

A Digital Intervention to Prevent Initiation of Opioid Misuse in Adolescents in  
School-based Health Centers

NCT04109599

Informed Consent

3/9/2021

## COMPOUND AUTHORIZATION AND PARENTAL PERMISSION FOR PARTICIPATION IN A RESEARCH PROJECT

### YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

**Study Title:** “A digital intervention to prevent the initiation of opioid misuse in adolescents in school-based health centers”

**Principal Investigator:** *Lynn E. Fiellin, MD*

**Funding Source:** Department of Health and Human Services (*National Institute on Drug Abuse*)

### *Pilot Testing Parent/Guardian- Virtual*

### Research Study Summary

We are asking your child to join a research study.

- The purpose of this research study is to help us learn more about what types of things should be included in a videogame in order to help teens make good decisions while they are playing the videogame and in real life.
- Study activities will include: 1) your teen playing an iPad or sitting at a computer to play an original game developed by the play2PREVENT Lab, 2) your teen answering questions about their experience playing the game, and their thoughts, attitudes and knowledge around a health topic.
- Your teen’s involvement will require 1) 60 minutes of their time after school, two to three times per week, for two weeks (six sessions total) and 2) a signed parent/guardian permission form.
- There are no known risks of physical or psychological injury or inconveniences associated with this research project.
- The study may have no benefits to your teen. The study may help the researchers find out something that will help other teenagers later.
- Taking part in this study is your teen’s choice. They can choose to take part, or they can choose not to take part in this study. They can also change their mind at any time. Whatever choice they make will not have any effect on their relationship with their school or the research staff.
- If you are interested in learning more about the study, please continue reading or have someone read to you the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish for your teen to participate; if so, you will have to sign this form.

The misuse of opioid drugs has become a major problem in this country. Most opioid misuse begins during adolescence and young adulthood, with close to 40% of opioid misuse occurring during this time. Given the importance of this problem to the health and future of our youth, it is very important to develop ways to prevent the initiation or start of opioid misuse in youth. Videogames as interventions have the advantage of meeting adolescents “where they are,” while also being engaging and delivering important information. The purpose of this study is to develop and test an original videogame developed by the play2PREVENT Lab that aims to teach teens about making positive decisions around risky behaviors including around misuse of drugs such as opioids.

## **Invitation to Participate and Description of Project**

Your teenager is being invited to participate in a research study to help our research team learn more about what types of things should be included in a videogame in order to help teens make good decisions while they are playing the videogame and in real life. The study will focus on promoting healthy behaviors in adolescence and on providing strategies to assist adolescents in making decisions about the many challenges they face including those related to opioid misuse.

To help you decide whether or not you want your teen to participate in this research study, you should know if there are any risks and benefits to participating. This form gives you detailed information about the research study, which a member of the research team will discuss with you and your teen. We will go over all aspects of this research: its purpose, what will happen during the pilot testing, any risks, and possible benefits. Once you understand the study, you will be asked if you agree to allow your teen to participate. If so, you will be asked to sign this form.

## **Description of Procedures**

The purpose of this study is to learn more about how playing a videogame might help teens make good decisions while they are playing the videogame and in real life. In order to participate in this study, your teen must be between the ages of 16 and 19 and be willing to sit with a device (e.g., computer, iPad, etc.) and play a videogame for 60 minutes two to three times per week for two weeks (6 sessions total).

Your teen will play a game that is designed to be fun and engaging, while promoting healthy behaviors in adolescence, and providing strategies to assist adolescents in making decisions about the many challenges they face. Your teen's participation in this research study will be voluntary and confidential.

Your teen will be asked to play a videogame as well as complete questions after they play the videogame. After they finish playing the videogame, they may also be asked to answer a few more questions about their experience with the game that will be audiotaped. They may choose not to be audiotaped and still participate in pilot-testing. The goal of these questions is to learn whether they thought playing the game was fun, boring, or interesting, and what they would change about the game, the characters, and the storylines to make it better.

The study will require approximately 6 sessions (1 hour each) over the course of approximately 2 weeks. If you and your teenager decide that your teen will participate, here is what will happen: During your teen's first meeting, your teen will be asked to sign an adolescent assent form. Your teen will then begin the gameplay portion of the project, where they will play a videogame on their electronic device at home. A member of the research team will be available for help if needed at all times.

At the following meetings, your teen will continue the gameplay portion of the project. At the end of all gameplay sessions, your teen will be asked to complete a set of assessment questions that will take approximately 10-15 minutes to complete. The assessment questions will ask about their gameplay experience and knowledge they might have gained from playing the game. During the same time, they may be asked to participate in a group interview about their experience playing the game that will be audio recorded. The goal of these questions is to learn whether they thought playing the game was fun, boring, or interesting, and what they would change about the game, the characters, and the storylines to make it better. Questions such as: What did you think the goal of the game was? Your favorite and least favorite moment in the game? Was the game fun? will be asked. Your teen can decline to be audio recorded and still participate in the pilot project.

**Your child's participation in this research study will be voluntary and confidential.**

### **Risks and Inconveniences**

There are no known risks of physical or psychological injury or inconveniences associated with this research project. If your teen becomes very tired or uncomfortable, one of the researchers would ask them if they would like a break or discontinue participation in the videogame play or completion of assessments at that time and resume it at an acceptable time for them.

However, there is a slight risk regarding the confidentiality of your teen's participation in this study, if information about your teen becomes known to persons outside this study. The researchers are required to keep your teen's study information confidential; however, so the risk of breach of confidentiality is very low.

### **Benefits**

Your teen may not benefit from the study directly, but the study may help the researchers find out something that will help other teens later.

### **Economic Considerations**

Your teen will receive two gift cards for completing the pilot study. They will receive a \$20 gift card half way through their gameplay sessions (Session 3) and then a \$40 gift card at the end of the last session (Session 6). The total possible compensation for this study is \$60 per participant.

### **Confidentiality and Privacy**

If you decide to have your teen take part in this research study, all of the information that they give us, at all points in the study is confidential and available only to the people actually working in the study. Their name will not appear on any study materials. A study number will be used to identify such materials. The link between participant's identity and the study number is confidential and will be kept separate from all study data. Research data is kept in cabinets that are locked except when in use, and access to data stored in computers is password protected.

The Yale University Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records. All published results will be group data without identifying any individual information. Information that will be collected during the assessments and interviews will be erased 12 months after the completion of the study and after review of their content has been completed.

Audiotaped interview sessions about gameplay experience: Your teen's name will never be recorded on the tapes and the tapes will be coded by a number rather than a name in order to protect your teen's confidentiality. Your teen may decline to have their voice audiotaped during questions about their gameplay experience.

If we are worried by something we hear from your teen such as they are being harmed, we will let you know and we will discuss this with you. In addition, information may be released if we are worried about abuse, neglect, or harm to your teen or others. We will contact authorities if this is the case.

All members of the research team have completed mandatory reporter training; this includes mandatory reporting for abuse and neglect to appropriate officials via Careline at 1-800-842-2288. Suicidal risk will be reported to school official as well as parent/guardian. In extreme cases, 9-1-1 will be called.

Data may be shared by the following additional groups:

- Department of Health and Human Services-National Institute on Drug Abuse (Study sponsor)
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

By signing this form, you let us use the information in the way we described above for this research study. This authorization to use and disclose information collected during your teen's participation in this study will never expire.

The research staff at the Yale School of Medicine has to obey the privacy laws and make sure that your teen's information stays confidential. Some of the people or agencies listed above may not have to obey those laws, which means that they do not have to protect the data in the same way we do. They could use or share your teen's information in ways not mentioned in this form. However, to better protect your teen's health information, agreements are in place with these individuals and/or companies that require that they keep your teen's information confidential.

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 your teen 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 teen's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent your teen from voluntarily releasing information about themselves or their involvement in this research. If you want your teen's research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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

**What Information Will We Collect About Your Teen in this Study?**

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your teen’s health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

The specific information about your teen’s health that we will collect, use, and share includes:

- Your Name, telephone number, email address, your child’s name, phone number, and email address
- Research study records
- The entire research record held by the **Yale School of Medicine** created from 12/01/2019 to 11/30/2021.
- Records about phone calls made as part of this research
- Records about your teen’s study visits
- Information obtained during this research regarding
  - Field notes and questionnaires
  - Records about the study device

### **Investigator Interest**

Dr. Lynn Fiellin is the Principal Investigator for this study and is a Founder and on the Board of Directors of a new Yale company that will help to distribute game products such as the one developed and evaluated in the research project in which your child will be participating in order to help get the game intervention to teens who may benefit from it. There are no plans to provide financial compensation to any participants in the study or their families beyond the compensation your child will be receiving as part of the study. Dr. Fiellin and Yale University have a potential financial interest in this process. You may speak with Dr. Fiellin at any time should you have questions regarding institutional or investigator interests.

### **Voluntary Participation and Withdrawal**

Participating in this study is voluntary, which means you are free to choose not to allow your teen to take part in this study. Refusing to allow your teen to participate will involve no penalty or loss of benefits to which your teen is otherwise entitled (such as health care outside the study, the payment for health care, and health care benefits). However, your teen will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your teen’s information as part of this study.

Withdrawing, meaning you no longer want your teen to be in this study, will involve no penalty or loss of benefits to which your teen is otherwise entitled. If you decide to have your teen quit the study, all you have to do is tell the person in charge. This will not harm your teen’s relationship with his/her own doctors or with Yale-New Haven Hospital. The study investigators may remove your teen from the study if they believe that is in your or your teen’s best interests. You do not give up any of your legal rights by signing this form.

### **Questions**

We have used some technical terms in this form. Please feel free to ask about anything you don’t understand and to consider this research and the permission form carefully – as long as you feel is necessary – before you make a decision.

**Authorization and Permission**

I have read (or someone has read to me) this form and have decided to allow my teenager to participate in the project described above. Its general purposes, the particulars of my teen's involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I may request a copy of this permission form.

By signing this form, I give permission to the researchers to use [and give out] information about my teen for the purposes described in this form. By refusing to give permission, I understand that my teen will not be able to be in this research.

\_\_\_\_\_(Check here.) Parent/guardian gave permission for audiotaping of his/her teen.

Name of Teen: \_\_\_\_\_

Parent/Guardian Name: \_\_\_\_\_

Parent/Guardian Signature: \_\_\_\_\_

Parent/Guardian Telephone Number: \_\_\_\_\_

Parent/Guardian Email Address: \_\_\_\_\_

Date: \_\_\_\_\_

FOR YALE UNIVERSITY ONLY
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\_\_\_\_\_  
Signature of Person Obtaining Permission

\_\_\_\_\_  
Date

If you have further questions about this project or if you have a research-related problem, you may contact the Project Director, Dr. Claudia-Santi Fernandes, at [claudiasanti.fernandes@yale.edu](mailto:claudiasanti.fernandes@yale.edu).

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.