

## Informed Consent Form

The Fred Hutchinson Cancer Research Center (Fred Hutch)

### Consent to take part in a research study:

## Randomized Trial of an Innovative Smartphone Intervention for Smoking Cessation (iCanQuit Study)

*Principal Investigator:* Jonathan Bricker, Ph.D., a scientist and Full Member at the Fred Hutch. Email: [jbricker@fredhutch.org](mailto:jbricker@fredhutch.org)

### We would like you to join this research study.

To help you decide if you want to join in the iCanQuit Study, this form tells you about the study and its activities. After that, you can also email us to ask any questions about the study.

We are doing this research study to see which of 2 smoking cessation programs is the most useful to help people quit smoking. A total of 2,510 people are expected to enroll. If you decide to join, your participation in the study will take a year. Study participation involves regularly using a mobile application “app” on your smartphone, and completing surveys.

We will ask you to complete 3 surveys that will tell us about how you are doing in the study. We will send you \$25 for each survey you complete. If you complete the online version of the survey within 24 hours of receiving it, we will give you an additional \$10.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

### Being in the study?

iCanQuit includes using a smartphone app and filling out 4 surveys. If you agree to be in this study, this is what will happen.

- First you will fill out a survey, called the *Baseline Survey*. It is a 15-20 minute web-based survey that asks questions about:
  - Your interest in quitting smoking
  - Details about your current smoking and smoking history

- Demographics (for example, marital status and education)
- Information to help us contact you for future study activities

You will have up to 2 weeks to complete this first study survey.

- Next, you will be randomly assigned (like a coin toss) to one of two quit smoking app programs. Both programs provide:
  - (1) Tools for dealing with urges to smoke
  - (2) Step-by-step guides for quitting smoking
  - (3) Help planning for quitting and staying tobacco-free
  - (4) Scientifically-based recommendations for how to select medications to help you quit smoking (However, medication will not be provided by the study)

To help you quit smoking, you are welcome to use your assigned program as often as you wish and for as long as you wish. We encourage you to use the program for 45 days: 14 times between now and your quit date and every day for 30 days after you quit.

- We will electronically record information on your use of the app (for example: which pages you opened and for how long).
- We may also ask you to tell us how you are managing your urges to smoke, your commitment to quitting, your smoking behavior, and satisfaction with the app you are viewing.
- You may be randomly selected for verification of your smoking status through a mailed saliva sample and proof of your identification.
- To learn about your overall experiences with your smoking cessation program, we will send you three 15-20 minute surveys. These surveys can be filled out either online, by telephone, or mail. We will send you a survey after 3 months of being in the study, then again at 6 months and 12 months after joining.

### **How long will I be in this study?**

Your study participation will last for 1 year. This includes your time using the app and the 3, 6, and 12 month surveys.

If you leave the study, your survey results and information cannot be removed from the study records.

### **Risks of being in this study**

- You may experience some short-term discomfort associated with nicotine withdrawal. You should consult your doctor if you have any concerns or questions regarding nicotine withdrawal symptoms.

- You may be randomly selected for verification of your smoking status through a mailed saliva sample and proof of your identification, both of which may make you feel short-term discomfort.
- Because this study uses an app and online surveys, there is a very small risk that your study information will be viewed online by an unauthorized party. However we have protected against this risk in the following ways: (1) your contact information data (e.g, name & phone number) will be collected and stored separately from all survey information; (2) your connection to the iCanQuit website, where you fill out the surveys will be password restricted and protected by secure-socket-layer (SSL) encryption; and (3) the website's server will sit behind a hardware firewall.
- The survey questions we ask you about your health history are sensitive and may make you feel uncomfortable.

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

We do not know if this study will benefit participants.

Your participation in this study may help you quit smoking. Your participation will also help Fred Hutch see which of the two smoking cessation programs is the most useful to help people quit smoking. We hope the information we learn will help people with quitting smoking in the future.

You also may personally benefit by the feeling that you have helped in this research.

### **You have other choices besides this study.**

You do not have to join this study. You are free to say yes or no. Your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

Your other choices may include:

- National Cancer Institute's smoking cessation website: [www.smokefree.gov](http://www.smokefree.gov).
- Your state quitline (available in all 50 states) by calling 800-QUIT-NOW.

## **Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information**

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Some organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- The study sponsors and their agents.
- Institutional Review Boards (IRB), including Fred Hutch's IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, a court may order study information to be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

We will respect your privacy. We will only contact you at email addresses and phone numbers that you provide to us. Also, (1) we will only leave voice messages if you have told us it is okay to do so, (2) we will only email study-related letters to the email address(es) you provide to us for such emailings.

A description of this clinical trial is available on <http://www.clinicaltrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

### **Will you pay me to be in this study?**

You will be sent \$25 after you complete the 3, 6 and 12 month surveys. If you complete those surveys online within 24 hours of receiving them, we will give you an additional \$10 for each survey you complete. Therefore, you will receive up to \$105 if all three of these surveys are completed within 24 hours of receiving them. This compensation will be sent to the mailing address you provide us.

If this research shows that our study app works to help people quit smoking, it might become a product that is patented and sold. If that happens, you will not be paid for use of the patent.

### **How much will this study cost me?**

There are no costs for being in this study.

### **What if I get sick or hurt in this study?**

For a life threatening problem, call 911 right away or seek help immediately. Contact us when the medical emergency is over or as soon as you can.

For all other problems related to the study, please contact the 877-250-6641. . There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

### **Your rights**

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.

- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

**For more information**

If you have any questions or concerns about this study you would like answered before deciding to participate, please email us at [iCanQuit@fredhutch.org](mailto:iCanQuit@fredhutch.org). We are committed to answering your questions within 2 business days.

Other people you can talk to are listed below.

<b>If you have questions about:</b>	<b>Call:</b>
This study (including complaints and requests for information)	877-250-6641 (Dr. Jonathan Bricker, Principal Investigator)
If you get sick or hurt in this study	877-250-6641 (Project Manager)
Your rights as a research participant	206-667-4867 (Karen Hansen, Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

**I consent to participate in this study (check box and click)**

[Website proceeds to the Baseline Survey & Contact Form]

[If you have 15-20 minutes now, you can go ahead and do the first study survey. If not, please use the link emailed to you. You must complete this survey within 2 weeks of receiving it to be eligible to continue in the study.]

**I do not consent to participate in this study (check box and click)**

[Website proceeds to the Decline Screen that asks “To help us improve this study, please tell us why you decided not to participate.” Open-ended written answers provided.]

Protocol: iCanQuit  
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