Evaluation of the Be Vape Free Curriculum of the Tobacco Prevention Toolkit

Informed Consent Form

NCT05493982

July 9, 2025

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Bonnie Halpern-Felsher, Ph.D.

Protocol Title: Evaluation of the Be Vape Free Curriculum of the Tobacco Prevention Toolkit

PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Bonnie Halpern-Felsher, Professor of Pediatrics, Stanford University, 3145 Porter Drive, [redacted], Palo Alto, CA 94304

CONCISE SUMMARY:

Purpose: Dr. Halpern-Felsher is seeking consent to participate in a voluntary research study to evaluate an e-cigarette prevention curriculum developed at Stanford University called You and Me, Together Vape-Free.

Procedures:

- Half the schools in the study will teach the Stanford curriculum; the other half will teach either another vaping/e-cigarette prevention curriculum or no curriculum at all.
- 2, 20-minute online surveys which include questions on nicotine, cannabis products and dependence on those products (addiction).
  6 additional surveys over the next 3 years.
  Some students who receive the Stanford curriculum may be invited to participate in a 1-hour interview regarding their thoughts about the curriculum.

Risks: Discomfort with some survey questions; responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study; potential loss of privacy with respect to participation in the study and to survey responses.

Benefit: We cannot and do not guarantee or promise that your child will receive any benefits from this study.

Alternatives: Receive whatever health education, including vape/e-cigarette prevention information your school provides but not participate in the study surveys.

DESCRIPTION: You are invited to participate in a research study being conducted by Dr. Bonnie Halpern-Felsher from Stanford University to evaluate a curriculum of the Stanford Tobacco Prevention Toolkit.

1. The Toolkit is a free online educational curriculum for use by teachers to provide health education lessons to students regarding tobacco products.
2. This study is being funded by the U.S. National Institutes of Health.
3. Information from this study will help the designers of the Stanford Tobacco Prevention Toolkit evaluate its effectiveness in teaching students about tobacco products and the potential risks associated with their use.

Key elements in the study to evaluate the new curriculum are the following:

- We will be comparing schools who use the Toolkit for tobacco education to schools that use another curriculum or that do not use a formal curriculum at all.
- There is an approximately 50% chance that your child's school will be using the Toolkit curriculum or another curriculum.
- In accordance with the design of this evaluation, the research study is looking for 10,800 students from approximately 60 schools primarily in California along with some schools in other parts of the United States.

The evaluation consists of a series of surveys that will include questions about the following:

1. participants' knowledge regarding tobacco products generally and familiarity with specific tobacco products whose use among your child's age group is of high concern such as cigarettes and electronic cigarettes (e-cigs or vapes)
2. perceptions of risk associated with and attitudes toward use of these tobacco products; about how acceptable using these products is to participants
3. participants' use of these tobacco products and/or openness to using them in the future
4. participants' sociodemographic characteristics such as age, grade and race/ethnicity.

The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement of the consent, we do not intend to disclose this information.

If you agree to be in this study, the following will occur:

1. You will sign this form consenting for your child to participate in this study. If you are a parent consenting for your child, your child will sign the enclosed form assenting to participate in this study. You will complete participant information sheet

2. At school, in the classroom with the teacher, your child will meet the people working on the project and learn about the project. Your child will be taught either the Stanford Tobacco Prevention Toolkit or the school's current tobacco prevention lessons.

3. Your child will then be given a web link. The survey should take a total of about 20 minutes to complete.

4. The study will go on for 3 more years with 6 follow-up surveys. Every 3 to 6 months, your child will receive a reminder requesting that they complete an online follow-up survey, which they will do using a phone, tablet or computer. These surveys will ask the same kinds of questions as the surveys in class. Responding to survey questions is voluntary, and your child may skip any question in the surveys at any time.

You can withdraw consent for your child's participation in the study at any time. Should you want to review a copy of the survey at any point during the study, please contact study coordinator David Cash at [redacted].

5. After the first survey we may ask your child to participate in an interview on topics relating to the study. Participation in this additional activity is voluntary, and declining to participate in an interview will not affect their participation in other parts of the study. If you consent and they agree to participate in the interviews, your child will receive incentives for these additional efforts. Interviews will be audio recorded and transcribed, and identifying information will then be removed from the transcripts prior to analysis. Recordings will then be destroyed.

Do you give consent for your child to be audiotaped during this study:

Please initial: ___Yes ___No

Future use of Private Information

Your child's information will not be used or distributed for future research studies even if all identifying information is removed. It is possible that based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

A description of this randomized controlled 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.

RISKS AND BENEFITS: The risks associated with this study are potential loss of confidentiality and discomfort in answering survey questions.

In this study, your child will be asked about personal use of tobacco and tobacco-related products (such as cigarettes and electronic cigarettes). The researchers will keep information about your child as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions research records have been subpoenaed by a court. However a Certificate of Confidentiality has been issued by the National Institutes of Health to this research project to shield records from legal proceedings.

Also, it may be inconvenient to participate in this study due to the time required to fill out the surveys. Also, some of the questions may be uncomfortable to answer. Your child has the right to refuse to answer particular questions and may withdraw from the study entirely at any time.

We cannot and do not guarantee or promise that your child will receive any benefits from this study. However there are potential benefits to future students as we try to measure the effectiveness of the Stanford Toolkit curriculum versus other tobacco education curriculums.

Your decision whether or not to participate in this study will not affect your child's grades or other school status.

TIME INVOLVEMENT: Your child's participation in this experiment will take approximately 2.5 hours over the course of 3.5 years: 2 15-minute surveys followed by 6 20-minute surveys

An additional hour would be required if your child is invited and chooses to participate in interviews later in the study.

PAYMENTS: As an incentive for participation in the study, your child will be provided with a $[redacted] gift card link for each survey completed.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to consent to your child's participation in this project, please understand your child's participation is voluntary and you have the right to withdraw your consent or discontinue your child's participation at any time without penalty or loss of benefits to which your child is otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your child's identity will not be disclosed**.** Your child has the right to refuse to answer particular questions.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse, neglect, or reports or threats of harm to self or others.

Authorization To Use Your Child's Health Information For Research Purposes

Because information about your child and your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your child's health information will be used or disclosed in the study. Your child's information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to evaluate the effect of The Stanford Tobacco Prevention Toolkit curriculum on participants' perceptions of and attitudes towards tobacco products and their use. Participants will be asked about personal use of tobacco products at various time points in order to determine whether or not the curriculum influences changes in participants' tobacco use.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, your child will not be able to participate in this research study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Bonnie Halpern-Felsher, Department of Pediatrics, 3145 Porter Drive, [redacted], Palo Alto, CA 94304
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What Personal Information Will Be Obtained, Used or Disclosed?

Your child's health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, name, phone numbers, electronic mail address, date of birth, school name, parent contact

information (email & cell number), participant street address, additional contact name and phone number, race and ethnicity, tobacco and cannabis use, and mental health indicators.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your child's health information in connection with this research study:

- The Protocol Director Dr. Bonnie Halpern-Felsher
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your child's health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The U.S. National Institutes of Health

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your child's health information will end on December 31, 2035 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____

Signature of Legally Authorized Representative (e.g., parent, guardian or conservator) Date

_____

Print Name of Legally Authorized Representative (e.g., parent, guardian or conservator)

_____

Legally Authorized Representative's Authority to Act for Participant (e.g., parent, guardian or conservator)

WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw your child from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to your child.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

SPONSOR: The U.S. National Institutes of Health is providing financial support and/or material for this study.

CONTACT INFORMATION: Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director Dr. Bonnie Halpern-Felsher, 650-724-1981. You should also contact her at any time if you feel your child has been hurt by being a part of this study.

Alternate Contact: If you cannot reach the Protocol Director, please contact Project Coordinator David Cash at [redacted].

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

The extra copy of this signed and dated consent form is for you to keep. If you are completing this consent online, a signed pdf copy will be available to you to save once you submit the form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative Date
(e.g., parent, guardian or conservator)

_____
Print Name of Legally Authorized Representative

_____
Legally Authorized Representative's Authority to Act for Participant
(e.g., parent, guardian or conservator)

The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature of Witness Date

_____

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*