

## APPENDIX A. RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE:** Optimizing Text Messaging to Improve Adherence to Web-Based Cessation Treatment

**PROTOCOL NO.:** R01 DA038139-01A1

**SPONSOR:** National Institute on Drug Abuse

**INVESTIGATOR:** Amanda L. Graham, PhD  
Schroeder Institute for Tobacco Research & Policy Studies  
900 G St NW Fourth Floor  
Washington DC 20001

**SITE(S):** Truth Initiative  
Schroeder Institute for Tobacco Research & Policy Studies  
900 G St NW Fourth Floor  
Washington DC 20001

**STUDY-RELATED PHONE NUMBER(S):** 202-709-8587

### INFORMED CONSENT

#### **ABOUT THE STUDY**

You are invited to participate in a research study. The study is called *Optimizing Text Messaging to Improve Adherence to Web-Based Cessation Treatment*. The research is sponsored by the National Institute on Drug Abuse of the National Institutes of Health (NIH) and is being conducted at the Truth Initiative, which is located at 900 G St NW Fourth Floor, Washington DC 20001. Dr. Amanda Graham is the Primary Investigator.

#### **WHAT IS INFORMED CONSENT?**

The purpose of this consent form is to help you decide if you want to be in the study. Please scroll through and read this entire consent form carefully. To join a research study you must give your informed consent. "Informed consent" includes: (1) reading this consent form and (2) asking questions about anything that is not clear. You should not join this research study until all of your questions are answered.

If you have any questions, please contact the study investigator, Dr. Amanda Graham, at [EX\\_Study@truthinitiative.org](mailto:EX_Study@truthinitiative.org) or 202-709-8587.

Things to know before deciding to take part in a research study:

- Taking part in the study is entirely your choice - if you choose not to join the study, you can continue to use the BecomeAnEx website however you wish;
  - Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;
  - You may withdraw from the study at any time.
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If you decide to take part in this research study, you will be able to print or save a copy of this consent form.

### **WHY IS THE STUDY BEING DONE?**

The purpose of this study is to investigate the effectiveness of a smoking cessation website called BecomeAnEx.org when it is used alone, and when it is used along with social network support and/or nicotine replacement therapy (nicotine patch, gum, or lozenge). The study also hopes to identify ways to improve the effectiveness of the BecomeAnEx.org website in helping smokers to quit smoking.

About 600 subjects are expected to enroll in this study.

### **WHAT IS INVOLVED IN THE STUDY?**

*Joining the Study:* If you agree to take part in this study, here's what will happen. First, you will sign this Informed Consent page by entering your initials at the bottom of the page and clicking "I Want to Participate." This page must be signed before any study-related procedures are performed. Second, you will be asked to provide some basic contact information, including your name, email, and mobile telephone number. Third, you will be asked to complete an online survey that includes questions about your use of the Internet and your cell phone, your smoking habit, and your health in general. This survey should take about 5-8 minutes to complete. Fourth, we will send you a text message at the phone number you provided to confirm your enrollment in the study. To fully enroll in the study, you must text back "OK" this welcome text message.

*Being in the Study:* Once the survey is completed, you will be "randomized" into one of the study groups. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researchers will choose what group you will be in. If you are randomized to Group 1, you will have full access to the BecomeAnEX.org website to use as you desire. If you are randomized to Group 2, you will also have full access to the BecomeAnEx.org website and you may receive text messages over the next month. You will have an equal chance of being assigned to either Group.

*Follow-Up Surveys:* You will be contacted by email at three different time points by study staff to complete follow-up Internet surveys. If we are not able to reach you by email to complete the surveys, a research assistant will attempt to reach you to complete them over the phone. These follow-up surveys will occur at 3, 9, and 15 months after you join the study. The surveys will ask about your smoking, your health in general, and your feedback about being in the study. Each follow-up survey will take about 12-15 minutes to complete.

**The follow-up surveys are a critical part of the study – we need to hear from everyone, even if you are still smoking and/or have not used the website or the text message program.**

Your participation will last about 15 months, if you complete the study.

### **RISKS AND DISCOMFORTS**

*Quitting Smoking:* If you decide to quit smoking, you may experience mood changes, anxiety, irritability, decreased concentration, restlessness, increased hunger or trouble sleeping. These symptoms usually last for about 1 to 2 weeks after quitting.

### **NEW INFORMATION**

You will be told about any new information that might change your decision to be in this study. You may be asked to read and submit a new online consent form if this occurs.

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## **POSSIBLE BENEFITS**

By taking part in this study, you may quit smoking or cut down the number of cigarettes that you smoke which will improve your health, but this cannot be guaranteed.

## **COSTS**

There is no cost to you to join the study or to participate in the study.

## **PAYMENT FOR PARTICIPATION**

You will not be paid for completing the baseline survey. You will be paid \$50 via Amazon gift card emailed to you for completing each of the three follow-up surveys. If you do not complete all follow-up surveys, you will be paid for the surveys you complete.

## **ALTERNATIVE TREATMENTS**

You do not have to participate in this study. You can continue to use BecomeAnEx.org however you wish. There are also other quit smoking programs available, such as telephone support available at 1-800-QUIT-NOW and community agencies such as the American Lung Association.

## **CONFIDENTIALITY**

All information collected from you for the study will be kept confidential to the extent of the law. Confidentiality will be protected at all times and several steps will be taken to reduce any risks to confidentiality. Complete confidentiality cannot be guaranteed. All information collected via the Internet will be kept secure using the Secure Socket Layer (SSL) Protocol, the same technology used to encrypt credit card numbers during transmission over the Internet. You will be asked to designate a username and password to access the website. All data will be stored in a database subject to both physical and electronic protection. All participants will be assigned an identification number that will be used to link responses, but no identifying information will be kept with those responses.

Please note that study staff involved in processing your payment for participation will be aware of your identity.

The results of the research study will be shared with other people and will be published in scientific reports; however, your name and the fact that you were in the study will be kept confidential.

The funding agency, the National Cancer Institute, may see your information if it is audited. The federal auditors can use this audit information only for audit or evaluation of the program.

## **COMPENSATION FOR INJURY**

We do not expect any injuries to result from this research study. If an unexpected injury occurs as a result of your participation in this study, you will receive treatment that Truth Initiative considers to be fair and appropriate for that injury, without charge to you. Truth Initiative does not intend to provide you with any other money or payment if this happens. Agreeing to participate in this study does not change any of your legal rights. For more information regarding this provision, please contact Ryan Desrosiers in the Office of Grants Management at Truth Initiative at 202-454-5555.

## **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

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The decision whether to be in this study is entirely up to you. Participation is voluntary. Also, if you decide now to participate, you can to change your mind later and withdraw from the study.

There will be no penalty if you decide not to participate, or if you withdraw from the study. The research team may choose to end your participation in this study at any time prior to the completion of the study for any reason.

The researcher will provide you with additional information as it becomes available that may affect your decision to continue in the research study.

### **SOURCE OF FUNDING FOR THE STUDY**

This study is funded by the National Institute on Drug Abuse of the National Institutes of Health (NIH).

### **QUESTIONS**

Please contact the study investigator, Dr. Amanda Graham, for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, input or complaints about the research, you may contact:

Chesapeake IRB  
6940 Columbia Gateway Drive, Suite 110  
Columbia, MD 21046-3403  
Telephone: 410-884-2900  
<http://www.chesapeakeirb.com/>

Chesapeake IRB is a group of people who independently review research.

Chesapeake IRB will not be able to answer some study-specific questions. However, you may contact Chesapeake IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not agree to participate in this study unless you have had a chance to ask questions and have gotten satisfactory answers.

### **CONSENT**

I have read this consent form. All my questions about the study and my part in it have been answered. By entering my initials in the box below, I freely consent to be in this research study.

By agreeing to participate in this study, I have not given up any of my legal rights.

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