

**INFORMED CONSENT/ASSENT FORM**

**STUDY TITLE: IMPROVING ADHD TEEN DRIVING**

**FUNDING ORGANIZATION: NIH**

Jeff N. Epstein, Ph.D.

Name of Principal Investigator

513-803-1343

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.

In this research study we want to learn more about how to help teens with Attention Deficit Hyperactivity Disorder (ADD/ADHD) become safer drivers. We want to test two types of training programs that may help improve the driving of teens with ADHD. You will be assigned to one of the two training groups at random. You have an equal chance of being in any of the two types of training programs.

We are asking you and other adolescents with ADD/ADHD to be in the research, because you may be diagnosed with ADD/ADHD. You may be eligible if

- You have been diagnosed with ADD/ADHD in the past or you suspect you may have ADD/ADHD.
- You are between the ages of 16 to 19 years old.

**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 the National Institutes of Health (NIH) to do this study.

**WHO SHOULD NOT BE IN THE STUDY**

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

- You do not have a valid driver's license
- You engage in significant risky behaviors while under the influence of drugs or alcohol

**WHAT WILL HAPPEN IN THE STUDY?**

The research staff will explain each visit to you and may give you a handout that explains each visit in more detail. You will be able to ask questions to make sure that you understand what will happen to

you.

If you qualify and decide you want to be in the study, you and your parent will come to CCHMC eight (8) times over the next year.

These are the things that will happen to you while in the study:

First, you and your parent will be interviewed to see if you will be eligible to take part in this study. You will be asked to review this consent form and if you chose to participate in this study you will be asked to sign it. In addition, the study staff will collect information about you. If you agree to participate in this study, the following will happen:

- You will be asked to complete an IQ screen and complete an interview about your ADHD symptoms. This interview will take about 60 minutes to complete.
- Your parent or guardian will complete an interview about your ADHD symptoms. This interview will take about 30 minutes to complete.
- If you are found to be eligible based on these assessments:
  - Your parent or guardian will complete several questionnaires.
  - You will participate in a variety of assessments including questionnaires and cognitive testing. These questionnaires cover a number of different topics including driving behaviors, mood and substance use. If we are concerned about any of your answers to these questionnaires, we will talk to you and provide you with community resources as needed. In addition, we may talk to your parents if you are engaging in risky behaviors while using drugs and/or alcohol (e.g., driving while intoxicated or doing things you would not typically do while under the influence).
  - You will complete a simulated drive which lasts about 30 minutes. You will be instructed to drive as you normally would and will also be asked to complete some tasks while driving such as searching for letters. Your eyes will be followed using an eye tracking system. The eye tracking system records your eye movements while driving.

The total length of this visit will be approximately 4 hours.

If you are on ADHD medication and have taken it today, you will be asked to schedule a second visit and to not take any ADHD medication the morning of this second visit; at that visit you will complete the simulated drive. For your safety, you must get a ride to this second visit from someone else.

After the initial visit(s), you will be asked to bring the car that you are most likely to drive this next year to a local store where a set of DriveCam cameras can be installed. One camera records the road and the other camera records the driver's face. The cameras only keep recordings that occur right before and right after a driving incident such as hard braking, swerving, or a crash. These cameras also contain a Global Positioning System (GPS). These cameras will stay in the car for 12 months after you complete your training visits.

At the end of this visit, we will schedule a series of five driver training visits. 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 any one study group.

The two study groups will use a different training strategy for improving your driving behavior. Each week, for five weeks, you will be asked to return to the Center for ADHD for further training. At the

end of each of these training visits, you will complete a drive in the driving simulator. Each of these training visits will take approximately 2 hours. Your parent will also be oriented to the training you are receiving at the first and fifth sessions.

1-month and 6-months after completing the training, you will return for a comprehensive driving assessment that will include a few questionnaires and a 30-minute drive in the driving simulator. These visits will take approximately 1 ½ hours. If you are taking ADHD medications, we will ask you not to take your medications on the morning of these visits. For your safety, we ask that someone else drive you to these visits.

6-months and 12-months after you complete the training, we will ask for your permission to request your driving records from the Bureau of Motor Vehicles (BMV). Additionally, at 12-months we will email you a short survey to complete through a secure program called REDCap and we will ask you to return to the store that installed the DriveCam camera to have it removed from your car.

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

Being in this study may not help you right now. When we finish the study, we hope that we will know more about whether computer-based training can improve the driving of teens with ADHD/ADD. This may help other children with ADHD/ADD become safer drivers later on.

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

We do not know of any risks related with the driver training, driving simulator, DriveCam or eye tracking system. It is possible that you will become bored or annoyed during the research study. Also, you might feel sore muscles because of how long you will drive, and/or you might have motion sickness from the simulator. If you would like, we will give you a SeaBand which is worn around the wrist to help with motion sickness.

There are also risks associated with you not taking psychostimulant medication the morning of some of the study visits. Usually there is little risk associated with not taking stimulant medication for a day. For example, it may impact your school or job performance for a day. Driving while not taking your medication could also be a serious risk. This is why we need someone else to drive you to the visits on days when you are not taking ADHD medication.

You may become frustrated if you are asked questions during testing that you do not know how to answer. You will be told at the beginning of the testing and reminded during the testing that you do not need to answer any questions that you do not wish to answer and that you can stop the testing at any time.

There is a risk that the installation and de-installation of the DriveCam camera in your car could accidentally damage your car. We will pay to have installation experts mount the camera to your car's windshield behind the rear view mirror. Experts will route the wires from the camera behind your windshield's trim or headliner and connect these wires to your car's fuse box. There is the possibility that during the installation and de-installation of the DriveCam camera that damage could occur to your car such as a tear in the headliner or a broken fuse. If any damage occurs to your car during the installation or de-installation process, the company doing the installation/de-installation will pay for repairing your car. Finally, since the DriveCam is connected to your car's battery through the fuse box, there is the rare possibility that your car's battery could drain or fail. If this occurs, we would work

with the installation team to diagnose and fix the problem.

There is a risk that the recordings of your driving behavior with the DriveCam recordings might contain information that could be used against you or another driver of your car or a driver of another car. We have a Certificate of Confidentiality that allows us to keep all of the recordings of your driving behavior with the DriveCam cameras confidential.

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 remains private is important to us. To protect your privacy in this research study we will:

- Keep your records confidential to the extent provided by federal, state and local law.
- Not include any information that would identify you in future research publications. The data will be combined with data from other families and presented together as a group. You will not be personally identified on any publications or reports about this research.
- Store paper data, including the questionnaires you fill out in locked file cabinets in the research team's office. This office will be locked at all times. Only the principal investigator or other qualified members of the CCHMC research team will have access to the paper data.
- Code data stored in electronic database at CCHMC by unique number identifiers that cannot be traced back to you. The code sheet with your name and unique identifier will be kept separate from all other information in a password-protected file at CCHMC. Only research staff members at CCHMC will have access to this coding sheet. All electronic information will be maintained in a password-protected database on a firewall-protected server.
- Make sure that your consent will expire at the conclusion of the research study.
- Make sure that a copy of this consent form will be included in your research record.
- Have you registered in the Cincinnati Children's Hospital Medical Center's computer system as a research subject.
- We will destroy all recordings at the end of this research study.

To help us protect your privacy by ensuring the recordings of your driving behavior from the DriveCam cameras are kept confidential, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a family member from voluntarily releasing information about yourself. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse or harm to self or others.

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 study results. You can search this website at any time.

### **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. For example, the researchers may decide to take you off this study if:

- The researchers believe that participation in the research is not safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.
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### **WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?**

There are no costs to be in the study. You will be responsible for the costs of transportation to and from the study site.

If you are referred to a mental health provider as a result of findings from our interviews with you, you will be responsible for the cost of those services if you choose to pursue them.

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

You will be reimbursed for your time, effort, and travel 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, 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.

You will be paid \$80 for the baseline visit, \$20 for each of the five training visits, \$50 for the 1-month post-training visit, \$50 for the 6-month visit, and \$20 for completing the final survey and returning the DriveCam at the end of the study. This compensation is to reimburse you for your time and effort.

### **WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?**

If you believe that you have been injured as a result of this research you should contact Dr. Jeff Epstein as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

**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.

## **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 CCHMC medical records
- Your research records

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

- Reports and notes from research observations
- If applicable, information concerning drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions.

### **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.
- Data from this study will be shared with the following study co-investigators who are at other institutions:
  - Dr. Annie Garner at Saint Louis University
  - Dr. Don Fisher at University of Massachusetts
- Lytx, which is the company responsible for collecting, analyzing, and temporarily storing the video data on their servers from the DriveCams.

### **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 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 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

\_\_\_\_\_  
Signature of Research Participant (aged 18-19)  
Indicating Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Research Participant (aged 16-17)  
Indicating Assent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of 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