

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Teen Vaping Cessation Intervention - Consent Form for RCT

TITLE: Social Media Intervention to stop nicotine and cannabis vaping among adolescents

PROTOCOL NO.: T31IR1910
WCG IRB Protocol #20204627

SPONSOR: Tobacco-Related Dis. Res. Prog. - U

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STUDY RELATED TELEPHONE NUMBER: (415) 502-0758

This is a research study led by Dr. Pamela Ling, M.D. from the University of California San Francisco. Dr. Ling and study staff are available to explain the study to you or answer questions. They can be reached at quitthehit@ucsf.edu.

The study is voluntary, meaning that you do not have to participate if you don't want to.

You are being asked to take part in this study because you are using e-cigarettes or vapes.

Study Title: Quit the Hit: Social Media Intervention to Stop Nicotine and Cannabis Vaping Among Adolescents

1. Why is this study being done?

The purpose of this study is to see if support on social media can help teens quit vaping.

In this study, the researchers are doing an online intervention to reduce vaping. The California Tobacco-Related Disease Research Program is paying for this research.

2. How many people will take part in this study?

About 500 people will participate in this study.

3. Am I eligible to participate in the study?

To participate in the study, you need to be between 13-21 years old today and use e-cigarettes or vapes.

4. What will happen if I take part in this study?

This study is about vape use. You do not have to quit vaping to be in this study. If you agree to be in this study, you will complete four surveys on your smartphone or computer. The surveys ask about personal information (like age, ethnic background, school), vaping, and other health issues like COVID or stress. Before we send you the first survey, we will ask you to register on QuitTheHitCA.com with your name, Instagram handle, email, phone number and address. You will only be able to complete each survey one time. It will take you about 20 minutes to complete each survey.

Study participants will be assigned at random to one of the two study groups, described below:

Texting Group

Participants in the control group will be given a referral to KickItCA.org, a website from the California Smokers' Helpline with free support services such as chat, quitline, and a texting program to help quit vaping.

Instagram Group

Participants in the Instagram group will be assigned to a private Instagram group (direct message chat thread) along with up to 15 other teens or young adults. Groups will be assigned based on your age when you join the study (either 13-17 or 18-21). Once we have recruited enough participants to start a group, Quit the Hit staff will make daily posts to the thread for 5 weeks, Monday through Friday, and you are encouraged to join in the discussion and activities, but your

participation is completely voluntary. You will also be able to chat individually with a vaping cessation counselor via direct message (DM) if you choose. You will have access to the Instagram thread for 120 days (about 4 months) after the group ends.

There is a one in two chance that you will be placed in the Instagram group, and a one in two chance you will be placed in the referral group. Group placement is completely random. A computer program will place you in one of the groups.

Surveys

If you consent to participate in this study, you will fill out a 20-minute survey about you, your vaping, and other health behaviors before being assigned to a group. You will be paid a \$10 electronic gift card for completing this survey.

- **About 30 days after you begin the study**, you will fill out a 20-minute survey about your vaping and other health issues. You will be paid a \$15 electronic gift card for completing this survey. Plus you can earn 2 bonuses:
 - If you complete the survey within 24 hours, you will get a \$5 bonus.
 - If you have quit vaping, and you agree to provide a saliva sample, you will be mailed a saliva sample kit, and asked to provide two pictures by email or direct message with the result of the test. If you complete this successfully, you will get an additional \$5.
- **4 months after you begin the study**, you will be asked again to complete a 20-minute survey. You will be paid a \$20 electronic gift card for completing this survey. Plus you can earn the same 2 bonuses:
 - If you complete the survey within 24 hours, you will get a \$5 bonus.
 - If you have quit vaping, and you agree to provide a saliva sample, and you complete the saliva test and email or Direct Message it back successfully, you will get an additional \$5
- **7 months after you begin the study**, you will be asked to complete a final 20-minute survey. You will be paid a \$25 electronic gift card for completing this last survey. Plus you can earn the same 2 bonuses:
 - If you complete the survey within 24 hours, you will get a \$5 bonus.
 - If you have quit vaping, and you complete the saliva test and email or Direct Message it back successfully, you will get an additional \$5.

In total, you will be paid up to \$100 in electronic gift cards for completing the surveys, earning bonuses for prompt responses, and sending confirmation of saliva tests for quitting vaping.

5. How long will I be in the study?

You will be enrolled in the study for 7 months. If you are assigned to the Instagram group, it will last for 5 weeks. If you are assigned to KickItCA.org, some of the services you choose on that

site may last for several weeks. You will complete the first survey when you join the study, and we will contact you about 1 month, 4 months, and 7 months after your first survey to complete more surveys. These four surveys will take about 20 minutes each to complete, or 1 hour and 20 minutes total.

6. Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

7. What risks can I expect from being in the study?

Although we will do our best to protect your study information, there is still a risk to loss of privacy. Though the Instagram groups/message threads will be entirely private, participation in the group may make your Instagram profile name known to other users who are also part of the study. Your Instagram profile name will not be connected to your survey responses in any way. It is possible that Instagram will change their privacy settings, which might affect your privacy.

In this study, you will be asked about use of tobacco products and cannabis. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, research records have been subpoenaed by a court.

It is possible that some of the survey questions may make you feel uncomfortable. You are free to decline to answer any questions that you do not wish to answer or to end the surveys at any time.

Another risk is stress or feeling uncomfortable due to quitting vaping. The researchers will attempt to minimize this risk by providing referrals and materials that might help decrease stress if you decide to quit.

For more information about risks and side effects, ask the study doctor.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state or local civil, criminal, administrative, legislative, or other proceedings.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we will voluntarily disclose information about things where safety is an issue, like child abuse, and intent to hurt

yourself or others. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily telling about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

8. How will information about me be kept confidential?

We will do our best to make sure that the personal information is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will do our best to make sure that the personal information we collect about you is kept private and secure. ***We will never sell, rent, or lease your contact information.***

All of the surveys you take for the study will be on Qualtrics, an online survey platform that meets UCSF and federal guidelines for collecting and storing information privately for research. Once your surveys are completed, data will be securely transferred to a UCSF-approved online protected environment with network servers that are stored off-site and tightly controlled. The servers are guarded by multiple firewall and intrusion detection systems. All electronic connections to the data storage environment are encrypted.

The privacy of any information you put on Instagram (like posts and comments) is controlled by Instagram and Instagram is responsible for sharing its privacy policy with you directly. We will transfer some of the information that you share on Instagram, including the group direct message threads as well as individual direct message threads with the study counselor onto a secure server as described above.

The completed online surveys will be kept separate from information which identifies you, like your name. Only a small number of researchers will have direct access to the completed surveys and Instagram message threads.

Organizations that may look at and/or copy your information for research, quality assurance, and data analysis include:

- People who work with the research sponsor
- Government agencies
- Representative of the University of California
- The Institutional Review Board (IRB) that reviewed this research

If you have any questions about how we protect the privacy of your information, please contact us by email at quitthehit@ucsf.edu, or by using one of the other options described at the bottom of this consent form.

9. Are there benefits to taking part in this study?

You may benefit by changing your vaping habits, and perhaps eventually quitting vaping, but this can not be guaranteed. Also, this study will help doctors learn more about how to address vaping with adolescents through social networking platforms.

10. What other choices do I have if I do not take part in this study?

If you choose not to participate in this study, you may use another program to quit vaping, such as teen.smokefree.gov.

Your other choices may include:

- Getting treatment for vaping without being in a study.
- Taking part in another study.
- Getting no treatment.

11. Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study. You will not be charged for any of the study activities.

12. Will I be paid for taking part in this study?

You will receive an electronic gift card [or payment via CashApp] for completing the baseline (**\$10**). You will be paid for completing follow-up surveys at 1-month (**\$15**), 4-month (**\$20**), and 7-month (**\$25**) surveys. When each of the follow-up surveys are sent to you, you can also receive a \$5 bonus e-gift card for completing the survey within 24 hours. You will also receive \$5 for each time you report quitting vaping on your survey and you send confirmation of your saliva test results.

When	Complete survey	Complete survey within 24 hrs	Report quitting vaping and returning test kit results
At beginning of study (Baseline)	\$10	Does not apply	Does not apply
1 month	\$15	\$5	\$5
4 months	\$20	\$5	\$5
7 months	\$25	\$5	\$5

You can receive up to \$100 if you complete all surveys within 24 hours and return saliva test results. Gift cards will be sent through Instagram or email after each time point.

13. What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

14. Who can answer my questions about the study?

You can talk to the study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Dr. Pamela Ling at 415-514-8627 or the research staff at quitthehit.ucsf.edu.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.