PARENT CONSENT FORM

STUDY TITLE: CONCUSSION DEVICE AUDIOLOGICAL MEASURES

STUDY NUMBER: 2013-5717

FUNDING ORGANIZATION:

Gregory D. Myer, PhD
Name of Principal Investigator

(513) 636-0249
Telephone Number

INTRODUCTION

We are asking your child to be in a research study so that we can learn new information about an investigational device that may help others. If you decide not to have your child be in this study, we will still take good care of you. If you decide to have your child 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 to learn more about an investigational device that may help prevent concussions. We are asking your child and other approximately 1000 people who are at between 8-50 years old, and healthy to be in the research, because we want to find out more about how the investigational device affects mild jugular pressure and the body's response.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Gregory Myer is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study. This study is being funded by CCHMC.

WHO SHOULD NOT BE IN THE STUDY

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

- Brain swelling
- Recent head or brain trauma (within 3 months)
- History of vein problems
- History of blood clots
- Known open eye injuries

- Neck injuries
- Any known airway obstruction
- Any known seizure disorder
- Active concussion symptoms
- Ventricular shunt or neurologic condition
- Internal or external hardware that has been surgically placed in the neck
- Any altered level of consciousness
- Brain cancer
- Recent ear infection diagnosed within the past month
- History of ear surgery, other than ear tubes
- Hearing loss (abnormal oto-acoustic emission and hearing screening)
- Significant blockage of the ear canal (eg., wax or drainage)

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain the visit to your child and may give your child a handout that explains the visit in more detail. Your child will be able to ask questions to make sure that he/she understands what will happen.

If your child qualifies and decides to be in the study, your child will come to the testing site. During the testing session, your child will wear a device around his/her neck.

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

1. Oto-Acoustic Emissions: This test will place an earplug in your child's ear that is a recording microphone that picks up the emission coming back from the inner ear. During this testing your child will also be fitted with a compressive neck collar which can provide variable levels of pressure. The pressure is achieved by inflatable pods that sit next to the wind pipe affixed to a non-stretch adjustable collar. Manual inflation is regulated and monitored by an experienced technician. Testing will occur without pressure and then with pressure.

2. Hearing Assessment: This testing session will consist of a hearing assessment which will be administered by an audiologist from Cincinnati Children's Hospital.

   This research is being done to see if changes occur in the inner ear following activation of the protective. If this is found to be possible this technology might be helpful to make sure the device is activated when it is put on for protection against concussions.

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

Being in this study may not help your child right now. When we finish the study, we hope that we will know more about this investigational device and how it potentially contributes to preventing concussions and traumatic brain injury. This may help other people with preventing concussions and traumatic brain injury later on.

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

One device that your child will be wearing throughout the testing sessions will be placing light pressure on your child's neck. While this may be uncomfortable, the pressure on your child's neck will mimic that of wearing a necktie or "choker" necklace. Studies have shown that there is no significant change in blood flow pattern to the brain with prolonged wearing of a tight necktie and therefore the risk of wearing this device is low. Some tests will occur without pressure and then with the gentle pressures on the neck. If there is ever discomfort the pressure can be removed at any time during the test.

There is also a minimal risk that the data collected may be viewed by individuals outside the research team. The risk that confidential data may be viewed is relevant for both the written forms and the electronic databases.

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. Participating in this research is completely voluntary. Your child will not be punished if you decide not to participate.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your child's privacy in this research study we will: keep the results of this study confidential. No subject identification will be made public record in any form unless you give your expressed written permission of release of your child's name, photograph or likeness captured on video. You have the right to privacy. We will protect your child's privacy to the extent allowed by law. All facts about this study that can describe a subject's name will be kept private. Results of the study will be summarized regarding age, etc., but we will take every precaution necessary to keep names private. All subject data will be blinded from the researchers with the use of an identification code. Personal information and identifiers will be securely recorded and filed by the administrative assistant. The data will be encrypted with a password and stored on a personal computer and backed up on a network drive. We will be available for any questions that might arise.

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.

The Food and Drug Administration (FDA) may choose to inspect your records since you are a subject in this investigation of an unapproved device.

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?

Participating in this study will not cost your child anything other than time and effort.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

Your child will receive a t-shirt and a free hearing test by participating in this study.

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

If you believe that your child has been injured as a result of this research you should contact Greg Myer at (513) 636-0249 as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC, however the cost will be billed to you to your insurance. 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 Greg Myer, PhD at (513) 636-0249.
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.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?
By agreeing to participate in this study, you are also agreeing to be contacted about future research projects that you may be eligible to participate in.

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:
- 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 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 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 Indicating Consent — 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