

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*)

Randomized Controlled Trial- Parent/Guardian

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 on an iPad or sitting at a computer to play either an original game developed by the play2PREVENT Lab or a series of commercial games (e.g., Minecraft, Escape the Room), based on their random assignment, 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 during or after school, one to two times per week, for up to 6 weeks (six sessions total); 2) completing assessment questions (that take approximately 20-30 mins to complete) at different time points associated with the study (baseline, post-gameplay [6 weeks], 3 months, 6 months and 12 months); 3) preferably attending a school with a school-based health center and preferably being enrolled in their school’s school-based health center.
- and 4) having a signed parent/guardian permission form.
- 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 your teen if they would like a break or to discontinue participation in the videogame play or completion of assessments at that time and resume at an acceptable time for them.
- Your teen may benefit directly from the study as the purpose of the study is to increase perception of risk of harm from initiating the misuse of opioids, decreasing actual misuse of opioids, as well as improving decision making and knowledge to optimize abilities to negotiate around risky behaviors. The study may help the researchers find out something that will help other teens 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 either electronically with confirmation via videoconferencing or in-person.

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 study, 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 either electronically with confirmation via videoconferencing or in-person.

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 1) be between the ages of 16 and 19; 2) be willing to sit with a device (e.g., computer, iPad, etc.) and play a videogame for 60 minutes during or after school, one to two times per week, for 6 weeks (six sessions total); 3) complete assessment questions (that take approximately 20-30 mins to complete) at different time points associated with the study (baseline, post-gameplay (6 weeks), 3 months, 6 months and 12 months); 4) preferably attending a school with a school-based health center and preferably be enrolled in their school’s school-based health center and 5) have the consent of a parent or legal guardian to participate if they are under 18 years of age.

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 several assessments (questionnaires) before and after they play the videogame. The goal of the assessments is to collect data about their behaviors (what they do) and perceptions (what they think) about opioid misuse, their knowledge of opioid misuse, attitudes and other basic questions about themselves. Your teen 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 the study. 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 6 weeks and 3 additional follow up meetings with the study team to complete questionnaires. 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 and complete assessment questions that will take approximately 20-30 minutes and will be conducted confidentially (their answers will be kept private) in a secured, private location. They will be assigned a study number, so that their answers will be kept confidential. The assessment questions will be supervised by a member of the research team and will be available to help if needed. After completing the initial assessment questions, your teen will then begin the gameplay portion of the project, where they will play the videogame one to two times per week for 60 minutes for 6 weeks in a secured, private location. A member of the research team will be available for help if needed at all times.

After the 6 weeks, your teen will be asked to complete additional assessment questions that will take approximately 20-30 minutes to complete. The assessment questions will ask about their gameplay experience, knowledge they might have gained from playing the game, as well as about their beliefs and attitudes towards opioid misuse. During the same time, they may be asked to participate in an 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 study.

Your teen will also be asked to complete follow-up assessment questions 3 months, 6 months and 12 months after the beginning of the study that will take approximately 20-30 minutes to complete.

Schedule of Assessments

Assessment	Baseline	Post-gameplay	Month 3	Month 6	Month 12
Demographic, substance use and mental health	X				
Perception of Harm Scale	X	X	X	X	X
Intentions to Misuse Opioids	X	X	X	X	X
Self-efficacy to refuse drug use	X	X	X	X	X
Substance use behaviors (includes prescription and illicit drugs, tobacco, alcohol) lifetime and in past 30 days	X	X	X	X	X
Attitudes toward misuse and its risks	X	X	X	X	X
Knowledge about opioid misuse and its risks	X	X	X	X	X

Perceived norms as they relate to opioid misuse	X	X	X	X	X
Decision-making skills	X	X	X	X	X
Gameplay experience surveys and qualitative interviews from adolescent participants who played the game		X			
In-game data		X			

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.

Risk of Remote Consenting: Like online shopping, videoconferencing technology has some privacy and security risks. It is possible that that information could be intercepted by unauthorized people (hacked) or otherwise shared by accident. This risk can't be completely eliminated, however Yale has approved the use of an encrypted version of Zoom for videoconferencing sessions because the appointments take place over a secure network. We want to make sure you are aware of this. Video sessions can be conducted using a smart phone, tablet, or personal computer enabled with a camera/microphone and internet connection. You should use your home computer or personal device, and not a shared network or work device, and use a home (private) Wi-Fi network, and not free (public) Wi-Fi for your internet connection. To use Zoom, an email will be sent to you including for how to log-in. When meeting with the team remotely for study-related activities, you should be in a private space.

Benefits

Your teen may benefit directly from the study as the purpose of the study is to increase perception of risk of harm from initiating the misuse of opioids, decrease actual misuse of opioids, as well as improve decision making and knowledge to optimize abilities to negotiate around risky behaviors. The study may help the researchers find out something that will help other teens later.

Economic Considerations

Your teen will receive a gift card for completing each assessment. They will receive a \$55 gift card for completing the assessments at baseline, a \$35 gift card for the assessment completed right after gameplay (6 weeks) and \$45 gift cards for completing 3-, 6- and 12-month follow-up assessments. They may be asked to participate in an audio-recorded interview where they will be asked questions about gameplay experience and provided an additional \$10. The total possible compensation for this study is \$225-\$235 per participant. Taxes are not withheld from your teens payments. You may be responsible for paying state, federal, or other taxes for the payments you receive for being in this study.

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. Once your teen's information is de-identified, it could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. 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. It is possible someone may recognize your teens voice, 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.

De-Identified Data Sharing

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
- Yale IRB and Human Research Protection Program

The study sponsor, the National Institute on Drug Abuse, requires that we share your teen's de-identified data with other researchers to help learn how to prevent opioid use and misuse. Project staff will protect your teen's personal information so no one will be able to connect your teen's responses with any information that identifies your teen (names, contact information). Any personal information that could identify your teen will be removed or changed before any data files are shared with other researchers or results are made public. Also, tribal affiliations will not be included with shared data. This is referred to as de-identified data.

Your teen's de-identified data will be protected, following laws that protect the use of health information, and studied only for health research purposes. Your teen's de-identified data may be used in the following ways:

- To understand how opioid use is developed and prevented.
- Combined with data from other studies to help our understanding about opioid misuse prevention and advance science and public health.
- Shared with researchers participating in a group of 10 NIDA-funded studies on ways to prevent opioid misuse. For example, these researchers may compare data across studies to look at how substance use changes over time, look at costs of different interventions, or answer other research questions.
- Publish summaries of results in scientific journals, on clinicaltrials.gov, on the internet or at meetings so that other researchers may learn about this project. Your teen's name or any other data that identifies your teen will not appear in any of these summaries or publications.
- After this project is finished, the data will be stored at a highly secure data library to be shared with researchers more widely who may analyze the data to answer other questions about things like use of alcohol or marijuana. Before sharing any data with these other researchers, it will be made even harder to identify who participated. For example, information regarding where data were collected may be removed.
- Share it with regulatory agencies to help to make de-identified research data more available to researchers.

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 09/01/21 to 12//31/2024.
- 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.

Intellectual Property/Patent Interests

Dr. Lynn Fiellin, principal investigator, Dr. Claudia-Santi Fernandes and Mrs. Tyra Pendergrass Boomer for this study, are named as co-inventors on a patent application covering PlaySmart, which is being tested in this protocol. They may have a potential financial interest in this research if it leads to the development of products

that will be commercialized. If this happens, there is no plan to share any financial gain with you. You may speak with Dr. Lynn Fiellin, Dr. Claudia-Santi Fernandes or Mrs. Tyra Pendergrass Boomer at any time should you have questions regarding these 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 regarding the teens' gameplay experience.

Name of Teen: _____

Parent/Guardian Name: _____

Parent/Guardian Signature: _____

Parent/Guardian Telephone Number: _____

Parent/Guardian Email Address: _____

Date: _____

FOR YALE UNIVERSITY ONLY

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 Mrs. Tyra Pendergrass Boomer at tyra.pendergrass@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.