

## **INFORMED YOUTH ASSENT FORM**

**PROJECT TITLE: GIRL2GIRL: HARNESSING TEXT MESSAGING TO REDUCE TEENAGE PREGNANCY AMONG LGB GIRLS**

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**SPONSOR: OFFICE OF ADOLESCENT HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **INFORMED ASSENT/CONSENT SCRIPT: RANDOMIZED CONTROLLED TRIAL**

The Center for Innovative Public Health Research has developed a sexual health and teen pregnancy prevention program for lesbian, gay, bisexual, and other sexual minority girls. The program will be sent through text messaging. This research study is sponsored by the Office of Adolescent Health at the U.S. Department of Health and Human Services.

You are being asked to take part in the randomized controlled trial of the program. Program text messages talk about things like sex, preventing pregnancy and STDs, using dental dams and condoms, and choosing not to have sex.

Your participation will last for about 18 months.

#### **Procedures**

There are two different text messaging programs that we are testing. We do not know which program is better at promoting healthy sexual behavior. You will be randomly assigned to either program. This means you have an equal chance of being in either program. We will not tell you 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:

1. Complete an online survey before you start receiving program messages.
2. Then, you will receive between 5-10 text messages every day for 7 weeks. You may also be randomly matched to a "text buddy", another girl in this study, who you'll be able to talk to about the things that you are learning in the program. You may also have access to G2Genie, which would send you on-demand advice about various topics (like dental dams).
3. After 7 weeks, the daily text messages will stop, and we will ask you to complete a brief survey that we will send you by text message. We will then send you a couple texts per week for the next 3 months. After that, you will receive a "review week" where you will receive 5-10 messages again each day.
4. Finally, after the review week, we will send you a brief survey to complete by text and then you will get a survey every 3 months for the next year (so a total of 4 more surveys). The first and third surveys will be over text message, and the second and last of these surveys are online.

## **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 taking part in a research study that talks about things related to your sexual identity. Also, people may be able to see your survey answers if they can see your device that you are using to complete the survey. It is very important that you use a device that is private and in your control.

It also is possible that a question in the survey we ask 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 randomized controlled trial completely.

## **Benefits**

We don't know if you will benefit from being part of the study, but your participation is very important. Your experience will really help us design a better health program, which will benefit young women like you in the future.

## **Compensation**

You will receive up to \$105 for taking part in this study. Here's how it breaks down. You will get:

- \$5 after completing the intervention end survey at the end of the 7 weeks
- \$5 after completing the survey at the end of the review week
- \$10 after completing the 3-month text message survey
- \$30 after completing the 6-month online survey
- \$10 after completing the 9-month text message survey, and
- \$45 after completing the 12-month online survey.

You can choose to receive these incentives as Amazon gift cards or as a charity donation. You also have the choice to not receive an incentive at all, if you'd prefer.

## **Confidentiality**

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.

The sponsor, the sponsor's representatives, the Department of Health and Human Services, and Chesapeake IRB may have access to the study data.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). This Certificate means that we can keep your information private even if we get a court order telling us to share your information. We will use the Certificate to refuse to give anyone information that will identify you, except when you tell us it is okay to do so. But in the unlikely event that you tell us that you are currently or in the past have been harming someone else or are being harmed, then, under applicable law, we may be required to report this information to the appropriate authorities.

## **Rights of Refusal and Withdrawal**

It is your choice to take part in the study or not. If you decide not to take part, nothing bad will happen.

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.

### **Questions and Contact Numbers**

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

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

If yes (participant provides consent/assent):

Great! I will email you a copy of this form. If you have questions about this study, please contact the study manager by email at [Tonya@InnovativePublicHealth.org](mailto:Tonya@InnovativePublicHealth.org) or call 1-877-302-6858, ext. 806.

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

If you have any concerns about your rights in this research, you can contact the Study Subject Adviser at Chesapeake IRB by email at [adviser@chesapeakeirb.com](mailto:adviser@chesapeakeirb.com). The adviser can also be contacted by calling toll free at 1-877-992-4724. Please reference the following number when contacting the Study Subject Adviser: Pro00013202.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law.

If no (participant does not provide consent/assent):

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

[record answer]