Terms and Conditions

1. **Why is this research study being done?**

Soccer, basketball, cross country and general track and field are among the most participated sports in the United States. There are many health and economic benefits to participating in sports; however, 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 and optimizing performance. The purpose of this research study is to generate data to inform the development and validation of an injury risk management software (RICHLoad) based on an evidence-informed multivariable screening tool – the Musculoskeletal Injury Risk (MIRisk) Index. 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:

i. Complete study consent forms and a baseline/preseason screening questionnaire that will collect demographic data, past and current injury and medical history, load and sleep data (all on the RICHLoad mobile app).

ii. Download the RICHLoad app on your cell phone at baseline to complete these baseline forms (as indicated above) and for weekly load and wellness (any

soreness/aches and sleep data through the week) monitoring through the 2022/2023, 2023/2024 and 2024/2025 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. You will be expected to complete the Weekly Athlete Survey every Saturday (an automated prompt will be sent at 9 pm CT and a final reminder at 11pm CT). The Weekly Athlete Survey is a quick survey to report your perception of the intensity of your practice, training (strength/conditioning) and/or game sessions and any lower limb problems for the week, on the RICHLoad mobile app that you download at baseline.

iii. Complete a post-season questionnaire.

iv. Every Sunday, during the 2023/2024 and 2024/2025 seasons, you will receive weekly reports regarding your risk for sustaining injury/injuries or any inadequate adaptation to soccer/basketball-related load in the current week based on your RICHLoad software algorithms, the MIRisk Index. Your coaches, and medical team staff may receive same information. If your report suggests a high injury risk category, you the RICHLoad app will advise you on specific interventions (based on identified risk factors) to minimize your risk of injury through that week. Your coaching/medical staff may also intervene (if applicable) to help you reduce your risk for injury.

To obtain data on any injuries you may sustain through the study period, we may 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, including illnesses, should you have any further consultation beyond an athletic trainer's evaluation/intervention. In addition, we may review records of load data traditionally collected by your coaches to supplement or fill-in missing data for this study. We may also use relevant baseline testing data routinely collected by your coaching/training staff in our data analysis. 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 3 competitive seasons (2022/2023 to 2024/2025), adding up to 3 years. The baseline testing and mid-season retest will take about 20 minutes each time for each season. The Weekly Athlete Survey, will take about two minutes to complete. We will reach out to you via email to request your completion of the post-season questionnaire.

The research study, that is all data collection, is expected to be completed by the end of June of 2026. Data analysis and dissemination are expected to continue through July 2027.

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 benefit directly from participating in this research study. You and your team will have access to your MIRisk Index to help you manage your risk for injury throughout the season (i.e., the baseline report and/or weekly feedback on the app), and you may find this information helpful in making decisions to reduce the risk of injury. The knowledge gained from this research project may benefit the general population of student-athletes towards reducing the risk of injuries in collegiate sports 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. To protect your information, the research team will assign you a study id (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 may be paid for participation. You will receive an incentive of a $20 gift card (per season) if you complete the weekly athlete surveys by up to 90%. 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.