PARENT CONSENT FORM

STUDY TITLE: Novel protection against potential brain injury during competitive non-helmeted sport in females.

STUDY NUMBER: 2016-0988

FUNDING ORGANIZATION: Q30 Sports Science, LLC

Gregory D. Myer, PhD
Name of Principal Investigator

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Telephone Number

INTRODUCTION

Based on your child's participation in the initial phase of this project, we are asking for your permission for your child to participate in phase II of this research study. Our goal is to repeat the phase I study in the athletes remaining on the soccer team so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child 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 allow your child to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In phase II of this research study we want to learn more about the long term effects of device that was previously investigated presently called the "Q collar (see Figure below), which may help prevent concussions. The neck collar device is made of soft plastic, and silicone, over a gentle embedded metal "spring" that is fitted around the neck providing comfortable compression to two of the veins on the side of the neck. Based on phase I results, we are continuing to test the theory that this mild compression will help prevent concussions by back-filling the empty space around the brain with some blood and thereby acting like "bubble wrap" around it. It has been suggested that many "head banging animals" may be using a similar protection in the wild.

In addition, for phase II of the project we wish to learn more about how the brain responds to concussive impacts during sport and if it returns back to normal without head impact exposure over the past year. .

We are asking your child who participated in phase I of the study because we want to learn more

about how well the device works in preventing brain microstructure alterations in a subsequent study period. In addition to determine the long term effects of collar wear and recovery on brain microstructure, those participants from Phase I who have graduated or are not playing soccer will be asked to participate in a single follow-up visit in the late summer/fall of 2017. This single study visit will consist of brain MRI and EEG tests.

WHO IS IN CHARGE OF THE RESEARCH?

Greg Myer, PhD 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.

WHO SHOULD NOT BE IN THE STUDY

Your child cannot be in this study if he/she has 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
- Did not participate in phase I of the project

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 your child. We will also ask parents/guardians of study participants to complete a brief behavioral rating scale that assesses indications of ADHD. We will send you a link via email to complete this questionnaire via a REDCap online survey. This questionnaire will take you no longer than 5-10 minutes to complete.

If your child qualifies and you decide you want your child to be in the study, your child will come to CCHMC at least 3 times over the next 9 months. If your child is diagnosed with a concussion during the sports season, your child may be asked to come to CCHMC for additional study visits. The study visit will take about 90 minutes to complete.

Pre-season study visit
Post-season study visit
Follow-up study visit (8-12 weeks following post-season visit)

Concussion follow up study visit – completed within 1-5 days of reported concussion
Acute knee injury follow up study visit - completed within 1-5 days of reported injury

If your child was NOT assigned to the device-wearing group in phase 1, your child will wear the Q collar during their practices and games that will fit around their neck which will place light pressure on their neck. While most do not find this uncomfortable, the pressure on your child's neck will feel like wearing a necktie. The neck collar device is made of plastic, silicone, and metal that is fitted to the neck providing comfortable pressure around the neck. Studies have shown that there is no significant change in blood flow or oxygen uptake pattern or any negative cognitive effect to the brain (even with prolonged similar physiology of wearing a tight necktie) and therefore the risk of wearing this device is low. It has also been tested during high intensity exercise and has shown no effect on performance, and has been deemed safe.

This device is ONLY to be used during the soccer team games and practices. This device will NOT go home with the athlete.

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

1. Neck Circumference, Height, Weight, and Body Fat % Measurements: We will measure the circumference of your child's neck with a measuring tape. We will also measure your child's height, weight, and body fat percentage using a standard measuring stick for height and a scale for weight and body fat percentage. This will be completed once at pre-season and once at post-season.
2. IMPACT (Immediate Post-Concussion Assessment and Cognitive Testing) Test: This test will be administered on a computer and will assess your child's verbal and visual memory, processing speed and reaction time. This test will be completed at pre-season and at post-season.
3. Eye Tracking: For this test, your child will look at several points in order to calibrate the desk-top eye tracker .Your child then will be asked to follow a moving object with his/her eyes on a computer screen. This test will be completed at pre-season and at post-season.
4. MRI Imaging: Your child will be asked to lie down in a machine that will take images of her brain. For part of this test, your child may be asked to lay still. For other parts of this test, your child may be asked to answer questions that will assess his/her thinking and memory. This test will be completed at the pre-season and post-season time points and will take approximately 60 minutes to complete. Prior to the imaging appointment, your child will be asked to complete a screening questionnaire to ensure that she does not have any contraindications to this type of scan. If any contraindications are revealed (i.e. permanent metal dental/orthodontic work, cochlear implant, cardiac pacemakers, orthopedic pins/screws/plates, etc) your child will not complete the MRI imaging portion of this study. This will not affect their participation in the remaining parts of this project.
5. Accelerometers: An accelerometer is a device that measures how fast something is moving. Your child will be provided with an X-patch accelerometer that will collect information on the collisions that happen while playing soccer. An accelerometer is a very small device that measures the acceleration and rotation of the head. Your child's play will not be affected by this.
6. Injury tracking: We will be monitoring your child's injuries throughout the competitive sports

season and collecting information about your child's injuries from the athletic trainer.

7. Menstruation questionnaire- Your child will complete an online questionnaire monthly, while participating in the study. Answers from this questionnaire will allow study staff to determine the approximate status of their menstruation cycle. Subjects will be emailed the link to complete the questionnaire each month during participation in the study. Your child will also complete a menstruation questionnaire at the time of the pre-season study visit.
8. Follow Up Visits – If your child is diagnosed with a concussion during the competitive sport season, we will have your child come in for an additional study visit 1-5 days after your injury. During this visit, your child would be asked to complete all of the same tests plus complete a Post-Concussion Symptom Inventory (PCSI) form. If your child has a concussion, her care will be not affected by participation in this study.

Group Assignment: Your child will be assigned to the OPPOSITE group as they were last season in phase I 1) Subjects wearing the Q-collar device (seen in Figure on page 1) around the neck or 2) Subjects not wearing the Q-collar device for the season. Both groups will complete the same testing. Ultrasound will be used to ensure proper fitting of the collar. This fitting visit will be completed at the school before the first official practice. The study coordinator will visit the team weekly to monitor the use of the collar. The school athletic trainer will be there daily to ensure proper use and compliance.

In addition to determine the long term effects of collar wear and recovery on brain microstructure, those participants from Phase I who have graduated or are not playing soccer will be asked to participate in a single follow-up visit in the late summer/fall of 2017. This single study visit will consist of brain MRI and EEG tests.

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 device and its effectiveness in preventing concussions. This may help us prevent concussions later on. We do not currently know if this device will protect your child from suffering a concussion injury.

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

There are no known risks of wearing the Q collar device. There are no known negative effects from exposure to the magnet or radio waves used in the MRI at this time; however it is possible that harmful effects could be recognized in the future. The tight space of the MRI may make some people feel uncomfortable. One known risk is that the magnet can attract certain kinds of metal. Therefore, we will have all subjects complete a pre-MRI screening questionnaire. If there is any indication from this questionnaire that the MRI is not safe your child will not have the MRI testing. The MRI testing will require your child to lie on their back and remain still for the duration of the test, which could last about 60 minutes. Due to the nature of the test, there will be a loud knocking noise that your child will hear while the test is being performed. Your child will be instructed that if at any

point during the test, you can signal to the research staff to stop the test if you get too uncomfortable.

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.

Wearing this device does not allow your child to adjust the safety measures put into place about how to play the sport of soccer in a safe manner.

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 have your child be in it. Participating in this research is completely voluntary. Your child will not be punished if she decides not to participate.

HOW WILL INFORMATION ABOUT YOUR CHILD BE KEPT PRIVATE?

Making sure that information about your child 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. Your child has 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.

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 child's records since your child is 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 child's health, safety or your willingness for your child to stay in this study.

The MR imaging that your child is having as part of this research study will be reviewed by a qualified radiologist just as it would be if you were having the MRI as part of your child's routine medical care. There is a possibility that while reviewing your child's MRI 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 FOR YOUR CHILD TO BE IN THE RESEARCH STUDY?

Participating in this study will not cost you anything other than time and effort. Your insurance will not be billed for any testing associated with this study.

WILL YOU/YOUR CHILD 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 (your child) will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your (your child's) 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 child's Social Security number. This form will be given to the CCHMC 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 (your child) will be paid $50 Clincard Mastercard ® at the first study visit, and a $100 Clincard Mastercard® for completing the second study visit. If you are diagnosed with a concussion, you will receive an additional $50 Clincard Mastercard® for completing a follow up study visit after the concussion diagnosis. If you suffer an acute knee injury, you will receive an additional $50 Clincard Mastercard® for completing a follow up study visit after the injury. Subjects that have graduated, no longer participating in soccer, or not participating in a second season as a study participant, will receive $100 Clincard Mastercard® gift card for completing a one-time follow-up testing session. You will receive a $100 Clincard Mastercard® for completing the follow-up testing session 8-12 weeks after your post-season session.

WHAT HAPPENS IF YOUR CHILD IS INJURED FROM BEING IN THIS STUDY?

This research does not require that the participant maintains participation in their sport. The desire to participate in the sporting event is an independent, personal decision separate from the decision to

enter into this study. During the course of this study, we expect that injuries consistent with the sport being played will occur, such as head injuries, sprains, fractures, and muscle injuries. Some of these injuries may be severe and have severe consequences. *The choice to participate in the sports and accept the risk of the participation in the sport you have chosen is entirely a choice made by you.* Neither the study investigator (Dr. Myer) nor CCHMC will be responsible for the medical treatment of any sport related injuries. While the likelihood of an injury related to this research is small, if you believe that you have been injured as a result of this research you should contact Gregory Myer, PhD 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.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?
If you are diagnosed with a concussion during participation in this study, your medical care will not be affected by your participation. While your insurance will not be billed for any testing associated with this study, any further care or treatment will be billed accordingly.

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 child's "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 child's PHI as part of this study. This PHI will come from:
- Your child's CCHMC medical records
- Your child's 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 child's protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's 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 child's PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's 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 child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's 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 your child 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 child's other medical care be impacted?

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