HIV Prevention Trials Network

Summary of Changes Included in the Full Protocol Amendment of:

HPTN 096

Getting to Zero among Black Men who have Sex with Men (MSM) in the American South: Testing the Efficacy of an Integrated Strategy

DAIDS Document ID: 38561

The Amended Protocol is identified as:

FINAL Version 3.0: 3 August 2023

The modifications included in this protocol amendment and the associated rationale is briefly summarized below. This Summary of Changes and corresponding protocol Version 3.0 will be submitted to Advarra, which serves as the single IRB (sIRB) for HPTN 096, for review and approval. Approval must also be obtained from any applicable study community-specific regulatory entities if required per the policies and procedures of the regulatory entities. This protocol does not include the requirement for protocol registration (Protocol Section 16.1); thus, no Institutional Review Board/Ethics Committee (IRB/EC) approvals or other documents will be submitted to DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center by study communities.

This Amendment and all related IRB/EC correspondence will be retained in the HPTN Leadership and Operations Center (LOC) central study files.

RATIONALE

This full protocol amendment includes changes to the implementation of the social media and peer support components of the study's integrated strategy. For the social media component, it allows for the inclusion of social media advertising, which was shown to be a promising methodology in reaching Black men who have sex with men (MSM) during the pilot, as well as an anonymous mechanism to determine if these ads are reaching their intended population audience. For the peer support component, it allows for limited compensation for those who complete their first session and brief surveys about their experiences participating in the program. In addition, it clarifies that the sample ICF for the peer support program will not be used if the requirement for consent is waived by an IRB/EC. Finally, it clarifies that a waiver of parental permission will be sought for those between 15 and 17 years old who participate in the study.

IMPLEMENTATION OF MODIFICATIONS

1. Several sections of the protocol are revised to clarify that a waiver for parental permission will be sought for those between 15 and 17 years old who participate in the study.

2. Pilot Appendix Section 5.0 is revised to include the use of social media advertising and additional pilot outcome measures to determine if the social media-based messaging is reaching the intended population of Black MSM.

3. Pilot Section 7.1 is revised to include compensation for program clients for completing an initial support session and brief surveys about their experiences using the peer support program.

4. Pilot Section 7.3 is revised to state that the sample ICF for the peer support program will not be used if the requirement for consent is waived by an IRB/EC.

5. Appendix IIC-I (Sample ICF for Pilot Peer Support) is revised to reflect the changes outlined in Pilot Section 7.1.

6. Minor typographical errors were corrected.

Modifications are listed in order of appearance in the protocol. Deletions to the protocol text are indicated by ~~strikethrough~~; additions are indicated in **bold**.

Revision 1: Section 8.4.1 Informed Consent

As described in Section 14.3.1 and per 45 CFR 46.408(c), a waiver of parental/guardian ~~consent~~ **permission** will be requested for those 15 to 17 years old. These participants will still be required to provide assent by completing the electronic consent in the same process used for adults. When any participant first accesses the peer support platform, a peer support worker will orient them to the app, including review of the elements of the informed consent form. Peer support workers will be trained to provide additional information to those younger than 18 to ensure that they understand that they are participating in a research study and how to safeguard their own privacy. All participants will have access to a copy of their informed consent form within the platform.

Revision 2: Section 10.6.1 Informed Consent

As described in Section 14.3.1 and per 45 CFR 46.408(c), a waiver of parental/guardian ~~consent~~ **permission** will be requested for those 15 to 17 years old. These participants will still be required to provide assent by completing the informed consent process. Staff will be trained to provide additional

information to those younger than 18 to ensure that they understand that they are participating in a research study.

Revision 3: Section 14.3.1 Additional Considerations for Minors

Per 45 CFR 46.408(a), it is expected that adolescents participating in this study would be deemed capable of providing assent. Specific assent considerations for this population are described in the component-specific sections 8.4.1 and 10.5.1. However, per 45 CFR 46.408(c), this study is designed for a population (Black MSM in the southern US) for which parental or guardian ~~consent~~ **permission** is not a reasonable requirement to protect the study participants. There is concern that parent/guardian knowledge of a participant's involvement in the study may pose significant risk to participant's privacy and confidentiality, particularly for those whose parents are not aware or supportive of their sexual orientation, and stigma may prevent these adolescents from participating in the study. As such, a waiver of parental/guardian permission will be requested from the sIRB. Maintaining the requirement for assent will serve as a mechanism to protect these adolescents, in combination with additional counseling that will **be** provided to this age group as described in the above-referenced component-specific protocol sections.

Revision 4: Pilot Appendix Section 5.1 Pilot Component Description

(The following information will be added to the end of this section.)

In addition, the study team will use an advertising-based methodology to disseminate information via social media. Black MSM, or other individuals who are recognized by or are known to have influence in the Black gay community, will be approached to create content; however, existing content will also be considered, such as HIV-related content made by public health institutions, foundations, public-private partnerships, or other organizations that support Black MSM. While existing content may be readily available and professionally produced, new content will augment resources that may resonate with Black MSM because it is non-establishment, relatable, based on lived experience, and unique. This combination of new and existing content will allow the team to create a library of advertisements so that messaging remains fresh. By creating social media advertisements with both existing and newly created content, the study will leverage the broad knowledge and experience of the Black gay community, as well as existing resources, to reach Black MSM within study specific communities. While social media advertising has been used by others to disseminate health information with the goal of behavioral change, the innovation of this approach will be that the campaign takes place within a community where the barriers that Black MSM face with regard to HIV prevention and care are being lowered by the other three study components. These ads are intended to encourage men to seek out HIV testing, PrEP and care, and they will be doing so in an environment where these options are more accessible and welcoming.

One of the current limitations of social media advertising is that it cannot be used to target ads based on race or sexual orientation. Instead, advertisers try to reach their intended audience by choosing interests – for example specific entertainers or popular celebrities – that the social media algorithms use to distribute the content. But how social media platforms currently work, it is not possible to determine who sees the ads beyond location, age and gender. For example, an ad can be sent to men in Dallas who have expressed interest in RuPaul, Queen Sugar and Diana Ross – but social media metrics do not measure and report if Black MSM see the ad. HPTN 096 will gather

data using standard website analytics tools and methods from the people who see these ads to determine if they are reaching the study population.

Revision 5: Pilot Appendix Section 5.2 Pilot Outcome Measures

5.2 Pilot Outcome Measures

For activities involving social media influencers, ~~T~~the pilot outcome measures for the SMI component are the same as described as the process measures for this component in the main protocol, with one exception, and are reiterated below. The one exception is that in the main study protocol, "time spent on links/videos" is included, and for the pilot, this measure has been replaced with "number of views per post." The reason for this change is because some social media platforms do not consider engagement as a "view" until a certain amount of time has been spent, thus, it was felt that enumerating the number of views per post is a better measure of engagement.

- Measures of penetration of the SMI activities:
  - Number of SMIs in each region/community
  - Metrics of social media engagement, including the following:
    - Clicks on links/videos
    - Number of views per post
    - Number/types/demographics of followers of SMIs
    - Number and types of reposts/retweets
    - Comments (stratified by social media platform and SMI components)
    - Types of content developed
- Measures of fidelity to the planned SMI activities:
  - Retention rate of SMIs in each community
  - Frequency of SMIs postings and activity
  - Content analysis of SMIs' postings and activity as compared to content guide

For activities involving social media advertising, all ads will be monitored for reach and engagement. These data will be captured in real-time and used to adjust subsequent ads. As all ads will include a link back to the HPTN 096 webpage, the team will monitor both social media advertising and website metrics. This monitoring will include the temporal relationship between ad distribution and ad engagement. In addition, website and ad viewing data collection measures will also include short, non-invasive, anonymous, questions asked to viewers of ads and those who land on the HPTN 096 webpage (e.g., a pop-up window that asks, "Is the information on this website useful to you?") and may also collect information about race, gender and sexual orientation.

In addition to determining whether the ads are reaching the study population, the team may conduct A/B testing to compare different ads, or different distribution elements (e.g., the interests used to target the ads), to determine which approach works best. Some social media platforms (e.g., Meta, which includes Facebook and Instagram) have the capacity to distribute two ads simultaneously to two equivalent segments of the intended audience, ensuring that no one sees both ads. This allows for a head-to-head comparison of the performance of each ad. Lessons learned from this testing will be incorporated into the next iterations of ad distribution.

Process measures for social media advertising will include:

- **Measures of penetration of the social media activities:**
  - **Number, topic, type (e.g., video, text-based, etc.) and the social media platform used for distribution of all social media advertisements deployed in each intervention community**
  - **Metrics of social media advertising engagement, including the following:**
    - **Impressions (number of views) and reach (number of unique individuals viewing each ad). These metrics will be compared to the estimated number of Black MSM in each study community.**
    - **Clicks on embedded links**
    - **Number and types of other engagement (e.g., saves, likes, comments, reposts, etc.)**
- **Measures of engagement with and use of the HPTN 096 website**
  - **As all ads will include links back to the HPTN 096 website, website analytics will be used to capture engagement, which will include, but are not limited to:**
    - **User location**
    - **Page views**
    - **Average time on page**
    - **Average session duration**
    - **New and repeat visitors**
    - **Event tracking (captures actions visitors do on the page, for example going from one page to another)**
  - **To determine if Black MSM are seeing the ads, pop-up questions will be employed to collect additional anonymous information on those who click on the ad links and land on the HPTN 096 webpage. These questions may include, but are not limited to:**
    - **Yes/no feedback on utility of information provided on website**
    - **Questions about whether the user likes the ads/website**
    - **Questions to better understand who is viewing the ads, such as race, sexual orientation, and gender identity**
- **Measures of fidelity to the planned social media activities:**
  - **Creation and distribution of at least four social media advertisements each quarter (16 per year) to intervention communities**

Revision 6: Pilot Appendix Section 5.3 Human Subjects Considerations

5.3 Human Subjects Considerations

~~There~~ **In general, there** are no differences with regard to human subjects considerations between the pilot and what is described in the main study protocol for the SMI component. **However, the limited data that will be collected from some people who see and interact with the social media advertisements is considered to be human subjects research. As individuals will not be enrolled in the study and data will be collected anonymously, it is expected that this activity will meet the definition for exemption under 45 CFR 46.104(d)(2)(i). The questions to be answered anonymously will be submitted to and approved by the IRB prior to implementation.**

Revision 7: Pilot Appendix Section 7.1 Pilot Component Description

(The following information will be added to the end of this section.)

Program clients will be compensated for attending an initial support session in the pilot. **They may also be compensated for responding to brief surveys about their experiences using the peer support program**. **They will not receive compensation for participating in subsequent peer support sessions.**

Revision 8: Pilot Appendix Section 7.3 Human Subjects Considerations/Confidentiality

As described in Section 14.3.1 and per 45 CFR 46.408(c), a waiver of parental/guardian ~~consent~~ **permission** will be requested for those 15 to 17 years old, as described in the main study protocol. These participants will still be required to provide assent by completing the electronic consent in the same process used for adults. All clients will have access to a copy of their informed consent form within the platform. The revised ICF, which now includes information about the study pilot, is included in Sub-Appendix I. **If an IRB/EC waives the requirement of obtaining informed consent, it will not be utilized.**

Limited personal and sociodemographic information (such as ~~your~~ name, age, ethnicity, phone number, email address, etc.) may be collected from clients in order match a client with a peer support worker and may be linked to the data for acceptability and process measures. This information will be maintained confidentially and stored securely. Study data collection forms will be identified by a coded number only to maintain client confidentiality.

Revision 9: Appendix IIC-I Sample Informed Consent/Assent Form for Peer Support – Introduction, Section 2

Sixteen communities are participating in this research study. In eight communities, various programs will be put in place. In the other communities, these programs will not be available. The four programs are described below:

- One program will provide training to medical providers. This training seeks to make their clinics friendlier towards Black gay, bisexual and other men who have sex with men.
- The second program seeks to work with community groups to help Black MSM overcome barriers to preventing and treating HIV.
- The third program will ~~work with popular people on~~ **use** social media to raise awareness about HIV testing, PrEP use and provide information about HIV care and prevention.

- The last program provides peer support and health education for those living with and without HIV. This program is described in more detail in the remainder of this form.

Revision 10: Appendix IIC-I Sample Informed Consent/Assent Form for Peer Support – Risks of the Study, Section 4

- Sensitive questions or topics may be discussed. This may occur during conversations with your peer support worker.
- Discussing your sexual behavior and ways to protect against HIV and STIs may make you uncomfortable.
- Only people in the study can access this support. We ask that you not share your personal information with anyone else to ensure your information and the information of others who are a part of the program stay private.
- It may be possible that others will learn you have joined this study and they may treat you unfairly. For instance, your family members or friends could treat you unfairly because they think you are involved in a study about HIV. They may assume that you have HIV. The peer support workers can help you deal with any feelings or questions you have.
- There is a possibility that you may exceed your data plan limit on your personal device (cell phone or tablet) if you use it to access the program and may have to pay extra for that.
- You are asked to follow the rules of the study. If you or others share inappropriate information, your participation in the program may be stopped.
- As part of this study, you may be required to use one or more of the following: a phone or ~~website or~~ **computer to** complete ~~a~~ survey**s** about your experience with the program. ~~While using these, y~~**Y**ou may be asked to provide limited personal and sociodemographic information (such as your name, age, ethnicity, phone number, email address, etc.) that may be shared with the **peer support workers and** researchers conducting this study.
- Additionally, there may be unknown risks.

Revision 11: Appendix IIC-I Sample Informed Consent/Assent Form for Peer Support – Other Information about the Study, Section 9

9. ~~There is no cost to you to be in this study. You will not be paid to be in the study.~~ **You will receive xx for conducting an initial support session.**

You will not receive compensation for participating in subsequent peer support sessions. You may receive xx for responding to brief surveys about your experience using the peer support program.

Revision 12: Appendix IIC-I Sample Informed Consent/Assent Form for Peer Support – Other Information about the Study, Section 10

A description of this **study** ~~clinical trial~~ will be available on http://www.ClinicalTrials.gov. This ~~website~~ **Web site** will not include information that can identify you. At most, the ~~website~~ **Web site** will include a summary of the results. You can search this ~~website~~ **Web site** at any time.

Revision 13: Appendix IIC-I Sample Informed Consent/Assent Form for Peer Support – Other Information about the Study, Section 12

Please reference the following number when contacting the Study Subject Adviser: ~~(insert PRO number)~~ Pro00056458.

Revision 14: Appendix IIC-I Sample Informed Consent/Assent Form for Peer Support – Signature Page

SIGNATURE PAGE

HPTN 096
Getting to Zero among Black MSM in the American South:
Testing the Efficacy of an Integrated Strategy

FINAL Version ~~2~~**3**.0
~~2 March 2022~~ **3 August 2023**
INFORMED CONSENT/ASSENT FOR PEER SUPPORT

If you agree to the information in this form and you voluntarily agree to join the study, please print and sign your below. **A copy of this consent form will be available to you at any time.**

_____ _____ _____

Participant Name (print **first and last name**)~~Participant Signature and Date~~

_____
Date

_____
Email Address (to receive an electronic copy of the signed consent form)

_____
Code word or phrase for verification purposes.
The peer supporter will ask you for this prior to your first session.

Do you voluntarily agree to join the study?
_____ Yes
_____ No

_____
Participant Signature

Checkbox: ***I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.***

~~A copy of this consent form will be available to you at any time.~~

Revision 15: Appendix IIC-II Sample Informed Consent Form for Adults and Assent for Individuals Ages 15 to Age of Majority for Pilot Baseline Cross-Sectional Assessments with LDMS (Communities with Local LDMS Laboratory) – Other Information about the Study, Section 12

Please ask the study staff if **you** would like more information about local HIV testing.

Revision 16: Appendix IIC-III Sample Informed Consent Form for Adults and Assent for Individuals Ages 15 to Age of Majority for Pilot Baseline Cross-Sectional Assessments with LDMS (Communities without Local LDMS Laboratory) – Introduction, Section 1

- You will be in the part of the study where we are measuring how many Black men like you have HIV. We are also checking to see how many are taking medication to **treat or** prevent HIV. Answering these questions will tell us if the other parts of the study are working to decrease HIV in some communities in the southern US.

Revision 17: Appendix IIC-III Sample Informed Consent Form for Adults and Assent for Individuals Ages 15 to Age of Majority for Pilot Baseline Cross-Sectional Assessments with LDMS (Communities without Local LDMS Laboratory) – Introduction, Section 3

The purpose of both assessments is to find out how many Black men in your community have HIV. We are also checking to see how many are taking medication to **treat or** prevent HIV. Finally, we will ask questions about your life and opinions.