HealthMpowerment Stigma

Increasing engagement and improving HIV care outcomes via stigma reduction in an online social networking intervention among racially diverse young men who have sex with men and transgender women.

Funding Sponsor:

The National Institute on Minority Health and Health Disparities (NIMHD)

SIGNATURE PAGE

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

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Date: 5/6/2024

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral treatment
BL	Baseline
CAI	Condomless Anal Intercourse
CASI	Commuter Assisted Self-Interview
CDC	Centers for Disease Control and Prevention
CFAR	Center for AIDS Research
CRF	Case report form
DBS	Dried blood spot
DSMB	Data Safety Monitoring Board
DCF	Data Collection Form
GLMM	Generalized linear mixed models
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HMP	HealthMpowerment
IGHID	Institute for Global Health & Infectious Diseases
IRB	Institutional Review Board
LGBTQ	Lesbian, Gay, Bisexual, Transgender, and Queer
MSM	Men who have sex with men
NIH	National Institutes of Health
OCS	One Cow Standing
PI	Principal Investigator

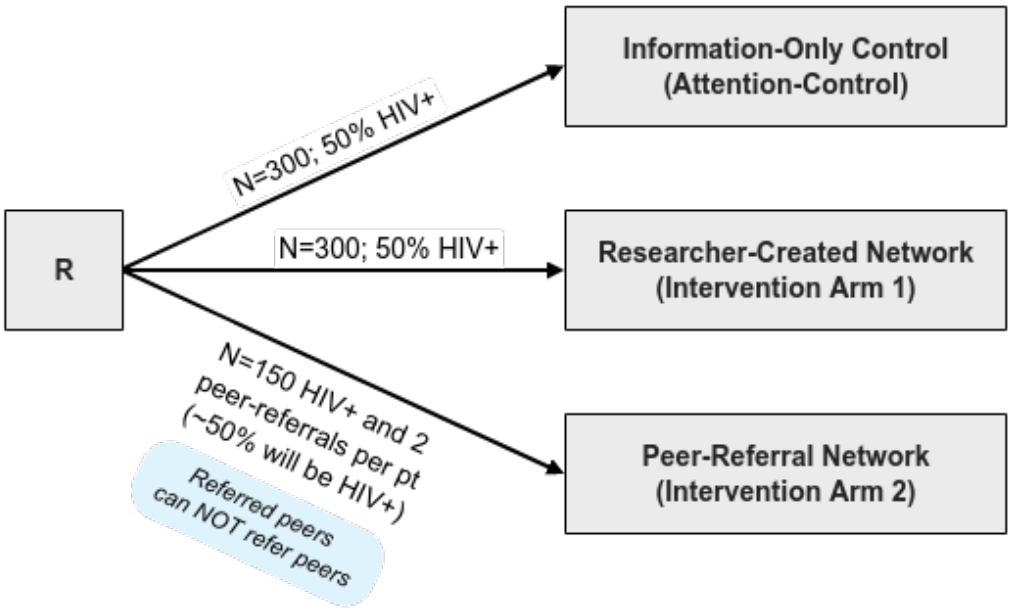
PID	Participant ID
OHRP	Office of Human Research Protection
RCT	Randomized controlled trial
SEM	Structural equation modeling
SID	Study ID number
SMS	Short text message service
SSL	Secure Socket Layer
UNC	University of North Carolina
U. Penn	University of Pennsylvania
VS	Viral Suppression
YAB	Youth Advisory Board
YBLMT	Young Black or Latino men who have sex with men and transgender women
YBMT	Young Black men who have sex with men and transgender women
YMSM	Young men who have sex with men

STUDY ABSTRACT

Multiple stigmas related to sexuality, race, and HIV infection negatively impact HIV testing, engagement in HIV care, and consistent viral suppression (VS) among young Black or Latino men who have sex with men and transgender women (YBLMT). At present, few interventions have addressed the effects of intersectional stigma among HIV-infected *and* uninfected populations. In response to the National Institutes of Health RFA-MH-18-606, this study tests whether a smartphone application (app) intervention tailored for intersectional stigma amelioration can elicit online social support, promote intervention engagement, and mitigate the impact of multiple stigmas on HIV-related outcomes. We will recruit and enroll 1,050 young (ages 15-29), racially and ethnically diverse men who have sex with men and transgender women affected by HIV across the United States. Using a HIV-status stratified randomized trial design, participants will be assigned into one of three conditions (information-only control, a researcher-driven social network intervention, or a peer-referred social network intervention). Behavioral assessments will occur at baseline, 3, 6, 9 and 12 months; biomarkers (viral load) are scheduled for baseline, 6 and 12 months (for HIV-positive participants). HIV negative/status unknown participants may order through the app up to 3 HIV OraQuick self-tests.

The primary outcome is stratified by HIV status and defined as *successful engagement in care* (consistent VS for HIV-positive participants and routine testing for HIV-negative participants). The specific aims are: 1) Test whether a smartphone application (app) intervention that promotes user-generated content and engagement to address intersectional stigma is associated with improvements in the HIV prevention and care continuum (HIV testing, antiretroviral adherence, VS) as compared to an information-only control arm; 2) Explore whether user engagement, as measured by quantitative and qualitative paradata, mediates the intervention's stigma- and HIV care-related outcomes; and, 3) Examine how changes in intersectional stigma and improvements across the HIV care continuum vary between the researcher-driven vs. peer-referred social network intervention conditions. Our research study is innovative given its focus on intersectional stigma as a key target of intervention, and its ability to assess how different kinds of online social network structures influence participants' engagement over time, reduce experiences of intersectional stigma, and improve successful engagement in care. This research addresses a critical need to reduce the effects of multiple stigmas in a priority population using an intervention delivered through a highly appealing, widely utilized technology. If effective, this form of stigma amelioration via online support can be broadly disseminated to reduce HIV transmission and improve care among YBLMT.

STUDY SCHEMA



	Baseline	3 mo	6 mo	9 mo	12 mo
Survey (all pts)	☑	☑	☑	☑	☑
HemaSpot (HIV+ pts)	☑		☑		☑
HIV Home Test (HIV- pts)	*pts may request <=3x and must be >=3 mo apart*				

1.0 INTRODUCTION

1.1 Background

Young Black and Latino men who have sex with men (MSM) and transgender women who have sex with men (YBLMT) have the highest rates of new HIV infections compared with non-Hispanic White peers of the same age.[1] Dynamics within YBLMT's social and sexual networks (e.g., stigma, discrimination, social isolation) likely contribute to higher HIV incidence even when engaging in fewer individual-level risk behaviors,[54-56] and limit their continued engagement in the HIV care continuum.[12,15,16,19,57-59]

Intersectional stigma impedes efforts across the HIV care continuum by inhibiting protective behaviors (e.g., condom/PrEP use, sustained viral suppression) and decreasing care utilization (e.g., linkage and retention in HIV care).[5,6,9,11-18,57,58,60] These effects are particularly severe for YBLMT who face multiple sexual minority-, race/ethnicity-, and HIV-related stigmas,[6,10,11,19,61] as these stressors can have additive or multiplicative negative health effects.[11,62-68] These overlapping stigmas also foster environments that enable and drive high-risk behaviors[20-22] and limit options to build healthy relationships and supportive networks.[20,21,23]

Social networks offer powerful means for improving the HIV prevention and care continuum for YBLMT,[31,69-71] yet few interventions have focused on intersectional stigma as a key intervention target for HIV prevention and care.[30,38,41-46] To date, most stigma-focused interventions are delivered in-person, focus on an older or general age range, or exclusively focus on either HIV-positive or HIV-negative populations. The logistical requirements of these interventions may not fit the realities of YBLMT, particularly if they anticipate and/or have experienced stigma. Given that nearly all YBLMT in the United States (U.S.) have regular access to a smartphone, computer, or internet-enabled device,[72,73] the Internet's 4A's: *affordability, accessibility, availability*, and *anonymity* may circumvent YBLMT's stigma concerns, facilitate open dialogue, and encourage HIV testing and care through supportive interactions with peers across the country.[48,74-76]

Few published eHealth interventions have been developed specifically for YBLMT.[44,48,77-80] While a growing number of studies describe intersectional stigma among YBLMT,[81-84] few interventions have addressed intersectional stigma on HIV care outcomes and none have done so for HIV-positive and HIV-negative YBLMT together. HealthMpowerment (HMP), a mobile web-based intervention, was designed to remove logistical, financial, and social stigma barriers[48] by engaging HIV-positive, negative, and status-unknown YBLMT in a supportive, online community.[47] HMP provides a platform to capitalize on the strength of social networks.[47,78,85,86] In a randomized controlled trial (RCT) with 474 YBMT (ages 18 – 30; 8.4% also identified as Latinx/Hispanic; 2.7% transgender), the social support features of HMP Original were the most frequently used intervention components. Engagement with these features was associated with improved HIV care outcomes (see Preliminary Findings below). HIV-negative and HIV-positive MSM participants in the original HMP intervention also demonstrated a decrease in condomless anal intercourse (3 months).[47] Among HIV-positive participants, increases in viral suppression (VS) at 3, 6 and 12 months was seen among both intervention and control participants.[87] In HMP Stigma, we will capitalize on the social support elicited through HMP Original to curtail intersectional stigma and strengthen YBLMT's continued engagement in HIV care (i.e., routine HIV testing for HIV uninfected, and sustained VS for HIV-infected YBLMT).

1.2 Rationale

Across every stage of the HIV care continuum, YBLMT underperform compared to their White peers.[2-4] Among interventions for Black or Latino sexual and gender minorities,[26-46] few focus on intersectional stigma as a key intervention target.[30,38,41-46] Stigma-reduction interventions are primarily delivered in-person, focus on older ages, or include either HIV-positive or HIV-negative MSM. HealthMpowerment (HMP Original; R01MH093275) was designed to engage HIV-positive, negative, and status-unknown YBLMT and to reduce sexual risk via a mobile optimized online platform.[47] This approach helped remove logistical, financial, and stigma barriers to intervention participation; however, engagement as measured by detailed data collected as users interact with mHealth interventions (i.e. paradata) varied greatly between participants.[48] Through a R21 study (MH105292), we explored whether participants in the HMP intervention arm reported reductions in HIV-related stigma outcomes. Using behavioral data and intervention paradata, our mixed-methods results suggest that participants' user-generated content (e.g., discussions in HMP's diverse forums) regarding intersectional stigma was associated with improved psychological well-being and HIV care outcomes.[49-51]

A gap in knowledge exists regarding how participants' engagement with mHealth interventions is linked to HIV prevention and care outcomes.[88,89] Paradata can provide purposeful process metrics (e.g., timestamps in system logs to quantify time spent using the intervention, types of features used) to assess intervention engagement.[88,89] We will use paradata to gauge how intersectional stigma and HIV care continuum outcomes differ based on participants' frequency (exposure), time spent (engagement), and types of intervention components participants used (usage) in the app. We will also use paradata to characterize YBLMT's discussions with each other within HMP Stigma social networks, and study how these exchanges influence intervention engagement and HIV care continuum outcomes over time.

We propose to enhance HMP (HMP Stigma) by leveraging the social support elicited through user-generated content to focus centrally on intersectional stigma reduction and promote YBLMT's *successful engagement in care*. Furthermore, given that paradata can help identify what intervention components should be kept, removed, or redesigned between versions of a smartphone application (app) intervention,[52,53] we will leverage lessons learned from HMP Original alongside feedback from our Youth Advisory Board (YAB) to improve intervention engagement (e.g., expanding HMP's gamification elements, improving chat and upload features). Given that HMP is fundamentally relational in nature, we will also test whether HMP Stigma is as efficacious and engaging when participants are recruited by researchers (i.e., researcher-created HMP network) as compared to being referred by participants themselves (i.e., peer-referred HMP network). This approach offers a unique opportunity to understand who participates in these networks, what network structures emerge, and how peer exchanges differ between the two HMP networks.[99-105] *We hypothesize that participants assigned to the peer-referral condition will have greater success in eliciting peer social support, promoting intervention engagement, and achieving the desired stigma- and HIV-related outcomes than participants in the researcher-created HMP network.*

We will recruit a sample of 1,050 racially and ethnically diverse men who have sex with men (MSM) and transgender women (ages 15-29) affected by HIV across the United States. Using a HIV-status stratified randomized trial design, participants will be assigned into one of three conditions (information-only control, a researcher-driven social network intervention, or a peer-

referred social network intervention). Behavioral assessments will occur at baseline, 3, 6, 9 and 12 months; biomarkers (viral load) are scheduled for baseline, 6 and 12 months. The primary outcome is also stratified by HIV status and defined as *successful engagement in care* (consistent viral suppression for HIV-positive participants and routine testing for HIV-negative participants). We will also collect mixed-methods paradata (e.g. number of log-ins and posts, total time spent, features used, length and stigma content of posts) to characterize the nature of virtual exchanges between participants and examine if their discussions of intersectional stigma over time result in improvements in HIV outcomes.

Our study is innovative given its focus on intersectional stigma as a key target of intervention. This research addresses a critical and significant need to reduce the effects of multiple stigmas in a priority population using an intervention delivered through a highly appealing, widely-utilized technology. If effective, our intervention can be broadly implemented to address intersectional stigma and to optimize successful engagement in HIV prevention and care among YBLMT.

2.0 STUDY OBJECTIVES

2.1 Primary Objective:

The primary outcome is successful engagement in care, defined as consistent viral suppression for HIV-positive participants and routine testing for HIV-negative participants.

2.2 Secondary Objective:

A secondary objective is whether user engagement, as measured by both quantitative and qualitative paradata, mediates the intervention effects observed in stigma and HIV care outcomes.

An additional secondary outcome is how changes in intersectional stigma and improvements across the HIV care continuum vary between the researcher-driven vs. peer-referred social network intervention conditions.

2.3 Study Hypotheses/Research Questions

Our proposal is built on the scientific premise that network interventions can encourage behavior change.[31,90-95] Given that YBLMT widely use social networking sites and applications (apps) to socialize with similar others,[28,48,76] HMP Stigma seeks to promote social support by creating a virtual community for YBLMT; thus, we hypothesize that:

A. Compared to YBLMT assigned to an information-only condition, YBLMT assigned to HMP Stigma will report greater reductions in stigma, and be more successful at buffering the negative sequelae of intersectional stigma and circumventing barriers to successful engagement in the HIV care continuum.[71,96]

3.0 STUDY DESIGN

The study will consist of two phases:

1) Refinement and finalization of HMP Stigma
2) A three-arm RCT of HMP Stigma

3.1 Study Population

We will enroll 1,050 YBLMT from across the United States into this 3-arm randomized trial. Participants' self-reported HIV status at baseline will be used for allocation in our HIV-status stratified randomization procedure.

3.2 Sample Size

Participants self-reporting as HIV positive at baseline will be randomized across the three arms (N=150 per arm). Participants who self-report being HIV negative or serostatus unknown at baseline will be randomized (N=150 per arm) into either the Information-Only Control (Attention-Control) or the Researcher-Created HMP Network (Intervention Arm 1). Given that we are allowing the 150 HIV-positive participants assigned to the Peer-Referral version of HMP (Intervention Arm 2) to invite two peers into their social network, we do not know the baseline HIV prevalence among recruited peers. To avoid a priori assumptions of who will be invited, we estimate that half will be HIV-negative or sero-unknown.

3.3 Study Randomization, Stratification, or Description of Non-Random Assignment Procedures

3.3.1 Refine and Finalize HMP Stigma.

During Year 1, we will work with our technology partner, One Cow Standing (OCS), to build the HMP Stigma app. Once refinements are finalized, members of the research team, technology partner, and YAB will conduct internal usability testing of the app to ensure full functionality of HMP Stigma and the backend data-capture. All features of HMP Stigma will be tested during this time including ordering HIV test kits and HemaSpot protocols. OCS will fix any technical problems and finalize the platform for the RCT. The three domains to be modified in Year 1 are:

Technical Refinements: Technical refinements to HMP will focus on (1) the deployment of the peer-referral mechanism for participants assigned to the peer-referral HMP arm, and (2) system for ordering and tracking HemaSpot/HIV in-home test kits across three arms. We will also enhance our paradata tracking system, as we observed that many participants in the original HMP engaged with content (e.g., reading posts, viewing multimedia, scrolling through, liking content) even if they had not posted (these users are often termed "lurkers"). In HMP Stigma, we will extend our paradata metrics to collect detailed data on exposure and engagement with app content, whether as a contributor or lurker. This approach will allow us to fully track the underlying network structure of app engagement and its influence on the intervention's outcomes.

Modifications to Intervention Content: Modifications to intervention content will be informed by our prior results of HMP and the Stigma framework. We will bolster HMP's social support components to create a virtual space that elicits sharing and discussion from participants about their stigma-related experiences. The YAB will be significantly engaged in refining the final intervention content. YAB members will review a selection of the pre-populated Forum topics and the Knowledge Center's written content in terms of readability and relevance. In addition, we will elicit YAB member contributions of new content in terms of articles, forum posts, and discussion topics to reflect recent advances in HIV (e.g., PrEP, U=U), to be inclusive of our populations'

diverse identities around race/ethnicity, HIV status, and gender, and to make HMP feel "lived-in" before enrolling study participants.

Modifications to Promote User Engagement. In HMP Original, those who remained more engaged in the intervention had greater improvements in study outcomes.[47] HMP Stigma will use multiple strategies to ensure participants are engaged with the intervention. First, we will employ and expand the most highly rated and frequently utilized features of the original HMP intervention (the Forum, Ask an Expert (provider Q&A), Knowledge Center and Quizzes). Second, we will convert the original HMP points-based reward system (which was not highly rated by participants) to a system whereby participants earn badges for completing activities and milestones within the app. We have used a similar badge system within a medication adherence app for YMSM which was rated with high acceptability by participants.[187] We will further incentivize this system by releasing new badges throughout the course of the study.

3.3.2 Intervention and control arms

Participants in all arms will have access to a Care Navigator through the intervention or control app. The Care Navigator will utilize existing online databases of resources (e.g. AIDSVu.org Locators, CDC's GetTested.cdc.gov locators, POZ.com's Service directory) to connect participants to trusted HIV testing and care services in their communities as needed. The Care Navigator will also monitor the Forums to identify additional HIV knowledge needs and manage the Ask an Expert provider Q&A to triage medical questions to one of two board-certified HIV care providers. During all study years the Care Navigator will work closely with the YAB to elicit service-related needs and concerns among YBLMT that can be integrated into HMP Stigma.

Control Arm: The HMP Stigma Information-Only Control Arm will feature a streamlined version of the app that provides curated information and other content for YBLMT. This content will follow the design of HMP Original where control arm participants had access to HIV-related Knowledge Center articles of the main intervention without access to the engagement features such as the interactive forums or doctor Q&A. HIV-negative and sero-unknown participants will also be able to request HIV home test kits. Our choice of control arm balances equipoise with research study design; in HMP Original, control arm participants also experienced a statistically significant intervention benefit.[47] We have taken this effect into account in our sample size calculations.

HMP Stigma: We have used the Stigma Framework[128] alongside our findings from HMP Original to guide the design of our proposed intervention features and content (Table 1) and study measures (Table 2). Eligible, enrolled participants who are randomized to intervention Arms 1 (researcher-created network) and 2 (peer-referred networks) will have access to all the features of HMP Stigma. These features include forums where users can start or participate in threads, a knowledge center filled with short articles on a range of topics that can be added and commented on, a provider platform where health questions can be submitted to be answered by a health care provider, a user profile where users can personalize and update their information, and finally, an ordering platform where users can order and track testing kits.

Table 1: HMP Stigma Core Intervention Components and Scientific Rationale

Intervention Feature & Description	Scientific rationale	Paradata metrics[a]

HMP Forums: Discussion boards where users can start new discussion threads or respond to or "like" content posted by other participants.	Pre-populated thread topics will correspond to stigma framework constructs.	# of: posts created, posts read/liked; total time spent; content of posts
Knowledge Center: Brief articles on health and wellness tailored for YBLMT, including featured sections on HIV/STI prevention and care.	Content will correspond with original HMP intervention, and aligns with the Integrated Behavior Model.	# of: articles read, quizzes completed; total time spent
Provider Platform: HIV/STI/sex questions answered by a prevention and HIV care doctor within 72 hours.	Provide evidence-based answers to users' health questions, including linkage to care.	# of: posts created, posts read; total time spent; content of questions
User Profile: Profile page showing participant's username, favorites, and badge progress.	Personalization and gamification features may incentivize continued user engagement.	# of: times visited, badges earned
Test ordering: Ability to order HIV self-test kit.	Provide an opportunity to get tested if users experience barriers to get tested locally.	# tests ordered

[a] Each unique user action on HMP will be captured with date and timestamps.

Peer-referred HMP Network Arm: Participants randomized to Intervention Arm 2 (peer-referred network) will be enrolled into a parallel (but separate) version of HMP Stigma. The only difference between Arm 1 and Arm 2 is that participants in Arm 2 will have a referral feature in their profile that allows them to earn $20 in e-gift cards if they successfully refer and enroll 2 peers of their choosing ($10 per peer) in the first 45 days of their study participation. The referral feature will create a customized link for each participant that can be emailed or text messaged to invite peers into the study.[189] Simple instructions will be provided at enrollment and in the app describing how to refer them. Participants may send referral links until two of their peers have screened eligible and enrolled in the study. Participants may send referrals from Day 1 – 45 of their time in the trial. If two of a participant's referred peers successfully enroll within that time window, at that point, the original participant will receive a notice from the study team that they have successfully reached their referral quota and the referral feature will deactivate. their referral incentives and HMP usernames of their referrals within their profile. While they will be able to see whether their peer has enrolled and what username the peer created, they will not receive any information about any of their peers' survey responses, including those who screened ineligible. Referred peers will see the HMP username of their referrer; they will not be eligible to refer their own peers.

4.0 SELECTION AND ENROLLMENT OF STUDY PARTICIPANTS

4.1 Inclusion Criteria (All study arms)

- Aged 15-29 years (inclusive) at time of screening
- Identify as Black/African American and/or Latino/Hispanic
- Current U.S. resident (verified by zip code)
- Speak and read English
- Report anal intercourse in the past 6 months
- Assigned male sex at birth (no restrictions on current gender identity)
- Has a smartphone
- If HIV-positive, does not report a hemophilia diagnosis or current use of anti-coagulation medication

Additional Inclusion Criteria (Referred Peers from Peer-Referral Arm)

- Invited by current participant in Intervention Arm 2 (approximately 300 participants)
- Any race/ethnicity

4.2 Exclusion Criteria

- Under the age of 15 years
- Over 29 years of age
- Does not speak or read English
- Assigned female at birth
- Reports 0 episodes of anal intercourse in the past 6 months
- Currently incarcerated
- Planning to move out of the United States in next 12 months
- Does not reside in the United States
- Does not have a smartphone
- If HIV-positive and reports a hemophilia diagnosis or current use of anti-coagulation medication

4.3 Recruitment

We will reach the population using social media ads on sites including Facebook, Tumblr, Instagram, BGC Live, Jack'd, Grindr, Scruff, and other comparable social media platforms (see example copy and images in "Recruitment materials.docx"). Final platforms and materials will be developed alongside our YAB. Social media platforms allow us to specify our audience based on socio-demographic characteristics (e.g., age, race/ethnicity) to increase their specificity to our population. Ads will link interested individuals to a Qualtrics screener where they may verify their eligibility, email the team, or locate a toll-free number if they want to talk to a team member about the study. Via co-I Hirshfield, we have access to an online registry with over 1,000 U.S. men, many of whom are HIV-positive, who have expressed interest in participating in other HIV-related studies. We will collaborate with online groups (e.g., Young Black Gay Men's Leadership Initiative; Trans Women of Color Collective) and other advocacy groups to post study and recruitment information. We foresee recruiting 25-30 participants per month during Years 2-4; this staggered design will allow us to accommodate the enrollment and testing of YBLMT in the trial and also allow time for the social networks to develop.

4.4 Informed Consent

Informed consent/assent. Individuals interested in screening for study participation will be consented/assented for screening after reading information about the study and screening procedures. Those who consent to take the screener survey will answer questions to determine their eligibility. Those who do not consent to take the screener will be routed to a public site (e.g., Google). Individuals who complete the screener but are initially ineligible will be asked if they would like provide their first name and email address to be contacted about other research studies in the future, then will be routed to a public site (e.g., Google). For those who are initially eligible based on their screener responses, we will confirm they are eligible by our HIV status quotas. If ineligible by HIV status, we will send an email to inform them. If eligible by HIV status, we will

email each person a unique link to the study's informed consent form. The consent/assent form describes all study procedures, including confidentiality and privacy, information about potential risks, discomforts, benefits of participation, and information regarding who they can contact with further questions. It also states that participation is voluntary, that participants may decide to not take part or to withdraw from the study at any time without penalty or loss of any benefit to which they might otherwise be entitled, and that study participation is in no way related to being able to access care or services.

Waiver of parental consent. We will request that the U. Penn IRB as the central IRB (IRB of Record) grant a waiver of parental consent to participate in this research study for youth participants who are 15 to 17 years of age. The research team has been granted waivers of parental permission for prior studies with sexual minority youth. Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and "an appropriate mechanism for protecting the children who will participate as research subjects is substituted" and "that the waiver is not inconsistent with Federal, State, or local law." A waiver of parental permission for studies with lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth that do not involve greater than minimal risk is a common practice among researchers working in the area of gay and lesbian health/mental health. This is done to avoid the selection biases operating in only recruiting youth whose parents are both aware of and comfortable with their sexual orientation. Commonly these youth have explored their sexual orientation without their parents' knowledge as the youth struggle with issues of disclosure and its consequences within the social, religious, and economic context of their families. A requirement for parental permission in this type of study could not only affect a person's willingness to participate, but could also potentially impact the ability of researchers to engage in this type of research with sexual minority youth. Additionally, minors can often seek sexually transmitted infection (STI) and HIV prevention services without parental/legal guardian permission, depending on each site's state laws.

If the purpose of requiring parental permission as stated in CFR is to protect the minor subject, then requiring parental permission for youth in these circumstances is not a reasonable requirement. Additional privacy protections are provided in that all assessments, notes, reports, and other records will be identified by only a coded number to maintain participant confidentiality. These records and any forms that do contain identifying information will be kept in a locked, limited access area (such as a locked file cabinet) at the participating site.

4.5 Screening

As part of app development, we will create a web-based research dashboard for use with the HMP app. We will use a secure (256-bit), HIPAA-compliant dashboard for app content, participant information, and participant app data. Individuals who consent to take the screener survey will be asked to provide their first name, email address, and phone number, then to answer questions to determine their eligibility. Those who do not consent to take the screener will be routed to a public site (e.g., Google). All individuals who complete the screener will be asked if they would like to be contacted about other research studies in the future, then will be routed to a public site (e.g., Google). For those who are initially eligible based on their screener responses, we will then confirm they are eligible by our HIV status quotas. If ineligible by HIV status, we will send an email to inform them. If eligible by HIV status, we will email them a unique link to the study's informed consent form. Consented participants will complete a 30- to 50-minute baseline survey.

Compared to the gold standard (in-person interviewing), a limitation of online research – like mail and phone surveys – is the challenge of verifying a respondent's authenticity. Using best practices[190,191] (see "HMP SOP-Applicant Verification.docx") we will attentively reduce the likelihood of duplicative entries, bots, and/or catfishing (fake online personas). Verified participants will be allocated to the study arms using our HIV-stratified randomization procedure.

Web-based recruitment screener: The online survey is hosted by Qualtrics, which will include the eligibility script, consent/assent to be screened, and the screener questions. For those who meet eligibility criteria, we will ask for the first name, email, and phone number of the participant. We use Secure Socket Layer (SSL) encryption for online transfers of information, and data will be stored on Qualtrics' secure, HIPAA-compliant servers.

5.0 STUDY PROCEDURES

5.1 Enrollment Procedures

We will enroll a total of 750 participants. Of these participants, 300 will be HIV-negative and 450 will be HIV-positive. After participants are consented, participants will complete a baseline CASI survey and then will be randomized into the Tailored Information-Only Control (Attention Control), Researcher-Created HMP Network (Intervention Arm 1), or HMP with Peer-Referral Network (Intervention Arm 2). Intervention Arm 2 will only have 150 HIV-positive participants randomized to it, as the remaining participants will be peers who are referred by their peers and enroll if eligible. Upon enrollment, all participants will be provided a link to access the HMP app through the Apple App Store or the Google Play Store for Android. Once downloaded, participants will create their app account by entering their email address, creating a username, password, and PIN, entering their mailing address, opting in or out of notifications, and selecting an avatar.

Those randomized in the Tailored Information-Only Control (Attention Control) will be given a streamlined version of the app. They will have access to the Care Locator and Knowledge Center articles and be able to message the Care Navigator. HIV-negative and sero-unknown participants will be able to request HIV home test kits. HIV-positive participants will be sent HemaSpot devices at Baseline, 6 months, and 12 months. They will not have access to the interactive forums, activities, or the Ask and Expert feature.

Those randomized in the Researcher-Created HMP Network (Intervention Arm 1) will have access to the full HMP app, including access to the Arm 1 Forum in which participants will be able to create threads and comment on any threads in the forum, whether moderator- or user-generated.

Those randomized to the Peer-Referral Network (Intervention Arm 2) will have access to the full HMP app, including access to the Arm 2 Forum in which participants will be able to create threads and comment on any threads in the forum, whether moderator- or user-generated. The only difference between this version and the Intervention Arm 1, is that two thirds of the users (300) that comprise this group are added by peer referral by the 150 participants who were randomized into this arm.

Intervention Arms 1 (Researcher-generated) and 2 (Peer Referred) will operate as two distinct virtual communities. Participants will not be able to communicate across arms and will only be able to view the posts of participants in their Arm.

5.2 Locator/Contact Information

Once a participant has been consented, enrolled, and downloaded the study app, they will be asked to provide a phone number in addition to their email address where they can be reached. Participants will also be asked to provide their mailing address so we can send their HIV test kit or HemaSpot device to them. Study staff will not send mail unless the participant has confirmed their mailing address and is aware they will be receiving a package. The app will assure participants that HIV test kit and HemaSpot packaging does not reveal their participation in a research study. Additionally, the app will tell participants that all email and text message correspondence will not include any protected health information or information related to study participation.

5.3 Randomization Procedures

Research-team recruited participants will be allocated to the 3 arms using a computer-generated blocked randomization, with stratification by HIV status. For that purpose, randomly permuted blocks of sizes 3 and 6 will be used in order to maintain the integrity of the randomization process. Participants recruited into Intervention Arm 2 through peer-referral will not be randomized as the social network component requires these participants to remain clustered with their nominator.

5.4 Intervention/Investigation Procedures

5.4.1. Randomized Trial Design

We will test whether a smartphone application (app) intervention (HMP Stigma) that promotes user-generated content and engagement to address intersectional stigma is associated with ***successful engagement in care*** as compared to an information-only control arm consisting of online informational articles and resources curated for YBLMT (Specific Aim 1). We will then examine how user engagement mediates the changes observed in stigma and HIV care outcomes across the 12-month follow-up period (Specific Aim 2). To describe how the social network composition of HMP Stigma affects user engagement and our HIV prevention and care outcomes across a 12-month follow-up period (Specific Aim 3), we will allow the composition of the intervention networks to vary. Participants randomized to Intervention Arm 1 will engage in a researcher-created network where half of the participants are HIV-positive. Participants randomized to Intervention Arm 2 will engage in a peer-referred network in which they may invite 2 peers (irrespective of race/ethnicity and/or HIV status) into the study. All participants who are randomized into Arm 2 will be HIV positive and we assume that peers they refer will be a mix of HIV-negative, HIV-positive, and HIV-unknown status.

5.4.2 HemaSpot Package, Delivery and Tracking:[120]

At baseline and months 6 and 12, HIV-positive participants will be mailed a HemaSpot package which contains: 1) one HemaSpot kit with all necessary materials to perform a finger prick, a biohazard bag, and study labels; 2) an instructional booklet for how to properly collect a specimen for the HemaSpot device; 3) a return envelope addressed to the processing lab with pre-paid postage; and 4) a lab sheet which includes the participant's study ID. The U. Penn team will

coordinate the shipment of HemaSpot kits. Upon receipt of the package, participants will read an instructional booklet (which we have already developed at an 8th grade reading level) that describes how to collect the specimen, complete the lab sheet, and mail the package. The instructional booklet will also direct participants to an instructional video online, developed by the study team. Additionally, participants will be able to view the instructional booklet and video in the app. After collecting their blood specimen, YBLMT will mail their HemaSpot device and lab sheet directly to the processing lab using the provided return envelope with the pre-paid USPS label. The processing lab will then update a kit receipt log spreadsheet documenting the participant's study ID and date of receipt. Laboratory staff will store HemaSpot devices and test them in batches (and note the testing date), according to their internal protocol. Study staff will track all outgoing and incoming packages using USPS tracking numbers. Participants are informed they will not receive the HIV VL results of their HemaSpot devices, as it is not a valid FDA-approved clinical device; it is solely for research purposes. Our team has successfully used these methods before with YBLMT.[120]

If the processing lab receives a HemaSpot device with a sample that cannot be processed (e.g. broken device, inadequate specimen, inappropriate specimen), the U. Penn team will review the study app's paradata to determine whether that participant viewed the instructional video. If the participant viewed the instructional video, the U. Penn team will contact them and ask if they want to try completing another test. If the participant agrees, the U. Penn team will ship them another HemaSpot kit. Once the lab receives the second completed kit, the participant will receive a second $20 incentive, regardless of the specimen's viability. If a participant submitted a HemaSpot device with a sample that cannot be processed but they did not view the instructional video, they will not be offered another kit.

5.4.3 HIV Testing

Participants who self-report as HIV negative or unknown will be able to request up to 3 in-home OraQuick HIV tests. These HIV tests help maintain equipoise with the HemaSpot procedures for HIV-positive counterparts in the trial. We have made these HIV test kits optional. Some participants may benefit from an in-home test if they experience HIV stigma in their communities, yet others may prefer to get tested in-person (e.g. at a local community-based agency, primary care doctor, or testing bus). We will ask participants to upload a photo to the app of the HIV test stick that shows their test result. This is also an optional activity. In post hoc analyses, we will compare those who requested in-home test kits with those who report testing at community agency in the follow-up assessments. If participants report a HIV positive result (whether through in-home test kit testing results, a flagged HIV status change in their follow-up surveys, or by notifying the study team directly in the app), our Care Navigator will reach out within 3 business days to support and facilitate linkage to resources and care, including identifying a convenient location for confirmatory testing (if needed) at a local agency. The study team will not report HIV positive OraQuick results to local health departments, as this is a screening test, not a diagnosis. The Care Navigator will encourage and support participants in seeking confirmatory testing and linkage to care for the remainder of their time in the study.

5.4.4 Surveys

As noted in Table 2, we include a summary of the primary and secondary outcomes, key intervention mechanisms of change, and potential covariates. Assessments will not take more than 50 minutes to complete. We have taken several steps to ensure that the assessments are developmentally appropriate. Consistent with best practices, we will use validated measures developed as part of the NIH Adolescent Medicine Trials Network (ATN) for HIV/AIDS

Interventions studies. We will use gate-keeping questions to decide whether participants should receive other probes within a domain. For example, a participant who has not reported lifetime substance use will not be asked additional substance use questions.

5.4.5 Qualitative interviews

A purposive sub-sample of up to 45 participants (approximately 5 from control and 20 from each intervention arm) will be invited to complete qualitative interviews during the intervention. Interviewees will be chosen to represent a variety of participant perspectives based on intervention engagement (intervention high/low users, lurkers), as well as sociodemographic profiles. Interviews will be completed remotely using a HIPAA compliant videoconferencing platform such as VSee or Zoom. The UNC Project Coordinator will conduct interviews following a semi-structured guide focused on overall intervention satisfaction, HMP's perceived impact on stigma and HIV outcomes, and participants' evaluation of the social networking features (intervention arms only). Control arm participants are included in this evaluation as we expect the information-only intervention will also show a modest impact. Interviews will be conducted at various points during the intervention to better understand intervention use over time and to reduce "survivors bias" of only interviewing participants who are retained for 12 months. Interviews will last 30 to 45 minutes, will be audio recorded with the participant's consent, and will be transcribed by study staff or a HIPAA compliant transcription service (e.g. Verbalink, Transcriptionstar). Multiple interviews may be conducted with the same participant to assess changes in intervention engagement and social support over time.

5.4.5 Research Staff Training

The Principal Investigators and all project personnel satisfy the NIH requirement for training in the protection of human research participants. The requirement is successful completion of a course designed to provide investigators and their staff with a comprehensive understanding of ethical and regulatory aspects of conducting research on human subjects, including online security and data safety. Successful completion entails a self-study review of selected resources and the achievement of a passing grade on an individualized on-line test. Training and successful completion of the on-line examination has been documented and is on file for all personnel listed on this application. Furthermore, all study personnel will have either completed the Human Subject Training established by their institution or the CITI program. In addition, in compliance with the new NIH policy, graduate students and staff will participate in at least 8 hours of mandatory case study and discussions regarding scientific integrity and human subjects. Any additional personnel who may join the project will complete this training before they handle any subject data. Further, issues regarding confidentiality will be reinforced prior to each intervention and data collection with project personnel.

5.4.6 Intervention Monitoring/Quality Control

In accordance with the National Institutes of Health (NIH) requirements, we will adopt a Data and Safety Monitoring Plan. The Principal Investigators (Bauermeister & Muessig) will provide oversight of all study procedures and quality assurance checks. The Data Safety and Monitoring Plan includes the following protocols: All records pertaining to the study and all of the original and electronic files containing collected data will be securely stored by the Principal Investigators at each site in a locked metal file cabinet housed in an off-site office location. To ensure participants' safety as well as the data's validity and integrity, only staff with extensive experience in the area

of HIV prevention will be hired. As noted throughout the proposal, staff will be trained related to data collection procedures (recruitment, data collection, HIV rapid testing, dried blood spot testing). Staff will also be extensively trained relating to confidentiality and required research ethics training and certification. All staff will have signed a confidentiality agreement.

We have several mechanisms to ensure the security and integrity of the data. The intervention content, questionnaires, and personal information will be secured with role-based security that will provide different types of users with different access privileges. Further, we will have separate data collection modules, located in different firewalled servers, to collect personal identifying information, questionnaire data, and to run the study app. At a high level, the three user types and their associated privileges are:

a. Participants –will be the actual participants and, once consented, they will be able to go through the intervention screener, assessments, and use the study app.

b. Research Project staff – will view/access personal data related to participants. They will also be able to process participant incentives and email/call participants to remind them of follow-up assessments. Research staff at the MPIs' institutions (University of Pennsylvania; University of North Carolina) will be able to maintain users (view/add/modify users), and generate export files for analysis.

c. Research Investigators – will be the master users with access to the study app and OCS dashboard and will be required to use a valid user ID and password to log into/access these systems.

Data Monitoring: Ongoing monitoring will be conducted by the MPIs and Project Directors throughout the study. In addition, the University of Pennsylvania IRB (as prime IRB) will conduct regular reviews of study protocols, changes in study protocols, and adherence to protocols in the field. The PIs are required to report any unexpected study-related adverse events to the IRB and NIH. We will convene a Data Safety and Monitoring Board which will consist of experts in HIV medical care and prevention, clinical trials, and a biostatistician.

Data Safety and Monitoring Board (DSMB): We will convene a Data Safety Monitoring Board (DSMB). The DSMB will meet biannually to review the study progress, review modifications, and monitor compliance with IRB rules, human subjects' procedures and the Office of Human Research Protection (OHRP) regulations. The DSMB will advise the PIs, and Co-investigators on participant safety and efficacy of the randomized controlled intervention. The overall purposes of having the DSMB will be to:

- Protect the safety of trial participants
- Identify unexpectedly high dropout rates that threaten the study's ability to produce credible results
- Identify protocol violations that suggest clarification of changes to protocol are needed
- Identify unacceptably slow rates of accrual
- Identify high rates of ineligibility
- Ensure the validity of study results

Responsibilities of the DSMB: The primary responsibility of the DSMB is to safeguard the interest of study participants. Therefore, the DSMB must approve the safety measures in the protocol to preserve the study credibility and facilitate the availability of timely and reliable findings to the broader clinical community. In addition, the DSMB will:

- Provide written documentation confirming review of the protocol and agreement with the study design and the data safety monitoring plan.
- Be available to the Investigator for consultation concerning any adverse study events.
- Review the progress of the study carefully and diligently with special attention to reports of adverse events, drop-outs, or perhaps some other reports generated by group leaders
- Provide a written report to the IRB which summarizes oversight activities and recommendations, and any concerns regarding subject safety.
- Consider the impact of newly published findings bearing on the safety profile of the study.

DSMB Process: The first meeting will discuss the study protocols and establish guidelines for monitoring the study including plans for interim analysis and stoppping rules based on NIH guidelines for this study. Part of the meeting will be open with the PI and Study Team present and part will be closed with only DSMB members. Throughout the duration of the project, biannual meetings or calls will take place. In addition, the MPIs will send quarterly emails to the DSMB members to update them on project progress.

We will use a unique registration ID for each participant and have the rest of their details maintained securely outside of the computer database. Code numbers and contact information will be accessible only to the Research Investigators and Research Project staff. All data will be secured during transmission by using a 256-Bit SSL encryption or higher. The SSL certificate will be from VeriSign or other certificate providers of repute. Critical data fields will be encrypted and stored in the database. The database server itself will be located within the security of the secure and dedicated university firewalls. Breaks in confidentiality will occur in the event that a participant is a danger to themselves or to others, or is in danger from others. We will report this in accordance with rules for mandatory reporting. There is a statement in the consent form and assent form notifying participants of this possibility.

6.0 EVALUATIONS AND MEASURES

6.1 Behavioral Evaluations (all CASI survey instruments are attached to the protocol)

6.1.1 Pre-entry or screening evaluations/measures

- *CASI Survey*

6.1.2 Pre-intervention (baseline) evaluations/measures

- *CASI Survey*

6.1.3 Three-month evaluations/measures

- *CASI Survey*

6.1.4 Six-month evaluations/measures

- *CASI Survey*
- *Qualitative interview (approximately 22 interviews completed by this mid-point)*

6.1.5 Nine-month evaluations/measures

- *CASI Survey*

6.1.5 Twelve-month and Closeout evaluations/measures

- *CASI Survey*
- *Qualitative interview (approximately 45 total interviews completed by study end)*

6.2 Clinical and Laboratory Evaluations (if applicable)

6.2.1 HemaSpot Testing

- HIV-positive participants submit HemaSpot devices by mail for viral load testing at baseline, 6- and 12-month follow-up points.

6.2.2 In-Home Oral HIV Testing

- Participants will submit photos of their in-home oral HIV testing results throughout the 12-month active study.

7.0 DATA COLLECTION AND SITE MONITORING

7.1 Development of Protocol and Case Report Forms

The research team at UNC-CH is responsible for the development of this protocol, and in assisting the research team at U. Penn with the Case Report Forms (CRFs) or Data Collection Forms (DCFs) needed to collect the information required to implement this protocol.

7.2 Data Records

Participant-related study information will be identified through a study ID number on all participant CRFs or DCFs, audiotapes and Computer Assisted Self Interviewing (CASI) files. Participant names or other personally identifying information will not be used on any study documents. All study-related information will be kept on secure servers in password-protected files..

7.3 Data Collection

7.3.1 CRFs /DCFs

Study monitoring data, including information about eligibility, demographic data, and monitoring untoward effects, will be collected on CRFs created in the OCS dashboard. All CRFs for this study must be entered into the OCS dashboard in order to be saved on a secure UNC server.

The OCS dashboard will be used to collect key study enrollment data (e.g., enrollment and randomization assignment), study milestones such as completion or discontinuation, study laboratory results, and adverse events (AE). During active study conduct, the research team will maintain the CRFs within the OCS dashboard.

7.3.2 CASI Data – Study surveys

All CASI data will be collected through the secure HIPAA-compliant Qualtrics platform. Participants will utilize their own devices (phone, tablet, computer/laptop) to complete online CASI surveys. A description of the survey, including a time estimate, will be provided at the beginning of each survey. Participants will have 45 days to complete the survey, which will be sent to the participant via email, text, as a push notification from the app, and/or as an in-app notification. Surveys are attached: "Qualtrics_Baseline.docx," "Qualtrics_3-Month_FUP.docx," "Qualtrics_6-Month_FUP.docx," "Qualtrics_9-Month_FUP.docx," and "Qualtrics_12-Month_FUP.docx". We use SSL encryption for transfers of information online and data will be stored on secure HIPAA-compliant servers.

7.3.4 CASI Data Security

CASI Data Security
Only authorized research team members with a login name and password will be able to access and open survey responses through Qualtrics. To ensure data privacy, as soon as data is entered (in real-time), it will be encrypted and immediately stored in a secure database.

7.3.5 Video Platform Description

A HIPAA-compliant video platform will be used for this study. Either Zoom or a comparable platform may be used to conduct qualitative interviews (offered to select participants at 6 and 12 months) remotely, or may be used as an option for participants to speak with study staff during enrollment. Participants will have the option to conduct face-to-face video chat, video chat in which they can see the interviewer, but the interviewer cannot see them, or audio chat only. Zoom is compatible on PCs, tablets, and smartphones; as well as maintains the option to conduct an audio conference without the video component.

End-to-end encryption: Zoom encrypts all presentation content at the application layer using the Advanced Encryption Standard (AES) 256-bit algorithm. Zoom end-to-end chat encryption allows for a secured communication where only the intended recipient can read the secured message. Zoom uses public and private keys to encrypt the chat session with Advance Encryption Standard (AES256), and session keys are generated with device unique hardware ID to avoid data being read from other devices. This ensures that the session cannot be eavesdropped or tampered with.

Cloud Control Infrastructure: A distributed network of low-latency multimedia routers (software) resides on Zoom's communications infrastructure. With these low-latency multimedia routers, all session data originating from the host's device and arriving at the participants' devices is dynamically switched — never stored persistently through the Zoom communications infrastructure. Zoom's communications infrastructure for real-time video, audio, and data communications resides on Zoom dedicated servers, which are housed in SSAE 16 SOC2 compliant datacenters on opposite sides of the US. Zoom sessions are completely temporary and operate analogously to the popular mobile conversation over the public mobile network. In addition to unique security benefits, Zoom's communications infrastructure also enables an extremely scalable and highly available meeting infrastructure unrestricted by the limitations of physical data centers.

The Zoom client communicates with the multimedia router to establish a reliable and secure connection. At the time of instantiation, the Zoom client will determine the best method for communication, attempting to connect automatically using udp and tcp port 8801, 8802 and 8804 or HTTPS (port 443/TLS).The Zoom sessions will contain identifying information, as in VSee above, but this information will be stripped form the recorded Zoom sessions before they are sent to the analysis team for content analysis.

7.3.6 Backup Recording

All qualitative interviews may also be recorded using a back-up digital audio recorder. Audio files will be erased after being transcribed and transcripts will be de-identified. All audio files will be kept confidential and stored in a locked/limited access folder on secured servers, which is only accessible to designated study staff. All members of the research team will be trained in confidentiality and have signed confidentiality agreements. A professional transcription service, experienced in the handling of confidential data, will be used to fully transcribe verbatim all audio files. Prior to receipt of the first audio file, the transcription service will be instructed to exclude from the typed transcript identifying information (e.g., a name) that may have been verbalized during the course of the interviews.

7.4 Data Submission

7.4.1 CRFs

CRFs will be used to collect data on adverse events (AE), protocol deviations, early participant terminations, and social harms. The research staff will complete and store the CRFs in the secure (256-bit) HIPAA-compliant dashboard built by OCS.

7.4.3 CASI Data Transmission

Only authorized research team members with a login name and password will be able to access and open the survey through the internet site. To ensure data privacy, as soon as data is entered (in real-time), it will be encrypted during transmission to the study staff using Secure Socket Layer technology. The data will then be immediately stored in a secure database on a server within the research data center.

7.4.4 Retention data

7.5 Data Quality Assurance

Investigators receiving federal funding must adhere to the Code of Federal Regulations (CFR) to protect research participants and produce reliable study information. Sites participating in research sponsored by the NIMHD need to have an internal quality assurance plan that will identify problems and correct errors in research study records.

7.6 Role of Data Management

We will use a secure (256-bit) HIPAA-compliant dashboard built by OCS to manage all participants. Datasets will identify participants using an ID number.

8.0 PARTICIPANT MANAGEMENT

8.1 Tracking Participants / Follow-up

A detailed retention plan (see "HMP SOP-Recruitment and Retention.docx") will draw on our prior successful protocols with hard to reach populations to achieve ≥80% retention rate for the 3-month assessment.[47] In our experience, successful retention has several key elements. First, it is critical to obtain accurate follow-up contact information. We will use best practices to retain participants while being sensitive to undue disclosure of YBLMT participating in the study. One barrier to retention among youth is changing cell phone numbers. Study staff will include a reminder for participants in the 3-, 6-, and 9-month survey emails to update their email and SMS contact information if it has changed in the past 3 months. Every effort will be made to reduce attrition as retention is critical to our study efforts. In the event that participants do not respond complete a follow-up survey within 7 days of the first email and in-app request, they will receive a second email with the link and an in-app notification. A third attempt will be made before the study coordinator or Care Navigator calls participants. Correlates of missing data and attrition will be carefully examined. Participants who miss one or more follow-up assessments may still continue in the study. We will compare those who completed different follow-up interviews with those who did not on key predictors from the baseline assessment to check for possible sample bias. The use of the Expectation-Maximization algorithm in the longitudinal analyses will also aid to overcome missing data concerns when appropriate.[192,193]

8.2 Compensation

We will collect behavioral assessments at baseline (BL), 3, 6, 9, and 12 months. Participants will earn up to $340 for completing the 5 behavioral surveys. Amounts per assessment vary based on estimated survey duration (BL-$50, 3mo-$35; 6mo-$50, 9mo-$35, 12mo-$60). Any participant who completes four of the five behavioral assessments will receive a $50 bonus incentive at the end of the study. We will collect HemaSpot blood samples for HIV Viral Load from HIV-positive participants at BL, 6, and 12 months. For equipoise, we will also offer free in-home HIV testing kits for all HIV-negative and HIV-unknown YBLMT. Participants will receive $20 for using the pre-paid shipping packaging to return HemaSpot device to the lab for processing (if HIV-positive) or for uploading a photograph of the HIV test stick that shows their in-home HIV test result (if HIV-negative or sero-unknown). HIV-positive participants are eligible for the incentive if they return their HemaSpot device to the lab within 45 days of receiving it. If an HIV-positive participant submits a HemaSpot device with a sample that cannot be processed and we confirm in the app's paradata that they have viewed the instructional video, they will be offered a chance to redo the

test kit. If they complete a replacement test and mail it to the lab, they will receive another $20 incentive, regardless of the specimen's viability.

Participants who report seroconverting during the study or who upload a positive HIV test stick photo, after receiving confirmatory testing will be eligible to begin receiving HemaSpot device testing and incentives following the study's planned schedule. We will use paradata metrics to characterize users' engagement across the three arms.

8.3 Intervening on "Social Harms"

Potential Risks
We identified the following items as possible risks to subjects and described how we plan on addressing those risks:

1. **Emotional discomfort:** Some participants may be uncomfortable answering questions about their past and/or current HIV risk behaviors (e.g., sexual behavior, substance use). Participants may also feel uncomfortable answering questions about their sexual attractions, or their sexual and gender identity. However, it is important to note that emotional discomfort is an event encountered routinely in daily life and potential discomfort would likely not exceed what is typically encountered in these youths' experiences. All information used in enrollment and recruitment describing the research activities will include a detailed description of the content and expected participation of the respondent, such that the respondent is aware of the nature of the questions to be included in the surveys. The study app will provide these details in full, during the consent process, and once the participant has created their password protected profile they will be able to access full information on the expectations of participation and the types of questions they will be asked. Informed consent documents will inform research participants of the need to keep answers to questions confidential.

2. **Psychological distress** is a potential risk to participants during the completion of the surveys, reading the intervention content and during the qualitative interviewing. We will provide participants with information to allow them to contact the study team at any time if they experience psychological distress related to participation in the study. If psychological distress is apparent, we will refer crisis cases to the National Runaway Safeline which is available 24 hours a day, 7 days a week. We will use established protocols from our prior studies conducted with youth and men who have sex with men (MSM) for research staff to guide them in responding to crisis or harm situations, including attempting to contact the participant to assess risk level and provide appropriate follow-up (e.g., crisis hotline, safety check, suicide hotline). We will notify participants when we must engage in mandatory reporting during the consent process and when the participant decides to share a reportable event with study staff.

3. **Unintended disclosure** is also a potential risk. Data will be protected by extensive confidentiality procedures as described below. Data will be collected confidentially; this will be fully described in the informed consent. We have extensive data procedures already in place to ensure security of the data and information provided by participants:

- Data will be encrypted at all times, from the point of entry into CASI to the point of backup and to analysis. Data will be encrypted using standardized software (e.g., 256-bit, PGP).
- Data will be de-identified and linked by the Study ID to minimize risk of inadvertent disclosure.
- Data will not be released to non-study staff at any time.
- All electronic data sharing between sites will be done only on the secure server.

Study staff will be trained on confidentiality standards and proper interviewing techniques. This will include the following points:

- Always maintain anonymity of the participant data and confidentiality of person.
- Participant names will not be included in any data collection instruments, biomarker containers, or intervention forum posts. The only numbers used to label and identify data from the participant are the Participant ID or their username (app handle) for the intervention.
- Questionnaires and audiotapes are to be linked using the Survey ID number and the interview date. No personal identifiers should be written or affixed to the test results or lab slips.
- Protect the electronic security of all databases.
- Computers that can access electronic data should be physically secured and should be protected by coded passwords. Networks must be demonstrated to be secure by the IT department prior to use.
- Only authorized persons are to have access to electronic databases.
- Project staff must shred documents containing sensitive information before disposing of them.

4. **Privacy and confidentiality concerns:** Participants will be reminded at the beginning of each survey to consider their surroundings and the privacy of their device and internet connection. All communication between study staff and participation will not include sensitive information about HIV, MSM, or anything that may reveal their participation in a study or answers to any of the questions answered in the surveys.

   Participants will be asked to provide two forms of contact information. Because participants are providing these pieces of identifiable information, there is a possibility that their participation in a research study could be disclosed in the following ways: (1) if someone other than the participant sees the intervention content; (2) if someone besides the participant reads the email sent with the link to the follow-up survey in which participants will enter their results; or (3) if someone besides the participant sees the study text messages, or online surveys on participants' computer, tablet or phone. The risk of disclosure of participation in a research study through receiving study related emails, receiving text messages, interacting with the online surveys or with the study application on the participants' cell phone will be minimized in the following ways: (1) participants must enter a PIN to gain access to the app if it has been 5 minutes since the app was open on their device, or 15 minutes if the app was open but inactive as a fail-safe to avoid unintended disclosure; (2) emails with a links surveys will not make any reference to the nature of the survey; (3) participants will be encouraged to delete any text messages received as part of the study to protect them from an unauthorized individual viewing the messages, and to interact with the study application when in private (e.g., turn on screen

lock, complete surveys when alone). Participants will be notified of these risks in the consent process.

5. **Emotional distress:** Participants who learn that they are HIV-positive during the course of the study may be distressed to learn of their health condition. This poses the greatest emotional and physical risk to participants in the research study. The informed consent documents will outline the HIV testing process, stating that results will be delivered the same day for HIV testing, and will explain in full what a positive, negative, or indeterminate HIV test result means. Individuals who receive a positive HIV test result will be offered counseling, confirmatory testing, and referrals to care that are appropriate to their economic situation (e.g. those eligible for Ryan White Care will be linked to the appropriate services). All those receiving a positive result will be linked directly to the Care Navigator who can assist them in finding appropriate resources and/or linking to a case manager at a local agency.

6. **Risk of coercion**: Although most participants in our trial will be recruited using online advertisements, participants in the HMP open network intervention arm (Peer-referral network, Intervention Arm 2) will be incentivized to refer two eligible peers into the study. Our consent processes and instructions for peer referral will ask participants to avoid unintentionally coercing peers. Peers who are invited into the study will have access to consent documents which will fully explain the study procedures, potential risks, and potential benefits. Referred peers will also be reminded that the study participation is voluntary and that refusing to participate in the study or withdrawing from the study is an option at any time.

7. **Risk of offensive/upsetting language or cyber bullying**: We will strive to create a safe and comfortable app environment for all study participants. However, it is possible that participants in the two treatment arms may experience emotional discomfort or upset due to things other participants post through the intervention app' forums. The forums are monitored by study staff, however we do not require posts to be pre-approved by study staff before they go live in the app. We will include "community guidelines" as part of the intervention app's on-boarding process. This information is also included within the app as its own screen and reminders will be provided at all study follow-up assessments. These guidelines were developed and used successfully for participants in the original HMP intervention. Indeed, only one post out of 1497 posts met the criteria for a guideline violation. Thus, we believe the likelihood and seriousness of this risk is minimal. During the adaptation and final development of HMP Stigma we will ask Youth Advisory Board members to review and help update the guidelines to ensure they are comprehensive given the regular evolution of online environments and social media tools. The guidelines will continue to include language around non-discrimination, non-offensive language, openness and confidentiality. As in the original HMP intervention, during the study RCT, study staff will monitor all participant posts during business hours with posts made outside of business hours reviewed in the morning of the next business day. If a participant posts something that could be considered in breach of the guidelines, study staff will remove the post, contact the participant to notify them, explain why the post was removed, provide them with a copy of the guidelines to review again and post a note from the study team to the forum reminding all participants to review and adhere to the guidelines. If a participant accumulates three violations of this nature, they will be immediately discontinued from the study. Any threat of harm to others would be grounds for considering immediate study

stop. The reason we choose to allow more than one violation is that one of the key mechanisms of change for the intervention is for participants to become more aware of the conscious and unconscious stigmatizing beliefs they hold – as well as to challenge these stigmatizing views in others. Thus, we think that these violations can provide a learning opportunity for all parties if handled intentionally. The grounds for discontinuation will be made clear during the informed consent process and will be stated explicitly online within the app use guidelines. Study protocol will include a Standard Operating Procedures manual for staff that will include directions for referral and follow-up in the event that a participant expresses emotional discomfort, distress, threats to self or others, or suicidality.

8.4 Criteria for Premature Study Discontinuation

The principal investigator has the authority to withdraw any participant at any time if in their opinion it would be in the best interest of the participant. The participant will be informed of this withdrawal and explained the rationale. Withdrawal will be documented in the study tracking system.
Subjects will be prematurely discontinued from the study if any of the following occurs:

- The subject withdraws consent/assent;
- The study is cancelled by the *NIMHD*;
- The study is cancelled for other administrative reasons;
- The subject becomes incarcerated or placed in detention during the study; or
- Death of the subject.

Participants may end their participation in the study at any time. No further data collection will occur from the date the decision is made to permanently discontinue the subject from the study. Participants who experience distress during the study will be provided a list of community referrals via phone or email. Any adverse events will be immediately reported to the U Penn IRB and the respective sites' IRBs if applicable. The *Study Stop and Adverse Event Forms* will be completed at this time.

9.0 MONITORING UNTOWARD EFFECTS ASSOCIATED WITH OR RESULTING FROM STUDY

Site staff must first follow their own IRB's procedure for reporting and managing untoward effects.

There are three types of untoward effects to be identified: (1) those related to the participant, (2) those related to the study staff, and (3) those related to the neighborhood/community.

First, the study will catalogue any untoward effect related to the participant. Reporting is required for occurrences including social harms, psychological distress and serious life-threatening events such as suicide attempts. These may be immediately apparent to the study staff, such as the participant's emotional upset requiring referral for counseling; or they may be delayed and reported later to study staff, such as physical harm to an individual for having participated in the study. Study staff will notify the team of these untoward effects by email. Study staff will be briefed during the training on the scope of possible untoward effects and instructed to report events.

Second, study staff may encounter untoward events during sessions that personally affect them. Training and guidance will seek to minimize this risk. Nonetheless, an assessment of the cost of

conducting this study must include cataloguing these events as well. The protocol chairs should be notified of these events so that they may be immediately addressed, evaluated, and guidance modified or expanded to minimize similar risk to other staff.

Third, a critically important area any community-based study intends to evaluate is the impact, including untoward effects, of the project on the community. This will be done informally for this protocol with untoward events being reported to the protocol team.

10.0 STATISTICAL/ANALYTIC CONSIDERATIONS

10.1 Introduction

10.1.1 Paradata Metrics

We will measure temporal engagement by examining users' visits to the app and time spent on app using HMP's paradata timestamps at each login and logout. The paradata will also include information allowing us to link engagement for users who create, like, read, or otherwise interact with content in the app. We will also calculate scores for each participant based on their levels of "active" (posting, commenting) and "passive" (reading) engagement. Active engagement scores will be calculated by assigning one point for each time a participant posted or commented on app content. Passive engagement scores will be calculated using the paradata database to assign a participant one point for each time they read content. Aggregate engagement scores for each participant will be included as indicators and latent factors, as appropriate, in our analyses. This strategy will allow us to examine how different forms of engagement (e.g., temporal engagement, active engagement, passive engagement) influence our study outcomes.

10.1.2 Mixed-Methods Paradata Forum Coding

Expanding on the procedures developed and successfully employed in our R21,49 we will conduct a mixed-methods analysis of user-contributed content to the forums. All content and associated paradata of each user post will be captured by HMP's backend database. We will use Dedoose cloud-based qualitative data analysis program to catalogue and code all instances of stigma-related content and characterize their potential contributions to HIV risk and care behaviors. First, two coders will independently identify all posts that contain stigma-relevant content. Next, they will conduct a content analysis to categorize the nature of the coded stigma content as enacted, community, anticipated, internalized, or challenged stigma. Coding discrepancies will be reviewed and resolved by a third analyst. Ongoing analysis progress will be discussed during biweekly YAB meetings and feedback sought on YAB members' interpretations of participant forum conversations and emergent themes. The final coded dataset will be used for qualitative analyses and publications, as well as to create user-specific variables representing their engagement with each type of stigma-related domain. These data will be used to examine how engagement with stigma content is associated with changes across HIV outcomes (HIV testing, VS) directly and through proposed mediators (e.g., social support and isolation, substance use, depression). We successfully used this methodology in our R21 analysis and have established analytic protocols to carry out these procedures.49-51

10.2 Power Estimates

The primary outcome for the proposed trial is stratified by HIV status and defined as *successful engagement in care*. For HIV-positive participants at baseline, we define successful engagement in HIV care as consistent VS across the 12-month trial (per IOM guidelines[218]). For HIV-negative

or sero-unknown at baseline, we define successful engagement in care as participation in routine HIV testing (2 HIV tests with at least 3 months apart from one another, per CDC guidelines[219]). We define power as correctly identifying the difference in the proportions of YBLMT with sero-specific engagement in HIV care within 12 months of each intervention arm (2 arms: HMP Stigma with researcher-created network, HMP Stigma with peer-referred network) to the control arm (Information Control), thus powering for 3 independent hypothesis tests. Our sample size calculations are based on pair-wise HIV-stratified comparisons of the 3 groups in terms of proportion of successful engagement using a two-sided significance level of 0.05 altered by the number of comparisons using a Bonferroni adjustment (significance level is 0.017 for 3 comparisons). To have 80% power to detect a ***minimum*** effect size (OR=1.9) of successful engagement in care between the 3-arm trial, we will require at least 450 HIV-negative and 450 HIV-positive participants to detect a 17% difference in successful engagement in. In the event of a 20% loss to follow-up, we will have sufficient power to detect an OR=2.1 (18% difference) at alpha=.017. Participants may continue the study even if they miss an assessment intermittently. We will compare those who completed different follow-up interviews with those who did not on key baseline predictors to check for possible sampling bias. Our analysis will use ITT as appropriate.

10.3 Statistical Analysis Plan

10.3.1 Specific Aim 1:

Specific Aim 1 is to test whether a smartphone application (app) intervention (HMP Stigma) that promotes user-generated content and engagement to address intersectional stigma is associated with ***successful engagement in care*** as compared to an information-only control arm consisting of online informational articles and resources curated for YBLMT. Clinical and demographic characteristics will be described for the entire sample, and by treatment group. These will be compared between treatment groups using ANOVA or Kruskal-Wallis test for continuous variables, and chi-square tests for categorical variables. We will conduct primary analyses of our *successful engagement in care* outcome using logistic regression analyses to compare each active treatment group to the control in pairwise comparison tests at an adjusted significance level of 0.017 to reduce Type-I errors in our 3-arm trial. This approach allows us to also test for differential efficacy between the two intervention conditions (i.e., Does peer-referral HMP outperform the researcher-created HMP arm?).

Logistic regression analyses will be stratified by serostatus. The regression will be run with group assignment only in the model. Among HIV-positive participants, we will examine how intervention conditions influence YBLMT's likelihood of consistent VS over 12 months. We will also test intervention effects on retention in care per IOM guidelines (i.e., proportion of HIV-positive participants who obtain at least 2 viral load tests (at least 3 months apart) within 12 months). For HIV-negative YBLMT, we will compare the proportion of participants who obtain at least 2 HIV tests (at least 3 months apart) within 12 months across arms. Estimates will be calculated and presented with corresponding 95% exact binomial confidence intervals. In secondary outcome analyses, we will compare arms across other HIV care continuum outcomes, as well as stigma-related (e.g., reduction in HIV-related stigma) outcomes, using a logistic regression with group assignment on the model assuming no imbalances due to successful randomization.

10.3.2 Specific Aim 2:

Specific Aim 2 is to explore whether user engagement, as measured by paradata, mediates the intervention effects observed in stigma and HIV care outcomes.

10.3.2.1 Quantitative Analyses

Building our theoretical framework, we will use structural equation modeling (SEM) to test whether engagement with stigma content predicts changes in stigma-related outcomes over time (e.g., decreases in anticipated HIV stigma), and changes in HIV care outcomes over time (e.g., repeat HIV testing; consistent VS). In these HIV-stratified analyses, we will use latent class analysis to characterize users' engagement in the app. We will estimate the independent contributions of passive and active engagement on both stigma and HIV outcomes, as well as how cumulative engagement in stigma-related discussions influences these outcomes. Key sociodemographic predictors will be included as covariates (e.g., age, time since diagnosis). We will also examine the contribution of specific mediators (e.g., social support) in these models by decomposing the total effects into direct and indirect effects. In exploratory analyses, we will use multigroup SEM analyses to test whether these proposed models differ based on latent classes of users (e.g., active forum contributors vs. lurkers; low, moderate, high engagement). Multigroup analyses allow us to compare the strength and direction of the effect sizes in our models and their overall fit across these engagement groups. Ideal models will have values of .90 or higher among fit indices and values of .06 or lower for RMSEA as acceptable indicators.[85] The proposed study has sufficient power to carry out these subsample analyses in our model identification and model testing stages. MacCallum et al.[220] show that power of .80 is achievable with alpha=.05 and 30 degrees of freedom in cross-sectional analyses with a sample of 366 for a close model fit (for df=100 the minimum sample size is 178). Thus, we have ample power for these SEM analyses, even when dividing the sample by HIV status or engagement profile.

10.3.2.2 Qualitative Analyses

Using our latent class analysis of users' engagement profiles (e.g. high/low users, lurkers), we will select a subsample of up to 45 enrolled participants (approximately 5 from control and 20 per each intervention arm) across different sociodemographic and user engagement profiles to complete qualitative evaluation interviews (described above in section 5.4.5) Study staff, under the guidance of Dr. Muessig, will create a codebook of *a priori* and emergent themes including operational definitions of all codes and sample quotations to illustrate how to apply each code. Two study team members will use the codebook to independently code the data while a third team member will review these coded sections and resolve discrepancies. We will use Dedoose and Excel matrices to assist with theme identification, coding textual data, and describing relationships among codes (via code co-occurrence and memoing functions).[221] Analysis results will be used in conjunction with participants' survey responses, biological outcomes, and usage profiles to present a mixed methods intervention results analysis.

10.3.3 Specific Aim 3:

Specific Aim 3 is to examine whether changes in intersectional stigma and YBLMT's improvements across the HIV care continuum differ based on the network structure underlying user engagement in the two versions of HMP Stigma. To understand the role of social network dynamics between the two intervention conditions, we will compute social network parameters (e.g., size, density, centrality) for each version using the statnet and igraph packages in R.[222] Paradata indicators of active engagement (e.g., forum replies/likes) and passive engagement

(e.g., reading forum posts) will be used to model threaded engagement networks between users. We will use these structures to describe types of users (e.g., discussion starters, contributors, lurkers), their location within the network (e.g., centrality), the frequency of exchanges between users (e.g., reciprocity), and presence of subgroups (e.g., cliques). Core social network metrics will be computed at the participant-level (e.g., centrality; popularity), as well as by stigma-related topic (e.g., trending, liked). We will use these network parameters to model (1) user engagement in HMP and (2) changes in HIV care continuum outcomes. We will use the general framework of generalized linear mixed models[101–103] (GLMM) to model these longitudinal outcome trajectories.[110–112] Given that some of our outcomes are binary, some count and some continuous traits they will be treated differently (identity for continuous outcome, logit for binary outcome and natural log for count outcomes). We will use the estimated network parameters as covariates in our models, measuring how network characteristics are associated in differences in outcomes across the two treatment groups. In addition, GLMM also allows us to link YBLMT's individual trajectories with social network changes by adding them as time-varying covariates. For example, one analysis will examine how changes in networks' characteristics effect changes in YBLMT's VS, after adjusting for changes in stigma. These follow a network autocorrelation metric, whereby a term is added to the general model to captures a (weighted) average of peers' outcomes. Exploratory analyses will determine if random effects should be included. Maximum likelihood estimation will be used for fixed effects. To ensure robustness, we will also apply an exchangeable working correlation structure to its corresponding generalized estimating equation model.[104]

Note: Any deviations from the analysis plans outlined above or in the sections that follow will be documented and justified in the Statistical Analysis Plan developed for this protocol.

10.4 Missing Data

Several procedures will be used to conduct data analysis when data for either outcomes or covariates are missing. The first step will be to assess the extent and pattern of missing data. If data are missing for only a few cases, then data analysis will be conducted only on study participants with complete data. However, when such a strategy would result in loss of data from a substantial proportion of participants, or if this approach would lead to biased or inaccurate results, then some form of imputation will be performed. The form of imputation used will depend on the nature of the data that are missing. For example, data that are collected repeatedly might be imputed using the "last value carried forward" method; and in some instances, interpolation between neighboring points might also be used.

When the primary endpoint is missing, one data analysis will be conducted using only cases with the endpoint. Subsequent analysis will be done where missing endpoints are imputed. Hot-deck imputation or regression imputation may also be used in this context.

11.0 HUMAN SUBJECTS

This study will be conducted in compliance with the protocol, International Conference on Harmonization Good Clinical Practice guidelines, and 45 CFR Part 46.

11.1 Participants' Confidentiality

All laboratory specimens, questionnaires, evaluation forms, reports, and other records will be identified by a coded number only, to maintain participant confidentiality. All records with personally identifying information will be kept in a locked, limited access area (such as a locked file cabinet). All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without written permission of the participant (and parent or legal guardian, when applicable), except as necessary for monitoring by the NIMHD.

Every effort will be made to ensure that study participants are protected from risks. The main risk is breach of confidentiality.

Further risks may be specific to each project and these details can be found in the human subjects section accompanying each research project.

Breach of Confidentiality
A potential risk to participants is violation of confidentiality. We will take the utmost caution to protect the confidentiality of all responses. We will minimize this risk by maintaining confidentiality and discretion throughout all research procedures and data management and analysis.

Participants may be concerned about the security of their data, particularly since it is collected and stored electronically. Our research team has significant experience developing security protocols for Internet-based studies, and we will take a variety of steps to ensure participant security, including using a dedicated server behind a firewall, encryption of data, separation of identifiers from responses, and password-protected access to data. Therefore, we believe that this risk will be minimal.

Certificate of Confidentiality
This research specifically targets a vulnerable population, children (YBLMT ages 15-17). We will take every available step to minimize the risk of identifying/linking data being subpoenaed, stolen, or inadvertently released. First, this study will receive a Certificate of Confidentiality from the NIH. Second, all research staff members are required to complete ethical clearance certification regarding protection of human's subjects through their relevant IRBs. Third, this study will have documented procedures to safeguard against the risk of the linking information being stolen by keeping such information in a locked spaces to which only essential study personnel who have completed CITI certification for human subjects research ethics training (http://citiprogram.org) will have access.

A Certificate of Confidentiality for this project will be sought prior to enrolling participants. As noted on the NIH website (http://grants.nih.gov/grants/policy/COC/faqs.htm#187), a Certificate of Confidentiality will help the research team "...avoid compelled 'involuntary disclosure' (e.g., subpoenas) of names and other identifying information about any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect." We have applied for and received Certificates of Confidentiality for other NIH-funded research projects, and given the sensitive nature of the data collected for this project, do not foresee difficulty securing one for this study.

11.2 Participants' Confidentiality

11.2.1 Risks

The measurements that are involved in this study require finger pricks to collect blood samples. This procedure may cause local discomfort, bleeding, or bruising. This measurement should not be condisered greater than minimal risk in and of itself given its routine use in general health care delivery.

To minimize the risk of participants feeling uncomfortable about answering personal questions, we will use Computer Assisted Self Interview (CASI) methods for the study's surveys. In CASI, participants read and respond to survey questions on a laptop, tablet, smartphone.

To minimize risks to confidentiality, we will secure study data with all appropriate physical, electronic and operational protections. Data will be stored in a physically secure environment. All data files will have encryption and strong password protection. Any identifiable data will either be stored on University of Pennsylvania or UNC-CH's secure servers or will be on fully encrypted laptops. CASI surveys and online eligibility screening will take place on an encrypted commercial survey website, Qualtrics. This site has been used by the investigators for numerous online surveys with MSM with no data security breaches. Access to data will be on a role-based standard; only those study staff who require access to each type of data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data.

We will also develop procedures to minimize indirect disclosure that a participant is participating in an HIV-related research study, or a study that enrolls MSM and transgender women. No study-related messages will ever mention HIV prevention or the nature of the research study. Additionally, all scripts for email, text message, and telephone contact with participants will be reviewed and approved by the University of Pennsylvania's IRB before being used for contact with participants (see "HMP SOP-Communications.docx").

We use SSL encryption for transfers of information online. Qualtrics uses Transport Layer Security (TLS) encryption (also known as Hypertext Transfer Protocol Secure (HTTPS)) for all transmitted data. Survey data are protected with passwords and HTTPS referrer checking. The data is hosted by third party data centers that are Statement on Standards for Attestation Engagements (SSAE)-16 Service Organization Control (SOC) II certified. All data at rest are encrypted, and data on deprecated hard drives are destroyed by U.S. Department of Defense methods and delivered to a third-party data destruction service.

Qualtrics deploys the general requirements set forth by many Federal Acts including the Federal Information Security Management Act (FISMA) of 2002. They meet or exceed the minimum requirements as outlined in Federal Information Processing Standards (FIPS) Publication 200. All client data are considered confidential, and treated as such.

Related to HIPAA, Health Information Technology for Economic and Clinical Health Act (HITECH) are updated assessment rules to ensure that data are properly protected and best security practices are followed. By using secure and certified data centers, Qualtrics ensures the highest protection and testing as per HITECH requirements. We will use Dedoose software to perform all qualitative analyses. Dedoose is a web-based application for organizing and analyzing textual, audio, and video data (qualitative) along with outstanding functionality for their integration with survey, test score, ratings, and demographic data (quantitative). Dedoose employs the highest levels of data encryption available for a web application in all data storage, back up, and

transmission. Dedoose allows for project specific encryption feature. When using this feature, only Dr. Muessig or her designee will hold the additional encryption key needed to be entered in order to view the project. This gives Dr. Muessig exclusive control over who can view the project under any circumstances.
In addition to a Certificate of Confidentiality, we will protect participants in the following ways (which correspond to the potential risks described in 8.3):

1) *Breach of confidentiality*: We will take every precaution to minimize risks to study participants. All research staff members are required to complete ethical clearance certification regarding protection of human subjects through UNC-CH or U. Penn. We also have a strong data and safety monitoring plan in place to protect participants. Adverse events will be reported to the U. Penn IRB, individual research PI institutional IRBs using Adverse Event Reporting Forms created by the research team. Reports will be sent within 24 hours of notification by the PIs. Annual updates on enrollment and retention will also be sent to the IRBs.

All study personnel names on this application have completed training and received certification in Human Subjects Research Protection (CITI Program) and HIPAA regulations. They will continue to renew this training in compliance with institutional policies.

11.2.2 Benefits

The risk to individual participants is small and the potential benefit to both the individual and society is substantial. The main benefit of the proposed study to society is the development of a potentially feasible and acceptable mobile platform that reduces intersectional stigma and improves individuals' adherence to the HIV care continuum (i.e. increased testing for YBLMT without HIV; adherence to treatment for YBLMT living with HIV). Participants may experience improvements in their own experiences with stigma, thereby potentially reducing their risk for HIV infection, transmitting HIV, and the associated risks and costs to society. Therefore, the risk/benefit ratio is favorable. Study participants will be compensated for their time.

Black/African American YMSM account for the highest number of new HIV diagnosis of all YMSM, followed by Hispanic/Latino YMSM.[221] If successful, our intervention will improve these outcomes in our subject population. Given this high potential impact and low potential hazards to participants, we find that a clear examination of these research questions outweighs the previously mentioned risks. The effectiveness of a novel, scalable, technology driven intervention to address intersectional stigma is understudied with this population. Given the significant adverse health outcomes associated with HIV infections, and the paucity of intervention programs for this population of young adults, the knowledge to be gained from this research is significant. The risks to participants are reasonable in relation to the importance of the knowledge to be gained.

11.3 Institutional Review Board (IRB) Review and Informed Consent

This protocol, the informed consent documents and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for the oversight of the study. The informed consent will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

Written informed consent will be obtained from the participant (or parent, legal guardian, or person with power of attorney for participants who cannot consent for themselves). The participant's assent must also be obtained if he or she is able to understand the nature, significance, and risks of the study. The signed original consent/assent form will be kept on file at the site and a copy of the consent/assent form will be given to the participant and to the parent or legal guardian, if applicable. The informed consent/assent form is found in "Revised ICF-031320-clean.docx".

11.4 Waiver of the Requirement for Parental Permission for Special Circumstances

University of Pennsylvania IRB will request a waiver of parental permission to participate in this research study for youth participants under the age of (18).

Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and "an appropriate mechanism for protecting the children who will participate as research subjects is substituted" and "that the waiver is not inconsistent with Federal, State, or local law."

Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and "an appropriate mechanism for protecting the children who will participate as research subjects is substituted" and "that the waiver is not inconsistent with Federal, State, or local law." A waiver of parental permission for studies with lesbian, gay, bisexual, transgender, and questioning (LGBT) youth that do not involve greater than minimal risk is a common practice among researchers working in the area of gay and lesbian health/mental health. This is done to avoid the selection biases operating in only recruiting youth whose parents are both aware of and comfortable with their sexual orientation. Commonly these youth have explored their sexual orientation without their parents' knowledge as the youth struggle with issues of disclosure and its consequences within the social, religious, and economic context of their families. A requirement for parental permission in this type of study could not only affect a person's willingness to participate, but could also potentially impact the ability of researchers to engage in this type of research with sexual minority youth. Additionally, minors can often seek sexually transmitted infection (STI) and HIV prevention services without parental/legal guardian permission, depending on each site's state laws.
If the purpose of requiring parental permission as stated in CFR is to protect the minor subject, then requiring parental permission for youth in these circumstances is not a reasonable requirement. Additional privacy protections are provided in that all assessments, notes, reports, and other records will be identified by only a coded number to maintain participant confidentiality. These records and any forms that do contain identifying information will be kept in a locked, limited access area (such as a locked file cabinet) at the participating site. A waiver of signed consent will be requested from UNC-CH IRB.

11.5 Prisoner Participation

NIMHD has concluded that this protocol does NOT meet Federal requirements governing prisoner participation in human subject research and should NOT be considered by local IRBs for the recruitment of prisoners. Subjects enrolled who subsequently become incarcerated or are placed

in detention may not continue study participation. Study visits cannot be conducted during the period of incarceration or detention.

11.6 45 CFR Parts 160 and 164 Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule" Pursuant to the Health Insurance Portability and Accountability Act - HIPAA)

Both UNC-CH and the University of Pennsylvania are responsible for adherence to their individual institution's HIPAA policies and procedures.

11.7 Study Discontinuation

This study may be discontinued at any time by the NIMHD, UNC-CH, U Penn, or other government agencies as part of their duties to ensure research participants are protected.

12.0 PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract or manuscript will be made available for review by the study sponsors prior to submission.

13.0 BIOHAZARD CONTAINMENT

HemaSpot devices are not considered hazardous materials by USPS and may be shipped by standard mail if secured within a secondary container before placing inside the mailer. The HemaSpot device is considered the secondary container and renders the blood sample safe and secure after closing.

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