INFORMED CONSENT/ASSENT SCRIPT: RANDOMIZED-CONTROLLED TRIAL

PROJECT TITLE: HARNESSING THE POWER OF TEXT MESSAGING TO INVIGORATE AMSM HIV PREVENTIVE BEHAVIOR

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SPONSOR: NATIONAL INSTITUTE OF MENTAL HEALTH

Background/ Purpose

Researchers at the Center for Innovative Public Health Research and Northwestern University have developed a healthy sexuality and HIV prevention program for teenage guys who are gay, bisexual, and queer. The program will be sent via text messaging. This research study is sponsored by the National Institutes of Health.

You are being asked to help us test the program to see if it helps youth make safer choices and helps prevent HIV. Your participation will last for about 4.5 months. You will receive text messages every day for a total of 6 weeks (with a five-week break in between the 5th and 6th weeks of messages). The messages will talk about things like dating, sex, choosing not to have sex, and using condoms when you do have sex.

Procedures

There are two different text messaging programs that we are testing. We do not know which program works better to promote healthy sexual behavior for guys like you. Your assignment to either program is random. This means you have an equal chance of being assigned to either program. We will not tell you to which program you are assigned to until after everyone has finished the program.

If you choose to take part in the research study, here's what we will ask you to do:

- Complete an online survey at the beginning of the study.
- Then, you will receive between 5-10 text messages every day for 5 weeks. You may also be randomly matched to a "text buddy", who is another guy in this study who you'll be able to talk with about the things that you are learning in the program. You may also have access to G2Genie which would send you advice about various topics (like condoms) when you text him.
- At the end of 5 weeks, we will ask you to complete a short survey over text messaging.
- Then, 6 weeks later you will receive one more week of daily text messages.
- Finally, 6 weeks later (4.5 months after you have enrolled), we will ask you to complete an online survey.

You will receive up to $45 in an Amazon gift card for your complete participation:

- We will send you a $15 Amazon gift card after you complete the text messaging survey at the end of the 5 weeks of messages.
- We will send you a $20 Amazon gift card after you complete the online survey at the end of the program (4.5 months from now)
- Because your answers to the program end survey are really important, you will receive an extra $10 if you complete this last online survey within 48 hours of being notified by text message to complete it.

Risks and Discomforts

It is possible that your privacy will be broken. For example, if someone sees your cell phone, this person may see that you are receiving messages that talk about being gay, bisexual, or queer and about guys who have

sex with guys. Please think about what it would mean for you if this happens. We want you to be sure it's safe for you to take part in the program. It is important to consider password-protecting your phone.

It also is possible that a question in one of the surveys might make you feel uncomfortable. If this happens, you can skip the survey question. If the program messages make you feel uncomfortable, you can stop being in the study completely.

Compensation for Injury

You have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

Benefits

We don't know if you will benefit from being part of the study, but your participation is important. Your participation will help us determine which health program is better, and will benefit guys like you in the future.

Confidentiality

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location. We will keep a copy of your answers so that we can look at them later. Only Dr. Ybarra and people who work with her will be able to see your answers. Your name and contact information will be kept separate from your feedback. Findings will be reported only for the whole group. Your individual results will not be reported.

To 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 to share information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal administrative legislative, or other proceedings. We will use this Certificate to fight demands for your information unless you tell us you want us to share the information. But in the unlikely event that you tell us that you are currently abusing or planning to abuse a child, or you're planning to harm yourself or another person, then we will report this information to the appropriate authorities. For additional information about Certificates of Confidentiality see http://grants1.nih.gov/grants/policy/coc/faqs.htm.

Rights of Refusal and Withdrawal

It is your choice to take part in the study or not. You can drop out of the study at any time. Your complete participation during the entire study however, will help us determine which program works best.

Do you have any questions about the information that I just read to you, or about the study?

[Conduct Capacity to Consent]

Do you agree to participate in this study? [Record answer]

Does your parent/legal guardian agree that you may participate in this study?

Questions and Contact Numbers

For those who assent:

Great! You will be emailed a copy of this assent form. If you have questions about this study, please contact me by email at Tonya@InnovativePublicHealth.org or call 1 877.302.6858, ext. 806. You can also contact the Principal Investigator, Dr. Michele Ybarra (email: Michele@innovativepublichealth.org; telephone: 877-302-6858, ext. 801). This contact information can also be found on the first page of this form.

If you have any concerns about your rights in this research, please contact the Study Subject Adviser at Chesapeake IRB by email at adviser@chesapeakeirb.com . The adviser can be contacted by calling toll free at 877-992-4724.

Please reference the following number when contacting the Study Subject Adviser: Pro00007481.

An IRB is a group of people who review research studies to protect the rights and safety of research participants.

For those who don't assent:

Thank you for your time. We respect your decision not to take part in the program. To help us design future studies, can you please tell me why you decided not to take part? [Record answer]