

**University of Wisconsin-Madison  
Consent to Participate in Research and  
Authorization to Use/Disclose Identifiable Information for Research**

**TITLE OF THE STUDY:** Virtual-reality and Emotion Regulation in Adolescents (VERA)

**LEAD RESEARCHER:** Ryan Herringa, M.D., Ph.D.; (608) 263-6068

**INVESTIGATORS:** Ryan Herringa, M.D., Ph.D., Associate Professor, Department of Psychiatry  
Justin Russell, Ph.D., Post-doctoral Fellow, Department of Psychiatry

**INVITATION**

We invite you to take part in a research study about the use of virtual reality (VR)-based biofeedback treatment to better understand how boys and girls might learn to regulate and control their body. We are interested in finding out whether our treatment is feasible for youth, and whether it can work to improve youths' ability to self-regulate and relatedly, reduce mental health symptoms and/or problem behaviors. We are inviting your child to participate because your child meets the eligibility requirements for this study.

The purpose of this consent and authorization form is to give you the information you need to decide whether you want your child to be in the study. It also explains how health information will be used for this study and for other research in the future and requests your authorization (permission) to use your child's health information. Please ask questions about anything in this form that is not clear. If either of you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want your child to be in the study. This process is called "informed consent."

Your child can participate in the study only if you give your permission. We will also ask your child if he/she is willing to take part in the study after receiving your permission.

**STUDY SUMMARY**

**What is this study about?**

The purpose of this study is to determine whether a virtual reality-biofeedback treatment for emotional dysregulation is feasible (i.e., can it be done?) and efficacious (i.e., does it work?). This research is a pilot study being conducted with a small group to determine whether the treatment should be investigated in larger trials. Information gathered during this process will help us change the treatment to make it more effective.

**What will happen during the study?**

Your child will be asked to participate in up to six sessions of a virtual-reality game, where they use their breathing to move through various

underwater scenes. This game is to teach youth how to control their body and breathing, and in turn, regulate their emotions and arousal in a safe and healthy way. A respiration belt will help your child learn to engage in deep, rhythmic breathing. Assistants will be monitoring the game at all times and will be available to help your child if he or she has any questions. After each session, they will be asked to answer questions about their feelings or behaviors. This will take place in a private room 30 minutes each. After your child finishes the game and questions, he or she will be given \$30-\$40 for their participation in each session, and up to \$200 for completing all six sessions. You will not be required to take part in the study in any way.

**How much time will my child spend on the study?**

There may be up to six sessions in total, to be completed not more than one session per day. All six sessions will be offered if your child is still in residence. Study activities are considered complete at the time of discharge, regardless of how many sessions are complete. Each study session will take around 1-hour. All sessions will be completed at their Dane County Juvenile Court Program facility. At each session, we will ask your child to complete the 30-minute game and a set of online survey questions that should take approximately 10-20 minutes to complete.

**Could taking part in the study help me or my child?**

We anticipate that completing the treatment might reduce the severity of your child's mental health symptoms or increase awareness about/improve emotion regulation skills. However, this treatment is still in initial testing, and it is possible no effect will be observed.

**What are the main risks of taking part in the study?**

All procedures have possible risks. The risks of this study are low, and we will watch for any problems during the study procedures so that we can stop if necessary. The consent form explains the possible risks in more detail. For this study, there are some

important risks for you to know. First, your child may have difficulty answering questions about their history and mental health symptoms. Though unlikely, your child might experience motion sickness symptoms while in the virtual environment. The underwater environment in the virtual reality game may be overwhelming to your child. There is also a small risk to your confidentiality if someone outside the study team obtained the study data.

**How is research different from health care?**

Participating in a study helps answer a research question. Test results will not be used for your child's health care.

**Questions about the study?**

Contact the research team, The BRAVE Research Center by phone at 608-265-3610 or via-email at [braveyouthlab@psychiatry.wisc.edu](mailto:braveyouthlab@psychiatry.wisc.edu)

**Questions about your child's rights as a research participant?**

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

**MORE INFORMATION ABOUT THIS STUDY****Why are researchers doing this study?**

The purpose of this research study is to learn whether a VR-based treatment is possible among youth highly vulnerable to difficulties in emotion regulation. We want to learn if the treatment is comfortable, tolerable, and even enjoyable for kids. We are doing this research because we want to learn more about whether we can perform future studies which will tell us about the efficacy of VR treatments (i.e., do they work) and how we can improve the VR experience for kids. We hope that any differences we find will help us create better treatment options. This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of up to 135 youth between the ages of 13-17 and their caregivers will participate in this study. Funding for this study is provided by the Brain & Behavior Research Foundation.

## What will happen in this study?

### Overview

If you agree to your child's participation in this research study, the researchers will ask your child to participate in up to six study sessions, with no more than one session per day, that will take place at your child's Dane County Juvenile Court Program facility in Madison, Wisconsin. Sessions will be approximately one hour in length. There will also be surveys that your child to complete after each session. If you agree to your child's participation, study activities during each session will include the following for your child: answering questions about thoughts, feelings, and behaviors, then completing a task that involves wearing a virtual reality headset while wearing sensors that monitor activity in the body. The sensors are stickers that we'll ask your child to wear on their torso and fingers to tell us about their heart activity and sweat levels, as well as a respiration belt to measure breathing. The VR sessions will put your child in some calm scenic environments as we collect some baseline data, then through an underwater adventure that will last around 15 minutes (software provided by Explore DEEP Ltd.). For the first virtual reality session, your child will play a training version of the game and navigate a serene coral reef environment. For sessions two through six, your child will have the option to play the training version again or choose to play a more challenging version of the task that is darker in color and has lower lighting, making it feel deeper underwater. Your child may skip any question during the online or in-person questionnaires that they do not wish to answer, and they may discontinue the study at any time.

### Sharing Data Across Studies

If you participate in other studies in Dr. Herringa's lab, we may be able to share data across studies to decrease burden. Sharing data may mean not having to complete certain tasks at study visits if they have already been completed in the course of another study within a specified timeframe. These data may include questionnaires and/or behavioral data. If you are interested, a study team member can explain all the options and details of completing more than one study in the Herringa lab.

A description of this clinical trial will be available on <http://www.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.

## Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your child's physical or mental health that includes their name or other information that can identify them, like their date of birth or medical record number. To do this study, we will collect and use the following kinds of PHI from your child:

### From procedures done for this study:

- Body responses from your child, including muscle tension, perspiration, heart rate, and respiration.
- Questionnaire and interview information about your child's thoughts and experiences.
- Results of tests or procedures done as part of the study
- Things you tell the researchers about your child's health

We are requesting your email address so we can answer any general questions you may have. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the study team at 608-265-3610. You do not have to provide your email address to participate in this study.

**How long will my child be in this study?**

Your child's participation will include up to six study sessions. Study sessions may happen whenever availability allows, but may not be more than once per day. All six sessions will be offered if your child is still in residence, so they may complete only a subset of the sessions if they leave the facility. Study activities are considered complete at the time of discharge, regardless of how many sessions are complete.

**How is being in this study different from my regular health care?**

This study is not part of your child's health care. Participation in this study will not involve any treatment intervention or follow-up care. This study is observational in nature.

**Do I have to be in the study? What if I say "yes" now and change my mind later?**

No, your child does not have to be in this study. Taking part in research is voluntary. This means that you decide if you want your child to be in the study. If you decide now for your child to take part, you or your child can choose to leave the study at any time. If you decide to enroll your child in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

If you decide not to enroll your child in the study, or if you choose to leave the study, your choice will not have any impact his or her treatment, sentence, or length of stay in the Dane County Juvenile Court program. This decision will not impact any treatment relationship you or your child have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you or your child receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you or your child. Neither you nor your child will lose medical care or any legal rights.

Your authorization allows researchers to use your child's protected health information (PHI) indefinitely.

However:

- You can choose to take back your authorization for researchers to use your child's health information at any time before or during participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, your child will not be able to continue to take part in the research study.
- To take back your authorization, you will need to tell the researchers by contacting the Lead Researcher, Ryan Herringa, MD, PhD, at (608) 263-6068.

**Will being in this study help my child in any way?**

Being in this study may or may not help your child directly. Your participation in the study may benefit other people in the future by helping us learn more about new treatments for emotion dysregulation in kids. We hope, but cannot guarantee, that your child might experience improved self-regulation or a reduction in mental health symptoms or problem behaviors from taking part in this study. However, though this study investigates a potential treatment for youth highly vulnerable to difficulties in emotion regulation, this study is not a substitute for your regular medical care. Your child should continue to see their regular medical providers.

**Will I receive the results of research tests?**

All the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your child's doctors the results of these research tests except in the following scenario: If we believe that your

child’s responses on the questionnaires indicate potential for self-harm, or danger to self or others, the staff at your child’s Dane County Juvenile Court facility will be informed in case help is needed.

**What are the risks?**

There is a risk that your child’s information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

Psychological Discomfort

Some questions may make your child feel uncomfortable. These questions are similar to what would be asked in a clinic. Your child may choose not to answer such questions. Some people may also feel uncomfortable answering questions about their thoughts and feelings. This may be especially true for participants when asked about their traumatic experiences. It may be painful or upsetting to recall details of the event.

Some of the underwater scenes in the virtual reality game are designed to increase physiological arousal through the use of darker colors and lower lighting and visibility. This may cause your child to become overwhelmed or distressed while playing the game. However, your child has complete control of ending the game at any time.

Motion Sickness

Some people who use virtual reality or other types of immersive media (e.g., 3D movies) can find that the experience causes symptoms similar to motion sickness – nausea, fatigue, general discomfort. This can be caused by a ‘disconnect’ in awareness of the body’s true physical movement, and the input being provided to the eyes and ears by the virtual environment. Such symptoms typically resolve shortly after leaving the virtual environment. While we have taken several steps in designing the virtual environment that minimize risk of motion sickness, there is still a risk that your child may experience these symptoms.

**Will being in the study cost me anything?**

There will be no cost to you for any of the study activities or procedures.

**Will I be paid or receive anything for being in this study?**

We will pay your child \$30-\$40 after each session that they complete:

<b>Study Day 1</b>	\$30	<b>Study Day 4</b>	\$35
<b>Study Day 2</b>	\$30	<b>Study Day 5</b>	\$35
<b>Study Day 3</b>	\$30	<b>Study Day 6</b>	\$40

Payment will be made in cash or via a debit card and will be kept with your child’s personal belonging for them to receive upon discharge. If your child completes all the study activities, they may receive up to \$200. If they choose to leave or we take your child off the study for any reason, they will only receive the payment for completed visits. If they choose to withdraw from the study at any time during a visit, you will receive payment for that entire visit.

Researchers may develop products from the samples and information you provide for this study. Some of these products may have commercial value. If the research team or others use your samples or information to develop products of commercial value, you will not receive any profits from products created from your samples or information.

## What happens if I am injured or get sick because of this study?

If your child is injured or gets sick because of this study, medical care is available to you through UW Health, your child's local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your child's regular health care provider.
- Call the Lead Researcher, Ryan Herringa, MD, PhD, at (608) 263-6068 to report your child's sickness or injury.

Here are some things you need to know if your child gets sick and/or injured because of this research:

- If the sickness and/or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if your child gets sick or is injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights your child may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

## How will researchers keep my research information confidential?

We have strict rules to protect your child's personal information and protected health information (PHI). We will limit who has access to your child's name and other information that can identify them. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify your child directly without your permission. Further, your child's research information will not impact your child's adjudication proceedings in any way whatsoever, nor will it be released to anyone in the Dane County Juvenile Court Program.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

## Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Accounting and billing personnel, or do other tasks related to this study

## Who outside the UW-Madison may receive my information?

- Collaborating researchers outside UW-Madison
- Explore DEEP Ltd.
- U.S. FDA

**Certificate of Confidentiality**

To help us protect your privacy, we will obtain a Certificate of Confidentiality from the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For example, if there is a court subpoena, we will use the Certificate to resist any demands for information that would identify your child, except as explained below. Once issued, the Certificate will retroactively cover information collected since the beginning of the study.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency-funded projects or for information that must be disclosed 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 we will not use the Certificate to withhold that information.

**What will happen to my data after my participation ends?**

We will keep all your child's data for an indefinite period, meaning we have no plans of ever destroying your data. Keeping data or samples for future research is called "banking." The banked data and will be kept in a secure location for use by researchers.

This is what will happen with your child's banked data:

- We will use the data in future research projects research on mental health. We may also use them for other types of research.
- The data may be shared with other researchers at University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data will be labeled with a code instead of your child's name.
- When we give your child's data to other investigators for research projects, they will not be able to use the code to figure out which data and biospecimens are your child's.
- The research team will maintain a link between your child's data and their identifiable information kept by the study team.
- You can request to have your child's data removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data:

- Banked data will not be shared with your child's healthcare providers or used in your child's treatment outside this study.

**Will information from this study go in my medical record?**

None of the information we collect for this study will go in your child's medical record.

**What if I have questions?**

Study team members are the primary point of contact if you have questions during a study visit. In addition, please contact the study team at 608-265-3610 or email [braveyouthlab@psychiatry.wisc.edu](mailto:braveyouthlab@psychiatry.wisc.edu) with any questions or comments you may have about the study. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research

HS IRB#2021-0185 (VERA)

**BRAVE ID:** \_\_\_\_\_

Lead Researcher: Ryan Herringa, M.D., Ph.D.; (608) 263-6068

Parent/Guardian Consent

compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.



### **OPTIONAL STUDY ACTIVITIES**

This part of the consent form is about additional related activities that you can choose to take part in. These activities are optional. You can still take part in the main study even if you say “no” to any or all of these. These activities will not help you directly. We will not tell you the results of these optional components. We will not put any of these study results in your medical records. We will not disclose any data to anyone outside the research study team, and it will not impact your child’s adjudication process in the Dane County Juvenile Court Program in any way. Taking part in the optional activities will not cost you or your child anything, nor will they involve any additional activities to be completed by your child.

#### **JUVENILE RECORD REVIEW**

We would like your permission to use your child’s case record for this study. From the case record, we want to collect information about the crimes your child has been arrested for. Everything taken from your child’s records will be recorded on a form without his or her name on it, and no one will be able to link the form to your child. The form will be stored in a private, online repository where only the study researchers have access to it. Only the main researchers in the study will have access to your child’s record and the record will only be accessed in the facility with the facility staff. Please orally indicate your preference for record access to a study researcher.

**Yes**, the research team **may access** my child’s juvenile court records; OR

**No**, the research team **may not access** my child’s juvenile court records.

#### **CONTACT FOR FUTURE STUDIES**

We would like to keep your contact information so that we can reach you for possible future studies, furthering our efforts to better understand how biology and experience affect child development. Your contact information will be kept in a secure location. This is completely voluntary and optional. You can choose to have the study team destroy your contact information after this study is completed, and you will not be contacted for any follow-up studies. Please orally indicate your preference on contact for future studies to a study researcher.

**Yes**, the research team **may** keep my contact information for possible future studies conducted in the BRAVE Research Center.

**No, I do not want** the research team to keep my contact information after this study is completed, and I do not want to be part of any future studies conducted in the BRAVE Research Center.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY  
AND  
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION**

You do not have to agree to participate. If you refuse, however, your child cannot take part in this research study.

If you agree to participate, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study and your child's participation, and the researchers have answered your questions.
- You agree to your child's participation in this study.
- You give authorization for your child's protected health information to be used and shared as described in this form.

You will provide oral consent to the researchers over the telephone. You will be given electronic access to a copy of this consent form for your record.