Official Title of the study: **Randomized Controlled Trial of Web Based Tools to Improve Medication Continuity in Adolescents With ADHD**

NCT number: **NCT04386096**

Document name: **Informed Consent Form**

Date of the document: **04/06/2020**

Web Based Tools to Improve Medication Continuity in Adolescents with ADHD

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Contact Info: *513-636-2576*

Funding: *National Institutes of Health*

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

Reason for the study:

The main reason for this research study is to test new tools on the meheath for ADHD website to engage adolescents with ADHD and their parents with issues related to medicine. We are asking you to be in the study because you have a child between the ages of 11-15, and your child has been treated by a pediatrician for ADHD.

Procedures:

If you agree to participate and qualify to be in this study, these are the things that will happen to you while you are in the study:

- Collection of pharmacy dispensing records: To confirm that your child is eligible for the study, a member of the research team will access your child's pharmacy dispensing records to assess medication use. We may retrieve these from your pharmacy, from an automated system run by your state, or from your child's electronic medical record. We will also access their pharmacy records at the end of the study.
- Randomization: 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 group will be able to access a version of the mehealth for ADHD website with new features for teens and use them from August 1st 2020 – December 1st 2020. The

other group will be able to access the current version of the mehealth for ADHD website.

- Visit 1: At the beginning of the study, you will meet with the study coordinator who will go over the consent and assent forms with you and your child, and show you how to use the mehealth for ADHD website. You and your child will each complete a set of surveys. This visit will take about 2 hours. You will be paid $200 for this visit. The visit can take place at any Cincinnati Children's Hospital location, or another location that is convenient for you.
- Visit 2: At the end of the study (around December), you and your child will come in for a second visit to complete your second set of surveys. This visit will take about 1 hour, and you will be paid $100. These surveys can also be completed online if needed.

We expect that you will be in this research study for about 10 months.

Risks to Participate:

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.

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved outcomes for adolescents with ADHD.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

Your alternative to participating in this research study is to not participate.

Cost to Participate:

It will not cost you anything to be a part of this study.

Payment:

If you agree to take part in this research study, you will be reimbursed for your time and effort while you are in this research study. 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 youare being paid for your participation, Cincinnati Children's 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

Cincinnati Children's 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.

You will be paid $200 for your first visit, which will take about 2 hours, and $100 for the second visit, which will take about 1 hour. You can receive as much as $300 for your participation in this research study.

Additional Study Information:
The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Dr. William Brinkman**	Phone: 513-636-2576
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Lead Study Coordinator**	Phone: 513-803-1931
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the Study Coordinator.

Total number of participants:

We expect about 44 adolescents and their families will be a part of this research study.

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.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Samples and/or data collected for or generated from this study could be shared and used for future research. De-identified samples and /or data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution.

A description of this 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.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use 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 information about your health and behavior to NDA. 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 the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments and

outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who are conducting this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

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?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your child's Cincinnati Children's medical records
- Your child's research records
- Your child's pharmacy dispensing 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

Who will share, receive and/or use your protected health information in this study?

- Staff at Cincinnati Children's Hospital
- 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 Cincinnati Children's 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 never expire.

Will your child's other medical care be impacted?

By signing this document, you / your child agree to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/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 you/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.

Optional National Institute of Mental Health Data Archive (NDA):
I authorize the study staff to upload my de-identified data to the NIMH Data Archive.

☐ YES ☐ NO

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent — Date

_____ _____
Signature of Parent or Legally Authorized Representative* — Date

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

_____ _____
Signature of Individual Obtaining Consent — Date