

Data Protection Notice template

Information for the participant on the processing of personal data

<u>Title of the study:</u> 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

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1 CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

As part of the study entitled "Effect of foam properties and cushioning position of running shoes on injury risk in leisure-time runners: A randomised trial" (RRI_Interv5), we will need to collect and process some of your personal data to enable us to meet the scientific objectives of the Study.

The LIH and Decathlon are jointly responsible for collecting, analysing and, more generally, processing your personal data, and for ensuring that it is protected, in accordance with the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 (known as the GDPR) and all subsequent texts replacing or supplementing this Regulation, in particular, Luxembourg's law of 1 August 2018 on the organisation of its National Commission for Data Protection and the implementation of the GDPR (collectively known as the Law on Data Protection).

2 What type of data will we collect?

If you choose to take part in the study, we will only collect the personal data we need to achieve the scientific aims of our study.

We will collect the following data from you by means of questionnaires in electronic format, and connected devices.

The following data will be collected directly:

- Data relating to your health (weight, height, chronic diseases, previous running-related injury, running-related musculoskeletal complaints during follow-up);
- Personal data (name, email, phone, age, sex, country of residence);
- Other categories of processed data: level of education, socio-professional category, type of work, gross annual household income, running experience, training practice in running, competition and performance in running, application connection log (data collected indirectly).

[RRI_Interv5] Document version: Version 2.0 Page 1 of 3
Version date: 17.12.2024



Data Protection Notice template

The data relating to your running activities (date, duration, distance, speed, elevation) will be collected indirectly from your sport watches via your Garmin Connect, Polar Flow or Suunto account. Alternatively, you will have the possibility to download the GPX files of your running sessions (i.e., raw data from any activity tracker with GPS) and upload them into the electronic system "STRIDE". In all cases, no geolocation data will be collected.

3 ON WHAT LEGAL BASIS WILL WE PROCESS YOUR DATA?

The use of your personal data is based on your explicit consent (art. 6.1a and art. 9.2a of the GDPR).

You can agree to or prohibit the use of your personal data, collected during the course of this Study, for any other purposes by ticking the relevant box on the consent request form.

4 Who will have access to your data?

Apart from the Medical Principal Investigator, only the following categories of persons will be able to access your data in relation to their respective duties:

Names or data that directly identifies you (first name, last name, address, telephone number, etc.): A limited number of authorized persons from the *Physical Activity, Sport and Health* (PASH) research group (including the Scientific Principal Investigator in order to reply to any requests from the study participants) and *Competence Center for Methodology and Statistics* (CCMS) will have access to the Study's correspondence table, linking your identity data to the code assigned to you for the Study.

Coded (pseudonymised) data: Other members from the PASH research group

Aggregated or anonymized clinical data (no link to your personal data) will be shared with Decathlon.

We may also need to grant access to your data to service providers carrying out work on our behalf, such as IT companies (responsible for hosting or maintenance services, for example). These organizations are bound by stringent security and confidentiality obligations, as required by the law, and the services they provide are subject to contractual agreements. Finally, in cases where particular study monitoring, inspections or audits need to be carried out, the study monitor and competent authorities may have access to your personal data.

Your data will not be used for any fully automated decision-making processes or for any profiling purposes.

5 What are your rights?

You will have the right to access and amend your personal data. In accordance with the conditions set out by the law *, you will also have the right to object to the way in which your data is being used, to request that your data be deleted, to ask to restrict 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/or to withdraw your consent to process your personal data. If you wish to exercise your rights, you should contact the research team.

Lastly, you have the right to raise a complaint with Luxembourg's National Commission for Data Protection (CNPD) in relation to the processing of your personal data.

For information about how the LIH processes your personal data, please contact the LIH's Data Protection Officer by email at dpo@lih.lu or by post at the following address:

LUXEMBOURG INSTITUTE OF HEALTH

[RRI_Interv5] Document version: Version 2.0 Page 2 of 3
Version date: 17.12.2024



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Protection des données 1A-B, rue Thomas Edison L-1445 Strassen LUXEMBOURG

* The LIH will examine all your requests to exercise rights in accordance with the GDPR and the Luxembourg law of August 1, 2018 on the organization of its National Commission for Data Protection and the implementation of the GDPR.

6 How do we protect your personal data?

Decathlon and LIH take appropriate security measures, based on the sensitivity of the information concerned, to protect your data from the risk of unauthorized access, loss, fraudulent use, disclosure, modification and destruction. Your data will be treated as strictly confidential. It will also be pseudonymised, meaning that your name will be replaced by a confidential reference code. This code will not directly identify you and will only be used to process your data for scientific purposes. Your identity will never be disclosed in any document produced for the public or for other institutions. The correspondence table showing the link between your name and the reference code will be kept confidential and secure by the research team and will be stored separately from the other data associated with the Study. Only a small number of people will have access to it (see "Who will have access to your data?" above).

7 FOR HOW LONG WILL YOUR DATA BE STORED?

Your data will be stored, in accordance with the applicable legal provisions, for a period of 25 years following the end of the study (defined by the last participant's last visit, expected in April 2026). The data allowing your identification will be deleted 2 years after the end of the study. After this period, the table linking your identity to the other data will be deleted, meaning that LIH will be no longer able to satisfy your requests, as we will have no way to re-identify you. As such, you will not be able to withdraw from the study after this period neither we will be able to provide you any report.

Your identifiable information being deleted, it means that the study data collected for the purpose of the study will be anonymized (no direct link between your study data and you). Be informed that LIH will continue to process your anonymous data for research purpose for a period of 23 years.

The relevant documents including Informed Consent Form, source documents and other participant records will be retained after the last participant last visit of the study for at least 25 years.

8 Transfers of data outside the European Union.

None of your personal data will be transferred outside the European Union.

For more detailed information on the appropriate measures taken by the LIH, please send your request by email to the LIH's Data Protection Officer at dpo@lih.lu.

[RRI_Interv5] Document version: Version 2.0 Page 3 of 3
Version date: 17.12.2024