Community-Engaged Sport Safety

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Department of Biomedical Engineering

COMMUNITY-ENGAGED SPORT SAFETY

Informed Parental Consent Form to Participate in Research
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SUMMARY

Your child is invited to participate in a research study. The purpose of this research is to assess knowledge, attitudes, and beliefs of coaches, parents, and league officials related to youth football head impact exposure to inform the development and implementation of a practice structure to reduce head impact exposure and improve safety in the sport. Your child is invited to be in this study because your child is a member of a team enrolled in this study. Your child's participation in this research will involve wearing a sensor inside your child's helmet to measure how hard and how often athletes hit their head during football activities and will last the duration of the football season (3-4 months). Your coach will be participating in a research study aimed to improve safety of youth football practices.

All research studies involve some risks. A risk to this study that your child should be aware of is inadvertent public disclosure of these sensitive data in a manner that could directly link an individual subject to his study information. The risk of inadvertent public disclosure of individual study-specific information will be minimized by entering all data into a database with unique numerical patient identifiers. There is not the possibility that your child may benefit from participation in this study.

Your child's participation in this study is voluntary. Your child does not have to participate in this study if your child does not want to. Your child will not lose any services, benefits, or rights your child would normally have if your child choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. Your child can ask any questions if your child need help deciding whether to join the study. The person in charge of this study is Jillian Urban, PhD, MPH. If you or your child have questions, suggestions, or concerns regarding this study or your child want to withdraw from the study his/her contact information is: [redacted].

If you or your child have any questions, suggestions or concerns about your child's rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

Your child is invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. Your child is being asked to take part in this study because your child is a member of a team enrolled in this study. Your child's participation is voluntary. Please take your time in making your decision as to whether or not your child wishes to participate. Ask your child's study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to assess knowledge, attitudes, and beliefs of coaches, parents, and league officials related to youth football head impact exposure to inform the development and implementation of a practice structure to reduce head impact exposure and improve safety in the sport. We aim to (1) understand under impact exposure in youth football and (2) determine the awareness and receptivity to creating a safer practice structure to reduce head impact exposure in youth football among key stakeholders. Your child's involvement in this portion of the research study pertains to aim 1 of the study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

25-30 youth football players will take part in this study. An additional 60 athletes will be followed across four teams throughout the 2023 and 2024 Season in Winston Salem participating in a practice intervention program.

WHAT IS INVOLVED IN THE STUDY?

Your child will be provided a sensor that fits in their helmet. The sensor measures the motion of his/her head when your child has been hit. It also contains components which power, save, and store this information, including a small battery. All of which are embedded in the device. Data from the sensors are stored in the device and downloaded after a practice or game. Your child will wear the sensor during all practice sessions and all home and away games while your child is in the study.

Your child's coach / coaches will be taking part in a research study to improve safety of youth football practices Information from your child's sensor informing the force of hits to your child's head and video of practices and games will be used to understand the results of the research study.

As part of this research study, your child will be photographed/videotaped/audiotaped. This is being done to understand the context in which head impacts occur. You understand that your child may request the filming or recording be stopped at any time during the course of the research study. Your child can also withdraw his/her consent to use and disclose the

photograph/videotape/audiotape before it is used. Your child should also understand that your child will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Athlete Intelligence, the helmet sensor company, may pursue publicity, including images or videos of the athlete using the sensor, subject to your organization's approval. Athletes will not be identified by name unless permission is granted.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____I would like the photographs/videotapes/audiotapes of me to be destroyed once their use in this study is finished.

_____The photographs/videotapes/audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?

Your child will be in the study for about 3-4 months, depending on the length of the football season.

Your child can stop participating at any time. If your child decides to stop participating in the study, we encourage your child to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to your child. Your child should discuss the risk of being in this study with the study staff. There is a slight risk of a breach of confidentiality. We will do our best to protect your child's confidential information. There also may be other risks that we cannot predict.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that your child considers confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your child's information safe.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

The helmet sensor is not a concussion diagnostic tool. The data cannot be used to identify whether an athlete has a concussion. Your organization must follow its standard concussion protocols for assessing whether a player should be removed from play and/or seek medical attention. Athlete Intelligence does not provide or pay for medical care due to participation. Contact your health insurer for additional information.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your child may or may not have direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your child's alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your child's regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR CHILD'S RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Summary statistics of head impact data collected from samples of athletes in this study will be presented to stakeholders for discussion. Your child's identity and/or you child's personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of your child or others. There is always some risk that even de-identified information might be re-identified.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your child's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior and in some cases, you or your child's genetic information, to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You or your child may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will

report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share you or your child's information using FITBIR. If so, contact the researchers who conducted this study, and they will tell FITBIR, which can stop sharing the research information. However, FITBIR cannot take back information that was shared before you changed your mind. If you would like more information about FITBIR, this is available on-line at http://fitbir.nih.gov.

WILL YOU BE PAID FOR PARTICIPATING?

Your child will not be paid for participating in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institutes of Health and Wake Forest University Health Science. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study.

WHAT HAPPENS IF YOUR CHILD EXPERIENCES AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should your child experience a physical injury or illness as a direct result of your child's participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If your child are injured, the insurer may require information such as your child's name, social security number, and date of birth in order to pay for your child's care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Jillian Urban, PhD, MPH* at [redacted]

WHAT ABOUT YOUR CHILD'S HEALTH INFORMATION?

In this research study, any new information we collect from your child and/or information we get from your child's medical records or other facilities about your child's health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** concussion diagnosis.

If this research study involves the diagnosis or treatment of a medical condition, then Protected

Health Information collected from your child during this study may be placed in your child's medical record, and may be used to help treat your child, arrange payment for your child's care, or assist with Medical Center operations.

We will make every effort to keep your child's Protected Health Information private. We will store records of your child's Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your child's personal health information and information that identifies your child ("your child's health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your child's health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your child's health information. If disclosed by them, your child's health information may no longer be covered by federal or state privacy regulations. Your child's health information may be disclosed if required by law. Your child's health information may be used to create information that does not directly identify your child. This information may be used by other researchers. Your child will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your child's Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your child's Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from your child in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your child's medical record will either be destroyed or it will be de-identified.

You can tell Jillian Urban that you want to take away your child's permission to use and share your child's Protected Health Information at any time by sending a letter to this address:

Jillian Urban, PhD, MPH
[redacted]

However, if you take away permission to use your child's Protected Health Information your child will not be able to be in the study any longer. We will stop collecting any more information about your child, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your child's Protected Health Information for this study.

If your child chooses to participate in this study, your child's medical record at Wake Forest University Baptist Medical Center will indicate that your child is enrolled in a clinical trial. Information about the research and any medications or devices your child are being given as a participant may also be included in your child's medical record. This part of the medical record will only be available to people who have authorized access to your child's medical record. If your child is not a patient at this Medical Center, a medical record will be created for your child anyway to ensure that this important information is available to doctors in case of an emergency.

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 your child. At most, the website will include a summary of the results. You can search this Web site at any time.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. Your child may choose not to take part or your child may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which your child are entitled. If your child decides to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your child's participation in the study at any time. This could be because your child failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your child's willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, *Jillian Urban, PhD, MPH* at [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your

child's rights. If you have a question about your child's rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, You should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved for your child.
- You understand that even if you give your permission, your child may choose not to take part in the study.

Statement of Consent

I give my voluntary permission for my child to take part in this study. I will be given a copy of this consent document for my records.

Signature of Parent/Guardian_____Date:_____Time:_____am pm

Printed Name of Parent/Guardian:_____

Printed Name of Minor:_____

Statement of Person Obtaining Informed Consent

I have carefully explained to the parent of the child being asked to take part in the study what will happen to their child.

I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of his or her child's participation.

I also certify that he or she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her

- Does not have any problems that could make it hard to understand what it means for his or her child to take part in this research.

Signature of Person Obtaining Consent:_____Date:_____Time:_____am pm

Printed Name of Person Obtaining Consent:_____