IRB#: 2000026487

PARENT PERMISSION FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: ***A Digital Intervention for HIV Prevention in Black Adolescent Girls***
Principal Investigator: *Kimberly D. Hieftje, PhD, Kimberly.hieftje@yale.edu*
Phone Number: *203-737-5595*
Study Funding: Eunice Kennedy Shriver National Institute of Child Health & Human Development

Randomized Controlled Trial Participants Ages 14-18

Research Study Summary:

- **We are asking your child to join a research study.**
- **The purpose of this study is to learn more about how playing a videogame might help teens learn how to make healthy decisions while they are playing the videogame and in real life.**
- **Study activities will include: playing a videogame about healthy decision-making and taking assessments about your child's health behaviors (what they do) and perceptions (what they think), risky situations they might have encountered, their knowledge about health topics such as HIV and other basic questions about themselves before and immediately after they play the game, and then again at 4 months**
- **Their involvement will require 4-5 hours.**
- **There may be some risks from participating in this study. Participants will be asked to play a videogame and answer questions. If your child becomes tired, they may stop playing and take a break and return to playing the game or answering questions later.**
- **The study may have no benefits to your child. The study may help the researchers find out something in the future that will help other children like yours.**
- **Having your child take part in this study is your choice. You can choose to have your child take part, or you can choose for your child to not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your child's school.**
- **If you are interested in learning more about the study, please continue reading 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 child to participate; if so, you will have to sign this form.**

Invitation to Participate and Description of Project

Your child is being invited to participate in a research study 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. 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 behaviors associated with HIV infection.

To help you decide whether or not you want your child 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 child. Together you will go over all aspects of this research: its purpose, what will happen during the group discussion, any risks and possible benefits. Once you understand the study, you will be asked if you agree to your child to participating; if so, you will be asked to sign this form.

Description of Procedures

The purpose of this study is to learn more about how playing a videogame might help teens make good decisions while they are playing the videogame and in real life. In order to participate in this study, your child must be between the ages of 14 and 18 and be willing to play a videogame for one to two hours, two times, for a total of 2-4 hours of gameplay.

Your child will play a game that is designed to be fun and engaging, to promote healthy behaviors in adolescence, and to provide strategies to assist adolescents in making decisions about the many challenges they face involving risky behaviors. Your child's participation in this research study will be voluntary and confidential. After your child is enrolled in the study, they may or may not be assigned to play a multiplayer videogame about healthy decision-making.

Your child will either be assigned to play the intervention videogame or an off-the-shelf videogame such as JackBox, which is a non-violent, PG-rated multiplayer trivia game. They will be asked to play the game as well as complete assessments (questionnaires) before and after they play the videogame, and again at 4 months after they play. The goal of the assessments is to collect data about their health behaviors and perceptions, risky situations they might have encountered, their HIV-related knowledge and other basic questions about themselves. If they played the intervention videogame, we will also ask them if 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. If they played the off-the-shelf game, they will still do the later assessments.

The study will last about 4 months. If you decide that your child will participate, here is what will happen: During your child's first meeting, they will be asked to complete an online assessment that will take 30 minutes and will be conducted confidentially using the secured data collection platform, Qualtrics.. They will be asked questions about their behaviors related to dating, risk-taking, and decision making. If your child is completing the assessment remotely, their survey completion progress will be supervised by a member of the research team and the team member will be available to help your child if needed. After completing the initial assessment, your child will play their assigned videogame two times for one to two hours each time, for a total of three to 4 hours of gameplay. The gameplay will take place online through Yale-secured Zoom video conferencing. The research team will audio-record all gameplay sessions, and members of the research team will be available at all times during gameplay if needed.

Risks and Inconveniences

The risks associated with this study are minimal. One possible effect of playing a videogame is that your child may become tired. If your child experiences this or any tiredness, 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. We will also provide a 15-minute break after 30 minutes of gameplay. There is a slight potential risk associated with maintaining the confidentiality of participants enrolled in the study and information relating to them, but copies of the data will be stored securely. Finally, playing the videogame may pose a potential psychological risk to participants in that we address sensitive issues around risk-taking and its consequences. Research staff will be available to provide assistance to the participants, answer their questions, and serve as a resource if any distress or concern arises. If participants need additional or more intensive attention, Dr. Kimberly Hieftje will provide consultation to the participant.

Benefits

The study may help the researchers find out something that will help teens be more aware of risk-taking behaviors and prevention of HIV and other STIs.

Economic Considerations

Your child will receive $30 compensation for completion of assessments for a total of $120 for participating in this study.

Confidentiality and Privacy

If you decide to have your child 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. Data will be kept for a period of five years before identifiers with the data are destroyed.

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

Information may be released if we are worried about abuse, neglect, or harm to your child or others. We will contact authorities if this is the case.

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; 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 Institutes of Health which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself/child or their involvement in this research. If you want their 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.

We will not share any of your child's information with other researchers for future research studies, even if we remove all identifiers such as your child's name.

What Information Will You Collect About My Child 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 child'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 child and your child's health that we will collect, use, and share includes:

- Research study records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
- HIV / AIDS test results
- Sexually transmitted diseases

How will you use and share my child's information?

We will use your child's information to conduct the study described in this consent form.

We may share your child's information with:

- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

What Information Will You Collect About Me 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 you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by [the name of institution or hospital created from: [start date] to: [end date] ________
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
- HIV / AIDS test results
- Hepatitis infection
- Sexually transmitted diseases
- Other reportable infectious diseases
- Physical exams
- Laboratory, x-ray, and other test results
- Diaries and questionnaires
- The diagnosis and treatment of a mental health condition
- Use of illegal drugs or the study of illegal behavior
- Records about any study drug you received
- Records about the study device

How will you use and share my information?
We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about [the new drug product or device] involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor or manufacturer of study drug/device
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your child's information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your child's information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your child's health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Voluntary Participation and Withdrawal

Participating in this study is voluntary, which means you are free to choose not to allow your child to take part in this study. You are free to decide whether or not you wish your child to participate in this study. Refusing to allow your child to participate or withdrawing from the study will involve no penalty and will have no effect on your or your child's relationship with this program. Data already collected from your child before you withdraw them from the study will still be used with group data during analysis. If you decide to have your child quit the study, all you have to do is tell the person in charge. This will not harm your child's relationship with his/her own doctors or with Yale-New Haven Hospital. The study investigators may remove your child from the study if they believe that is in your or your child'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.

Disclosure

Dr. Kimberly Hieftje is the Principal Investigator for this study and has a significant relationship with the videogame prototype company that developed the videogame intervention, One Night Stan, which your child may or may not be assigned to play during this research study. Given this conflict of interest, Dr. Hieftje will not be involved in the recruitment, enrollment, consent of participants, or data analysis of this study. You may speak with Dr. Hieftje at any time should you have questions regarding institutional or investigator interests.

Authorization and Permission

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

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

Name of Child: ______________________________

Parent Name:________________________________

Parent Signature: _____________________________

Parent Phone #: ______________________________

Date: _________________________

____ ____________________

Signature of Person Obtaining Permission Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Kimberly Hieftje *at (203) 737-5595 or kimberly.hieftje@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 Research Protection Program at (203) 785-4688. Additional information is available at https://your.yale.edu/research-support/human-research/research-participants/rights-research-participant.