RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR PARENTS/LEGAL GUARDIANS OF MINOR PARTICIPANTS (SA3)

Sponsor / Study Title:	**Virginia Commonwealth University (VCU) / "Impact VR: An Emotion Recognition and Regulation Training Program for Youth with Conduct Disorder"**
Principal Investigator:	**Nicholas Thomson, PhD**
Telephone:	**804-828-6386 (24 Hour)**
Address:	**VCU Health - West Hospital** **1200 E. Broad St.** **West Hospital, 5th Floor, West Wing, Rm 5-025** **Richmond, VA 23298**

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You and your child are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your child.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You and your child are invited to be in this research study because your child has either received services through VCU Health, was a referral, or participated with/in one of our community partnerships. Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

Dr. Nicholas Thomson is the founder of and has an ownership interest in Arche VR, LLC, the small-business sponsor of this project. As a result, the investigator may benefit financially from a successful study. Additional steps have been taken to manage the potential conflict of interest that this financial arrangement may create. Please speak with your study doctor if you have questions about this.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?
The purpose of this research study is to find out if a virtual reality emotion recognition intervention (Impact VR) is effective for reducing conduct problems. We think that youth who receive the Impact VR will see greater improvements than youth who do not receive the intervention. This study will allow us to learn more about the intervention's effectiveness. We also want to understand if the intervention affects other behaviors, such as emotion regulation, antisocial behaviors, and emotion recognition.

What will happen if I participate?
You will be asked to complete questionnaires and interviews about your child's behavior, personality, and experiences, as well as your own behaviors, personality, and experiences. Your child will also complete questionnaires and interviews about their behavior, personality, and experiences. This session will take you and your child about one to two hours to complete.

Your child will also be randomly assigned (like the flip of a coin) to one of two groups, either the control group or the Impact VR group. If your child is assigned to the control group, your child will complete a brief PowerPoint presentation on emotional faces and how to identify these emotions. If your child is assigned to Impact VR, your child will receive Impact VR, which includes four 20-minute sessions of virtual reality intervention over four weeks. One session will be conducted each week.

For all participants, you and your child will be invited to complete the same surveys again at 4 weeks and 3 months. If this is not convenient, we will arrange a time for you and your child to complete the follow-up session over the phone or the internet.

You and your child's participation in this study will last up to 3 months. Approximately 150 people will participate in this study.

What alternative treatments or procedures are available?
You have the option to take a paper survey instead of an electronic one. Ask the study staff if you would like a paper survey. This is a testing study only. No alternative treatment is provided.

What are the risks and benefits of participating?
There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now.

Risks, Discomforts and Benefits to You and Others	
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.	• The information from this research study may lead to improved interventions in the

• The study questionnaires and interviews ask questions that are sensitive, personal, and may be upsetting in nature and may make you feel uncomfortable or upset. Some of these questions discuss the use of drugs and criminal activities. • Study randomization may be uncomfortable or upsetting if you, or your child, do not like the assigned group.	future for violently injured youth.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

Non-Physical Risks (For You and Your Child)

- Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you or your child.
- Questionnaires may contain questions that are sensitive, personal, and potentially upsetting in nature. You and your child may refuse to answer any question that makes you feel uncomfortable.
- This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study. You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study.

WHAT ARE THE COSTS?

The sponsor is paying for everything in this study. You will not be charged for any study visits.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You and your child will each be paid $75 for each study visit. If you and your child complete all scheduled study visits, you will each have received a total of $225.

You will be paid following each completed visit.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

ALTERNATIVES TO PARTICIPATION

This research study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS

Any new important information that is discovered during the study which may influence your willingness to continue participation in the study will be provided to you.

CAN I STOP BEING IN THE STUDY?

You and your child can stop being in this research study at any time. Leaving the study will not affect your, or your child's, medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you or your child are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- The investigator thinks it necessary for your health or safety
- The sponsor has stopped the study
- You have not followed study instructions
- Administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services
- Advarra IRB

In general, we will not give you any individual results from the study. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

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 Website will include a summary of the results. You can search this Web site at any time.

We will not tell anyone the answers your child gives us. However, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we must let people in authority know so they can protect your child.

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In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study staff or another researcher without asking you for additional consent.

If you or your child are or should become involuntarily detained, confined or incarcerated (in a jail, prison, juvenile, or alternative facility), you should be aware that confidentiality regarding your or your child's status cannot be guaranteed. Personal information about you or your child might be shared with or copied by authorized representatives of the prison/juvenile facility and/or prison/juvenile system.

Certificate of Confidentiality

To help us protect your privacy, we will apply for a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers may share information about you or your participation, or your child, in the research study without your consent if a disclosure is made, such as child or elder abuse or neglect, or harm to self or others.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information. .

HOW WILL MY CHILD'S HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share your child's identifiable health information with us and/or permit us to access existing information from your child's healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires and added to your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

- Information about mental health

Who will use or share protected health information about me?
VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator, and research and study staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Research Collaborators
- Study Sponsor

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research study, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at the address listed on page one of this form.

If you decide not to sign this form, you will not be able to take part in the study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00069982.

STATEMENT OF CONSENT AND PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I and my child otherwise would be entitled. My signature indicates that I freely consent to participate and give permission for my child to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants

Adult Participant Name (Printed):_____

Adult Participant's Signature Date:_____

Name of Person Conducting Consent Discussion (Printed):_____

Signature of Person Conducting Consent Discussion Date:_____

Investigator Signature (if different from above)
_____ Date_____

Signature Block for Enrolling Child Participants – Parent/Legal Guardian Permission

_____
Name of Child/Youth Participant

_____
Name of First Parent/Legal Guardian (Printed)
Study staff – verify that this individual is the child's parent or legal guardian.

_____
Required First Parent/Legal Guardian Signature Date