Terms and Conditions

1. Why is this research study being done?
Soccer and basketball are among the most popular sports in the United States. There are many health and economic benefits to participating in soccer and basketball, the risk of musculoskeletal injuries associated with participation are significant, especially at the college level, and the consequences are serious. Load management is a target for minimizing injury risk. The purpose of this research study is to generate data to inform the development of an evidence-based load management software, which we have called the RICHLoad. We hope to spread the use of this product across the United States when completed.

2. What am I being asked to do?
You will be asked to do the following:

- Attend a baseline testing session before the start of the 2021/2022 and the 2022/2023 seasons to complete 2 questionnaires: a screening questionnaire that will collect demographic data, past and current injury and medical history, and the Athlete Sleep Screening Questionnaire. You will also undergo strength and balance tests, weight, height and body composition measurements.

- You will be asked to download a survey app on your cell phone at baseline to complete baseline forms and for daily load monitoring through the 2021/2022 and 2022/2023 competitive seasons.

  This app, specifically developed for this study, will be available for you to download for free on your phone. The app is available on both app store and google play store for iOS and Android cell phones, respectively. At the end of each day, you will be prompted to respond to a quick survey to report your perception of the intensity of your practice, training
(strength/conditioning) and/or game sessions for the day, on the mobile app downloaded at baseline. In addition, you will be prompted to self-report any pain/ache/soreness and your perception of the quality of your sleep through the week, at the end of each week (every Saturday), using the same mobile app.

- Every Sunday, during the 2022/2023 season, your coaches and members of your medical team will receive weekly report regarding your risk for sustaining injury/injuries in the current week based on our RICHLoad software algorithms. If your report suggests a high injury risk classification, you may be advised on specific interventions by your coaching/medical staff to minimize your risk of injury through that week.

To obtain data on any injuries you may sustain through the study period, we will review your injury records through the two study seasons. Our main source of information will be from athletic trainer records, but we will also review any relevant information from physician or physical therapist in/out-patient records, should you have any further consultation beyond an athletic trainer’s evaluation/intervention. In addition, we will review records of load data traditionally collected by your coaches to supplement or fill-in missing data for this study.

Identifiers might be removed from your data collected in this research, and used for future research studies or distributed to other researchers for future research studies without your additional permission.

3. How long will I be in the research study?

The time you may spend participating will last for 2 competitive seasons 2021/2022 and 2022/2023), adding up to 2 years (active in-season period only). The baseline testing (including consent and completion of baseline questionnaires) will take about 25 minutes to complete each before the start of the 2 seasons. The daily load monitoring survey will take about a minute to
complete each day throughout the 2 competitive seasons. The weekly (every Saturday) pain and sleep questionnaire will also take about a minute to complete.

The research study, that is all data collection, is expected to be completed by the end of December 2023. Data analysis and dissemination are expected to continue through July 2025.

4. What are the risks?

There are certain risks and discomforts that may occur if you take part in this research study. You may have potential discomfort while answering some of the questions in the study questionnaires. You may choose to skip any questions if you are uncomfortable.

As this study involves the use of your personal information (such as your name or email), there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to prevent or lessen these risks, as described in section 7 of this form.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. Are there benefits to being in this research study?

You may not benefit directly from participating in this research study. The knowledge gained from this research project may benefit the general population of student-athletes towards reducing the risk of injuries in soccer and basketball across the United States and abroad.

6. What other options are there?

You can choose not to participate. If you decide not to participate, there will not be a penalty to you or loss of any benefits to which you are otherwise entitled. Your decision to participate will have no effect (favorably or unfavorably) on your grades, class standing, or student/athlete status. You may withdraw from this study at any time.

7. Will my information be kept private?
The results of the research study may be published, but your name or identity will not be revealed, and your information will remain private. Results will be presented as aggregated data so that no individual's identity will be known. All the information collected online through study mobile app will be encrypted in a secured server. In order to protect your information, the research team will assign you a code number. Your name will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from your research data, so the research data cannot be linked directly to you. The master list will be kept electronically on a secure, password-protected network. Paper copies of any research data will be stored in locked file cabinets located in a locked research lab.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research studies), or other University officials may review your research study records. State or federal laws or court orders may also require that information from your research study records be released.

8. What are the costs and payments?

In this study, you will not be paid for participation. There will be no additional costs to you for taking part in this research study. All study related costs will be covered by the study team.

9. What happens if I am injured because I took part in this research study?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

10. Who can I call if I have questions?
If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call the researcher Dr. Olu Owoeye at 314-977-8546 or email olu.owoeye@health.slu.edu.

If you have questions, concerns or complaints about your rights as a research participant and would like to talk to someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

11. What are my rights and What else should I know as a research study volunteer?

Your participation in this research study is voluntary. You may choose not to be a part of this research study. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The researcher will let you know of any new information that may affect whether you want to continue to take part in the research study.

12. Am I sure that I understand?

I have read this consent document and have been able to ask questions and state any concerns. The researcher has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.
HIPAA Authorization Form

Privacy Protection for Research Volunteers

State and Federal privacy laws protect the use and release of your health information. Saint Louis University requires that private information about you be protected. This is especially true for your personal health information. Protected Health Information (PHI) is any health information that can identify you.

To take part in this research study, you must give the research team permission to access your health information and to use and share your PHI. The research team will only use and/or share your information as described below.

What Health Information about me may be used or shared for this research study?

The PHI in this study will include:

- Name
- Telephone Number
- Date of Birth
- Email Address
- Patient-Specific Dates

The PHI will be collected from the following sources:

- Hospital Medical Records
- Physician or clinic records
- Interviews or questionnaires/health histories

Who will my information be shared with?

Your PHI will be maintained by Dr. Owoeye, and his research team and they will only share the information as described below. The researchers may use or share your health information with:
• The Saint Louis University Institutional Review Board and other University personnel in order to provide research oversight
• Federal or state government representatives, when required by law
• Physicians who have access to your medical records when required for your medical care
• Your primary physician if researchers in the course of the research learns of medical condition

The researchers at Saint Louis University agree to protect your health information by using and/or disclosing it only as you authorize. However, if your PHI is shared with someone outside of the Saint Louis University research team and/or if you choose to share this information with others outside of this study, your health information may no longer be protected by HIPAA.

Am I required to sign this document?
Your decision to sign or not sign this document will not affect your standard medical treatment, payment or enrollment in any health plans or affect your eligibility for benefits. However, if you choose not to sign this form, you may not take part in this research study.

Does my permission expire?
This permission to release your PHI expires when the research study is over and all required study monitoring has ended.

If you choose to sign this document:
• You can change your mind and not allow the researcher to use and/or share your PHI (revoke your authorization)
• If you revoke your authorization, you must send a written letter to: Dr. Oluwatoyosi Owoeye, 3437 Caroline Street, St. Louis, MO, 63104 to inform him of your decision
• If you revoke your authorization, researchers may only use and/or share your PHI already collected for this research study.

• If you revoke your authorization, your PHI may still be used and/or shared should you have an adverse event (a bad effect).

• If you withdraw your authorization, you may not be allowed to continue in the study.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the University Privacy Officer at (314)-977-5545.