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Wake Forest School of Medicine

Department of Biomedical Engineering

COMMUNITY-ENGAGED SPORT SAFETY: PRACTICE STRUCTURE INTERVENTION

Informed Consent Form to Participate in Research

Jillian Urban, PhD, MPH, Principal Investigator

INTRODUCTION

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. The purpose of this research is to evaluate the feasibility, acceptability, and sustainability of an intervention aimed to reduce head impact exposure in youth football practices. You are invited to be in this study because you are a coach of a team within a local football organization. Your participation in this research will involve utilization of a practice structure, including guided practice plan and associated reference materials, during a season of youth football and completion of a pre-season training associated with the guided practice plan prior to the season. You will also be paired with a mentor (e.g., high school football coach) to guide you with practice planning to meet the needs of your team. You may not directly benefit from participation in this study; however, you may learn ways to reduce the number or severity of head impacts among athletes participating on the teams you are coaching.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. Please take your time in making your decision as to whether or not you wish to participate.

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

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

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) Determine the awareness and receptivity to creating a safer practice structure to reduce head impact exposure in youth football among key stakeholders. (2) Develop an evidence-based intervention to reduce head impact exposure in youth football practices, using a community-engaged approach. And (3) Pilot-test the evidence-based practice structure to reduce head impact exposure among two middle-school football teams. Your involvement in this portion

of the research study pertains to aim 3 of the study.

How Many People Will Take Part in the Study?

A total of two teams, including 8 coaches (4 from each team) and 30 athletes (15 from each team) will partake in the intervention portion of this study.

What Is Involved in the Study?

In the first part of this intervention, a pre-season educational clinic will be provided to youth football coaches. The educational clinic will include a panel discussion of high school football coaches around the topic of practice planning, presentations from medical and research professionals on head impact biomechanics and related sports medicine topics (e.g., concussion signs and symptoms, cardiovascular emergencies, heat precautions), and demonstrations of safe practice drills. You will be asked to attend the clinic.

Coaches participating in the intervention will be asked to follow guided practice plans that follow the North Carolina High School Athletic Association (NCHSAA) handbook for football practice drills with moderated time spent on live action or full contact drills. Coaches will also be provided a reference booklet developed in collaboration with local high school football coaches and a community stakeholder team with drill explanations, guidance on practice planning and drill selection, and frequently asked questions. You will be asked to follow the guided practice plans use the reference booklet for your football practices during the season.

Each team/coaching staff participating in this study will be paired with a high school football coach/coaching staff who will serve as a mentor. We ask that you meet with your peer mentor weekly throughout the season to provide guidance on practice planning throughout the season.

You will also be asked to complete pencil and paper surveys and participate in 1-3 interviews to provide feedback on your experience with the intervention program.

As part of this research study, your team will be photographed/videotaped/audiotaped and will only be used for data analysis. You may request the filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph/videotape/audiotape before it is used. You should also understand that you 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.

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?

You will be in the study during the duration of the football season.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as anonymous surveys, keeping research information secure and allowing only authorized people to have access, will be made to keep your information safe.

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

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may or may not have direct benefit from taking part in this research study; however, you may learn ways to reduce the number or severity of head impacts among athletes participating on the teams you are coaching. We hope the information learned from this study will benefit other people in the future. The results of this study will increase our understanding of non-concussive head impact exposure (i.e., head impacts that do not result in signs and symptoms of concussion) in youth football. The results of the proposed research will help to inform head impact safety efforts in youth football including how best to design and implement effective head impact safety interventions in this context.

WHAT ARE THE COSTS?

All study costs will be paid for by the study. Costs for any activity not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required.

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 you 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 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 collected from you for this study, 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 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 individually about specific studies.

You may decide now or later that you do not want to share your 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?

To reward all participants for attending research activities (i.e., events) such as key informant interviews, a gift card will be awarded, at each event, for the additional travel and time to attend the event. See the table below for gift card compensation amounts.

	Key Informant Interviews
Compensation for each event	$20
Number of events	1-3
Total compensation*	$20-$60

*if all events are attended

The gift card will be given to the subject at the time of the event. A record confirming receipt by the subjects of the gift card will be kept.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

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. Drs. Jillian Urban and Joel Stitzel at Wake Forest University Health Sciences (WFUHS) developed the custom mouthpiece instrumentation being utilized in this study. WFUHS and Drs. Urban and Stitzel may financially benefit if the mouthpiece is licensed for use related to this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you 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 you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first. The investigators also have the right to stop your participation in the study at any time. Information that identifies you may be removed from the data 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 willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study contact the study investigator, Jillian Urban at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your 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] or the Research Subject Advocate at [redacted].

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

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm