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Informed Consent Form

Fred Hutch Cancer Center

Consent to take part in a research study:
ACT on Vaping: Development of a Digital Therapeutic for Young Adult Vaping Cessation

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To help you decide if you want to take part in the study, this form tells you about the study and its activities. You can also email us at ACTonVaping@fredhutch.org to ask any questions you have about the study to help you decide whether or not you want to take part.

What is the purpose of the study?
We are conducting this research study to learn how digital programs can help motivate and support young adults to quit vaping.

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 if you say no or if you change your mind later.

We plan to enroll 60 people in this study. Although the study may or may not benefit participants directly, the information we learn will help us design better vaping cessation programs in the future.

Below is a more complete description of this study. Please read this description carefully. If you join this study, we will email you a copy of this form for your reference.

What are you asking me to do?
For this study, we will ask that you use one of two digital vaping cessation programs and fill out 2 surveys. Specifically, if you join this study, you will be asked to:

- Fill out a survey, called the *Baseline Survey*. It is a confidential, web-based survey that takes 15-20 minutes to complete and includes questions about:
    - Your current vaping habits, your vaping history and where you are in your thinking of being ready to quit vaping
    - Demographics (for example, education and employment)
- Use a digital intervention to understand your vaping behavior and explore quitting.
- We will electronically record information on your use of the program (for example: how many times you respond to messages asking about how much you're vaping). Study staff may reach out to you via telephone to offer technical

assistance if it appears that you have not engaged with your assigned digital program.

- Fill out a follow-up survey after 3 months of being in the study. This survey can be filled out online, by telephone, or by mail and will help us learn about your overall experieces with the digital program. The follow-up survey should take about 10-20 minutes to complete.
- We may call you on the phone and ask that you to briefly confirm some of your answers for any of the study surveys.
- After completing the 3-month follow-up survey, you may be asked to verify your vaping status by completing an at-home saliva cotinine test and uploading a picture of your result.
- If you experience a change in your physical or mental health or well-being during the study (e.g., illness, injury, or other difficulties with your physical or mental health), please report these changes to the project manager, particularly if you needed treatment or were hospitalized. A secure web-based form will be provided to submit these reports.

These details are described further below.

Vaping Digital Intervention

You will be randomly assigned (like a coin toss) to Group A or Group B. Assignment to either group is completely random, and you have the same chance of being selected to either group.

Group A (30 participants)
If you are assigned to Group A, you will receive a digital intervention to understand your vaping behavior and explore quitting, including periodic self-assessment of your vaping behavior. The program includes incentives for responding to SMS text messages about your vaping status.

Group B (30 participants)
If you are assigned to Group B, you will receive a digital intervention to understand your vaping behavior and explore quitting, including individual values and acceptance-based coping skills. The program includes incentives for responding to SMS text messages about your vaping status.

Research Surveys

You will be asked to complete two study surveys:

1. At the time you start your participation in the study.
2. Three months after enrollment in the study.

Surveys may take 10-20 minutes to complete. You will be asked about your vaping history, current vaping status, and your interest in quitting. At the 3-month survey, you will also be asked to give us feedback about the digital program you used.

Saliva Cotinine

At the 3-month survey, you may be asked to confirm your vaping status by completing a saliva cotinine test kit and sending us a picture of your result.

How long will I be in this study?
The total length of participation is 3 months. This includes your time using the digital program and completing the 3-month follow-up survey.

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

Will you pay me to be in the study?
Yes. You will receive up to $102 for your participation based on the following:

- You will be mailed $2 cash in a reminder letter for the 3-month follow-up survey.
- You will be mailed $50 cash after you complete the 3-month survey. If we have questions about your survey responses, payment will be delayed until we are able to reach you to confirm your answers. Incentives will only be sent to US addresses.
- If you complete the follow-up survey online within 24 hours of the first survey invitation being sent by email, we will give you an additional $10.
- You will be compensated $5 for each text message that you respond for a maximum of $15 for responding to all 3 messages. These incentivized text messages will include a reminder that you will receive $5 for responding to them. You will receive other text messages from the study, but there is no compensation for responding to those.
- If you are asked to confirm your nicotine and tobacco product use status at 3 months, we will give you an additional $25 after you send us your result.

Payment will be mailed to you after you respond to each text message, complete the 3-month study survey and the saliva testing (if asked).

If you agree to join the study, there is no cost to you for participating.

What are the benefits of being in this study?

- Participating could help us learn how to better help young adult e-cigarette users quit vaping, which could improve care options in the future.
- Participation in this study may help participants quit or cut back on how much they vape.
- Some people feel good when they help with research like this.

What are the possible risks or discomforts of being in this study?

- If you quit vaping, you may experience some short-term discomfort associated with nicotine withdrawal including irritability, depressed mood, restlessness, difficulty sleeping, headaches, difficulty concentrating, and cravings to vape. These symptoms typically last a few weeks and then go away. These symptoms can be improved by using FDA-approved medications for tobacco cessation that reduce nicotine withdrawal (e.g., varenicline, bupropion, or nicotine replacement therapies like nicotine patch or gum), over-the-counter medications for specific symptom relief (e.g. acetaminophen or ibuprofen for headache), or behavioral strategies for symptom management (e.g., physical activity to improve mood and sleep).

- You may feel discomfort from some sensitive survey questions (e.g., questions asking about your household income).
- People not working on this study could learn your identity or learn information about you from your surveys. We will do everything we can to keep this risk small and to protect all study particfipants against this risk in the following ways: (1) All of your identifying information will be kept in a password protected, secure database behind Fred Hutch firewall for 7 years after the study is over and will then be destroyed, (2) your connection to study documents, surveys, and programs will be password restricted and protected by secure-socket-layer (SSL) encryption; and (3) the study server will be kept at Fred Hutchinson Cancer Center behind a hardware firewall.

Do I have other options besides this study?
You do not have to join this study. You are free to say yes or no. If you decide not to take part in this study, you can still receive treatment to help you to quit vaping. Your other choices may include:

- Talking to your doctor
- National Cancer Institute's tobacco cessation websites (which includes information on vaping), apps, and text messaging programs: see www.smokefree.gov
- Your state quitline (available in all 50 states) by calling 800-QUIT-NOW
- Truth Initiative's This is Quitting text messaging program (text DITCHVAPE to 88709)

Protecting your privacy as an individual and the confidentiality of your personal information
Some organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers and research staff involved with this study.
- Datatope LLC, the company that maintains the study database and intervention programs
- The Fred Hutchinson Cancer Center Institutional Review Board (IRB). An IRB is a group that reviews the study to protect your rights as a research participant.
- The study sponsor, National Institutes of Health (NIH), The Office of Human Research Protections (OHRP), and other agencies as required.
- Food and Drug Administration (FDA)

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality.

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

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 research information if you give 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 the intent to harm yourself or others. For example, if you tell us you have plans to harm yourself or others, we may have to share this information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

What if I get sick or hurt during 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.

Study staff will not be monitoring your survey responses, and this program is not intended to deliver medical or mental health care. Should you experience suicidal thoughts during the study, seek assistance from a healthcare provider or crisis line:

- National Suicide & Crisis Lifeline: 988
- National Crisis Text: Text GO to 741741 (crisistextline.org)

For all other problems related to the study, please contact the project manager at 206-667-2428. 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 are free to join this study and it is up to you whether you choose to participate or not. 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.

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.

What else should I know
The study investigator may decide to stop your participation in this study at any time if:

- it is not in your best medical interest to continue;
- you do not follow study procedures (e.g., if study staff is unable to reach you to confirm any of your survey answers)
- funding is stopped, or
- new information becomes available that requires a change in your participation

Should the information we learn during this study lead to a commercial product or a patent, you will not receive any compensation.

For more information
Be aware that by agreeing to participate in this study, your information could be used for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

If you have any questions or concerns about this study you would like answered before deciding to participate, please email us at ACTonVaping@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)	206-667-7314 or jheffner@fredhutch.org (Dr. Jaimee Heffner, Principal Investigator)
If you get sick or hurt in this study	206-667-2428 or eserfozo@fredhutch.org (Project Manager)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

- ○ I consent to participate in this study
- ○ I do not consent to participate in this study