

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

Study Title: Smoking Tobacco and Drinking (STAND) Project

Research Project Director:	Danielle Ramo, Ph.D., Assistant Professor of Psychiatry [REDACTED]
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Project Coordinator:	[REDACTED]
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The Smoking Tobacco and Drinking (STAND) Project is a clinical research study and it is voluntary.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends or with your health care team. If you have any questions, you may ask the study staff.

You are being asked to take part in this study because you are a young adult who smokes cigarettes and drinks alcohol.

The lead researcher, Danielle Ramo Ph.D., from the University of California, San Francisco and study staff are available to explain the study to you or to answer questions. [REDACTED].

Why is this Study being done?

The purpose of this study is to help researchers compare two social media interventions for smoking and drinking.

How many people are participating in this study?

At least 225 people will participate in this study.

Am I eligible to participate in the study?

To participate in the STAND study, you need to be between 18 and 25 years old today, read English, smoke cigarettes and drink alcohol.

What will happen if I take part in this study?

If you agree to participate in this study you will be asked to complete four surveys and join a secret Facebook group, where you will be asked to comment on 90 posts over 90 days and participate in weekly live sessions with a counselor.

If you agree to participate and provide contact information you will be sent the first survey. The surveys will ask about smoking, drinking, other substance use, how you use social media, and demographic information (e.g., age, ethnic background, school, and employment history). They will each take you about 20-25 minutes to complete.

Once you have completed the survey, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor the study staff can choose the group you will be in. You will have an equal chance of being placed in either group. If you are interested and eligible, you will be invited to a completely private ("secret") Facebook group where we will conduct the group with participants like yourself and our study staff. You will be asked to remain in the group for 90 days and comment on one of our posts once a day for three whole months.

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

If you are in Group 1 -

Participants in the Group 1 will be invited to a private group on Facebook along with other people who feel the same way about smoking and drinking as they do. Participants will be notified when the group officially begins. STAND staff will be posting daily posts to the secret Facebook group for 90 days and you are encouraged to join in the discussions, but your participation is completely voluntary. There will also be times when you can talk directly with a counselor through the secret groups if you choose. You will have access to the secret group for 12 months from the day you join the group.

If you are in Group 2...

Participants in Group 2 will be invited to a different type of private Facebook group along with other people who feel the same way about smoking and drinking as they do. Participants will be notified when the group officially begins. Group format will be the same as group 1 but the posts will be different than in Group 1. There will also be times when you can talk directly with a counselor through the secret groups if you choose. Participation is completely voluntary. You will also have access to the secret group for 12 months from the day you join the group.

No matter what group you are in, all participants will be offered a free 14-day starter pack of nicotine patches. However, use of the nicotine patch will not be required for study participation. The typical length of a Nicotine patch use for maximum effect is 8 weeks. Participants will be encouraged to use the patches as recommended in the directions on the nicotine patch packaging. As per guidelines from the generic nicotine patch package, if Participants who smoked >10 cigarettes per day will start with step 1

i.e, 21mg pack and if they smoked <10 cigarettes per day they would start with 14mg pack and then move to 7 mg.

After the active part of the group is over (90 days) we will ask you to complete a survey. This survey will ask you some questions about what you liked or disliked about being in the Facebook group, and some other questions about smoking, alcohol, and other substance use. If, upon completing this survey, you report that you have quit smoking we will ask you for your postal address in order to send you a saliva test kit to confirm that you have indeed quit smoking. We will ask you to complete the test kit and email or Facebook message us a picture of the test results.

We will send you two additional surveys: one 6 months from now and another 12 months from now. You will be paid for completing each survey. If, upon completing these surveys, you report that you have quit smoking we will ask you to complete another saliva test kits and send us your results via email or Facebook messenger.

How long?

You will be enrolled in the study for 12 months; our study asks you to remain in a secret Facebook group for three months, where we will ask you to respond to one post a day, estimating that you may spend about 5-10 minutes a day for 90 days. You will also be asked to complete 4 surveys that will each take will take about 20-30 minutes to complete.

What side effects or risk can I expect from being part in the study?

1. Adverse effects due to use of nicotine patch: You may have side effects while using the nicotine patch. Possible adverse side effects of the nicotine patch include nausea/vomiting, sleep disturbances, headaches, flatulence, and local skin irritation. If you have any concerns about using the patch, you can share them in your Facebook group in live sessions with a smoking cessation counselor.

Please note that the study team is not a substitute for professional medical diagnosis, care, and treatment and participants should seek the advice of their personal physician where they reside regarding any side effects that they report to the study team.

Please initial below if you understand the following -

Initials	Understanding the Risks of the nicotine patch
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_____ Pregnant women and people with serious health issues should talk to their doctor before using NRT. Serious health issues can include lung disease and heart problems.

_____ **If you are pregnant or breast-feeding, we will not distribute the nicotine patch to you as part of this study.** Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known, so we will not be giving it to you through our study.

_____ I understand that reporting side effects to the study team is not a substitute for professional medical diagnosis, care, and treatment.

_____ I understand and agree that I will seek the advice of my personal physician where I reside regarding any side effects that I report to the study team.

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2. Randomization risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective than the other study treatment(s) or other available treatments.

Are there any risks to my privacy?

Participation in research can cause a loss of privacy. The researchers will keep information about you as confidential as possible, but due to the nature of Facebook, complete confidentiality cannot be guaranteed. Additionally, University of California may look at Research Records after the study is complete.

Although we will do our best to protect your study information (see below), there is still a risk of loss of privacy. Any information that you disclose on Facebook as part of this study may be shown to others in your Facebook network, depending on your privacy settings and the terms of agreement dictated by Facebook. Furthermore, although Facebook groups are entirely private, participation in the group may make your Facebook profile name known to other users who are also part of the study. Your Facebook profile name will not be connected to your survey responses in any way. The

completed surveys will be kept secure and separate from information which identifies you including your name, email, and phone number. Only a small number of researchers will have direct access to completed surveys. If this study is published or presented at scientific meetings, names and other information that might identify you will not be used.

Each person can only complete each survey one time. In order to help us make sure this happens, we will also keep track of your computer's IP address. The IP address will not be linked to your survey data in any way.

In order to send you the surveys to complete, and to send you compensation for study participation, we will ask for your email address and phone number if you agree to participate in the study. If you give us your email address and/or phone number, we may send you a secure, encrypted email or text message asking you to complete the each survey. The email address or phone number you provide will not be linked to your survey data.

So that we may verify that you are a real person we will also ask you to take a picture of an ID that has your name, a picture of you, and your birthdate (like a driver's license) or a screenshot of your Facebook profile with your name, picture, and birthdate so that we can make sure you are eligible to participate in the study.

Finally, some of the survey and/or group questions may make you feel uncomfortable or raise unpleasant memories. You are free to stop the surveys or the group at any time.

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 incidents such as 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 releasing information 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.

Are there benefits to taking part in the study?

You may benefit by changing your smoking or drinking habits, and perhaps eventually quitting smoking or drinking, but this cannot be guaranteed. However, the information

that you provide may help health professionals better understand/learn more about tobacco and alcohol use among young adults through social networking sites.

Can I say “No”?

Yes, you do not have to complete any surveys or participate in the secret groups. If you choose not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from UCSF if you are a patient.

Are there any payments or costs?

There are no costs for participating in this study.

Will I be paid for taking part in the study?

You are able to earn a total of \$155 for participating in this study. You may receive \$25 for completing the initial survey, \$30 for commenting on all of the 90 posts on Facebook over 90 days, \$25 for completing the survey at the end of 3 months, another \$25 for completing a survey in 6 months and another \$25 for completing our final survey in 12 months. Finally, if you complete all four surveys you will earn a bonus of \$25.

What are my rights if I take part in the 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 in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor [National Institute on Drug Abuse], depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Who can answer my questions about the study?

If you have any questions concerning this research study, please do not hesitate to contact our study staff. [REDACTED]

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814 or email at irb@ucsf.edu.

Thank you for considering our study. Your participation is greatly appreciated.

Please check one of the boxes below:

- ☐ Yes, I agree to participate in this survey.

- No thanks, I would not like to participate.

Please sign below using your mouse/finger (if using a touch screen) if you agree to participate -

 **SIGN HERE**

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