Consent: Virtual

Hello,

This informed consent form includes important information about the study you or your child is agreeing to participate in. Please read it carefully. Once you complete and submit the form, you will be emailed a .pdf file for your records.

Please feel free to reach out to the study team if you have any questions while you are reviewing or completing this form.

Thank you,

[ra_name]

Consent Version ◯ 1. 10.08.2020, Exp. date: N/A

Informed Consent Form and HIPAA Authorization Form

Study Title: Immersive Virtual Reality as a Tool to Improve Police Safety in Adolescents and Adults with ASD

Version Date: October 8, 2020

Consent Name: Cycle B CHOP Main Study Consent

Study Principal Investigator: Julia Parish-Morris, PhD

Telephone: (267) 425-1175

Study Overview In this document, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

You are being asked to take part in this research study because you are between the ages of 12 and 60 and have been diagnosed with autism spectrum disorder (ASD).

We are doing this study to test whether virtual reality could be a useful way for people with autism to practice interacting with police officers.

If you agree to take part, your participation will involve up to 3 study visits over a 6-week period and a follow-up visit 4 weeks following your last visit. The first visit will last about 4 hours. If you participate in additional study visits, these visits will each last up to 1 hour. If you take part you will be asked to:

Complete clinical testing and questionnaires;

Briefly interact with a study staff member;

Participate in either a virtual reality (VR) or treatment-as-usual condition;

The main risks of this study are from the VR and viewing videos. Risks of VR include seizures, migraines, injury, nausea, or eye-strain. You may experience eye-strain while viewing videos.

If one or both of the interventions improves police interaction skills, it is possible that you might benefit. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this study may help researchers learn if VR is an effective tool for improving interactions with police officers.

Participation in this study is voluntary. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

If you are interested in learning more about the study, please continue to read below.

How many people will take part?
Up to 400 people may take part in this study.

What are the study procedures?
The study involves the following tests and procedures.

Clinical Evaluation: Clinical testing will be performed to learn more about your ASD diagnosis. We will also measure your basic cognitive (thinking or intellectual) ability and language skills. This testing is done to make sure that you meet study eligibility requirements. If you don't meet these requirements, you may not continue with the rest of the study.

Medical Record Review: We may look at medical records that you provide to confirm your ASD diagnosis.

Questionnaires: Depending on your age and developmental level, you or your parent will be asked to complete a series of questionnaires about your medical history, development and behavior. We will ask you and/or your parents some demographic questions about you. These questionnaires can be completed online or on paper.

Baseline Assessment: Prior to the study intervention, you will complete a short role play with a study staff member. You will be recorded during this interaction.

Study Intervention: You will be randomized into either a VR group or a treatment-as-usual (TAU) group. You have a 50:50 chance of being in the TAU group and a 50:50 chance of being in the VR group.

If you are selected for the VR group, you will engage with VR scenes presented using a headset that you will wear on your head. You will engage in multiple scenes, each lasting up to 5 minutes. The virtual reality scenes will involve interacting with police officers. You will also be asked to do some additional activities related to the VR that you engaged in. After the sessions, you will be asked about your experience with virtual reality and how you feel.

If you are selected for the treatment-as-usual group, you will use VR at the beginning and the end of the study period.

(about 3 weeks) and will answer some questions, but will not undergo any intervention.

Each group will have 3 training visits over 6 weeks. Immediately following your final training visit, we will see how much you learned about interacting with police officers. About 4 weeks later, we will assess how much you learned again.

Police Interaction:At some point during the study, you will interact with a police or security officer avatar. You will be recorded during this interaction.

Video/Audio Recording: Study procedures (including testing, intervention, and follow-up activities) will be recorded using video cameras and audio recorders. These recordings are important for the research. Video images and audio recordings will be used for clinical training, education, and research purposes. Visits and procedures performed virtually will be recorder through the videoconferencing platform.

Future Use of Data: We may wish to use the information collected about you in this study in a future study. This information will be given a unique code and will not include information that can identify you. Information that can identify you may be kept permanently in a computer database in the Center for Autism Research at CHOP. Only the study doctors and those working with them on this study will be able to see information that can identify you. If your information is shared outside of CHOP, no identifiable information will be included. If you leave the study, you can ask to have the data collected about you removed.

Visit Schedule
The table below provides a brief description of the purpose and duration of each study visit

Visit	Timing of Visit	Purpose	Main Procedures	Duration
Visit 1		Baseline/Training Visit	Clinical testing, baseline assessment, randomization into study groups, first intervention session	4 hours
Visit 2	within 5.5 weeks of visit 1	Training	Intervention session	1 hour
Visit 3	within 6 weeks of visit 1	Training and outcome assessment	Intervention session, testing how much you learned	1 hour
Visit 4	Within 4 weeks of visit 3	Outcome assessment maintenence	Testing how much you learned	1 hour

Will I receive any results from tests done as part of this study?
Feedback will be provided to participants in person or over the phone as needed, based on conversations between participating families and the study clinician.

What are the risks of this study?

Risk associated with virtual reality:

Seizures Migraines Injury Nausea Eye Strain

There is a low risk of seizures and migraines as a result of VR, so people who have a history of these will not be able to participate in this study.

There is also a risk of injury because of the difference between the VR scene and the real world. To reduce this risk, this module does not allow walking in any of the scenes. Study staff will always be in the room with you to help prevent injuries from bumping into things or falling. You will also rest between scenes/trials and after all sessions to allow you to readjust to the room.

Use of VR technology has been associated with nausea or eye-strain. To reduce these risks, you are required to rest between scenes/trials. Study staff will also repeatedly ask how you are feeling. If you report symptoms of nausea or eye-strain, sessions will be stopped.

Using VR may cause you stress or anxiety. The study staff are trained to address these feelings. You may take a break or stop the VR at any time.

Risk associated with viewing videos:
You might experience some eye-strain watching the videos. You can take breaks if needed.

Risk associated with the baseline assessment:
Completing the role play with a study staff member may cause you some nervousness or stress. The study staff are trained to address these feelings.

Risks associated with the police interaction:
You may become anxious or experience other negative feelings while interacting with the police or security officer avatar. Study staff are trained to help you deal with these feelings.

Risks associated with clinical testing:
You may find some of the tasks difficult, which may cause some nervousness. In addition, some of the testing may feel repetitive and you may become bored. Study investigators will provide breaks as needed.

Risks associated with breach of confidentiality:
As with any study involving data collection, there is the possibility of a data confidentiality breach. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms and in the research database instead of names and other private information. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

Risks associated with audio/video recording:
There is a possibility that your audio-video recording might be seen or heard by someone outside of the study team, for a reason other than educational, training, or research purposes. To reduce this risk, recordings will be kept on password-protected computers, which will be labeled with the participant's identification number only, and not with any identifying information, such as your name. A separate list will be maintained that will link your name to the study identification number so your identity can be kept private.

Do you need to give your consent in order to participate?
If you decide to participate in this study, you must sign this form. You can print or save a copy to keep as a record.

What are your responsibilities?
Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

Can you stop your participation in the study early?
You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?
The study team may remove you from the study if you experience negative effects from the study procedures, if they are concerned about your ability to interact safely with staff members during a study visit, or for other clinical reasons.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?
As part of this research, health information about you will be collected. This will include information from medical and research records, cognitive testing, and questionnaires. Information related to your medical care at SJU will go in

your medical record. Medical records are available to SJU staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation, except as otherwise consented.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data. These groups include:

Members of the research team and other authorized staff at CHOP; People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections; Representatives of Floreo who developed the VR technology used this research; The National Institutes of Health who is sponsoring this research Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability.

By law, CHOP and SJU are required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP and SJU to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

Can you change your mind about the use of personal information?
You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the site investigator in writing.

Joseph McCleery, PhD
Saint Joseph's University
Kinney Center
5600 City Avenue
Philadelphia, PA 19131

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you are in this study, the cost of your usual medical care - procedures, medications and doctor visits - will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you for taking part in this study.

Will you be paid for taking part in this study?

You will receive $20 for each visit. If you receive payment using a bankcard, the bank will have access to identifiable information necessary for the bank transfer. The bank will not have access to any medical information.

With permission, we may share your data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You will not receive any financial benefit from research done on your data.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the principal investigator, Dr. Parish-Morris at 267-425-1175. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Contact for Future Research StudiesPlease let us know if we can contact you about future research studies.

◯ I wish to be contacted about future studies
◯ I DO NOT wish to be contacted about future studies

Initials

_____

Date

_____

Use of Audio-Video RecordingsAs part of this research study, we will be recording some of the study procedures (which may include images of your face which can identify you, as well as your voice). If you allow CHOP to release these recordings to other individuals or organizations, please understand the recipients could use, distribute, broadcast, and/or publish them in ways that do no protect your privacy and that CHOP cannot control. Please indicate whether you will allow us to use these recordings for the following reasons by choosing the following:

For future research analysis at CHOP.	◯ Yes ◯ No
For future research analysis outside CHOP.	◯ Yes ◯ No
For presentations to professional and/or medical groups.	◯ Yes ◯ No
For publication in medical journals.	◯ Yes ◯ No

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research
By checking the box below, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP and SJU use and share your or your child's health information as explained above. If you don't agree to the collection, use and sharing of your or your child's health information, you or your child cannot participate in this study. NOTE: A foster parent is not legally authorized to consent for a foster child's participation.

Please type the name of the subject (who will be participating in this study)

_____
(First and Last name)

You Relationship to the Subject:

◯ Self
◯ Parent
◯ Legal Guardian
◯ Legally Authorized Representative (LAR)

Please type your name (Authorized Representative)

_____
(First and Last Name)

Date of Consent

_____

◯ CHECK HERE TO CONSENT TO PARTICIPATION IN THIS RESEARCH STUDY

Consent fully executed?

_____