STUDY TITLE: ADHD Portal Intervention Study

FUNDING ORGANIZATION: Agency for Healthcare Research and Quality

Jeff Epstein, Ph.D.
Name of Principal Investigator

513-636-8296
Telephone Number

INTRODUCTION

We are asking you to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you 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 be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want test new features on the ADHD web portal designed to make it easier for parents and teachers to set up and implement behavioral interventions for children with ADHD.

We are asking you and other parents with children with ADHD to be in the research.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Jeff Epstein is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

CCHMC is being paid by Agency for Healthcare Research and Quality to do this study.

WHO SHOULD NOT BE IN THE STUDY

You cannot be in this study if you have any of the following:

1. Do not have a child grades K-6 with ADHD.
2. Are not willing to have one of your child's primary teacher participate in the study.

WHAT WILL HAPPEN IN THE STUDY?

We are asking you and other parents to be in this study because you have a child who is treated for ADHD and are being cared for by a pediatrician who uses the mehealth for ADHD web portal to assist with ADHD assessment and treatment. We hope to enroll up to 200 families that use the mehealth for ADHD web portal.

If you agree to participate, you will be asked to complete a set of questionnaires that will ask you about your child's behavior and the care that your child receives. You will also be asked to

complete 3-4 questionnaires over the next year. The first set of questionnaires will take about 30 minutes to complete. Subsequent sets of questionnaires should take about 15 minutes to complete.

Your child's teachers will also be asked to complete a set of questionnaires about your child's behavior at the beginning of the study and 2-3 times over the next year. Your child's teacher will be asked if they wish to participate in the research study. If you consent to participate with more than a month remaining in the school year and your child's teacher decides they do not want to participate, your family will not be allowed to enroll in this research study. If you consent to participate with less than a month remaining in the school year, your child's teacher for the subsequent school year will be contacted about participating at the beginning of the next school year.

After you complete the first set of questionnaires, you will be "randomized" into one of two study groups. Being randomized means you will be put into a study group by chance, like flipping a coin. You will have an equal chance of being in either study group. One study group will receive immediate access to a set of integrated behavioral intervention features on the mehealth for ADHD web portal. If you are assigned to this group, we will ask you and your child's teacher to set up a behavioral reward system that will help with your child's behavior at home and/or school. For example, the feature may help your child's teacher to select specific child behaviors to target and allow the teacher to monitor these behaviors and provide daily feedback on the child's performance on these behaviors to the family. You (the family) can then use the teacher's feedback to reward the child for these behaviors at home. Your child's teacher may also choose to reward the child for these behaviors at school. We will ask that you try out the behavioral reward system with your child over the course of the next year.

- enhanced set of features on the ADHD portal. .

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

Being in this study may not help you right now. Possible benefits to you might be improved care through the ADHD web portal. And, we might learn something that could help parents of children with ADHD later on.

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

If you feel uncomfortable with study activities, at any time, you have the right to withdraw from the study and end your participation.

Loss of confidentiality is an unlikely, but possible risk. We will protect against this risk by storing study documents in locked cabinets in locked research facilities. Only the research team will have access to these documents.

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 be in it.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you and your child remains private is important to us. To protect your privacy in this research study, your name will not be on any study documents. All study documents and all data files will be secured in locked cabinets in locked research facilities, with access limited only to the researchers. We will keep your identifiers separate from your study documents and store the link between identifiers and survey IDs in a locked facility accessible only to authorized staff. The information from the research study may be published; however, you and your child will not be identified in such publication. The publication will not contain information that would enable someone to determine your or your child's identity as research participants without your authorization.

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 health, safety or willingness to stay in this study.

WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

There is no cost for participating in the study**.**

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be reimbursed for your time and effort while you are in this research study.

You will be paid $20 for each time you complete a set of questionnaires as reimbursement for your time and effort. Payments for this study will be 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. 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 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 Jeff Epstein at 513-636-8296. 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.

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 "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 PHI as part of this study.

This PHI will come from:
- Your medical and ADHD web portal records
- Your research records

The types of information that will be used and shared from these records include:
- Diagnosis and medications
- Reports and notes from clinical and research observations
- Information psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?
- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your 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 PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your 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 PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share 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 you 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 other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment <u>not</u> 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 you should participate in this research you will document your consent by signature below.

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

Printed Name of Research Participant Or Legally Authorized Representative*	Printed Name of Research Participant's Child
Signature of Parent or Legally Authorized Representative* Indicating Consent & Parental Permission	Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided

Signature of Individual Obtaining Consent	Date