

**STUDY TITLE:** Identifying and Mitigating Behavioral Barriers to Reading Success

**STUDY NUMBER:** 2018-3106

**FUNDING ORGANIZATION:** Place Outcomes Research Award at Cincinnati Children's Hospital Medical Center

Courtney M. Brown, MD, MSc  
Name of Principal Investigator

513-636-3778  
Telephone Number

## **INTRODUCTION**

We are asking for your permission for your child to be in a research study so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow your child to be in the study. You can ask questions at any time.

## **WHY ARE WE DOING THIS RESEARCH?**

In this research study we want to learn more about how children benefit when healthcare providers work more closely with parents and with schools. There are many services and strategies that can help kids focus, stay calm, get along, and succeed in the classroom. Some services are offered in the education system, and some are offered in the healthcare system. We are working to coordinate services better and communicate better -- with schools and with parents -- so we can be better and faster at figuring out what help kids need and getting them that help.

We are asking your child and other children who need more support with behavior to be in the research, because we want to know whether this closer communication helps to reduce behavior problems and keep children in the classroom and learning.

## **WHO IS IN CHARGE OF THE RESEARCH?**

Dr. Courtney Brown is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study. An internal grant from CCHMC is paying for this study.

## **WHO SHOULD NOT BE IN THE STUDY**

Your child cannot be in this study if he/she has any of the following:

- is not 5-12 years old
- if you are not the legal guardian

**WHAT WILL HAPPEN IN THE STUDY?**

The research staff will explain each visit to you. You will be able to ask questions to make sure that you understand what will happen.

If your child qualifies and you decide you want your child to be in the study, you will meet with our research staff twice over the next 6 weeks to 3 months at a location convenient for you.

There will be one visit at the time of enrollment, and another visit 6 weeks to 3 months later. Each visit will last 30-60 minutes.

At each visit, you will fill out the Child Behavior Checklist, an assessment of your child's behavior. If needed, our research staff can help you read the questions and record your responses.

We may request information from the school about the number of calls home about behavior, the number of disciplinary referrals, and the number of missed school days (including suspensions) for your child from the last 3 months of school until 3 months from now.

Throughout the study period, the doctors and psychologists on our study team will serve as additional resources to help you navigate the system of care for your child. We will NOT be providing any experimental treatment. We will contact you by telephone at least monthly (more frequently per your request) to find out how things are going and offer help with any barriers you have encountered in seeking help for your child.

**WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?**

Being in this research may not help your child directly. As part of this research, the doctors and psychologists on our research team will serve as an additional resource to help you navigate the system of care for your child, at no cost to you. We will give you copies of your child's behavior assessments for your records. You will be able to share these results with anyone you choose.

**WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?**

There are no significant risks involved in participation in this study. The only potential discomfort is the time and effort spent completing questionnaires. There may be other risks that we do not know about yet.

**WHAT OTHER CHOICES ARE THERE?**

Instead of being in this study, you can choose not to have your child be in it.

**HOW WILL INFORMATION ABOUT YOUR CHILD BE KEPT PRIVATE?**

Making sure that information about you remains private is important to us. To protect your privacy in this research study, we will take the following measures: Only the assessors and researchers will have access to the research records. Records will be stored by number and not by name. Records will be stored behind multiple electronic and physical barriers at CCHMC.

By signing this consent form you are giving permission for representatives of the Cincinnati Children's

Hospital Medical Center (“CCHMC”), the Researcher and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, to be allowed to inspect sections of your research records related to this study.

Information collected as part of this study may be published in a professional journal. All information from the questionnaires will be reported in summary form. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization. After the study has ended we will keep the data for three years.

The investigators have ethical and legal obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person.

### **WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?**

The study doctor will tell you if they find out about new information from this or other studies that may affect your child’s health, safety or your willingness for your child to stay in this study.

### **WILL IT COST YOU ANYTHING EXTRA FOR YOUR CHILD TO BE IN THE RESEARCH STUDY?**

There are no costs for participating in this study.

### **WILL YOU/YOUR CHILD BE PAID TO BE IN THIS RESEARCH STUDY?**

You will be paid \$20 for each study visit as reimbursement for your time and effort. Total possible reimbursement is \$40.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your child’s study chart. If you move, you will need to complete another W-9 with an updated address.

### **WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

### **CONTACT FOR FUTURE RESEARCH?**

It is possible that you may be eligible for and interested in future research studies. By checking the box below, you agree to allow us to contact you in the future to let you know about future research opportunities.

I agree to be contacted for future research studies.

### **AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH**

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

#### **What protected health information will be used and shared during this study?**

CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's CCHMC medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

#### **Who will share, receive and/or use your child's protected health information in this study?**

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

#### **How will you know that your child's PHI is not misused?**

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

#### **Can you change your mind?**

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

#### **Will this permission expire?**



Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

**Will your child's other medical care be impacted?**

By signing this document you agree for child to participate in this research study and give permission to CCHMC to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

**SIGNATURES**

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

\_\_\_\_\_  
Printed Name of Research Participant

\_\_\_\_\_  
Signature of Parent or Legally Authorized Representative\*

\_\_\_\_\_  
Date

\* Printed name and relationship of legally authorized representative (parent vs. other legal guardian)

\_\_\_\_\_  
Signature of Individual Obtaining Consent

\_\_\_\_\_  
Date