ADULT SUBJECT CONSENT FORM

STUDY TITLE: SEX AND AGE ULTRASOUND RESPONSE TO DIFFERENTIAL JUGULAR VEIN PRESSURE

STUDY NUMBER: 2016-8580

FUNDING ORGANIZATION: Q30 Sports Science, LLC

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Telephone Number

INTRODUCTION

We are asking you (and up to about 249 other people) 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 to learn more about an investigational device that may help prevent concussions. We are asking you and other approximately 249 people who are between 7-60 years old, and healthy to be in the research, because we want to find out more about how the investigational device affects mild jugular vein 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. CCHMC is being paid by Q30 Labs, LLC to do this study. In addition to conducting this research study, Gregory Myer is also paid for providing scientific advisory and consulting services for the company that manufactures the device being studied in this research.

WHO SHOULD NOT BE IN THE STUDY

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

- History of neurological deficits or severe head trauma
- Known increased intracerebral pressure, metabolic acidosis or alkalosis
- Any known increased pressure in eyes
- any known increased fluid on the brain
- Recent penetrating brain trauma (within 6 months)
- Known increased pressure in the brain

- Any known blood clots to the brain
- Any known airway obstruction

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain the visit to you in detail. You will be able to ask questions to make sure that you understand what will happen.

If you qualify and decide you want to be in the study, you will come to the testing site. During this testing you will have your neck measured with a tape measure. This will determine the size of the neck collars that will be used. You will also be fitted with compressive neck collars to provide different levels of pressure. Testing will occur without pressure and then with pressure. An experienced technician will be regulating and monitoring these pressures. A technician will take pictures of the inside of your neck using an ultrasound machine at each one of the different pressures. We anticipate that there will be three different pressures that we will take pictures of with the ultrasound. You may also wear an athletic headband that contains light emitting sensors that help us to measure blood volume in your head. You will not feel any discomfort.

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 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 you will be wearing throughout the testing sessions will be placing light pressure on your neck. While this may be uncomfortable, the pressure on your 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. You 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 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

name, photograph or likeness captured on video. You have the right to privacy. We will protect your 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.

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN related to this research we will only use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

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. There is a possibility that while reviewing your ultrasound we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

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

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

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 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 a $50 Clincard MasterCard ® at the study visit.

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 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.

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