***Title of research study*: Open-Label Trial of personalized medication experiments to inform decisions about future ADHD medication use**

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Contact Info: *513-473-1612*

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.

Parents/Guardians: This is a parental permission form for your child to participate and a consent form for your own participation. It explains this research study. You have the option to participate and to have your child join this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. This form also serves as consent for study staff to contact your child via call, text, or email regarding this study or future studies. 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 using personalized medication experiments to help parents and adolescents resolve uncertainty about whether ADHD medication is still helping or needed. We are asking you to be in the study because you have a child between the ages of 11-15, your child has been treated by a pediatrician for ADHD, and you and/or your child have expressed some uncertainty about future medication use.

Procedures:

If you agree to participate and qualify to be in this study, you and your adolescent will work with the study pediatrician to conduct a personalized ADHD medication experiment with close tracking of outcomes to inform your future decisions about medication use. Depending on the experiment that you and your child choose, this might involve starting, stopping, or changing ADHD medications. You will be asked to use a website, fill out a set of surveys, and come to Children's Hospital two times over the next 4 months.

At the beginning of the study, you will meet with the study coordinator by phone to go over the consent and assent forms with you and your child.

- 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.

- You and your child will then electronically complete a set of surveys.
- Visit 1: You and your child will then complete an in-person visit to select a medication experiment you would like to complete and outcomes to track using a website. We will provide detailed instructions for completing the experiment. You will complete some surveys. This visit will take about [60-90 minutes]. You will be paid $50 for completing the initial surveys and $100 for completing the visit. The visit will take place at the Center for ADHD on the Oak Campus at Cincinnati Children's Hospital.
- Visit 2: At the end of the medication experiment, you and your child will come in for a second in-person visit to meet with the study physician, review results from the medication experiment, and discuss what was learned. You will complete another set of surveys. This visit will take about [60-90 minutes], and you will be $100 for completing the visit. You will leave the visit with a summary of the medication experiment that you can share with your child's doctor.
- You can receive up to an additional $100 based on the amount of outcome tracking measures that you and your child completed throughout the duration of the medication experiment.
- We expect that you will be in this research study for about 4 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.

For dyads who select a medication experiment involving not taking medicine for some period of time, it is possible the adolescent could experience more ADHD symptoms than usual and/or a decline in functioning. For dyads who select a medication experiment involving taking medication on additional days (e.g., non-school days) or trying a different medication or dosage, it is possible the adolescent could experience side effects which s/he may or may not have experienced in the past. Both of these scenarios are the reason why clinical practice guidelines recommend that medication experiments are personalized, structured, and physician supervised. Dyads will be able to reach the study team between visits with any concerns. Medication experiments will end early, if needed.

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. The study physician will provide prescriptions, as needed, during trial participation, but you will be responsible for obtaining ADHD medication from your pharmacy as you do for typical clinical care, which may cost you money depending on your insurance plan.

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 you are 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 can receive as much as $350 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	**Principle Investigator;** **Dr. William Brinkman**	Phone: 513-473-1612
• Emergencies • General study questions • Research-related injuries	**Lead Study Coordinator;** **Alyssa Banister**	Phone: 513-803-1931

Who to talk to…	You can call …	At …
• Any research concerns or complaints		
• 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 30 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.

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.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent to Participate — Date

_____
Printed Name of Adolescent

_____ _____
Signature of Parent or Legally Authorized Representative Indicating Permission for adolescent to participate — Date

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

_____ _____
Signature of Individual Obtaining Consent — Date