Virtual Reality to Improve Social Perspective Taking in Youth With Disruptive Behavior Disorders

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

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ABOUT THIS RESEARCH

You and your child are being asked to participate in a research study. Scientists do research to answer important questions, which might help change or improve the way we do things in the future.

This consent and Authorization form will give you information about the study to help you decide whether you and your child want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You and your child may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you and your child are entitled and will not affect your relationship with the Indiana University School of Medicine.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine how different virtual reality programs may influence children's perception of their surroundings, including the thoughts and feelings of other people. You were selected as a possible participant because you have reported that your child is 9-12 years old and exhibits behaviors that may indicate the presence of a disruptive behavior disorder.

The study is being conducted by Dr. Tom Hummer from the Department of Psychiatry of the Indiana University School of Medicine, along with his research team. It is funded by the National Institute of Mental Health.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 95 parents/guardians who will be participating along with their children.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

Some procedures during the initial portion of the study may be carried out remotely. For all in-person visits, we will follow up-to-date Indiana University School of Medicine and IU Health safety guidelines. These guidelines may include screening for potential health risks, distancing, and/or a requirement for investigators and participants to wear masks.

The first portion of the study may take place over a single visit or may be broken up into multiple days. During this first portion of the study, you and your child will undergo a clinical interview to understand your child's mental health. This interview will involve questions about your child's current and past behavior, his/her personality, and how well he/she gets along with other people. This interview may be completed remotely through a secure video conference.

You and your child will also complete surveys that help us better understand your child, including questions about your child's background, family environment, medical history, physical development, emotions, behaviors, personality, media habits, and sleep patterns. These surveys include questions about you, your child, and your household. Surveys may be conducted in person or remotely. Some of this information will be used to determine whether your child meets our eligibility criteria.

Should your child indicate an immediate risk of harm to self or others, the research team will immediately notify a licensed clinical psychologist on the study team, who will activate standard IU Health clinical protocols for patient safety and management of self- or other-harm risk.

Remaining procedures must take place in person. Your child will be administered an IQ test. Next, your child will practice using the virtual reality equipment. During this activity, your child will wear a virtual reality headset, with a display screen and headphones. This is similar to virtual reality systems that can be used at home, in stores, or at arcades. During this time, your child will develop a virtual character that will be used during the other study visits. When this activity is complete, your child will complete brief surveys about how the virtual reality system makes them feel. In the rare case virtual reality activities were unable to be completed during Visit 1, they will be conducted at the beginning of Visit 2.

Your child will also be placed in a "mock" scanner that mimics the look, feel, and sound of an actual magnetic resonance imaging (MRI) scanner. If we are unsure whether your child's orthodontics or implants would interfere with our ability to acquire images of the brain, your child may also undergo a brief (roughly 10 minute) MRI scan to assess image quality.

We expect the total time for these procedures to last 3-4 hours: about thirty minutes for the surveys, 1-2 hours for the clinical interview, and 1-1.5 hours for the IQ test, virtual reality task, and mock scanner procedures.

Visit 2: If we determine that your child meets our eligibility criteria, we will schedule a second visit. During this visit, participants will undergo an MRI scan that will last about 1 hour. Prior to the scan, you will complete an MRI screening form and a log of the medications or caffeine your child has taken that day. Your child will practice the tasks they will perform during the MRI scan. After the scan, we will ask your child to identify which images were shown during the MRI scan. This visit will last about 2 hours.

Prior to Visit 3, we will provide a reminder of your Visit 3 timing with a list of the medications/caffeine you listed for your child at Visit 2. For the purposes of the study, it would be helpful if the same medications/caffeine were used on the day of Visit 3. However, this is not a requirement of the study. Please use your best judgement and follow your doctor's orders when providing any medications.

Visit 3: Your child will complete the virtual reality activity. During this activity, your child will wear the virtual reality headset. Your child will interact with different characters and objects in virtual environments, with goals to complete. The entire virtual reality session will be digitally recorded on a video camera that is in the room. This will allow us to look back at the duration and timing of any actions that we may have missed. Your child will also answer questions about how they feel about each scenario, the virtual characters, and the virtual reality system. Following the virtual reality procedure, your child will undergo another brain scan for about 1 hour. This scan may not be performed if the previous scanning session (at Visit 2) was not completed successfully. Prior to the scan, you will again complete the MRI screening form and medication log, and your child will briefly practice the tasks. After the scan, your child will again be asked to identify images from the scan. Lastly, your child will complete a survey assessing their opinions of the virtual reality technology, and we will ask you and your child about ideas for future research based on personal experiences. We expect this visit to last 2-3 hours.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While participating in the study, the risks, side effects, and/or discomforts include:

You and/or your child may experience some stress from the clinical interview or when completing surveys, including being uncomfortable answering some questions or increased tiredness. In addition, there is risk that information provided during the interviews will be disclosed, should you or your child provide any information that we are required by law to report to authorities, such as any indications of child abuse/neglect (including sexual abuse) or any actions that are placing the child or others in harm's way. Such disclosure may present civil or criminal liability.

If your child indicates thoughts or commits actions that present immediate danger to self or others, we will work with you and your child to make sure everyone is safe. The study team will not be responsible for any costs should your child require immediate medical care. Costs not covered by your health care insurer will be your responsibility. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

Your child may have some side effects associated with wearing the virtual reality headset and interacting with the virtual environment. Some people may experience temporary motion sickness, dizziness, nausea, or headaches that should improve when the headset is removed. In addition, your child may be distressed by the words or actions of characters in the virtual environment, and your child

may experience anger, distress or frustration while attempting to complete tasks in the virtual environment.

In addition, there is the possibility of loss of confidentiality.

Risks of Brain Imaging:
Anything that is drawn to a magnet can be pulled through the room toward the MRI scanner and potentially harm anyone who is lying in the scanner. To reduce this risk, all individuals involved in this study must remove all metal from their clothing and all metal objects from their pockets when in the scanning environment. There is also an established security zone to prevent objects containing iron from coming close to the magnet.

Other potential risks associated with the scanning procedure include the following:

Claustrophobia: MRI scans require people to remain still in a confined space. This may produce discomfort in some people. If the child becomes uncomfortable during the scan, he/she can be immediately removed from the scanner.

Implanted Devices: People with metal objects in their bodies are at risk for injury from MRI examinations. Subjects will be screened for the presence of any of these or other metallic objects by explicit questioning with a checklist and will be excluded from the study if they have any metal in their body.

Stress: Your child will see images depicting painful and non-painful actions during the scan. These images may cause some stress.

Medication Patches: The FDA has recently issued a warning against the use of transdermal medication delivery patches as they can result in burns to the skin if worn in an MRI. We will check to make sure the child is not wearing any medication patches.

Hearing Protection: The MRI scanner produces tapping sounds during operation, which may reach loud levels. To minimize discomfort from this noise, the child will be provided with disposable earplugs that suppress external noise levels but do not eliminate voice communication with the scanner operator.

Quench hazard: The MRI scanner requires cryogens (cooling agents) to maintain the superconductive state of the magnet. In the event of a quench (accidental loss of superconductivity), these cooling agents will rapidly vaporize. If the ventilation in the room is not adequate, the room can fill with gaseous helium. Breathing this over several minutes can cause asphyxiation. The scanner operator is well aware of this risk and knows the proper procedures to evacuate the facility in case of a quench.

We will take the following measures to reduce the risks of participation for you and your child:

While completing the clinical interview or surveys, you and your child can tell the researchers that you do not feel comfortable or do not want to answer a particular question. You or your child may discontinue the interview and the study if you do not feel comfortable.

To protect your confidentiality, we will take care to make sure that any and all personal information about you and your child is kept under lock and key or in protected computer files. We will work to protect this information from anyone who is not connected with this study, if telling them could identify you as the source of the information, except as required by law (See HOW WILL MY INFORMATION BE PROTECTED?).

If your child is distressed or feels unwanted side effects from the virtual environment, they may notify study personnel or withdraw from the study if they want. Removing the headset will help reduce any physical side effects. We will work together to calm your child, and you and your child can decide whether to continue in the study.

When risks of COVID-19 are present, you and your child may risk exposure to the virus by entering our research facilities. We will, however, have safety procedures in place to protect your health and the health of others present. Screening questions will be asked to you and to the research team prior to each visit. If any new symptoms consistent with COVID-19 are reported, the visit will be rescheduled.

When necessary, the following additional precautions will be taken. Masks may be provided for you to be worn in the facility for the duration of their visit. Social distancing guidelines will be followed whenever possible, and in some areas, protective barriers will be placed where face-to-face conversations occur. All portable equipment (electronic tablets, virtual reality headset) will be used cautiously and with care taken to keep them clean. We will use disposable eye guards with the virtual reality headset to minimize skin contact with the equipment. Hand sanitizer will be used after using any shared equipment, and all rooms and equipment will be thoroughly cleaned before and after each visit.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

There is a possibility of some improvement in perspective taking skills or insight for a short period of time. Your child may also directly benefit by getting to experience advanced virtual reality technology.

WILL I RECEIVE MY RESULTS?

We may learn things about your child from the study activities that could be important to your child's health or wellbeing. If there are abnormal findings from the clinical interview, such as indication of a previously undiagnosed mental health disorder, you will be notified. In addition, brain scans will be reviewed, and we will contact you to provide information regarding any abnormalities that are

detected. You may need to meet with professionals with expertise to help you learn more about these results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?

The study team will collect information about you and your child from the answers you both provide as part of the study. This information, some of which may identify you and/or your child, may be used for research-related purposes, such as making sure you and your child meet the criteria to be in this study, gathering information about your child's medical history to include in the research data, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will only include information you directly provide to us.

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law, including indications of child abuse/neglect (including sexual abuse) and threats of immediate harm to self or others. No information which could identify you will be shared in publications about this study.

Only research staff will have access to the video recordings. We will destroy these videos when the study is finished and all analysis is complete.

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

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH).

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;

(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;
(5) if required by the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you or your child for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

NATIONAL INSTITUTE OF MENTAL HEALTH DATA ARCHIVE

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified health information gathered during your research participation to the NDA. In the event that you do not agree to share your or your child's data, or you do not complete the entire protocol, data gathered during your study visits will not be sent. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

NIMH will also report to Congress and on its website about different studies that researchers are conducting using NDA study data. However, you will not be contacted directly about the health information gathered during your research participation. If you would like more information about the NDA, this is available on-line at:

https://ndar.nih.gov/ndarpublicweb/Documents/NDAR_data_sharing_language_fin.pdf .

WILL I BE PAID FOR PARTICIPATION?

You and your child will be paid for participation in this study. For remote participation, compensation will be provided via electronic gift cards. You will receive $25 for your participation and your child will receive $75 for initial study procedures ($25 for surveys, $25 for clinical interview, $25 for virtual reality practice/MRI mock scanner). In addition, your child will receive $100 for completing Visit 2 and $150 for completing Visit 3. You and your child will be paid in cash at the end of each study visit. You will also be compensated for parking at each visit with a parking voucher.

You will be paid for each visit separately. Your child will only be compensated for visits and tasks that have been completed. For instance, if you and your child complete the interview and surveys but your child does not complete the IQ test, virtual reality task, and mock scanner procedures, you will receive $25 and your child will receive $50. If you and your child withdraw prior to the MRI at Visit 2, your child will receive $25 for that visit, or if you and your child withdraw prior to the MRI at Visit 3, your child will receive $75 for that visit. Parking will be compensated in full for each visit.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you or your child for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Dr. Tom Hummer, at 317-274-8670. After business hours or in the case of an emergency, please call the IU Health operator at 800-622-4989 and ask for the physician on call for child psychiatry.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, let a member of our research team know.

If you choose to withdraw your authorization for use and disclosure of your or your child's protected health information, you must do so in writing by notifying Dr. Tom Hummer, 410 W. 10th Street, Room 1001R, Indianapolis, IN 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team or the research organizations may still use information about you and your child that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

You and your child's participation will be terminated by the investigator without regard to your consent if we determine that you and/or your child do not meet our eligibility criteria. In addition, participation may be terminated if there are adverse health consequences from using virtual reality equipment during practice or intervention or from any other study procedures. Inability to complete the MRI scan, including claustrophobia or an unforeseen health consequence, can also result in termination of participation.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Child's Printed Name:_____

Child's Address:_____

Participant's Printed Name:_____

Participant's Address:_____

Participants Signature:_____ **Date**:

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____