

## RESEARCH INFORMATION STATEMENT

### **Basic Information**

Title of Project: Young Men and Media Project

IRB Number: H-39323

Sponsor: The U.S. National Institutes of Health

Principal Investigator: Kimberly Nelson, PhD, MPH

Email: knel@bu.edu

Address: Boston University School of Public Health

801 Massachusetts Ave, 4th Floor

Boston, MA 02118

Study Phone Number: 617-353-6644

### **What is the purpose of the research?**

The purpose of this study is to see if an online sexual health education website we designed might help young men like you stay healthy and avoid sexually transmitted diseases. Your participation will help tell us if the website we designed is successful at reaching young men like you and if young men like you find the website informative. This study is sponsored by the U.S. National Institutes of Health.

### **What is experimental/new in this study?**

This study is testing whether a new website we developed focused on sexual health for young men is appealing to young men and whether it gives them new knowledge about sexual health. We are comparing this website to sexual health websites that are already widely available (e.g., through the Centers for Disease Control; aka the CDC).

### **What do I have to do in this research?**

If you decide to participate in the study, you will first complete a 25-35 minute online survey about your sexual health, including questions regarding your experience with healthcare, substance use, HIV and STD testing, sexual education, sexual behavior, pornography, and some demographic information. Some of the questions will be personal or sensitive, such as "Have you ever had voluntary sexual contact with another person?" You do not have to answer any questions you do not want to. You will be asked to provide an email address so that we can send you study related emails and links. If you agree to participate and provide your email address, you will be emailed a unique link to the first survey. Once you have completed the survey we will also use your email address to send you a \$15 Amazon.com gift card. If you do not complete the survey within 3 days of receiving the original email, you will be sent up to 3 reminder emails.

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Immediately after you finish the first survey, you will be randomly assigned one of two groups:

- Group 1 will be given access to the sexual health website we designed
- Group 2 will receive links to currently available sexual health resources

Being randomly assigned means that you are put into a group by chance. It is like flipping a coin. Which group you are in is decided by a computer. Neither you nor the researcher can choose what group you will be in. You will have an equal chance of being placed in either group.

If you are in Group 1, we will email you a link, log-in, and temporary password for the sexual health website we developed. You will be asked to explore the website and participate in the various online games and activities designed to teach you about sexual health. We're estimating it will take around 90 minutes to go through all of the parts of the website. You do not have to complete the website in one sitting. You can log out and log back in at any time. You will have access to the website for three weeks after you are emailed the log-in information. If you do not log-in within one week of receiving the original email, you will be sent up to 3 reminder emails.

If you are in Group 2, we will send you an email with links to currently available sexual health resources. You will be asked to go to those websites at least once to explore the information provided on them.

Three weeks after completing the first survey you will be sent a second online survey. It will take approximately 15-25 minutes to complete. This survey will cover similar topics to the first survey as well as questions about the website(s) you visited. You will be emailed a \$25 Amazon.com electronic gift card for completing this survey.

Fifteen weeks after completing the first survey you will be sent the last online survey. It will take approximately 20-30 minutes to complete. This survey will cover similar topics to the first survey. You will be emailed a \$35 Amazon.com electronic gift card for completing this survey.

Participants in the study who complete all three surveys will be emailed a bonus \$20 Amazon.com electronic gift card.

At the end of the first survey we will also ask you to provide a telephone number, whether we have your permission to leave a voicemail, and how you would like us to identify ourselves on the phone. We will only call this number if you have not completed the two follow-up surveys after the three reminder emails and you have not asked to stop participating. We will only identify ourselves using the name you have chosen and will only leave a voicemail if you have said that it is ok for us to do so.

### **Are there any risks involved in participating?**

There are two main risks to participating in this study: 1) you might be uncomfortable answering some of the questions in the survey or viewing some of the content on the website and 2) others may find out you are participating in the study.

We take every effort to reduce these risks for you. You can skip any question that makes you feel uncomfortable. You may also stop participating at any time. A list of youth-focused organizations and services will be given to all participants in the study as another way of helping with any needs or discomforts that you may have by being in the study. The steps we will take to reduce the chance that

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others will find out that you are participating are described in detail in a section called “What about my confidentiality?” below.

### **What are the benefits?**

You may find the information on the study website or the links you receive about sexual health, depending on which group you are randomly assigned to, may be helpful. In addition, the information you provide will be an important part in helping us better understand how to provide sexual health resources to young men, which may help other young men like you.

### **What are the costs?**

There are no costs to you for being in this research study.

### **What about my confidentiality?**

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you decide to stop participating.

To keep others from learning about your participation, we will not share your participation or answers with anyone. All data will be coded with a unique study number assigned to you to reduce the chance that your identity might become known. Your email address will be kept separate from the rest of the information you provide and deleted once data collection is complete. Electronic files containing study information from the surveys and the intervention website will be password-protected with encryption software. No individual identities will be used in any reports or publications.

Although we take every effort to protect your privacy, no system for protecting your confidentiality is completely secure. For example, if someone looks over your shoulder or you walk away from your computer or phone with a study survey or website still up on the screen, another person may view it. We encourage you to complete study surveys and website in a private place. To further protect you, the website will time out if you do not access content after 20 minutes. You will also only be able to move forward in the surveys, so if someone sees the survey on your phone or computer, they will not be able to go back and see your previous answers.

This study is also covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study, we will only share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and

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Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.

- Any people who you give us separate permission to share your information.

Also, if you indicate you are suicidal, want to hurt someone, or are being abused, we will need to try to get you help by telling the appropriate authorities and taking appropriate medical action. In a situation where the research team is worried about your safety, we may have to tell someone you are participating in the study.

Lastly, although we will only share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial is available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**What are my rights?**

By agreeing to be in this study you do not waive any of your legal rights. You may choose not to participate in the study or withdraw at any time. If you choose not to participate or if you choose to stop participating you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision to participate or not participate will not, in any way, change your relationship with or ability to go to youth-oriented community organizations, clinics, or Boston University.

**Other things I should know about this research?**

If we find out about new information from this research that may affect your health, safety or willingness to stay in this research, we will let you know as soon as possible. We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

**What are the pros and cons of participating?**

PROS	CONS
<ul style="list-style-type: none"><li>• You may enjoy sharing your thoughts and opinions</li><li>• You may learn something about yourself and sexual health by answering the questions or using the website content or weblinks</li></ul>	<ul style="list-style-type: none"><li>• You may feel uncomfortable answering some questions</li><li>• Although we will never knowingly share your information or identity with anyone, we cannot guarantee complete confidentiality on the Internet</li></ul>

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<ul style="list-style-type: none"><li>You may feel good about helping other men achieve better health</li></ul>	
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**Who should I contact with any questions?**

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Kimberly Nelson at 617-358-1482.

You may also call 617-358-5372 or email [medirb@bu.edu](mailto:medirb@bu.edu). You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

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We would now like to ask you some questions to make sure that you understand the study that you are being asked to participate in. If you answer a question wrong, you will be directed to the part of the information statement that will help you answer the question. You will have three chances to answer each question correctly.

**If you agree to be in this study, what are we asking you to do?**

- Complete three online surveys and be randomly assigned to access a website about sexual health topics or receive an email with online sexual health resources
- Complete three online surveys about your experience at school
- Complete three online surveys about how to get young men interested in a research career
- Complete three online surveys about how to get young men interested in a larger study about healthy eating

**How will it be decided which group of the study you are assigned to?**

- You get to choose
- The researcher chooses
- It is decided randomly, like flipping a coin
- The people funding the research choose

**What can you do if you experience distress while taking part in this study?**

- Stop participating in the study
- Skip the question or content that is causing distress
- Contact the primary researcher
- All of the above

**What are the potential risks of being in this study? (check all that apply)**

- I may feel uncomfortable when answering some of the questions
- I may have some bruising from the blood draw
- Someone else might find out that I am in the study
- I might find out that I have a disease or disorder that I did not know about before

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Now that we are sure that you understand what you are being asked to do, we would like to know if you would like to be in this study.

By checking the box to saying that you would like to participate in this research you are saying that you have read and understood the information we provided, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

If you would like to be in this study please click yes below. If you do not want to be in the study, it is OK to say no. You can stop being in the study any time you want to, and nobody will be upset with you.

**Would like to participate in the study?**

- Yes, I would like to participate -- > participants will be directed to the request for email address below
- No, I would not like to participate -- > participants will be directed to a community resource list

**Request for email address**

To move onto the first survey we will need your email address and your preference for the subject line of the email. Once we have this information we will email you a unique link to access the first survey.

**Email address:**

**Preferred subject line for the email:**