COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: ***A Digital Intervention for HIV Prevention in Black Adolescent Girls (RCT)***
Principal Investigator (the person who is responsible for this research): Kimberly Hieftje, PhD, 2 Church St South, Suite 515, New Haven, CT 06510
Phone Number: 203-737-5595
Study Funding: Eunice Kennedy Shriver National Institute of Child Health & Human Development

Research Study Summary:

- **We are asking you to join a research study.**
- **The purpose of this study is to learn more about how playing a videogame might help teens like you 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 health behaviors (what you do) and perceptions (what you think), risky situations you might have encountered, your knowledge about health topics such as HIV and other basic questions about yourself before and immediately after play the game, and then again at 4 months**
- **Your involvement will require 4-5 hours.**
- **There may be some risks from participating in this study. You will be asked to play a videogame and answer questions. If you become tired, you may stop playing and take a break and return to playing the game or answering questions later.**
- **The study may have no benefits to you. The study may help the researchers find out something in the future that will help other teens like you.**
- **Taking part in this study is your choice. You can choose to take part, or you can choose to not 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 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 to participate; if so, you will have to sign this form.**

Why is this study being offered to me?
We are asking you to take part in a research study to learn more about how playing a videogame might help teens like you learn how to make healthy decisions while they are playing the videogame and in real life. We are looking for 80 adolescent back girls aged 14-18 to be part of this research study.

Who is paying for the study?
This study is funded by the National Institutes of Health (NIH), Grant # 1R21HD098031-01.

What is the study about?

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 be between the ages of 14 and 18 and be willing to play a videogame for two times for one to two hours, for a total of three to four hours of gameplay.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

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

You 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. You will be asked to play the game as well as complete assessments (questionnaires) before and after you play the videogame, and again at 4 months after you play. The goal of the assessments is to collect data about your health behaviors and perceptions, risky situations you might have encountered, your HIV-related knowledge and other basic questions about you. If you played the intervention videogame, you will also be asked if 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 last about 4 months. If you decide that you will participate, here is what will happen: During your first meeting, you 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.. You will be asked questions about your behaviors related to dating, risk-taking, and decision making. If you are completing the assessment remotely, your survey completion progress will be supervised by a member of the research team and the team member will be available for help if needed. After completing the initial assessment, you will play the assigned videogame for one hour each session for a total of four sessions, or four hours of gameplay. Your gameplay will take place through Yale-secured Zoom video conferencing. The research team will audio-record all gameplay sessions, and a member of the research team will be available for help at all times during gameplay if needed at all times.

What are the risks and discomforts of participating?

The risks associated with this study are minimal. One possible effect of playing a videogame is that you may become tired. If you experience any tiredness, the researchers would ask them 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. 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 you, answer your questions, and serve as a resource if any distress or concern arises. If you need additional or more intensive attention, Dr. Kimberly Hieftje will provide consultation to you.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit other people?
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.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?
You will be paid for taking part in this study. You will receive $30 compensation for completion of assessments for a total of $120 for participating in this study (4 assessments).

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 your 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 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 you. We will contact authorities if this is the case.

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

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 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 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
- 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 your information?

We will use your information to conduct the study described in this consent form.
We may share your 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

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. 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.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Kimberly Hieftje at 2 Church St South, Suite 515, New Haven, CT 06510.

Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

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 also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?

Your data will still be used as part of the study, and cannot be withdrawn because they will be de-identified.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203-737-5595.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date