

## CONSENT TO TAKE PART IN A RESEARCH STUDY

**TITLE OF STUDY:** Game-based contingency management for smoking cessation

**Principal Investigator:** XXXX

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

XXXX or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

### **SPONSOR/S OF THIS STUDY:**

XXXX is the sponsor of this research study. The Principal Investigator is being paid to conduct this study according to a budget that will cover the costs of the study. The costs that are usually covered include things such as: subject participation stipend.

#### **A. Why is this study being done?**

To test a novel, videogame-based program to help people quit smoking.

#### **B. Why have you been asked to take part in this study?**

You have been asked to take part in this study because you are a smoker who would like to quit smoking and you are interested in trying to use a novel videogame-based approach to quitting.

#### **C. Who may take part in this study? And who may not?**

You may be eligible to participate if you are a regular smoker, healthy, age 18 or older, would like to quit smoking, and have a Facebook account. The first thing we will ask you to do is to complete a questionnaire about your social and medical history, and about your smoking and videogame use patterns. As with all questionnaires, you do not have to answer any question you do not wish to answer.

**D. How many subjects will be enrolled in the study?**

We plan to enroll approximately XX participants in to the study.

**E. How long will my participation in this study take?**

You will be asked to participate for a minimum of two weeks.

**F. Where will the study take place?**

The study will take place wherever you have access to the Internet (e.g., home, work, library, etc).

**G. What will you be asked to do if you take part in this research study?**

There is a lot of information to explain to you about this study. Please make sure to ask me questions at any time, if you do not understand something.

Trained research assistants will oversee your progress through the study. You will be asked to use a computerized, Internet-based system to measure how much you have been smoking.

We will monitor your smoking by taking breath carbon monoxide (CO) measurements. The CO device is about the size of a calculator, and you just blow into a small tube, similar to a breathalyzer. The device provides a read out of your CO level. Most of the time, CO samples will be considered “positive” (which means that you smoked recently) if they are greater than 4 parts per million (ppm), and negative if they are equal to or less than 4 ppm. The more you smoke the more CO is in your blood and the higher your CO reading. CO can also be elevated by smoke from other sources (e.g., second-hand smoke, marijuana), so it will be important to avoid these other sources of smoke while you are trying to quit.

We will mail you some equipment to borrow while you’re in the study so that you can measure your CO. You will be asked to make video recordings of yourself blowing into the CO meter. The video will be recorded with a web camera. You will be asked to send your video recording to us, the research staff, via the Internet so that we can verify your CO sample. We will loan you the web cam (if needed) and CO monitor. You are expected to return all equipment when you are done with the study.

You will usually be asked to provide breath samples twice per day. You will be able to record and send your video clip with little effort; it should take about one to three minutes. You will always receive feedback about your smoking status (whether you are positive or negative for recent smoking). If you miss a sample we will remind you that you missed a sample, and we will tell you the consequences of continuing to miss CO samples. We will make every attempt to work with you if your schedule presents problems, but please keep in mind that providing regular samples is an important part of the study. Video recordings can be submitted any time of day (24/7), so the schedule is very flexible.

During the study you will also be asked to play a videogame called “Up from the Ashes.” This videogame will consist of an under-developed inner-city urban environment, and your objective will be to make your neighborhood grow and prosper. We will explain more about how the game will work after you enroll, but you should know that you will have team members who you will be able to support, and who will be able to support you, in developing your cities and domains. You will be able to earn resources, which will help you build your cities and domains, in a few different ways. First, you will be assigned to one of two different groups, and how you earn game-based resources will depend on your group assignment. Some people may earn game-based resources by simply submitting CO videos, and other people may have to meet their smoking abstinence goals in order to earn game-based resources. Your team members may also provide you with resources at various times to help you advance your game, and you will be able to do the same for them. You will be able to play the game at your leisure.

Upon enrolling and then again at the end of the 2 weeks, you will complete a group of online questionnaires, asking questions about your mood, recent activities, and smoking and videogame patterns. You will receive \$XX for each group of assessments (\$XX total) and your answers on the questionnaires will not influence how much you earn for completing them. You will also earn \$XX for returning the equipment to us. In the event that you do not return the equipment, we will charge your credit card (information must be provided in order to enroll) to cover the cost of replacing the lost equipment (\$XX). To pay you for your participation in the study, we will give you a credit card that we can load with your payments when you complete each group of surveys and after returning the equipment.

**H. What are the risks and/or discomforts you might experience if you take part in this study?**

The primary risks involve discomfort from withdrawal symptoms associated with nicotine withdrawal, and the possibility of information being disclosed via your involvement with the videogame.

**I. Are there any benefits for you if you choose to take part in this research study?**

The benefits of the proposed work far outweigh the risks associated with participating. You will receive instructions regarding how to quit (via the "Clearing the Air" packet developed by the National Cancer Institute, Smokefree.gov, QuitSmokinghelpline.com, and the National Academies Press "Dying to quit."), and smoking is currently the number one preventable cause of illness and death.

**J. What are your alternatives if you don't want to take part in this study?**

There are no alternative treatments available. Your alternative is not to take part in this study.

**K. How will you know if new information is learned that may affect whether you are willing to stay in this research study?**

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you, you will be contacted.

**L. Will there be any cost to you to take part in this study?**

There are no costs to you if you decide to participate in this study, beyond what you already pay to have Internet access.

**M. Will you be paid to take part in this study?**

During the intervention periods, you can earn money that will be deposited on a credit card that we give you for the study. Once the money has been deposited on the credit card, you can use it however you wish. You will be compensated \$XX for each of the initial and final surveys, and \$XX when you return the equipment (total possible \$XX).

**N. How will information about you be kept private or confidential?**

Your identity will be kept confidential to the extent provided by law. Your information will be identified by a code number. The list connecting your name to this code number will be kept in a locked file cabinet in the laboratory. When the study is complete and the data have been analyzed, the list will be destroyed. Your name will never be used to identify any of the information obtained from you. We will ask you to select a user name so that it does not suggest your true name. We will download this information to a computer that will be accessible only by research staff. Also, the video files you send with your web cam are located on a secure, encrypted server and will be destroyed when the study ends. Only research staff will view your video files.

**O. What will happen if you are injured during this study?**

If you are injured in this study and need treatment, contact your primary care physician or seek medical attention from your local emergency department to seek treatment.

We will offer the care needed to treat injuries directly resulting from taking part in this study. XXX may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury. However, you may be responsible for some of those costs. XXX does

not plan to pay you or provide compensation for the injury. You do not give up your legal rights by signing this form.

If at any time during your participation and conduct in the study you have been or are injured, you should communicate those injuries to the research staff present at the time of injury and to the Principal Investigator, whose name and contact information is on this consent form.

**P. What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?**

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

XXXX

If you decide to withdraw from the study for any reason, you may be asked to participate in one exit meeting with the Principal Investigator.

**Q. Who can you call if you have any questions?**

The principal investigators on this project are XXXX and XXXX. Research assistance will be directed by XXXX. You should contact XXXX if questions or problems arise in connection with your participation in the research, including such schedule problems (e.g., an upcoming vacation). XXXX can be reached at XXXX, and her telephone number is XXX-XXX-XXXX.

**What are your rights if you decide to take part in this research study?**

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

You have already agreed to participate in a research study conducted by XXXX. We are asking for your permission to allow us video-record you as you are collecting your CO breath samples, as part of that research study.

The recording(s) will be used for determining whether or not you have abstained from smoking

cigarettes.

The recording(s) will include you submitting your CO sample from beginning to end, showing you from about the waist up.

The recording(s) will be stored on a secure Internet server until the data collection period has been completed.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

If you are still interested, please complete the Consent form and press submit when you are finished.

**Before proceeding, we want to make sure that you understand the procedure by having you answer the questions (select each correct answer):**

- 1) The study will last a minimum of:
  - a. 2 weeks
  - b. 7 weeks
  - c. 9 weeks
  - d. 12 weeks
  
- 2) We will monitor your smoking during the study by using small breath monitor to measure breath carbon monoxide (CO).
  - a. True
  - b. False
  
- 3) The money that I earn in this study will be deposited onto a credit card given to me at the beginning of the study.
  - a. True
  - b. False
  
- 4) In the videogame, you will be able to earn resources to help you develop your city/domain by:
  - a. Submitting CO videos
  - b. Meeting CO abstinence goals
  - c. It will depend on my group assignment
  
- 5) You have the right to withdraw from the study at any time.
  - a. True
  - b. False

### **AGREEMENT TO PARTICIPATE**

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name: \_\_\_\_\_

Subject Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Signature of Investigator/Individual Obtaining Consent:**

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_