Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: **Effect of Repetitive Soccer Heading on Biomechanics and Physiological Measures**

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Version 8

Principal Investigator: Kristy Arbogast Telephone: (215) 590-6075

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You or your child are being asked to take part in this research study because you are actively playing on a competitive soccer team.

The purpose of this study is to find out if repetitive head impacts (i.e. soccer headers) affect balance, cognitive function, and eye tracking.

If you agree to take part, your participation will involve one screening visit (lasting 30 minutes) and 2 study visits (each lasting 1-3 hours) scheduled in the next 3 months. You will be asked to head or kick a soccer ball 10 times and complete a report of symptoms and a set of assessments measuring brain performance before, after, and 24 hours after the heading/kicking intervention.

The main risks of this study are from the heading intervention or wearing testing devices. These include: temporary symptoms (i.e. headache, confusion, pain, fatigue, sensitivity to light, nausea and dizziness), skin irritation or burn, or allergic reaction.

You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Please see below for additional details about the study

How many people will take part?

About 60 soccer players will take part in this study.

What is involved in the study?

If you agree to take part, you will be assigned to either a kicking group or a heading group. You will complete a report of symptoms and a set of assessments measuring brain and neurological performance. If you are assigned to a heading group, you will be asked to perform 10 soccer headers over 10 minutes administered by a member of the study team. If you are assigned to a kicking group, you will be asked to kick a soccer ball 10 times. You will then complete the same report of symptoms and set of assessments immediately following the kicks or headers and at a follow-up visit 16-72 hours later. Please refrain from additional heading drills (e.g. as part of your soccer team) between your initial study visit and your follow-up visit. If you participate in such drills, we will have to reschedule your follow-up visit and require you to undergo repeat testing at a later time.

How long will you be in this study?

If you agree to take part, your participation will involve one screening visit (lasting 30 minutes) and 2 study visits (each 1-3 hours long) scheduled in the next 3 months.

If you sustain an orthopedic/head injury unrelated to the study before the intervention visit, you will be rescheduled to complete the procedures at a later date (up to one year). We will maintain connection with you via e-mail and/or telephone, and your continued willingness to participate will be confirmed at the point of rescheduling and before you come in to complete the intervention visit.

What are the study procedures?

The study involves the following tests and procedures. Subjects may not complete eye tracking, pupillometry, and other tasks while wearing the fNIRS device depending on equipment and study team availability.

Randomization and Intervention: Your assignment to heading or kicking will be determined at random, similar to a 'coin toss' as you will have an equal chance of being assigned into one kicking or 2 distinct heading groups. Based on your group, you will either complete 10 headers or 10 kicks. For the two heading groups, you will either head the ball frontally (directly back to the ball launch location) or obliquely (90 degrees to the right of the ball launch location). You will return for a follow-up approximately 16-72 hours after the heading/kicking to complete the set of assessments detailed below.

Mouthguard Fitting: If you are assigned to a heading group, you will complete a dental impression at consent to create a custom mouthguard or mold a premade mouthguard at the intervention visit to wear during the study. The dental impression kit being used is standard procedure for creating custom mouthguards, and the fitting of a premade mouthguard follows the boil-and-bite procedure. Both are widely used by youth and adult athletes.

Instrumented mouthguard: If you are assigned to a heading group, you will wear a custom-fit mouthguard that is equipped with devices that measure the speed and direction of your head motion while heading the ball. The custom mouthguard will be made between the screening visit 1 (in which a dental impression will be taken) and visit 2 (heading), or a premade mouthguard will be fit at visit 2.

Video: If you are willing, we wish to obtain video recordings during heading to confirm impact time and obtain impact location information. Video-recordings will show your body and face. Members of the study team may see these video recordings. Your recordings or still images with your blurred face may be shared outside the research team. A number of different groups of people could see these photographs and video recordings, including members of the general public, scientists and medical researchers.

Soccer Heading History: You will be asked to fill out questionnaires to tell us what activities you are doing and your sport history and experience. You will also detail your soccer heading experience and frequency.

Post Conccussion Symptom Inventory: You will be asked to self-assess concussion symptoms (e.g. headache, dizziness) on a Likert scale (0-6) to provide a physical, fatigue, emotional, and cognitive symptom assessment.

Clinical Concussion Examination: We will conduct CHOP's current standard of care for concussion assessment which includes balance (e.g. tandem gait), eye movement (e.g. saccades, smooth pursuits, vestibular-ocular reflex), and visual exams (e.g. near point of convergence, monocular accommodation).

- Vestibular/oculomotor screening (VOMS): You will be asked to rapidly move your eyes back and forth, track finger motion, and rapidly move your head back and forth while keeping your focus fixed.
- Accomodation and Convergence: We will test how well each of your eyes can keep letters in focus as typed letters are moved closer. We will measure how far the letters are from each of your eyes when they first get blurry.
- Balance Examination: The tandem walk assessment involves walking heel toe forwards and backwards with eyes open and closed. The tandem walk assessment may be performed with an accelerometer that monitors sway and while also performing a cognitive task, such as counting by sevens or reciting the months of the year backwards.

Eye Tracking: You will watch a video clip move on a computer monitor while the device records how your eyes move. The length of each session is approximately 5 minutes. You will be shown excerpts from G-rated videos.

Pupillometry: You will be asked to blink and then keep your eyes open as wide as you can for a few seconds while we hold a small, handheld device up to each of your eyes. The device will flash a bright light for less than one second. We will repeat the test on each eye approximately 3 times.

King-Devick Test: You will complete this brief task before and after heading/kicking that evaluates your eye movement by having you read numbers from left to right on test cards or a tablet. We will time how long it takes you to read the numbers and record any mistakes you make while reading.

Functional Near-Infrared Spectroscopy (fNIRS): You may complete the King-Devick test and standard clinical care vision and balance exams while wearing a functional near-infrared spectroscopy sensor (fNIRS). This sensor is a headband that wraps around your forehead and measures how much blood is flowing in your brain.

Visual Evoked Potential (VEP): You will be asked to watch as a series of patterns flip through on the screen while a band that lies across the scalp containing surface electrodes records electrical activity in the brain in response to flashed shapes or images.

Auditory Evoked Potential (AEP): You will be asked to listen to sounds while surface electrodes on the forehead and by each ear measure the electrical activity in the brain.

Maximum Voluntary Isometric Contraction (MVIC): You will be asked to flex your neck (forward/backward flexion, right/left lateral flexion, and right/left rotation) to measure head-neck strength.

Electromyography (EMG) Sensors: Wireless EMG sensors will be placed on the your neck muscles during heading to measure neck activation.

Some of the procedures in this study will be repeated several times, and some of the procedures may not be completed due to device availability

Visit Schedule

Visit	Purpose	Main Procedures	Duration
Visit 1	Initial visit	randomization, assignment to heading or kicking group, instrumented mouthguard fitting	30-60 minutes
Visit 2, Day 0	Intervention visit	Heading/kicking, Clinical exam, pupillometry (optional: eye tracking, fNIRS, visual evoked potential, auditory evoked potential), instrumented mouthguard fitting	2-3 hours
Visit 3, Day 1-3	Follow-up Visit	Clinical exam, pupillometry (optional: eye tracking, fNIRS, visual evoked potential, auditory evoked potential)	1-1.5 hour

What will be done with my data during this study?

During the study, we will collect medical history information and physiological function assessment data from you. By agreeing to participate in the study, you agree to give these data to CHOP for research purposes. Your data will be given a unique code and will not include information that can identify you. Information that can identify you may be kept in a secure database at CHOP. Only study members will be able to see information that can identify you.

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risk of Soccer Heading: While the effects of soccer heading are unknown, soccer headers have not been associated with causing concussive injury. The speed and number of headers in this study are designed to minimize risk. There is a possibility of developing temporary symptoms (i.e. headache, confusion, pain, fatigue, sensitivity to light, nausea and dizziness). If you feel discomfort or several symptoms, heading will be stopped

immediately. You will be assessed at the follow-up visit. If you have persistent symptoms for longer than 24 hours, please contact the Principal Investigator at 610-357-4269 and she will contact the study doctor on call. You may also contact the study email at mindsmatter@email.chop.edu.

Risk of fNIRS device: The fNIRS device does expose you to infrared light. However, the light intensity of the fNIRS is less than that of the sun so the risk associated with the use of fNIRS is less than the risk associated with spending an equivalent amount of time in the sunlight without a hat. Skin irritation and inflammation may occur from the attachment and removal of the sensor headband.

Risk of Physical, Balance, Eye, and Cognitive Examinations: There is a risk that the physical, balance, cognitive, and eye function tests may temporarily cause mild discomfort (e.g. headache from eye strain). The exams may be stopped any time if you start to feel uncomfortable.

Risk of Breach of Confidentiality: As with any study involving collection of data, there is risk of loss of confidentiality or the release of your personal health information. However, every precaution will be taken to make sure that your information is kept private.

Risk associated with the Instrumented Mouthguard: Risks of this device are not greater than minimal. There is a low probability for device breakage and component short circuiting. These may cause heating, and chemical/electrical burning. An allergic reaction to the material is possible and might also cause irritation. The risk is low due to the low total power of the battery used and the two layers of hypoallergenic material encompassing the electronics, which seals the device such that tissue does not come in contact with any electronics even after regular use of the mouthguard, including typical chewing and teeth grinding behavior. Any burn or allergic reaction would be immediated assessed by the study team, and participants may be referred to primary care or urgent care.

Risks associated with video-recording: Video-recordings will show your body and face. Only the study team will have access to these recordings on password-protected computers. There is the possibility that your video might be seen by someone outside of the study team. Although these video recordings will be used without your name, it is possible that someone might recognize you. Your recordings or still images with your blurred face may be shared outside the research team. A number of different groups of people could see these photographs and video recordings, including members of the general public, scientists and medical researchers. If images or recordings are shared with or released to other individuals or organizations, the recipients could use, distribute, broadcast and/or publish them in ways that do not protect your privacy and that CHOP cannot control. If you change your mind about taking part in this study after photographing, recording or filming is done, images or recordings that were released outside of CHOP may continue to be used. You will not be paid for the use or release of the images.

Risk associated with VEP, AEP, MVIC, and EMG: Skin irritation may occur from the attachment and removal of the sensors.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help determine the physiological effects of soccer heading.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to complete two study visits (4-5 hours total).

What happens if you decide not to take part in this study?

Participation in this study is voluntary.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study investigator take you out of the study early?

The study investigator may take you off of the study if:

- You develop severe symptoms while heading.
- The study is stopped.
- You cannot meet all the requirements of the study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical history questionaires and research procedures. This could include clinical exams or tests completed. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform health professionals and biomedical researchers. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP.
- Your fNIRS data will be sent to Drexel University, your pupillometry data will be sent to State University of New York (SUNY) College of Optometry, your head impact data may be sent to Prevent Biometrics, and your eye tracking data may be sent to Oculogica, Inc. Only a limited data set (no name) will be shared.
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Kristy Arbogast
The Children's Hospital of Philadelphia
Center for Injury Research and Prevention
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

If you participate in the intervention, you will be paid up to $100 in the form of cash or a gift card for your time and effort. You will be given $60 at the end of intervention visit and $40 at the end of the follow-up visit.

Who is funding this research study?

The Center for Injury Research and Prevention at The Children's Hospital of Philadelphia is funding this research.

What if you have questions about the study?

If you have questions about this study, call the study investigator, Dr. Kristy Arbogast at 215-590-6075.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What happens if you are injured during the study?

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator, Dr. Kristy Arbogast, at (215)-590-6075. She can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

Consent for Use of Data for Future Research

As part of the study, we will collect data from any assessments or questionnaires that you complete. We may wish to use your data in future studies about repetitive head impacts and concussion. Your data will be given a unique code and will not include information that can identify you. Information that can identify you may be kept permanently in a secure database at CHOP. Only study members will be able to see information that can identify you.

We may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Your identified data will be retained only if you agree to the future use of your data or to be contacted for future studies. If you leave the study, you can ask to have the data

collected about you removed. You can also ask us to remove information that identifies you from the data.

Please indicate whether you will allow the identifiable data to be used for future research by putting your initials next to one of the following choices:

_____ (initials) YES, My identifiable data may be used for other future research studies. If the data are shared outside of CHOP, only a limited data set (no identifiers except the dates of your visits to CHOP) will be included.

_____ (initials) NO, My identifiable data may not be used for future research. They may be used for this study only.

Consent for Contact About Future Studies

There may be studies in the future about repetitive head impacts or concussion that you would be eligible for. You are under no obligation to participate in these studies. However, if you are interested in learning about these studies indicate your preference below.

_____ (initials) YES, you may contact me in the future about other studies. I understand that I am under no obligation to take part.

_____ (initials) NO, I am only interested in taking part in this study.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.
NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older)	Date

Both Parents Must Sign this Consent Form (If Subject is Under 18)

Name of Authorized Representative #1	Relationship to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative #1	Date
Name of Authorized Representative #2	Relationship to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative #2	Date

If the second representative is unavailable, per §46.408(b) / §50.55(e)(2), explain the reason.

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____

Person Obtaining Assent

_____ _____

Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____

Signature of Subject (optional) Date