Information for the participant and Informed consent form

Title of the study: Effect of foam properties and cushioning position of running shoes on injury risk in leisure-time runners: A randomised trial

Number of the study, acronym: RRI_Interv5

Sponsors of the study: Luxembourg Institute of Health and Decathlon

Scientific Principal Investigator of the study: Dr Laurent Malisoux

Medical Principal Investigator of the study:

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SECONDARY USE OF YOUR DATA

You have agreed to donate your data to help researchers meet the objectives of the study RRI_Interv5. Thank you very much for agreeing to do this.

The details of this study have been set out for you in the main ethical consent form. These details describe in particular the use we will make of your data in the context of this study; this is called their *primary use*. Primary use refers to the fact that your data will be used for the purposes of the so-called *primary* study.

The purpose of this document is to address the possible reuse of your data, for another research project, conducted in the same field of the study RRI_Interv5. This is called a *secondary use* of your data.

With this document, you are now being asked if you agree to the reuse (secondary use) of your data (with the exception of your direct ID data) for future research in the field of running-related injury prevention.

As a reminder, your consent is entirely voluntary. This means that you can freely refuse the secondary use of your data without this affecting your participation in the study RRI_Interv5. Likewise, if you decide to agree to the reuse of your data, you may withdraw your consent at any time without having to give any reason.

In fact, if you give your consent, the LIH may make your data available for use in other research and development programmes in the field of running-related injury, conducted by the same institution and by other national or international organisations, only in accordance with which choices you make in the consent form that follows.

These choices depend on the consent options you select. These options are presented at the end of this document and differentiate secondary uses according to whether or not the investigator remains the same.

It should be noted that these secondary uses will in no case result in the marketing of your data.

The principles described in the primary study RRI_Interv5 documents will also apply to these future studies. Please read carefully the points described below.

1.1. Your data: Processing and Rights

Your data will be protected according to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data - the General Data Protection Regulation (GDPR) - and any other local legislation supplementing this text, in this case the Luxembourg law of 1 August 2018 on data protection.

You therefore have a right of access and rectification of your personal data. Under the conditions set by law and as described in the data protection notice sent to you, you also have the right to oppose the way your data is used, to request the erasure of your data, to request the restriction of certain aspects of the processing of your data, to retrieve your data so that you can send it to a third party (right to data portability), and to withdraw your consent to process your personal data. If you wish to exercise your rights, you may contact the research team.

For any requests for information regarding the processing of your data by the Sponsor, you can contact the Sponsor's data protection officer by email at dpo@lih.lu.

Finally, if you believe that the processing of your data constitutes a breach of the General Data Protection Regulation, you can lodge a complaint with the Luxembourg National Commission for Data Protection (CNPD).

1.2. Your data: Retention period

Your data will be retained, in compliance with legal provisions, for a period of 2 years from the last visit of the last participant included in the study, scheduled for April 2026. During this period, your data will be pseudonymised when they are used for research; this means that a code replacing your first name and last name will be used. After these 2 years, your personal data will be destroyed. The data we have collected and the data we produce from the analysis will be stored in anonymised form, in compliance with legal provisions, for a further period of 23 years. Any extension of this retention period will be subject to a request for a favourable opinion to CNER.

1.3. Your data: Transfer outside Europe

If you agree, your data may be transferred for reuse for research purposes outside of the territory of the European Union. Only data that does not make it possible to directly identify you (coded or anonymised data) will be transmitted outside of the European Union.

In the case of such transfers outside of the European Union/European Economic Area, the legislation in force regarding data protection may be less strict. If that is the case, the Sponsor will put in place appropriate measures to ensure the protection of your personal data by acting in accordance with your explicit consent.

1.4. Withdrawal of consent

As described above, you may withdraw your consent at any time, without giving any reason. However, it is important to note that the withdrawal of consent for these secondary uses is only possible for data that have not yet been reused. These data may indeed have been transmitted and/or reused in anonymised form (after erasure of the code assigned to you in the study) or pooled form (combined with data from other study participants), meaning that it will no longer be possible for us to associate these data with your identity.

1.5. Information on secondary uses

You may be informed of the secondary use projects authorised in the context of the study RRI_Interv5. Communications will be made on a dedicated website.

INFORMED CONSENT

SECONDARY USES OF DATA BY THE SAME INVESTIGATOR/RESEARCH TEAM/INSTITUTION:

For other subsequent projects in the same research area (running-related injury prevention) that are conducted by THE SAME INVESTIGATOR/RESEARCH TEAM/ INSTITUTION:		
1. I agree to the reuse of my pseudonymised/anonymised **data**	NO	☐
	YES	☐
2. My choices expressed above remain valid if the secondary use project involves a transfer of my data outside the European Union	NO	☐
	YES	☐

SECONDARY USES OF DATA BY OTHER RESEARCHERS:

For other subsequent projects in the same field of research (running-related injury prevention) that are conducted by OTHER INVESTIGATORS:		
1. I agree to the reuse of my pseudonymised/anonymised **data**	NO	☐
	YES	☐
2. My choices expressed above remain valid if the secondary use project involves a transfer of my data outside the European Union	NO	☐
	YES	☐

Participant's first and last name(s): ....

Date of signature (day/month/year): ....

Signature of participant: ....

One copy available in the electronic platform for the participant and one electronic copy for the institution responsible for the study.