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Study Name: Helping Eliminate Marijuana use through Pediatric Practice

NCT Identifier: NCT02744118

Study Consent Form Document Date: September 2018

AMERICAN ACADEMY OF PEDIATRICS
Julius B. Richmond Center of Excellence

ADOLESCENT CONSENT FORM

(Ages 18 and older)

Study Title: Adolescent Health in Pediatric Practice (AHIPP)- PHASE 3

Principal Investigator: V. Fan Tait, MD

Introduction and Purpose of the Study

You are being asked to participate in a research study. We are conducting this research study to find out about young people's health behaviors, and what health behaviors are normally discussed when you visit the doctor's office. You are being asked to participate because you are age 13 years or older. Approximately 900 young people from up to 10 doctors' offices will participate in the study. This study is being run by Dr. Fan Tait from the American Academy of Pediatrics (AAP) Julius B. Richmond Center of Excellence. The Richmond Center is being funded by the National Institute on Drug Abuse to conduct this research study.

Description of Study Procedures

If you decide to participate in the study:

- You will be asked to fill out a survey before you see your doctor, taken on an iPad device. The survey will take approximately 2-3 minutes to fill out. It asks about behaviors that some young people engage in (for example, marijuana use).
- Twenty percent of the participants who enroll will be asked to participate in a follow-up telephone survey in approximately 3-6 weeks. If you are chosen to participate in this survey, you will be contacted by the phone number you provide to the research team, as well as texted or emailed about the survey. The follow-up survey will take about 15-20 minutes to complete, and you will be asked about behaviors that some young people engage in that can affect their health. You will receive a $10 gift card by mail as a thank you for completing the survey.
- If you decide to take part in the study, you will be asked to provide your name, address, preferred phone number(s) and preferred email address on an electronic form that is sent to the research team. We will use this information to contact you for the telephone survey and will use your address to send you a $20.00 gift card by mail after the telephone survey is completed. This information will only be used to contact you for these purposes. We will not connect your name or other information. to your survey responses. If the research team attempts to contact you for follow up and finds that the phone number that you have provided is a disconnected/wrong number, the research team may contact your physician's office to obtain updated contact information.
- All information that you provide during the study is confidential which means your privacy will be protected at all times. No one, including your parents/legal guardians, your doctor or the office staff will be able to know your survey responses. The only time we would break confidentiality is if you tell us of anything likely to result in harm to yourself or others.
- If any of the research study questions are disturbing to you, or if you change your mind about participating, you can refuse to answer the questions or drop out of the study at any time.

Risks of Participation
There are minimal risks for your participation in this study. There is a potential risk of embarrassment. It may be inconvenient to spend time completing the survey. There is also the potential risk of accidental breach of confidentiality. Every effort will be made to avoid these risks.

Benefits of Participation
There are no direct benefits to participation. However, teens may benefit from health behavior information.

Alternative Procedures
You may choose not to take part in this research study.

Additional Costs
There will be no additional costs to you to participate in this research study.

Payments
If you participate in the study, you can receive compensation up to $30 value as a thank you for your time and participation: $10 for completing today's survey, and $20 if you participate in the telephone survey. Compensation will be provided in the form of a giftcard, which will be mailed to you using the contact information that you provide.

Permission to Use Your Personal Health Information
The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use your health information that will be collected as part of this research study. This section gives you information about what health information will be collected in this study, who will use this information and why, who the information will be given to, your rights to see your health information during the study, and your right to withdraw your authorization (approval) for any future use of your health information.

By signing this form, you are allowing your doctor's office to give the health information collected about you during this study to researchers and staff at the American Academy of Pediatrics and the National Institutes of Health.

The following personal health information about you will be collected and given to the research team: date of your visit, age, gender, ethnicity, race, and insurance status. In addition, the surveys will collect information about your health behaviors such as marijuana use and where you go for health information. This information will be used for the research purpose described on Page 1 of this form.

You will be given a code number. The key to this code number will be kept in a locked file and will be destroyed at the end of the research study. The exception to this will be the information collected so you can be contacted for the follow-up telephone survey. This information will only be given to staff that conduct the telephone surveys for the sole purpose of contacting you and will be destroyed after the surveys are conducted.

Your approval will be in effect until the study is complete or you cancel it. This information may be kept in a research repository (database). However, the research team may not re-use your information or give it to anyone else for another purpose other than the research study described in this form unless it gets permission to do so from the American Academy of Pediatrics Institutional Review Board.

Information collected solely for this research study that is not part of your regular care will be sent to the research team and will not be kept in your medical record. During your participation in this study, you will be able to see your medical record. The investigator is not required to give you information in the research records.

You may change your mind at any time and decide that you do not want your personal health information used or given to the research team. If this happens, you or your parent or guardian may contact the principal

investigator, Dr. Fan Tait, either by phone, by email, or in writing. She may be contacted at the phone number listed below in the "Contact Persons" section. Even if you withdraw your permission, the research team may still use your personal health information that was collected before your withdrawal of permission if that information is necessary for completing the study. If you withdraw your permission to use your information, you will be taken out of the research study.

You do not have to sign this authorization. If you decide not to sign, it will not affect your treatment by your doctors, the payment or enrollment in any health plans, or your eligibility for benefits. However, you will not be allowed to participate in the research study.

You will be given a copy of this form describing your confidentiality and privacy rights for this study. By signing this document you are permitting your doctors to give your personal health information to the research team for the research purposes described above.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). Confidentiality will be broken in cases where you reveal something that may cause immediate harm to yourself or others, including abuse and neglect; this is legally required to be reported. You should understand that 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Additional Confidentiality Measures

You will be given a confidential Patient Identification Number. Your name and other identifying information will not be written on any study materials that are sent to the research team other than on the electronic form that lists your contact information for the telephone survey. The information will be kept strictly private. Results of the study may be reported in scientific papers or at meetings but your name and other information will not be used. All surveys, data forms and any other study-related materials will be kept in a secured location at the AAP for 10 years following the conclusion of study data collection and then destroyed.

Voluntary Participation

Participation in this study is voluntary. This means that you are free not to participate or to drop out at any time, for whatever reason. If you choose not to participate, drop out, or are withdrawn by a parent/guardian, your present or future care will not be affected.

Contact Persons

If at any time you have a question about the study, you may feel free to contact V. Fan Tait, MD (principal investigator) at [redacted]. If at any time you have questions about your rights as a research subject, you may contact the IRB Administrator at the American Academy of Pediatrics, Erin Kelly, PhD, at the following toll-free number between 9:00 am and 4:00 pm, Central Time on weekdays: [redacted].

Signatures/Dates

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a **signed** copy of this form for my records and future reference.

Print Name: _____

Signature: _____

Date: _____

Office Staff Person Obtaining Consent

I have read this form to the *subject* and/or the *subject* has read this form. I will provide the subject with a signed copy of this form. An explanation of the research was given and questions from the *subject* were solicited and answered to the *subject's* satisfaction. In my judgment, the *subject* has demonstrated comprehension of the information.

Print Name and Title: _____

Signature: _____

Date: _____