Feasibility and Acceptability of the Cannabis Awareness and Prevention Toolkit

Informed Consent Form

NCT05521321

June 30, 2024

IRB Use Only
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PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY

☐ 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, [redacted] Palo Alto, CA 94304; Phone: 650-724-1981

Dr. Bonnie Halpern-Felsher, Professor of Pediatrics is recruiting California middle school students to participate in a research study to evaluate a health education curriculum called the Stanford Cannabis Awareness and Prevention Toolkit (CAPT) among California middle school students. Half the schools in the study will teach Stanford Cannabis Toolkit; the other half will teach either another curriculum or teach no cannabis-related curriculum at all. Study activities consist of students completing two 20-minute online surveys in class this fall 2022 and one 30-minute online follow-up survey approximately 6 months later. Some students who receive the Stanford curriculum may be invited to participate in 1-hour interviews regarding their thoughts about the curriculum.

Dr. Halpern-Felsher is seeking consent of parents/guardians for students to participate in this research study. Participation is voluntary. Parents/guardians may withdraw consent for their child's participation at any time, and participating students may withdraw their assent to participate in the study themselves at any time without penalty.

Risks to participants in the study include discomfort with some survey questions and potential loss of privacy with respect to participation in the study and to survey responses. Surveys include questions regarding participant use of cannabis products and dependence on those products (addiction). The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. However, participants are free to skip any questions with which they are uncomfortable. We cannot and do not guarantee or promise that your child will receive any benefits from this study.

If you choose not to participate in this study, the alternative is to receive whatever health education, including cannabis prevention information that your school provides but not

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participate in the study surveys. Students will receive health education instruction provided by their schools regardless of participation in the study.

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 Cannabis Awareness and Prevention Toolkit. The Toolkit is a free online educational curriculum for use by teachers to provide health education lessons to students regarding cannabis products. This study is being funded by the U.S. National Institutes of Health. Information from this study will help researchers, educators and other health professionals who have designed the Stanford Cannabis Awareness and Prevention Toolkit to evaluate its effectiveness in helping teachers communicate with students about cannabis products and the potential risks associated with their use.

In order to evaluate the Stanford Cannabis Awareness and Prevention Toolkit, we will be comparing schools who use the Toolkit for cannabis 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 chosen to use the Stanford Cannabis Toolkit curriculum or chosen **not** to use the Stanford Cannabis Toolkit curriculum but rather another curriculum or to provide no substance use prevention education at all. In accordance with the design of this evaluation, the research study is looking for 600 students from approximately 4 California schools.

The evaluation consists of a series of surveys that will include questions about participants' knowledge regarding cannabis products generally and familiarity with specific cannabis products whose use among your child's age group is of high concern such as smoked cannabis, edibles, and cannabis consumed in electronic cigarettes (e-cigs or vapes); about perceptions of risk associated with and attitudes toward use of these cannabis products; about how acceptable using these products is to participants; about participants' use of these cannabis products and/or openness to using them in the future; and about participants' sociodemographic characteristics such as age, grade and race/ethnicity.

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, then your child will sign the enclosed form assenting to participate in this study. You will complete the enclosed participant information sheet in order to provide us with contact, demographic and other information.

2. On the first day of the study, 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 have either received instruction using the Stanford Cannabis Awareness and Prevention Toolkit or have received instruction using another cannabis prevention curriculum,

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whichever your child's school currently uses. Your child will then be given a web link to a survey that asks about your child's age, grade, personal views and knowledge of and personal experiences with different cannabis products, including smoked cannabis, edible cannabis and cannabis consumed in electronic cigarettes (e-cigarettes or vapes). Your child should have time to complete the survey in class. However, he/she/they may be asked to complete it at a later time using a smart phone, tablet or computer. The survey should take a total of about 20 minutes to complete. Another survey will be implemented with your child at the end of the curriculum lessons. This survey will also take about 20 minutes to complete.

3. The study will go on for 6 more months with one additional follow-up survey. Six months after the initial surveys, your child will receive an electronic reminder, either through email or text depending on their preference, requesting that they complete an additional online survey. He/she/they will then click on the link to complete the survey using a smart phone, tablet or computer. If for some reason your child cannot access surveys through the Internet, the survey can be mailed to them. This survey will ask about your child's personal views and experiences with different products, including edibles, smoked cannabis and cannabis consumed in electronic cigarettes (e-cigarettes or vapes).

This survey should take 30 minutes to complete. You can withdraw consent for your child's participation in the study at any time.

4. After the first surveys 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 them will not affect their participation in the 6-month online survey in any way. If you consent and they agree to participate in the interviews, your child will receive incentives for these additional efforts. Invitations to these additional activities will contain relevant details and information. If your child participates in an interview, it will be audio recorded and transcribed and identifying information will then be removed from the transcripts prior to analysis. Voice recordings will then be destroyed.

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 and 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.

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

In this study, one of the things your child will be asked about is personal use of cannabis products (such as smoked cannabis, edible cannabis, and vaped cannabis). The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. 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. Please see below regarding the Certificate of Confidentiality for this study.

Also, it may be inconvenient to participate in this study due to the time it requires 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 cannabis 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 1.5 hours over the course of 1 year: 2 20-minute surveys followed by 1 30-minute survey

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

PAYMENTS: As an incentive for participation in the study, your child will be provided with a $10 gift card link for each survey.

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.

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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, documents, or biospecimens 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, documents, or biospecimens 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.

A description of this clinical 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.

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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 Cannabis Awareness and Prevention curriculum on participants' perceptions of and attitudes towards cannabis products and their use. Participants will be asked about personal use of cannabis products at various time points in order to determine whether or not the curriculum influences changes in participants' cannabis 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, [redacted], Palo Alto, CA 94304.

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, street address, electronic mail address, date of birth, school name and location, parent contact information, backup contact name, phone numbers and

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email addresses, race and ethnicity, and use of cannabis products. Health information includes your child's use or non-use of cannabis and questions that indicate whether or not they may be dependent on cannabis products.

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

_____
Print Name of LAR

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

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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.

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

_____
Print Name of LAR

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

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

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant

The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).

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 ("summary form"):
  > 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.