysis.

11.2.5 Sub-Group Analyses

Not Applicable

11.3 Qualitative Data Analysis

Qualitative data will be analyzed using a rapid qualitative analysis or general inductive approach.[32, 33] Findings will be directly derived from the raw data, specifically participants' comments. Study team members will meticulously read all transcripts and participate in an iterative group process to develop a coding manual that outlines category labels and descriptions. Independent raters will code all data and inter-rater agreement will be calculated. The qualitative software Dedoose will be employed for content analysis and extracting coded participant responses.

12 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

12.0 Informed Consent Process and Documentation

12.0.1 Consent Process

Informed consent is a process that is initiated prior to the individual's agreeing to participate

in the study and continues throughout the individual's study participation. The consent process will take place remotely via videoconference on e-consenting using REDCap. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document before the videoconference call. At the beginning of the meeting, the research staff will confirm the identity of the potential participant by viewing their driver's license or another form of identification. Then, research staff will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will be given as much time as needed for them to be comfortable with participating in this study. Participants will have the opportunity to carefully review the consent form and ask questions prior to electronically signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will electronically sign and date the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. An electronic copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted, and the form signed before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

12.0.2 Process to Document Consent in Writing
We will follow procedures outlined in HRP-093 Electronic Signatures for Documentation of Consent.

12.0.3 Process to Document Notification of Participants
Former and current participants will be notified regarding the addition of a final interview. We will reach out to all participants via phone, making up to five contact attempts. If a participant agrees to participate in a final interview, we will ask him to sign the revised version of the informed consent. The notification will be documented in an electronic form in REDCap (See Notification of final interview).

12.0.4 HIPPA Waiver
Type of Request:

☒ Waiver of Authorization for access to medical record for subject identification/recruitment. ☐ Waiver of Authorization for access to medical record to obtain data for the research.

Confirm that you will destroy or de-identify the information you collect at the earliest opportunity. ☒ ***I confirm***

Confirm that the information you collect will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible. ☒ ***I confirm***

12.1 Confidentiality and Privacy

Information collected will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible. Procedures to protect confidentiality of

information being sent are the following: de-identifying/coding reports, sending emails via secure transmittal, and password-protected files.

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 as per institutional policies.

The study participant's contact information will be securely stored in the University of Miami's password-protected electronic devices and University of Miami approved cloud-based storage systems 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 funding agency requirements.

Electronic case report forms for study data entry will be developed by staff at the University of Miami using Velos and RedCap, a HIPAA compliant database. Only Investigators and assigned research staff will have access to study data.

12.2 Resources Available

Prior to their exposure to any sort of personal health information (such as patient names and dates of birth, HIV status, etc.), study staff members will undergo training in the proper handling of sensitive medical information. Study staff will also be trained to respond to participants in a sensitive and empathic manner. In addition, all research staff will be required to complete University of Miami University's annual training on the Protection of Human Research Subjects.

In relation to the social, emotional, and psychological resources that participants might need, any study participant who experiences extreme or persistent affective reactions at any point during the pilot will receive appropriate care referrals to a psychiatrist or psychologist associated with their respective study site. As needed, participants will also be provided with a list of community resources in the Miami area that are prepared to deal with individuals in distress.

12.3 Study Auditing and Monitoring

This study will be monitored (as applicable) and may be audited according to the University of Miami requirements. See also http://research.med.miami.edu/clinical-research/crors/monitoring

Following the monitoring plan, the monitors will verify that the study is conducted, and data are generated and biological specimens are collected, documented (recorded), and reported in compliance with the protocol, International Conference on Harmonization Good Clinical Practice (ICH GCP), and applicable regulatory requirements.

12.3.1 Study Monitoring, Auditing, and Inspecting

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

all study-related documents and study-related facilities.

12.4 Quality Assurance and Quality Control

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

12.5 Data Handling and Record Keeping

12.5.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the study staff under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All research data (including unanticipated events data) will be entered into Velos and RedCap, HIPAA AND 21 CFR Part 11-compliant data capture systems provided by the University of Miami. These data systems include password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

12.5.2 Study Records Retention

All records and documents relating to research studies and participants must be kept confidential to the extent permitted by law; however, records and documents shall be available in a timely manner to the University authorized employees or other agents authorized by the University including IRB members and HSRO staff and appropriate governmental agencies.

Although PIs are responsible for the creation and maintenance of research records and documents, such records and documents (including data collected pursuant to research) are the property of the University. Until the temporal requirements for record/document retention are met, investigators or others may not remove or destroy research records or documents (or copies of such records or documents) without written permission from the Vice Provost of Research. This permission requirement extends to investigators leaving the University even if they plan to continue the research at another institution.

12.6 Compliance with Protocol

The investigator/institution should conduct the study in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was given approval opinion by the IRB.

The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor if applicable, and prior review and documented approval opinion from the IRB of an amendment, except where necessary to eliminate an immediate hazard to subjects, or when the changes involves only logistical or administrative aspects of the study (e.g. change in monitors, change of telephone numbers).

The investigator, or designee, should document and explain any deviation from the approved protocol.

The investigator may implement a deviation from, or change of, the protocol to eliminate

an immediate hazard to subjects without prior IRB approval opinion. As soon as possible, the implemented deviation or change, the reasons for it, and if appropriate, the proposed protocol amendments should be submitted:

a. To the IRB for review and approval opinion;
b. To the funding agency for agreement, if required,
c. To the regulatory authorities

12.7 Publication and Data Sharing

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

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 by contacting the PI. Considerations for ensuring confidentiality of these shared data are described in Section Confidentiality.

12.8 Conflict of Interest Policy

The independence of this study from any actual or perceived influence 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 study 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 research. The study leadership in conjunction with the National Institute on Minority Health and Health Disparities 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.

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