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Informed Consent Form

Fred Hutchinson Cancer Center

Consent to take part in a research study:

Full Scale Randomized Trial of an Innovative Conversational Agent for Smoking Cessation (QuitBot)

Principal Investigator: Jonathan Bricker, Ph.D., Professor at the Fred Hutchinson Cancer Center.
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Important things to know about this study.

You are invited to participate in a research study. We are doing this research study to see which of two smoking cessation programs is the most useful to help people quit smoking.

People who agree to join the study will be asked to connect to a QuitBot smoking cessation program that will contact you with automated messages for quitting smoking. People will be asked to use their assigned QuitBot program regularly and complete three follow up surveys.

You do not have to join this study. Although the study may or may not benefit participants directly, we hope the information we learn will help people to quit smoking in the future. Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, you can print a copy of this form to keep for future reference.

We would like you to join this research study.

We are doing a research study to examine how effective two smoking cessation programs are. Since you smoke cigarettes and would like to quit, we would like to ask you to join this study. To help you decide if you want to join in the QuitBot 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.

A total of 1520 people are expected to enroll. If you decide to join, your participation in the study will take 12 months. Study participation involves regularly using your assigned program, and completing three surveys.

We will ask you to complete three follow-up surveys, one each at 3, 6, and 12 months that will tell us about how you are doing in the study. We will send you $25 for

completing each follow-up survey. If you complete the online version of the surveys within 24 hours of receiving them, we will give you an additional $10.

If you join this program, you may be randomly selected to take a test to verify your smoking status during the follow up surveys. The testing device measures your saliva. If you are selected, we will mail you a testing device, and ask you to do an online survey with uploaded photos or a video call with us to show us your results. If you complete the test, we will give you an additional $35.

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

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 30 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 automated quit smoking programs.. Both programs provide:
    - (1) Tools to cope with urges to smoke
    - (2) Guidance 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. Note: 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 programs (for example: which messages you responded to 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 program you are using.
- 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, 6, and 12 months of being in the study.

- We may also send you an Alere saliva-based smoking status test in the mail. This is an instant test for tobacco use that measures the nicotine in your saliva. After you receive the smoking status test, we will email you a link to instructions for how to take the test and upload photos online. If you have any difficulty with the online version of doing the test, we will set up a time with study staff using Doxy.me, a secure and protected video conferencing system that will let you take the saliva test and show us your test results. After we send you confirmation of your test results, you can throw the saliva test away.

How long will I be in this study?

Your study participation will last for 12 months. This includes your time using your program 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.
- Because this study uses SMS text messaging, an app, online surveys, and may use the Doxy.me remote video conferencing system for those taking the smoking status test only, 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 QuitBot website, where you fill out the surveys will be password restricted and protected by secure Transport Layer Security (TLS) encryption; (3) Doxy.me is an encrypted live video-conferencing software that is accessible via smartphone, tablet, or desktop computer, does not require you to set up accounts or do downloads, plugins, or installations because it works in all popular web browsers, and does not record or store data; and (4) 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 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 for saying no or dropping out. Whatever you decide, your regular medical care will not change.

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.
- 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 sponsor and their agents.
- Fred Hutchinson Cancer Center and University of Washington.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center 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, federal Food and Drug Administration (FDA), 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.

A description of this clinical trial will be 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.

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 all to us for such emailings.

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 the surveys online within 24 hours of receiving them, we will give you an additional $10. So you could receive up to $105 for doing all three surveys.

If we send you the saliva smoking status test, once you complete the test online or over a Doxy.me secure video conference with study staff, we will send you an additional $35 for completing each saliva smoking test. Therefore, you could receive up to $210 for doing both the smoking test and the surveys at all three times ($35 plus $35 equals $70 times three follow-up time points equals $210). This compensation will be sent to the mailing address you provide us.

If this research shows that our study program 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 study PI at 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 quitbot@fredhutch.org. We are committed to answering your questions within 2 business days.
Other people you can talk to are listed below.

If you have questions about:	**Call:**
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 (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

☐ **I consent to participate in this study (check box and click)**
[Website proceeds to the Baseline Survey & Contact Form]
[If you have 30 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 <u>not</u> 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.]