



**BOE/CO
Friday Packet
September 29, 2023**

Upcoming Meeting Dates

10-4-2023 Finance Committee Meeting Agenda

FLHS Student Survey Proposal - - - Yale Videogame 'play2PREVENT'



Upcoming Board of Education Meeting Dates **2023**

October 4	5:00 PM	Finance Committee Meeting Superintendent Conference Room 501 Kings Hwy East
October 10	7:30 PM	Regular Meeting CO Board Room 501 Kings Hwy East
October 16	5:00 PM	Policy Committee Meeting Superintendent Conference Room 501 Kings Hwy East
October 18	2:30 PM	Facilities Committee Meeting Superintendent Conference Room 501 Kings Hwy East
October 24	7:30 PM	Regular Meeting CO Board Room 501 Kings Hwy East
November 1	5:00 PM	Finance Committee Meeting Superintendent Conference Room 501 Kings Hwy East

Town Meeting:
BoF Capital Planning Workshop
October 19, 2023
7:00 PM, Fire Training School

FAIRFIELD PUBLIC SCHOOLS

Board of Education Finance Committee

Regular Meeting Agenda

Wednesday, October 4, 2023

5:00 PM

Superintendent Conference Room, 501 Kings Highway East

To listen via your phone, call 408-418-9388, and use Meeting Number (access code): 234 677 64178

Please Note:

- ✓ If you call in, you will not be heard by the board members.
- ✓ Public Comment is in-person or via email to publiccomment@fairfieldschools.org; there is no live call-in option for public comment.
- ✓ The meeting will also be streamed (audio only) on the FPS YouTube Channel.

1. Call to Order of the meeting of the Finance Committee and roll call
2. Approval of minutes from September 6, 2023 meeting
3. Business/discussion items
 - a. District financial update, including impacts on policies about enrollment-based changes to elementary sections
 - b. Discussion on quantifying net financial benefit from in-housing certain special programming
 - c. Discussion on controls for facility rentals and athletic equipment use
 - d. Considerations about changes to preschool tuition and adding full-day preschool
4. Superintendent's report
5. Open committee and public comment
6. Adjournment



FAIRFIELD PUBLIC SCHOOLS

*Dr. Greg Hatzis
Head Principal
Fairfield Ludlowe High School*

September 29, 2023
Memorandum to the Board of Education

We bring this study from the PLAY2Prevent Lab at the Yale Center for Health & Learning Games forward to the Board of Education for their consideration as a first read of a student survey. The district has partnered with the PLAY2Prevent lab previously through our Health Department's use of their materials regarding smoking cessation. This program focuses on the prevention of opioid misuse. It is in line with our Health curriculum and would provide an age-relevant approach to share important information with our students. The survey portion is so the Lab can collect data as part of its research to report to the National Institutes of Health (NIH), the primary funder of the grant allowing for the program's development.

Attachment



Prepared by: Alana Metcalf

YALE VIDEOGAME PROJECT INTRODUCTION FOR FAIRFIELD LUDLOWE HIGH SCHOOL

**The play2Prevent Lab at the Yale
School of Medicine**



Table of Contents

<i>Packet Introduction</i>	<i>2</i>
<i>Parent Brochure</i>	<i>3</i>
<i>Parent Opt-out Form</i>	<i>5</i>
<i>Screening Tool</i>	<i>6</i>
<i>Screening Key</i>	<i>9</i>
<i>Gameplay Timeline.....</i>	<i>12</i>
<i>Parental Consent Packet (for eligible student to bring home and have signed).....</i>	<i>13</i>
<i>Supplementary Resource Packet (given to ineligible students)</i>	<i>21</i>
<i>Adolescent Assent Packet</i>	<i>28</i>
<i>Community Flier</i>	<i>36</i>

Packet Introduction

The play2PREVENT Lab has a wealth of experience creating and testing evidence-based videogames that aim to prevent adolescents from engaging in health risk behaviors. Currently, the play2PREVENT Lab is testing the efficacy of our newest videogame intervention, *PlaySmart*, that aims to increase support seeking behaviors and prevent the initiation of opioid misuse. We are working with schools around the state to recruit and enroll students to participate in this study. These schools include Stamford High School, Westhill High School, Academy of Information Technology and Engineering, New London High School, Fitch High School, CT River Academy, Coginchaug High School, West Haven High School, and Hamden High School. At these schools, we identify a site champion and other site partners (school staff or school health staff) that support us in executing the project. We have site partners and the site champion sign a Letter of Agreement outlining each parties' responsibility and the stipend provided to the school. While working in schools, we recruit students during lunch waves and with the assistance of school staff. To recruit and eventually enroll a student, we provide them with an opt-out to give to their parents, and they fill out a Qualtrics survey to provide their contact information. The opt-out is provided because the screener contains sensitive questions about depression, anxiety, and substance misuse. The student takes home the opt-out and shows their parents. If the student does not return the opt-out signed by their parents indicating their parents approve of them being screened and confirms the parents have okayed their participation in the project, the student can move onto the screening process. The screener (included in this packet) contains questions from the Generalized Anxiety Disorder 2-item form (assessing anxiety symptoms in last 3 months), the Patient Health Questionnaire 2-item form (assessing depressive symptoms in last 3 months), and several questions about lifetime substance misuse. A student is eligible if they are 16-19 and report some other non-opioid substance misuse and/or symptoms of depression and/or anxiety. Any student who reports opioid misuse is automatically ineligible since the intervention is designed to prevent the initiation of opioid misuse. If ineligible, the participant is sent home with a packet of mental health and school-based resources. If eligible, the participant is explained the project once again and given a parental consent form to take home and get signed. The student is followed up with via text from the study staff's work phone. Students can enroll once they have parental consent and provide adolescent assent. From there, they answer their first set of questions on REDCap P11, a Food and Drug Administration compliant database. They then complete the intervention, which is either *PlaySmart* or a set of control games over the course of a few weeks, accumulating up to 300 minutes of gameplay time. Once this portion of the project is complete, they move onto the follow-up assessments at 6-weeks, 3-months, 6-months, 12-months. Each time they complete an assessment they receive an Amazon gift cards, totaling \$225. The study staff is primarily responsible for conducting the assessments at these follow-up periods, as they cannot always be done within the school year (e.g. holiday or summer break).

By partnering with us, you will help us recruit our target sample size of 532 students while providing an evidence-based resource to all students in your school randomized to *PlaySmart*. The information and materials enclosed in this packet provide more information on each step in this process.

We appreciate the opportunity to potentially partner with Ludlowe High School and can happily provide any additional materials or information needed. Thank you for your time!

Parent Brochure

Parent brochures are distributed to any parent, stakeholder, potential site partner, school-based health center personnel, or any adult that is interested in our project and would like more information. The brochure contains information about what our lab does and goes into detail about what the study involves.

Who We Are

Harnessing video game technology to shape stronger and healthier lives

- The play2PREVENT (p2P) lab was created over 10 years ago with funding from the Eunice Kennedy Shriver National Institute of Health and Human Development (NICHD)/NIH.
- Our team consists of researchers and scientists, youth, educators, community leaders and community-based organizations, and game designers and developers working as a “collective brain”.
- We focus on the use of “play”, in the form of videogames, to create engaging and effective methods to teach kids and teens information and skills that lead to behavior change so they can live healthier and safer lives.



“ **Playful Functionality** ”

*play-ful | \ 'plā-fəl |
full of play*

*func-tion-al-i-ty /,fəŋG(k)SHə'nalədē/
the quality of being suited to serve a purpose well*

”

Contact Us

<https://www.play2prevent.org>
play2prevent@yale.edu

 @play2prevent

 play2PREVENT

 @play2prevent



The play2PREVENT Lab

part of The Yale Center for Health & Learning Games

Videogame Research Project

The Project

For our current project, we will be testing out our newest game in a 12-month trial to see if there is a difference in knowledge and behaviors between teens who play our game versus those who play a regular videogame, like *The Sims*. **Participants in the project have the chance earn up to \$225 in VISA gift cards in the process!**



IN ORDER TO PARTICIPATE IN THE VIDEOGAME PROJECT, YOUR TEEN MUST:

- Be 16-19 years old
- Be enrolled in their school's school-based health center
- Meet eligibility criteria on our screener survey
- Turn in a signed parent/guardian consent form (ages 16-17), or an individual consent form (ages 18-19)
- Be able and willing to sit and play assigned videogame(s) associated with the project for 1 hour, once a week, for 4 to 5 weeks

The Project (cont.)

PROJECT TIMELINE:

STEP 1: Students must: 1). turn in a signed parent/guardian consent form (ages 16-17) or an individual consent form (ages 18-19); 2). sign an adolescent assent form (ages 16-17); 3). turn in a school-based health center enrollment form if they are not already enrolled in the school-based health center.

STEP 2: Students will answer a few questions about their current knowledge, attitudes, and intentions around certain health behaviors **and get a \$55 gift card!**

STEP 3: Students will play assigned videogame(s) associated with the project for 1 hour, once a week, for 4 to 5 weeks. **Snacks will be provided!**

STEP 4: Students will answer follow-up questions at their last gameplay session **and get a \$35 gift card!**

STEP 5, 6, & 7: Students will answer follow-up questions 3 months, 6 months, and 12 months after gameplay sessions end **and get a \$45 gift card each time!**

If you have any questions about the project, you may contact:

Tyra Pendergrass Boomer, MEM
tyra.pendergrass@yale.edu
(203)-737-6101

Our Lab

Improving and sustaining the health and well-being of young people

- The p2P lab takes advantage of the popularity of videogames to build a collection of "serious games".
- "Serious games" are video games that serve a purpose beyond pure entertainment.
- We develop and evaluate games for the purposes of health and wellness promotion, risk reduction, social good, and educational interventions for young people.
- We use rigorous scientific methods and metrics so we can deliver effective interventions with much greater engagement, fidelity, reach, scalability, and impact.
- **Our games are made by teens, for teens!**



Parent Opt-out Form

The parent opt-out form is given to students interested in our project. The play2PREVENT team distributes this form during a school visit once a student has shown interest by filling out a form. This opt-out form allows the student's parent/guardian to give consent before we screen them, due to sensitive nature of our screening questions. By signing the form, parents indicate that they do not want their child to participate. We securely store all signed forms in a file cabinet at our lab.



Parent "Opt-Out" Form to Exclude Teen from Research Project Screening YALE UNIVERSITY SCHOOL OF MEDICINE



PLEASE NOTE: This form only needs to be returned if you do **NOT** want your teen to participate. Only parents/guardians with teens under the age of 18 need to return this form.

Project Title: A digital intervention to prevent the initiation of opioid misuse in adolescents in school-based health centers (Randomized Controlled Trial- Screening)

Principal Investigator: Lynn E. Fiellin, MD

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

Date: _____

Dear Parents,

We are writing to inform you about an exciting opportunity taking place at our school. We have partnered with the play2PREVENT Lab at Yale University (who develops videogame interventions to target health outcomes in children and teens), to test their newest videogame focused on health promotion in teens. The goal of this project is to help researchers learn how a videogame can be used to teach teens about making healthy decisions about things such as their mental health and substance use. Students who participate in the project could have the opportunity to play an original game that promotes healthy behaviors and assists them with making positive decisions.

To determine their eligibility to participate in the project, your teen will answer seven questions related to their thoughts and behaviors on certain health topics. Students will complete this assessment on a provided iPad in our School-Based Health Center (SBHC). If they are found eligible to participate in the project, we will send home an electronic or hard-copy parent/guardian permission form that will need to be returned to the SBHC to officially enroll them in the research project.

During the screening process, your teen's privacy will be protected. However, if there are mental health or substance use concerns that are revealed during the screening, we at the school-based health center will communicate these concerns with you as the parent/guardian. Screening question answers will be stored in a secure database accessible only to certified research staff.

We would like all eligible students to take part in this research project. However, the screening process that is needed to determine eligibility is voluntary. **If you do not want your teen to take part in this opportunity, please fill out the information below and turn it into the school-based health center within 3 days and your teen will not be screened for this project.** Declining to have your teen participate in the screening will not affect your teen's relationship with their SBHC or school. If you have any questions about the screening process or research project, please contact your SBHC at _____. Should you need further assistance after speaking with your SBHC, please contact Tyra Pendergrass Boomer at (203) 737-6101 or tyra.pendergrass@yale.edu.

Teen's name (please print) _____ Grade _____

I have read this form and do not grant permission for my teen to be screened for eligibility for the videogame research project.

☐ **No** – My teen may **NOT** be screened for the research project.

Parent/Guardian Signature _____ Date _____

Screening Tool

The screening tool is used to determine a student's eligibility for our study. Based on our criteria, a student is eligible if 1) *they are 16-19* 2) *they are at slight risk for anxiety OR depression OR drug & alcohol use* 3) *they have NEVER misused opioids*

1



Video Game Project Eligibility Screening Tool

Instructions: Please record your responses to these questions on the separate **Answer Key** sheet you were provided. **DO NOT RECORD YOUR ANSWERS ON THIS PAGE.** Your responses will be kept private and confidential.

Section A

1. Today's Date (MM/DD/YYYY)
2. First Name
3. Last Name
4. How old are you? (Age in years)
5. If you are found to be ineligible for the Video Game Study, would you be interested in being contacted for another project by the Video Lab?
☐ Yes (Please record as "Y" on answer key)
☐ No (Please record as "N" on answer key)
6. Cell phone number ((XXX)-XXX-XXXX)
7. Are you enrolled in your school's school-based health center?
☐ Yes (Please record as "Y" on answer key)
☐ No (Please record as "N" on answer key)
8. What is your date of birth? (MM/DD/YYYY)

PLEASE CONTINUE TO THE NEXT PAGE

Section B

1. Over the last 3 months, how often have you been bothered by the following problems?

1A) Little interest or pleasure in doing things.

- A. Not at all
- B. Several days
- C. More than half the days
- D. Nearly every day

1B) Feeling down, depressed, or hopeless.

- A. Not at all
- B. Several days
- C. More than half the days
- D. Nearly every day

2. Over the last 3 months, how often have you been bothered by the following problems?

2A) Feeling nervous, anxious or on edge.

- A. Not at all
- B. Several days
- C. More than half the days
- D. Nearly every day

2B) Not being able to stop or control worrying.

- A. Not at all
- B. Several days
- C. More than half the days
- D. Nearly every day

3. During the PAST 30 DAYS, did you do any of the following...

3A) Drink more than a few sips of beer, wine, or any drink containing alcohol?

- ☐ Yes (Please record as "Y" on answer key)
- ☐ No (Please record as "N" on answer key)

3B) Use any marijuana (cannabis, weed, oil, wax, or hash by smoking, vaping, dabbing, or in edibles) or "synthetic marijuana" (like "K2," "Spice")?

- ☐ Yes (Please record as "Y" on answer key)
- ☐ No (Please record as "N" on answer key)

PLEASE CONTINUE TO THE NEXT PAGE

3C) Use anything else to get high (like other illegal drugs, pills, prescription or over-the-counter medications, and things that you sniff, huff, vape or inject)?

- ☐ Yes (Please record as "Y" on answer key)
☐ No (Please record as "N" on answer key)
☐

3D) Use a vaping device* containing nicotine and/or flavors, or use any tobacco products?

- ☐ Yes (Please record as "Y" on answer key)
☐ No (Please record as "N" on answer key)

Opioids are a group of drugs that includes both prescription pain medications and illegal drugs like heroin. Examples of prescription opioids include: oxycodone (OxyContin, Percocet), hydrocodone (Vicodin), codeine, morphine, and methadone.

Opioid misuse means taking opioids in a way or dose not prescribed, taking another person's prescription opioids, taking opioids in order to "get high," or taking to prevent withdrawal symptoms.

****This does not include the use of opioids for the treatment of something painful, as prescribed by a medical provider.**

4. Have you ever IN YOUR LIFE misused opioids?

- ☐ Yes (Please record as "Y" on answer key)
☐ No (Please record as "N" on answer key)

5. Are you willing to sit for 60 minutes per session (for up to 6 sessions/each) to play a videogame?

- ☐ Yes (Please record as "Y" on answer key)
☐ No (Please record as "N" on answer key)

Thank you for your interest in our project and your time for completing this survey.

END OF SURVEY

Screening Key

The screening key is given to students along with the screening tool for them to write down their answers to the questions found on the screening tool. The screening key is formatted so that if anyone else were to accidentally glance at the form while passing by their answers would be ambiguous. Screening keys are looked over by a study staff member and initialed at the top. They are then taken back to the lab and safely stored in a manila envelope in a file cabinet.



Video Game Project Eligibility Screening Answer Key

Instructions: Please record your responses to the questions on the screening tool on **THIS** sheet only. Your responses will be kept private and confidential.

Section A

1. ____ \ ____ \ ____
2. _____
3. _____
4. _____
5. _____
6. (____) - ____ - ____
7. _____
8. ____ \ ____ \ ____

PLEASE CONTINUE TO THE NEXT PAGE

Section B

1A. _____

1B. _____

2A. _____

2B. _____

3A. _____

3B. _____

PLEASE CONTINUE TO THE NEXT PAGE

3C. _____

3D. _____

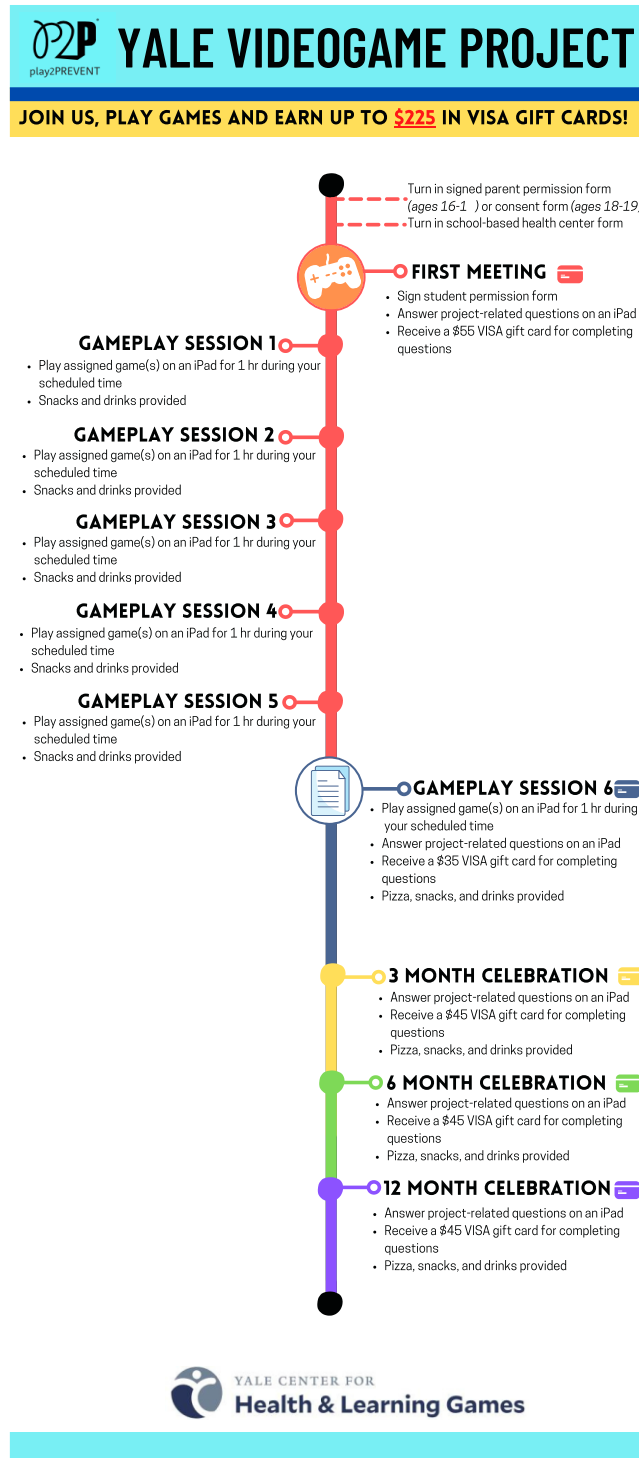
4. _____

5. _____

Thank you for your interest in our project and your time for completing this survey.

Gameplay Timeline

The gameplay timeline is attached to each consent packet that is given to students once they have screened eligible. The timeline provides an overview of what the project would look like and when participants can expect to receive each gift card.



Parental Consent Packet (for eligible student to bring home and have signed)

Once a student screens eligible, a study staff member will hand them a parental consent packet to take home. The packet must be signed by a parent/guardian and returned to study staff. Once collected, the packet is brought back to the lab where a study staff member will determine the legitimacy of the parent/guardian's signature. If any forgery has occurred, the appropriate protocols will be followed.

APPROVED BY THE YALE UNIVERSITY IRB 2/17/2023

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- Form for Participants 18+

Research Study Summary

We are asking you 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) playing an iPad or sitting at a computer to play an original game developed by the play2PREVENT Lab or a series of commercial games (e.g., Minecraft, Escape the Room), based on your random assignment, 2) answering questions about your experience playing the game, and your thoughts, attitudes and knowledge around a health topic.
- Your involvement will require: 1) 60 minutes of your 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 be enrolled in your school's school-based health center.
- There are no known risks of physical or psychological injury or inconveniences associated with this research project. If you become very tired or uncomfortable, one of the researchers would ask you if you 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 you.
- You 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.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make will not have any effect on their relationship with your 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 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

You are 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 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. 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 want 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, you 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 attend a school with a school-based health center and preferably be enrolled in your school’s school-based health center and 5) have the consent of your parent or legal guardian to participate if you are under 18 years of age.

You will play a game that is designed to be fun and engaging. Your participation in this research study will be voluntary and confidential.

You will be asked to play a videogame as well as complete several assessments (questionnaires) before and after playing the videogame. The goal of the assessments is to collect data about your behaviors (what you do) and perceptions (what you think) about opioids, your knowledge of opioids, attitudes and other basic questions about yourself. You may also be asked to answer a few more questions about your experience with the game that will be audiotaped. You may choose not to be audiotaped and still participate in the study. The goal of these questions is to learn whether you thought playing the game was fun, boring, or interesting, and what you 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 decide that you will participate, here is what will happen: During the first meeting, you will be asked to sign this form and complete

assessment questions that will take approximately 20-30 minutes and will be conducted confidentially (your answers will be kept private) in a secured, private location. You will be assigned a study number, so that your 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, you will then begin the gameplay portion of the project, where you 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, you will be asked to complete additional assessment questions that will take approximately 20-30 minutes to complete. The assessment questions will ask about your gameplay experience, knowledge you might have gained from playing the game, as well as about your beliefs and attitudes towards opioid misuse. During the same time, you 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 you thought playing the game was fun, boring, or interesting, and what you 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. You can decline to be audio recorded and still participate in the study.

You 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 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 you become very tired or uncomfortable, one of the researchers will ask you if you 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 you.

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

Benefits

You 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

You will receive a gift card for completing each assessment. You will receive a \$55 gift card for completing the assessment 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. You may have the opportunity to receive an additional recorded interview about your experience playing the game. The total possible compensation for this study is \$225-\$235 per participant. Taxes are not withheld from your 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 take part in this research study, all of the information that you give us, at all points in the study is confidential and available only to the people actually working in the study. Your 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 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. 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 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 confidentiality. It is possible someone may recognize your voice. You may decline to have your voice audiotaped during questions about your gameplay experience.

If we are worried by something we hear from you such as you 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 yourself 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 de-identified data with other researchers to help learn how to prevent opioid use and misuse. Project staff will protect your personal information so no one will be able to connect your responses with any information that identifies you (names, contact information). Any personal information that could identify you 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 de-identified data will be protected, following laws that protect the use of health information, and studied only for health research purposes. Your 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 name or any other data that identifies you 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.

The research staff at the Yale School of Medicine has to obey the privacy laws and make sure that your 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 information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your 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 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 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 you from voluntarily releasing information about yourself or your involvement in this research. If you want your 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 You 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 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 health that we will collect, use, and share includes:

- Your Name, telephone number, email address
- Research study records
- The entire research record held by the **Yale School of Medicine** created from 09/01/2021 to 12/31/2024.
- Records about phone calls made as part of this research
- Records about your 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 take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as health care outside the study, the payment for health care, and health care benefits). However, you 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 information as part of this study.

Withdrawing, meaning you no longer want to be in this study, will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to quit the study, all you have to do is tell the person in charge. This will not harm your relationship with your doctors or with Yale-New Haven Hospital. The study investigators may remove you from the study if they believe that is in your 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 participate in the project described above. Its general purposes, the particulars of my 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 me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

☐ (Check here.) Participant gave permission for audiotaping in an interview about gameplay experience.

Name of Participant: _____

Participant Signature: _____

Participant Telephone Number: _____

Participant 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.

Supplementary Resource Packet (given to ineligible students)

The supplementary resource packet below is given to students after they are screened ineligible. This resource packet provides information regarding mental health, opioids, and different resources for seeking help for mental illness – all of which are topics that our videogames focus on.


My Mental Health: Do I Need Help?

First, determine how much your symptoms interfere with your daily life.



Do I have mild symptoms that have lasted for less than 2 weeks?


- Feeling a little down
- Feeling down, but still able to do job, schoolwork, or housework
- Some trouble sleeping
- Feeling down, but still able to take care of yourself or take care of others



If so, here are some self-care activities that can help:


- Exercising (e.g., aerobics, yoga)
- Engaging in social contact (virtual or in person)
- Getting adequate sleep on a regular schedule
- Eating healthy
- Talking to a trusted friend or family member
- Practicing meditation, relaxation, and mindfulness

If the symptoms above do not improve or seem to be worsening despite self-care efforts, talk to your health care provider.



Do I have severe symptoms that have lasted 2 weeks or more?

- Difficulty sleeping
- Appetite changes that result in unwanted weight changes
- Struggling to get out of bed in the morning because of mood
- Difficulty concentrating
- Loss of interest in things you usually find enjoyable
- Unable to perform usual daily functions and responsibilities
- Thoughts of death or self-harm




Seek professional help:

- Psychotherapy (talk therapy)—virtual or in person; individual, group, or family
- Medications
- Brain stimulation therapies






For help finding treatment, visit www.nimh.nih.gov/findhelp.

If you are in crisis, call the National Suicide Prevention Lifeline at 1-800-273-TALK (8255), or text the Crisis Text Line (text HELLO to 741741).



National Institute of Mental Health
NIH Publication No. 20-MH-8134

www.nimh.nih.gov
Follow NIMH on Social Media @NIMHgov



TIPS for TEENS

OPIOIDS

THE TRUTH ABOUT OPIOIDS

SLANG: O.C./OXY/PERCS/VIKE/M/MONKEY/
WHITE STUFF/LEAN/SCHOOLBOY/SIZZURP/
PURPLE DRANK/LOADS

GET THE FACTS

OPIOIDS AFFECT YOUR BRAIN. Opioids are a class of drugs that include the illegal drug heroin, synthetic opioids such as fentanyl, and pain relievers available legally by prescription, such as oxycodone, hydrocodone, codeine, morphine, and many others.¹ They affect both the spinal cord and brain to reduce the intensity of pain-signal perception as well as brain areas that control emotion.² They can also affect the brain to cause euphoria or "high."³

OPIOIDS AFFECT YOUR BODY. Opioids slow down the actions of the body, such as breathing and heartbeat. Even a single dose of an opioid can cause severe respiratory depression (slowing or stopping of breathing), which can be fatal; taking opioids with alcohol or sedatives increases this risk.⁴

OPIOIDS ARE ADDICTIVE. Even though heroin is highly addictive, more people struggle with addiction to prescription pain relievers.⁵ Many young people who inject heroin report misuse of prescription opioids before starting to use heroin.⁶

OPIOIDS CAN KILL YOU. Drug overdose is the leading cause of accidental death in the United States, with 68,690 drug overdose deaths between March 2017 and March 2018.⁷ More than 46,000 of those deaths involved opioids.⁸

OPIOID ADDICTION IS TREATABLE. Methadone, buprenorphine, and naltrexone are medications that are FDA-approved to treat opioid use disorder. For more information, visit <https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder>.

? Q&A

Q. MY DOCTOR PRESCRIBED ME OPIOIDS. DOESN'T THAT MEAN THEY'RE SAFE?

A. Prescription opioids—when used long term or incorrectly—can cause the brain to become reliant on the drug and are addictive.⁹

Q. IF I USE OPIOIDS, WILL I BECOME ADDICTED?

A. Prescription opioids can cause physical dependence when used as directed or addiction if misused; illegal opioids such as heroin are also highly addictive. People who regularly use prescription opioids or heroin often develop tolerance, which means that they need higher and/or more frequent doses of the drug to get the desired effects.¹⁰

THE BOTTOM LINE:

Many people are prescribed opioids out of medical necessity, but opioids can still be dangerous and addictive. Even if someone is prescribed one of these medications—such as hydrocodone, oxycodone, and morphine—misuse of these substances is rampant. Talk to your parents, a doctor, a counselor, a teacher, or another adult you trust if you have questions.

LEARN MORE:

Get the latest information on how drugs affect the brain and body at teens.drugabuse.gov.

TO LEARN MORE ABOUT OPIOIDS, CONTACT:

SAMHSA
1-877-SAMHSA-7 (1-877-726-4727)
(English and Español)

TTY 1-800-487-4889
www.samhsa.gov
store.samhsa.gov



SAMHSA
Substance Abuse and Mental Health
Services Administration



BEFORE YOU RISK IT!

- 1 KNOW THE LAW.** Heroin is illegal and addictive.¹¹ If you are caught with prescription opioids that are not yours, you can be imprisoned, fined, or both.¹²
- 2 KNOW THE RISKS.** Using opioids repeatedly can lead to higher tolerance.¹³ Other risks include addiction and overdose death.
- 3 LOOK AROUND YOU.** A recent study found that 38.5 percent of the people who misused prescription pain relievers got them from a friend or relative for free; 34.6 percent were prescribed the medication by one doctor.¹⁴



KNOW THE SIGNS

How can you tell if a friend is using opioids?

Side effects of opioid use include:¹⁵

- Constipation, nausea, vomiting, and dry mouth;
- Sleepiness and dizziness;
- Confusion;
- Decreased breathing; and
- Itching and sweating.

Behavioral signs and symptoms of opioid addiction include:¹⁶

- A change in peer group;
- Carelessness with grooming;
- Decline in academic performance;
- Missing classes or skipping school;
- Loss of interest in favorite activities;
- Changes in eating or sleeping habits; and
- Deteriorating relationships with family and friends.



WHAT CAN YOU DO TO HELP SOMEONE WHO IS USING OPIOIDS?

BE A FRIEND. SAVE A LIFE.

Encourage your friend to stop using or seek help from a parent, teacher, or other caring adult.

For 24/7 free and confidential information and treatment referrals in English and Español, call SAMHSA's National Helpline at:

1-800-662-HELP (1-800-662-4357) or visit the SAMHSA Behavioral Health Treatment Services Locator at findtreatment.samhsa.gov

¹¹ National Institute on Drug Abuse. (2018). Opioids. Retrieved from <https://www.drugabuse.gov/drugs-abuse/opioids>

¹² National Institute on Drug Abuse. (2018). Misuse of Prescription Drugs. Retrieved from <https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classe-prescription-drugs-are-commonly-misused>

¹³ U.S. Department of Health and Human Services. (2014). The Facts About Buprenorphine. Retrieved from <https://store.samhsa.gov/system/files/sma14-4442.pdf>

¹⁴ Jones, C. M., Paulozzi, L. I., & Mack, K. A. (2014). Alcohol involvement in opioid pain reliever and benzodiazepine drug abuse-related emergency department visits and drug-related deaths - United States, 2010. *Morbidity and Mortality Weekly Report*, 63(48), 881-885. Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6348a1.htm>

¹⁵ Center for Behavioral Health Statistics and Quality. (2017). Medications for Opioid Use Disorder. Retrieved from <https://store.samhsa.gov/system/files/sma17-5053a2.pdf>

¹⁶ National Institute on Drug Abuse. (2018). Prescription opioids and heroin. Research Report Series. Retrieved from <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use>

¹⁷ National Center for Health Statistics (NCHS). (2018). Provisional Drug Overdose Death Counts. Retrieved from <https://www.cdc.gov/nchs/nvss/vsm/drug-overdose-data.htm>

¹⁸ National Institute on Drug Abuse. (2018). Opioid Overdose Crisis. Retrieved from <https://www.drugabuse.gov/drugs-abuse/opioids>

¹⁹ National Institute on Drug Abuse. (2018). What is heroin? Drug Facts. Retrieved from <https://www.drugabuse.gov/publications/drugfacts/heroin>

²⁰ U.S. Department of Justice & Drug Enforcement Administration. (2015). Drugs of abuse: A DEA resource guide. Retrieved from https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf

²¹ Addiction.com. (2015). Before You Share That Pain Medication. Retrieved from <https://www.addiction.com/2040/before-you-share-that-pain-medication/>

²² Substance Abuse and Mental Health Services Administration (SAMHSA). (2016). Opioids. Retrieved from <https://www.samhsa.gov/ated/opioids>

²³ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health. Retrieved from <https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report>

²⁴ Centers for Disease Control and Prevention. (2017). Opioid Overdose. Retrieved from <https://www.cdc.gov/drugoverdose/opioids/prescribed.html>

²⁵ National Institute on Drug Abuse. (2014). Principles of adolescent substance use disorder treatment: A research-based guide. Retrieved from <https://www.drugabuse.gov/publications/principles-adolescent-substance-use-disorder-treatment-research-based-guide/frequently-asked-questions/what-are-signs-drug-use-in-adolescents-what-role-can-parents-play-in-getting-treatment>

MORE INFORMATION

SAMHSA
Substance Abuse and Mental Health
Services Administration

FOR MORE INFORMATION OR FOR RESOURCES USED IN THIS "TIPS for TEENS,"
visit store.samhsa.gov or call 1-877-SAMHSA-7 (1-877-726-4727) (English and Español).
PEP NO. 18-09 REVISED 2019

SAMHSA complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.
SAMHSA cumple con las leyes federales de derechos civiles aplicables y no discrimina por motivos de raza, color, nacionalidad, edad, discapacidad o sexo.

Drugs and the Teen Brain

Adolescence is a critical time in brain development. That means teens are at greater risk of experiencing the harmful effects of drugs and alcohol.

Taking chances isn't always bad—it's part of growing up. But not thinking through consequences can be dangerous when it comes to decisions about drugs and alcohol.

BY THE TIME YOU ARE A TEENAGER, many parts of your brain have developed so much that you may be able to perform complicated calculations and even have a sharper memory than some adults (like how you might be able to memorize your home's random 11-character Wi-Fi password—while your parents never can!).

But one critical part won't be developed until your mid-twenties—putting teens at a higher risk for the harmful effects of drugs and alcohol.

Under Construction

The key brain part that's still developing is the **prefrontal cortex** and it's the area you use in critical thinking, such as when you weigh pros and cons before making a decision.

Because the prefrontal cortex is not yet fully developed, teens automatically rely more on the **limbic system** to make decisions. This system's network of brain structures is linked to emotions and experiencing rewards rather than critical thinking.

Because their prefrontal cortex is in development, teens are more likely to make decisions based on what provides instant gratification, such as a feeling of happiness. This focus can lead them to take more risks than adults. For example, your peers might pressure you to do something you later regret, such as pulling a prank that lands you in trouble. Rather than thinking carefully about the negative outcomes, the teen brain focuses more on getting the reward of your friends' acceptance.

Of course, taking chances isn't always a bad thing—it helps you grow into an adult and become independent. But not thinking through consequences can be dangerous when it comes to decisions related to drugs and alcohol.

That's one reason teens are more likely than adults to binge drink. Binge drinking is when someone consumes four to five alcoholic drinks within a few hours. Teens may be less able than adults to judge when to stop drinking (remember: underdeveloped prefrontal cortex!). The scary part? Studies have shown that even a few sessions of binge drinking can cause harmful changes to a developing brain.

Addiction Risk

Teens are also at a higher risk of developing the disease of **addiction**. Scientists believe that addiction is closely linked to **dopamine**, a chemical that helps transmit signals in the brain. A person taking drugs causes a surge of dopamine in the brain.

Any rewarding activity, such as enjoying a slice of pizza, causes a dopamine release. But the surge is much higher and more intense with drugs. Over time, repeated drug use can "teach" the brain to seek the substances over other, healthier rewards. That is addiction.

Teens have a higher risk of addiction because their limbic systems are very sensitive to dopamine. As a result, they may crave drugs more strongly than adults. The earlier someone starts drug use, the higher his or her addiction risk.



Brain Changes

As you grow and learn, your body strengthens pathways between **neurons** (nerve cells) in the brain and gets rid of ones that aren't used. These connections, called **synapses**, determine how your brain processes information. The network of synapses is what supports everything from your memory to your ability to learn and feel emotions.

Exposing the teen brain to drugs can change how these pathways are organized and how the brain functions. The negative impact

of drug use can cause problems with attention, memory, and problem solving that can last all the way through adulthood.

The good news is that by thinking through your actions now, you can have a positive impact on your brain for the rest of your life. Taking on challenges to build abilities and skills—such as learning a new sports move or picking up a foreign language—helps build new connections that make your brain stronger and better able to tackle future tasks. If you are good to your brain, it will be good to you.



Because the brain's **prefrontal cortex**

(the part in charge of critical thinking) is not yet fully developed in teens, they rely more on the limbic system (which is tied to rewards and emotions) to make decisions.

GET MORE

For additional facts about science and your health, visit scholastic.com/headsup and teens.drugabuse.gov.

From Scholastic and the scientists of the National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services

WHAT ARE SCHOOL BASED HEALTH CENTERS?

- **School-Based Health Centers (SBHCs)** are health care clinics base right in your very own school!
- SBHCs **DO NOT** take the place of your regular doctor, but provide additional services as you may need them (like physicals, mental heal counseling, and even dental care).



WHAT SERVICES ARE OFFERED AT MY SBHC?

- ☒ Physicals
- ☒ Nutrition and exercise counseling
- ☒ Acute illness treatment
- ☒ Behavioral Health
- ☒ Immunizations
- ☒ Dental
- ☒ AND MORE!

**TO ENROLL, VISIT
THE SCHOOL-BASED
HEALTH CENTER AT
YOUR SCHOOL!**

School Counselors

A Resource in your school

What do school counselors do?

- Help you make the right personal and educational decisions.
- Give you the necessary resources and support.
- Listen so you can talk about your feelings and concern
- Connect with external resources
- Build a more positive mindset
- Evaluate and create academic and career goals



Adolescent Assent Packet

Once study staff have received a signed parental consent packet with a legitimate signature, a site visit is then scheduled where a team member will go over the voluntary nature of the project, and the confidentiality of the students' information. The adolescent assent packet is then distributed for students to carefully read over and sign. It details what the study is about and what the participant will be doing. The packets are securely stored at our lab in the participant's assigned folder.

APPROVED BY THE YALE UNIVERSITY IRB 2/17/2023
HIC #: 2060036533

ADOLESCENT ASSENT 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- Adolescent Participants

Research Study Summary

We are asking you 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) 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) 2) answering questions about your experience playing the game, and your thoughts, attitudes and knowledge around a health topic.
- Your involvement will require: 1) 60 minutes of your 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 attend a school with a school-based health center and preferably be enrolled in the school-based health center; and 4) a signed parent/guardian permission form.
- There are no known risks of physical or psychological injury or inconveniences associated with this research project. If you become very tired or uncomfortable, one of the researchers would ask you if you 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 you.
- You 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.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make will not have any effect on your relationship with your 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 want to participate; if so, you will have to sign this form.

Opioids are medications that are strong pain relievers. Opioids are prescribed by a doctor or medical professional for many things like sports injuries, dental work, or surgery. While opioids can be very effective at treating pain, they can be very addictive if not used as recommended by a medical professional. 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 the misuse of drugs such as opioids.

Invitation to Participate and Description of Project

You are 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. As part of this study, you will be playing a videogame that may teach you some skills or may help you learn to make choices that are healthier for you.

To help you decide whether or not you participate in this study, you should know if there are any risks (problems that you might have as a result of the study) and benefits (how the study might help you or other adolescents) to participating. This form gives you detailed information about the research study, which a member of the research team will discuss with you. We will go over all aspects of this research: its purpose (the reason we are doing the study), what will happen during the research study, and any risks and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form. A parent/guardian will also be asked to allow you to be in the study.

Description of Procedures

The purpose of this study is to learn more about how playing a videogame might help teens learn how to make good decisions that are healthier for them while they are playing the videogame and in real life.

In order to participate in this study, you 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 attend a school with a school-based health center and preferably be enrolled in the school-based health center and 5) have the consent of your parent or legal guardian to participate if you are under 18 years of age.

You will be asked to play a videogame as well as complete assessments (questionnaires) before and after playing the videogame. The goal of the assessments is to collect data about your behaviors (what you do) and perceptions (what you think) about opioids, your knowledge of opioids, attitudes and other basic questions about yourself. You may also be asked to answer a few more questions about your experience with the game that will be audiotaped. You may choose not to be audiotaped and still participate in the study. The goal of these questions is to learn whether you thought playing the game was fun, boring, or interesting, and what you 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 decide that you will participate, here is what will happen: During the first meeting, you will be asked to sign this form and complete assessment questions that will take approximately 20-30 minutes and will be conducted confidentially (your answers will be kept private) in a secured, private location. You will be assigned a study number, so that your 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, you will then begin the gameplay portion of the project, where you 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, you will be asked to complete additional assessment questions that will take approximately 20-30 minutes to complete. The assessment questions will ask about your gameplay experience, knowledge you might have gained from playing the game, as well as about your beliefs and attitudes towards opioid misuse. During the same time, you 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 you thought playing the game was fun, boring, or interesting, and what you 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. You can decline to be audio recorded and still participate in the study.

You 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 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 you become very tired or uncomfortable, one of the researchers would ask you if you 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 you.

However, there is a slight risk regarding the confidentiality of your participation in this study, if information about you becomes known to persons outside this study. The researchers are required to keep your study information confidential.

Benefits

You 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

You will receive a gift card for completing each assessment. You will receive a \$55 gift card for completing the assessment 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. There may be an additional opportunity for you to earn an additional \$10 for participating in an audio-recorded interview. The total possible compensation for this study is \$225-\$235 per participant. Taxes are not withheld from your 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 take part in this research study, all of the information that you give us, at all points in the study is confidential and available only to the people actually working in the study. Your 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 our study records. All published results will be group data without identifying you as an individual. Once your 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 or your legally authorized representative (your parent or guardian). 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 your gameplay experience: Your 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 privacy. It is possible someone may recognize your voice if they hear the audiotapes. You may decline to have your voice audiotaped during questions about your gameplay experience.

If we are worried by something we hear from you such as you are being harmed, we will let you know and we will discuss this with your parent/guardian. In addition, information may be released if we are worried about abuse, neglect, or harm to you 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 de-identified data with other researchers to help learn how to prevent opioid use and misuse. Project staff will protect your personal information so no one will be able to connect your responses with any information that identifies you (names, contact information). Any personal information that could identify you 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 de-identified data will be protected, following laws that protect the use of health information, and studied only for health research purposes. Your 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 name or any other data that identifies you 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 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 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 information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your 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 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 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 you from voluntarily releasing information about yourself or your involvement in this research. If you want your 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 You 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 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 health that we will collect, use, and share includes:

- Names, telephone numbers, email addresses, parent/guardian names, parent/guardian phone numbers, and parent/guardian email addresses
- 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 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 take part in this study. You do not have to be in the study. No one will be upset if you don't want to do this. If you don't want to be in this study, you just have to tell us. If you want to be in the study, you just have to tell us. You can say yes now and change your mind later. It's up to you. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you 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 information as part of this study.

Withdrawing, meaning you no longer want to be in this study, will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to quit the study all you have to do is tell the person in charge. It will not harm your relationship with your school or the researchers. You need to know that your parents may ask you why you cannot be in the study or why you were asked to leave the study. It is okay if you decide that you do not want to be in the study or to stay in this study. You do not need to give a reason for not being in the study.

Writing your name on this page means that the page was read by you or to you and that you agree to be in the study. You know what will happen to you. You do not give up any of your legal rights by signing this form.

Questions

We have used some complicated terms in this form. Please feel free to ask about anything you don't understand and to think about this research and the assent form carefully – as long as you need to – before you make a decision. We encourage that you talk to your family about your decision as well. If you come up with questions after reading this form, contact Mrs. Tyra Pendergrass Boomer at tyra.pendergrass@yale.edu.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the things I will do in the study and possible risks and inconveniences have been explained to my satisfaction. My signature also shows that I have been given a copy of this assent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the reasons described in this form. If I decide not to give permission, I understand that I will not be able to be in this research.

☐ **Participant gives permission to be audiotaped for an interview about gameplay experience.**

Name of Participant: _____

Signature: _____

Parent/Guardian Name: _____

Parent/Guardian Telephone Number: _____

Date: _____

FOR YALE UNIVERSITY ONLY

 Signature of Person Obtaining Assent

 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 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.

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.

Community Flier

Community fliers are sent out to site partners at the end of every school year to update all of our partners on the progress of our study.



The play2PREVENT Lab

The play2PREVENT Lab is working towards educating and prevent the next generation of youth from being affected by the opioid and mental health crises with our videogame *PlaySmart*.

Evaluating PlaySmart

Goal: 532



- PlaySmart is currently being evaluated through a randomized controlled trial to assess its impact on healthy decision-making skills, perceptions of risk of harm, attitudes, and actual behaviors.
- The play2PREVENT Team has partnered with high schools in West Haven, Stamford, Durham, Bridgeport, Meriden, Groton, New London, Hamden, and East Hartford. For the 2023- 2024 school year, an additional partner in Hartford will join the project.
- The study will enroll 532 students from our partner high schools to participate in the project.

Background Info

- In 2018, an estimated 10 million people aged 12 or older misused opioids. (1)
- In 2020, an estimated 50 % of youth had a mental health disorder at some point in their lives. (2)

PlaySmart Videogame

- *PlaySmart* is an engaging, evidence-based videogame that equips teens with real-world skills to use when faced with mental health challenges and substance misuse.
- *PlaySmart* was developed over two years with input from adolescents, healthcare providers, substance misuse treatment providers, and those in treatment for substance misuse.
- Content around mental health, substance misuse, and skills to navigate relationships with healthcare providers was informed by discussions with these key stakeholders.



Year Two Synopsis

Participant Racial Makeup



Race	Percentage
Black	50%
White	24.4%
Other	12.8%
Asian	5.1%
Unknown	1.3%
Native Hawaiian/Pacific Islander	1.3%

Average Participant

Age: **16.5 years old**

Sex at Birth:

Female: **50.27 %**
Male - **49.73%**

We are proud to announce that *PlaySmart* has been awarded the gold medal for excellence in the 2022 International Serious Play Awards and has also been featured as a finalist in the 2022 EdTech Cool Tool Awards!

