**University of Pennsylvania**
**Consent to Participate in a Research Study**
**Consent Form Version Date:** 10/17/18

**Title of Study:** 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
**Protocol Number:** 829805
**Clinical Trials ID:** NCT03678181

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**What are some general things you should know about research studies?**

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**

The purpose of this study is to evaluate HealthMpowerment (HMP), a website designed to provide health and wellness information and education relevant to young men and transwomen in any state in the United States. The purpose of HMP is to help build community, reduce stigma, and provide information and resources about relationships, wellness, and STDs like HIV. If you agree to be in this study, you will be randomly assigned to one of three study groups. This means you have an equal chance of being assigned to any group.

Your use of the website and the feedback you provide will help us to improve the site and make it more inclusive to the diverse needs of the entire community. You are being asked to be in this study because, as a man or transwoman, you can help us determine whether the information and

tools on the website address your needs and assist you in making meaningful choices in your overall health and wellness.

Your feedback from the time you spend on HMP will help us test the website to make sure it's easy to use, that the information makes sense, but, most importantly, to make sure the site will be relevant to users.

**Are there any reasons you should not be in this study?**

You should not be in this study if any of the following apply to you:

- You were assigned female sex at birth
- Aged 14 years or younger or 30 years or older
- Do not speak or read English
- Did not have consensual anal sex with a male partner in the past 6 months
- You live outside of the United States
- You are currently incarcerated
- You are planning to move outside of the United States in the next 12 months

**How many people will take part in this study?**

If you decide to take part of HealthMpowerment, you will be one of approximately 1,050 people in this research study.

**How long will your part in this study last?**

If you agree to be in this study, your participation will last one year (12 months).

**What will happen if you take part in the study?**

If you agree to be in this study, you will be randomly assigned to one of three study groups. This means you have an equal chance of being assigned to any group. Two of the three groups will have more interactive content available to them. After you log in and create your own unique username and password, you will receive more information about your group assignment and will receive a brief orientation to the website.

You will be asked to complete a 30-minute survey before being shown the HealthMpowerment website. Some of the questions in the survey are sensitive in nature. You are asked to respond to all questions honestly and all answers you provide will remain confidential. You can skip any question for any reason. You will also be asked to complete at-home HIV tests or HIV dried blood spot test that you will mail to study staff when you start the study, 6 months in to your participation and after 12 months of using HMP. A guide on how to conduct this test will be provided to you and all costs associated with the mailing will be covered by the study team. All information given to us – both digitally and physically – will be confidential and not linked to your name.

All participants will be asked to log onto the HealthMpowerment website at least once a week for three months. You will be asked to spend at least an hour a week on the site. We will be able to track via the HMP website, where you go within the site, what features/articles you use, and the length of time you are on the site. At the end of the 3 months, you'll be asked to complete a

survey about your experience on HMP. You'll also be asked to complete a survey 6, 9, and 12 months after you first log on to HMP. Surveys should take about 30 minutes to complete. The different time points are below:

| **Survey Time Points** | Baseline | 3 months | 6 months | 9 months | 12 months |
|---|---|---|---|---|---|

Additionally, after approximately 6 or 12 months of participation in HMP, you may be selected to participate in an online interview. Topics that may be discussed include your overall experience with HMP, your opinions about the design and features of the HMP website, and general feedback or ideas for improvement. The interview will be done online via a videoconferencing platform (such as VSee or an equivalent technology). Interviewers will only be recording the audio-portion of the interview. No video of the interview will be recorded. Interviews will take about 45 minutes.

You may receive study-related emails, phone calls, Facebook messages and text messages asking you to complete surveys, to take place in an online interview, or to alert you to new content and features on HealthMpowerment. You may choose how you would like study staff to contact you and what you would like them to say. Any communications you receive from us will not identify you as participating in a research study about sexual health, nor will they contain other sensitive or confidential information. All communications from the HMP study team will be sent over a secure, encrypted and Health Insurance Portability and Accountability Act-compliant (HIPAA) server.

**What are the possible benefits from being in this study?**

You may not benefit personally from being in this research study. However, we believe that the content and information provided on the website will help young men and transwomen across the United States better address their health and wellness needs. Depending on the group to which you are assigned, you may receive more educational materials, access to resources, and information. We want to see which website is more successful communicating necessary health and wellness information over the others. Regardless of the group to which you are assigned, you will be receiving relevant health information and resources to help you better take care of yourself.

**What are the possible risks or discomforts involved from being in this study?**

A number of measures will be taken to ensure your confidentiality and privacy during this study. However, we want to make you aware of some potential risks or discomforts.

You may be uncomfortable logging onto the website or having others see you log onto the website. We suggest that you log in throughout the study from whatever place you feel most comfortable accessing it – via laptop, desktop computer, tablet, or a mobile phone. Only those enrolled in the study can access the website. You must not share your log-in information with others. If someone else sees HealthMpowerment or the survey questions you're asked to complete, they may know that you are taking place in a research study about sexual health. This would result in a breach of confidentiality for you as well as others who are using the website. We encourage you to consistently clear your browsing history on your computer, have your phone behind a password lock screen and to delete any messages sent from the study team after

they have been read to minimize the risk of someone finding out about your participation in this study.

If you are in one of the more interactive groups and choose to post or comment, it will be visible to others who are enrolled and log onto HealthMpowerment. The researchers and study staff discourage participants from providing information on the website that would allow their identity to become known; however, if you choose to provide identifiable information about yourself on the website, then there may be a breach of confidentiality from other participants. This breach could lead to emotional distress. You should only provide information that you are comfortable sharing.

We will strive to create a safe and comfortable online environment for all study participants. However, it is possible that you may experience emotional discomfort or upset due to things other participants post through the forums. The forums are monitored daily by study staff, however we do not require posts to be pre-approved by study staff before they go live to the website.

Messages will be sent to you from study staff via email, text, phone call or Facebook messages. The messages will mainly be reminders for you to log on to the website or take your surveys. None of the messages will provide sensitive health information or mention you are in a research study. You can choose how you would like study staff to contact you and what you would like for them to say. If you are between the ages of 15-18 years old, we will specifically ask if there are any special instructions for contacting you. To make sure no one who has access to your phone can read your texts and breach your confidentiality, you should change your text message settings and/or lock your main screen behind a password.

It is possible that you could complete an HIV home test kit and learn you have tested positive for HIV. If you test positive for HIV during the trial, we will offer you the chance to meet with a study care navigator to help link you to an agency in your community for confirmatory testing. We will provide you with the name of a referral agency, their location, telephone number, fee (if applicable), and information about the agency and the work they do. If you request it, we will help you contact the agency; however, we will not disclose any information about you to a referral agency. If you are not satisfied with your first referral, we will help you find services or providers better suited to your needs.

We will not report a positive HIV test result or your name to any health authority. When you visit a your local health care provider, they will conduct a confirmatory HIV test. At that point, if you receive a positive HIV test result, that provider will be responsible for any mandatory reporting to your local health authority.

The study has strict privacy standards in place as outlined in the section below. We also ask that you take active steps to protect your privacy.

**How will your privacy be protected?**

Every effort will be taken to protect your identity as a participant in this study. Confidentiality cannot be guaranteed, but the following steps will be taken to protect your identity. The information you share with study staff during the course of the study and from the surveys and

HIV tests you take are confidential and will not be linked to your name. You will not be identified by name in any report or publication of this study or its results. Instead, you will be known only through a study ID number. Any data linking your name to your study ID number will be kept in a locked cabinet in our private office. Any data that are collected from you online will be collected and stored on a secure, confidential, and HIPAA-compliant server that is run by members of the HealthMpowerment study team. Data from the study will be destroyed at the end of the study period.

Content that you choose to provide will only be associated with your username for this study. We encourage you to choose a unique username that is different from your real name in order to help protect your privacy. Any study-related messages that are sent you will not disclose the fact that you are in a research study. All messages will be free of any identifying information and will not have any of your personal health information. To further ensure your privacy, you can change the settings on your mobile phone to keep the body of texts from appearing on the main screen when you receive a message. Please be aware that if you choose to receive text message communication and are not the account holder your mobile phone (i.e, you're on a family plan), then whoever is the account holder may be able to see that you were contacted via text; however, they will not have access to the text message. Standard messaging rates for your cellphone carrier will apply. All messages generated by the study are sent and stored on a HIPAA-compliant server. Messages are only linked to your study ID and not your real name.

The research team has experience safeguarding your data. All staff will be trained and required to sign certifications of confidentiality before working with any sensitive information. Staff training is extensive and is not only about confidentiality, but also about respect for you and your safety. Additionally, all data will be secured using an SSL 256-bit encryption. SSL encryption is the standard for all web-based transactions.

If you decide to take part in the in-depth online interviews about HealthMpowerment, we will use a HIPAA-compliant videoconferencing platform to keep the content of that interview secure and confidential. All videoconferencing sessions will be end-to-end encrypted. We will only be recording the audio portion of the conversation. The audio will only be identified by your user ID and will be stored in an encrypted server on the University of Pennsylvania's campus.

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, another study participant, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study. You should understand that we will in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to yourself or others.

For example, in the case of someone mentioning they will attempt suicide or threatening the life of another person.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, have undermined the rights or privacy of another participant, or because the entire study has been stopped.

**Will you receive anything for being in this study?**
Depending on your study arm and activities, you may receive between $190 and $260 in e-gift cards for participating in all aspects of this study. Details about how this study's payments are provided are listed here:

**All participants:**
In total you can receive up to $130 in e-gift cards for completing HealthMpowerment surveys. The reimbursement plan is as follows:

| Baseline | 3 months | 6 months | 9 months | 12 months |
|---|---|---|---|---|
| $25 | $20 | $25 | $20 | $40 |

**All participants:**
In total, you can receive up to $60 for reporting your HIV at-home test results or returning your HIV self-test dried blood spot kits.

You will receive $20 for each reported or returned test and may complete up to 3 tests during the study period.

***Peer referral arm participants only:**
In total, you can receive up to $20 for referring friends to the study. Some participants will be randomized to a condition of the intervention where they may be asked to refer two friends into the study. For each friend that is successfully referred to the study, you will receive $10.

**Selected participants:**
If you are selected and complete a qualitative exit interview, you will receive an additional $50.

**Will it cost you anything to be in this study?**
There will be no costs for being in the study.

**What if you are a University of Pennsylvania student?**
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at University of Pennsylvania. You will not be offered or receive any special considerations if you take part in this research.

**What if you are a University of Pennsylvania employee?**

Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related considerations if you take part in this research.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 215-573-2540 or by email to irb@pobox.upenn.edu

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**Principal Investigators:** José Bauermeister and Kate Muessig

**Participant's Agreement for Overall Research Purposes:**

**Consent**
Please click below if you agree to be in this study. By agreeing to participate in this study, you will not give up any of your legal rights. A copy of the consent form will be available to you online in order to protect your privacy.

Do you agree to participate in the study?
_____ Yes, I agree to participate in the study.
_____ No, I do not agree to participate in the study.

Do you agree to allow us to keep your email address and contact you about future research opportunities in the next five years?
_____ Yes, you may keep my email address.
_____ No, you may not keep my email address.