

NCT04110756

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

Study Title: Promoting Adolescent Health Behavior Change with Clinically Integrated
Sample-Efficient Policy Gradient Methods

Research Project Director:	Elizabeth Ozer, PhD, Professor of Pediatrics. UCSF, [REDACTED], San Francisco, CA. [REDACTED]
Study Coordinator:	Alison Giovanelli, [REDACTED] [REDACTED] Marianne Pugatch [REDACTED] Carlos Penilla, [REDACTED] [REDACTED]

This is a study about developing an interactive computerized game for teenagers that focuses on teenage health and well-being, and particularly decreasing alcohol use. The principal investigator of this study is Elizabeth Ozer, Ph.D., from the Department of Pediatrics of the University of California, San Francisco (UCSF). The study research assistant or one of the study coordinators will explain this study to you.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a teenager between the ages of 14 and 17 who might provide useful information for the researchers who are developing the computer system.

Why is this study being done?

The purpose of this study is to develop an interactive computerized game for teenagers that focuses on teenage health and well-being, and particularly decreasing alcohol use.

This study is funded by the National Institutes of Health/National Cancer Institute.

How many people will take part in this study?

About 200 teenagers will take part in this study. If you agree, you will interact with a computerized game for health for teenagers.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

- The study researcher will email teenagers a link to a computerized game for health.
- Teenagers will interact with the computerized game for health which takes an average of about 30 minutes to play. Teenagers will also be asked to complete survey questions electronically on the computer immediately before and after playing the game. The survey asks questions about themselves and about their experiences interacting with the computerized game.
- Study location: The teenager will interact with the computerized game at home on their tablet (phone or computer).

How long will I be in the study?

Your participation in the study, including interacting with the computerized game for health and completing the survey electronically, will take approximately 60 minutes.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher if you decide you no longer want to participate in the study.

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

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

- There are no physical risks to participating in the computerized game for health . It is possible that you might feel

some discomfort in the time spent participating in the game and in some of the health topics explored. You do not have to engage in any part of the game that you are not comfortable with and you can stop game play at any time.

- One risk to participating in any research is a loss of privacy. Every effort will be made to protect your confidentiality. There is the chance that other teenagers will talk about what was discussed in the focus groups afterwards, and they will be asked not to do this. Additionally, you may be asked questions on a confidential survey about prior use of alcohol to help best interpret our research intervention. This information will not be shared with anyone else outside the research team and responses will not be able to be linked to any individual. No individual person will be named in publications or reports resulting from the study.
- In the case that you describe physical or sexual abuse from a parent or other adult, or you express intent to harm yourself or others, the study researcher is required to report this information to others to obtain the help you need, which would result in a loss of privacy.
- For more information about risks, you can ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help other teenagers who will receive important information about health behaviors, particularly alcohol use.

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

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study 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.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid in a \$30 gift card for taking part in this study.

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 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.

Who can answer my questions about the study?

You can talk to the study researcher(s) about any questions or concerns you have about this study. If you would like to talk to the primary researcher, please contact Dr. Elizabeth Ozer [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 office of the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

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

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date

Parent or Legal Guardian