INFORMED CONSENT FORM (for Parents/Legal Guardians)

1. What is the purpose of this document?

This form provides you with information about the biomedical research project *"Co-creating school community intervention program on physical activity to increase health equity in children and adolescents" (Connection)*. It explains the reasons for conducting the study, its procedures, potential benefits, risks, possible inconveniences, and other important information. If you decide to participate, we will ask you to sign this consent form, confirming your agreement to follow the instructions of the research team during the study. By signing this document, you consent to your child's participation in the research. Please take your time and read this document carefully. If you do not understand any word or statement, be sure to ask the research team any questions you may have. Before making a decision, you may discuss it with your family members, friends, or your doctor.

2. Why are biomedical research studies conducted?

Biomedical research is conducted to determine the relationship between environmental factors and children's health, with the aim of identifying changes that could reduce health risks caused by unfavorable environmental factors. Therefore, the purpose of this study is not to provide direct benefits to your child's health, but the collected research data will contribute to scientific progress.

3. Why is this study being conducted?

The Connection project aims to develop, implement, and evaluate co-created community-based social and physical environmental interventions that promote healthier eating and increased physical activity among children and adolescents living in disadvantaged social and economic conditions, with the ultimate goal of improving health equity.

4. Which individuals are selected to participate in this study?

The Connection study will involve children aged 12–16 attending VDU Atžalynas Progymnasium. This target group is selected based on the study's objectives, focusing on evaluating children's health indicators, lifestyle, and the impact of environmental factors.

In the first stage (cross-sectional study), approximately 200 children will be randomly selected. Participants must be healthy or have no medical or psychological conditions that could interfere with the study process. In the second stage (in-depth intervention study), 20 children from the first stage group will be selected. These participants will agree to wear a smart wristband for 7 days and take part in repeated measurements after 3 months.

Participation is voluntary, and all children and their parents will be fully informed about the study's objectives, procedures, potential benefits, and possible risks before participation.

5. Who is conducting this biomedical research?

This study is carried out by researchers from Vytautas Magnus University, funded by the Research Council of Lithuania under the ERA4health program. The Connection study will be conducted by scientists trained in performing anthropometric measurements, collecting personal data using computer programs and sensors, coding data, and creating and storing databases. The project researchers will be available to answer any questions you may have.

6. Probability of being assigned to different participant groups and participation characteristics

Participants will not be divided into groups and will not be required to change their daily lifestyle habits.

7. How long will your participation in this study last?

The duration of a participant's involvement in the biomedical research depends on the study stage: the majority (90%) will participate only once, while a smaller group (about 10%) agreeing to take part in the 7-day physical activity study will be invited for 2 additional visits:

1. **Cross-sectional study (initial stage):**

One-time participation lasting up to 30 minutes, including completing a questionnaire (up to 20 min) and physical measurements such as blood pressure, height, weight, and body composition (up to 10 min).

2. **In-depth (intervention) study:**

Two visits within a 7-day period:

a) **First visit:** Initial assessment, up to 10 min, placing the smart wristband and giving brief instructions.

b) **After 7 days:** Participants return the wristband, visit lasts up to 10 min.

c) **Second follow-up visit after 3 months:** Up to 20 min, repeated measurements and questionnaire completion, followed by another 7-day wristband use. Afterward, participants return the wristband and complete a questionnaire (visit up to 10 min).

Overall duration:

- Cross-sectional study: single visit, up to 30 minutes.
- In-depth study: two 7-day wristband wearing periods, two visits (~30 min each) and a follow-up after 3 months (~30 min).
- Total study timeline, including intervals, may last up to 4 months.

8. In which countries will this study be conducted?

The Connection project involves children from Portugal, Belgium, Spain, Lithuania, Latvia, Denmark, the Netherlands, and Italy.

9. How many participants are expected to take part in this study?

It is expected that approximately 200 children will participate in the biomedical cross-sectional study in Kaunas, and 20 children aged 12–16 years will take part in the in-depth (interventional) study.

10. What will you need to do?

While participating in this biomedical research, you will be asked to perform certain activities depending on the study stage.

In the first stage – the cross-sectional study, you and your child will participate once.

- Children: Will complete a questionnaire about health behavior, well-being, and environmental assessment.
- Parents: Will answer questions about social and demographic indicators and the living environment, necessary for evaluating air pollution exposure.

The information provided in the questionnaires will be anonymous and will not allow identification of your identity. Filling in the questionnaires will take up to 20 minutes. Children will undergo physical measurements, including blood pressure, height, weight, and body composition assessments, which will take up to 10 minutes.

If you are selected to participate in the second stage – the in-depth intervention study, your child will need to attend two study visits and wear a smart wristband for two separate 7-day periods.

- First visit: The wristband will be placed on your child to monitor physical activity, sleep quality, and heart function.
- After 7 days: At the second visit, you will return the wristband, and your child will answer verbal questions about their study experience.
- After 3 months: A follow-up study will be conducted, including measurements of blood pressure, height, weight, body composition, a short questionnaire, and another 7-day period of wearing the smart wristband.

Throughout all activities, researchers will ensure the safety and comfort of you and your child. You have the right to withdraw your child from the study at any time. Participation is voluntary, and all data will be handled confidentially and in accordance with legal requirements.

11. Will participation in this biomedical research be beneficial to you? / What benefits can you expect from participating in this study?

Participation in this biomedical research will not provide you with direct benefits. However, if requested, you will receive detailed results of your child's body composition, blood pressure, and other health indicators compared to recommended norms. This information can help you better understand your child's health status and lifestyle characteristics.
Additionally, your participation will contribute to important scientific research that may improve the diagnosis, treatment, and prevention of children's health problems in the future. The study will also use technologies such as smart wristbands to monitor your child's physical activity and sleep quality. Your contribution will be valuable to public health.

12. What risks and inconveniences are associated with participation in this study?

Participation in this study poses minimal risks and inconveniences. During physical measurements, such as blood pressure, height, weight, or body composition assessments, slight discomfort from contact with the devices may occur, but these are routine and short-term procedures. Wearing a smart wristband for 7 consecutive days may cause minor inconvenience as it needs to be worn continuously. All devices used are CE-certified and safe. The only potential risk is minor temporary discomfort, while all study procedures ensure participant safety and comfort. If any inconvenience arises, the research team will be ready to provide assistance immediately.

13. What if something goes wrong? (Insurance information)

Participation in the study will not pose risks or affect your or your child's health. There is no risk to your child's health condition. It is highly unlikely that your child's health will be harmed in any way due to participation in this study.

14. What choices will you have if you do not agree to participate in this study or decide to withdraw your consent?

Parents or a child who no longer wishes to participate in the biomedical research have the right to withdraw from the study, except in cases where this would conflict with the best interests of the child. You also have the right to withdraw consent if the participant is declared legally incapable or of limited capacity in the field of healthcare, or if due to their health condition they cannot reasonably assess their own interests.
You have the right to refuse participation in the study or to withdraw your written consent to participate at any time without giving reasons or explanations. To do so, you should inform the project leader Dr. Sandra Andrušaitytė (phone: +370 684 37989, email: sandra.andrusaityte@vdu.lt). If your child's health condition deteriorates and they are unable to decide on continued participation, your decision to withdraw consent will be respected.

15. Can you withdraw from the study?

If you decide to leave the study before it is completed, the researcher will ask you to provide a free-form written withdrawal request. You have the right to withdraw your informed consent to participate in the study at any time and without giving reasons. Once consent is withdrawn, data collection will stop; however, the data already collected will not be destroyed.

16. Circumstances and criteria for terminating your participation in the study

Participation in this study is voluntary; therefore, you have the right to refuse or withdraw from it at any time without providing reasons or explanations. You have the right to know what data has been collected about you and your child, and you can request correction or suspension of the processing of your and your child's personal data if you decide to withdraw before the planned end of the study. Biomedical research results, meaning data recorded in the study documents before the withdrawal of consent, will not be deleted.

17. Will you incur any expenses by participating in this study?

You will not incur any expenses and will continue your usual daily routine. All study procedures are free of charge, and no compensation will be offered for participation in the biomedical research, as participation is voluntary.

18. Will your personal data be kept confidential?

All information collected during this biomedical research that could identify you is confidential and may only be shared in accordance with the General Data Protection Regulation (GDPR), the Law on Patients' Rights and Compensation for Health Damage of the Republic of Lithuania, and other applicable data protection laws.
The data controller is Vytautas Magnus University, company code 111950396, address: K. Donelaičio g. 58, 44248 Kaunas.
To ensure confidentiality, you will be assigned a unique code, which will be used in all documents except the consent form, where your personal data is required. The list linking your name and code will be securely stored by the principal investigator in a locked cabinet accessible only to them and an authorized researcher.
Computers storing electronic research documents and data are password-protected, with login credentials known only to researchers and updated monthly.
Health information collected during the study is not considered confidential if disclosed in a way that does not allow your identity to be determined directly or indirectly.

19. Who will have access to your personal data and for what purpose?

By signing this form, you agree that the following parties may access the information collected about you for the purposes of this biomedical research:

- The study researchers;
- Institutions overseeing the research, such as the Kaunas Regional Biomedical Research Ethics Committee (Mickevičiaus g. 9, LT-44307, Kaunas, tel. +370 37 326889, email: kaunorbtek@lsmuni.lt), which issued the approval for this study;
- Authorized representatives of the study sponsor (Vytautas Magnus University) supervising the research.

All other parties will only receive coded health data that does not directly identify you. *"Coded"* means that documents will display a special number instead of your name, and only the principal investigator will be able to link this number to your identity.
You have the right to access your personal data and to request corrections if it is incorrect, incomplete, or inaccurate. Your personal data will be processed during the study to ensure the reliability of research results and participant safety. The study sponsor will process your personal data solely for scientific research purposes.
You may withdraw your consent for data collection and processing at any time without giving reasons. After withdrawal, your data will no longer be collected; however, data already collected before withdrawal will continue to be processed for the purposes of this research.

20. How long will the data collected during the study be stored, and who will be responsible for it?

All information collected during the study will be recorded in electronic and paper documents specifically created for this research and stored in the data repository of Vytautas Magnus University (company code 111950396, Universiteto g. 10-157, LT-53361, Akademija, Kaunas district) for 5 years after the project ends. This retention period is required by the sponsor to ensure data quality and control.
After this period, your personal data will be destroyed according to VMU's established procedures. The principal investigator and the data controller (VMU) will be responsible for data storage. Access to the data will be granted only to authorized research supervisors, the ethics committee or other oversight authorities, and researchers directly involved in the study.

21. Who has evaluated this biomedical research? / Whom to contact if you have questions?

For questions about your rights as a study participant, you may contact the Kaunas Regional Biomedical Research Ethics Committee, Lithuanian University of Health Sciences, Mickevičiaus g. 9, LT-44307, Kaunas, tel. +370 37 326889, email: kaunorbtek@lsmuni.lt, which granted permission for this research.
You have the right to ask questions related to the study at any time by contacting the principal investigator, Dr. Sandra Andrušaitytė, by phone at +370 684 37989 or by email at sandra.andrusaityte@vdu.lt (address: Universiteto g. 10-157, LT-53361, Akademija, Kaunas district).
You also have the right to file a complaint regarding personal data processing with the State Data Protection Inspectorate by mail (L. Sapiegos g. 17, 10312 Vilnius) or using its electronic services system (/go.php/lit/Prisijungti/37L). Contact phone number: +370 5 212 7532, email: ada@ada.lt.

CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH (for parents/legal guardians)

I have read this Informed Consent Form and understood the information provided to me. I was given the opportunity to ask questions and received satisfactory answers. I understand that I can withdraw from the study at any time without providing reasons[1]. I understand that the person for whom I am giving consent to participate in this biomedical research can also withdraw from the study at any time without giving reasons or explanations.[2] I understand that, if I wish to withdraw my consent to participate in the biomedical research, I must inform the researcher or another authorized study personnel in writing. I confirm that I had sufficient time to consider the information given to me about the biomedical research. I understand that participation in this study is voluntary. I confirm that I am giving my consent to participate in this biomedical research of my own free will. I allow the use of personal data to the extent and in the manner described in the Informed Consent Form.
I confirm that I have received a copy of the Informed Consent Form signed by the researcher or another authorized biomedical study personnel.

Participant (or other person legally authorized to give consent)

name	surname	Basis for representation	signature	Date of signing *MMMM-mm-dd*	Time of signing _:_

I confirm that I have provided information about the biomedical research to the person mentioned above. I confirm that this person (or another person legally authorized to give consent) was given sufficient time to decide on participation in the biomedical research, taking into account the nature of the study and other circumstances that could influence their decision. I encouraged the person (or other legally authorized individual) to ask questions and answered them fully.

Researcher or other person authorized to conduct the biomedical research

name	surname	Role in the study	signature	Date of signing *MMMM-mm-dd*	Time of signing _:_

I agree for my child to participate in the biomedical research in the following stage(s) (*please mark your choice***):**

☐ Cross-sectional study (only the first stage)

☐ Cross-sectional study and interventional study (stages 1 and 2)

Participant (or other person legally authorized to give consent)

name	surname	Basis for representation	signature	Date of signing *MMMM-mm-dd*	Time of signing _:_

I give permission for the researcher to contact me and send the study results by email (*please mark your choice***):**

☐ no

☐ yes (please provide email)_____

Participant (or other person legally authorized to give consent)

name	surname	Basis for representation	signature	*Date of signing* *MMMM-mm-dd*	Time of signing _:_

[1] If consent to participate in the study is given by the person themselves
[2] If consent to participate in the study is given by another authorized person