**INFORMED CONSENT FORM (VMU)**

Version No. 3, 2025-03-19

1. **What is the purpose of this document?**
   This form provides information about the biomedical/clinical study in which you are invited to participate. It explains the reasons for conducting the study, the scientific procedures involved, potential benefits and risks, possible inconveniences, and other essential information. If you decide to participate, you will be asked to sign this consent form, indicating that you agree to follow the instructions of the principal investigator and the research team. By signing this document, you confirm your voluntary agreement to participate in the research. Please read this document carefully before deciding. If you do not understand any term or statement, do not hesitate to ask the study physician or a member of the research team.
2. **Why are biomedical/clinical studies conducted?**
   During a biomedical/clinical study, health assessments will be conducted, but this type of study differs from routine clinical care. The primary aim of a biomedical study is to acquire new scientific knowledge that may benefit patients with cardiovascular diseases (CVD) in the future. Therefore, this study is not intended to provide direct health benefits to you, but your participation will contribute to scientific advancement. The specific objective of this study is to evaluate the relationship between exposure to ultrafine (PM0.1) particulate air pollution and noise with the risk of chronic diseases, as well as to assess the impact of a healthy lifestyle on metabolic indicators, including biological markers, waist circumference, and blood pressure. The study results will support the recommendations and development of health risk reduction strategies for individuals with overweight and elevated blood pressure to reduce the risk of CVD complications.
3. **Who is eligible to participate in this study?**
   You have been invited to participate because you took part in an online survey and responded to a call for volunteers in an experimental-clinical healthy lifestyle study. Survey participants were informed about the study purpose, main inclusion criteria, and researcher contact details. Upon contacting the researchers, you were asked to confirm information regarding your waist circumference, blood pressure, and place of residence. You are eligible for this study because you meet the following criteria: you are 45–64 years old, live in Kaunas city on a street with high air pollution levels, and have indications of metabolic disorders, such as increased waist circumference and/or elevated blood pressure. Participation in this study is voluntary, and you may withdraw at any time without any negative consequences.
4. **Who is conducting/sponsoring this clinical study?**
   This study is funded by the European Commission through the HORIZON research programme. Funding is allocated to Vytautas Magnus University researchers and covers health surveys expenses at Family Medicine Clinic of Kaunas Clinics. The study is carried out by scientists from the Faculty of Natural Sciences at Vytautas Magnus University, who will report the study data and findings results.
5. **Randomization and characteristics of study groups**
   Participants in the clinical trial will be randomly assigned to one of three groups. All participants will undergo a health check, maintain their usual lifestyle, and wear a sensor device (smartwatch) for 7 days to record physical activity, heart function, and sleep quality.

Blood samples (up to 20 ml) will be taken while fasting before the study and after 7 days to assess changes in metabolic markers. Group 1 will continue with their usual routine. Group 2 will walk briskly for at least 30 minutes daily in a city park. Group 3 will follow a healthy diet (Mediterranean diet). Participants will receive detailed instructions from the study physician, including contact details for consultations, sensor maintenance guidance, activity monitoring, and dietary recommendations. Random assignment is determined by a computer program, not by the researcher. You will be fully informed about your assigned group and expected behavior during the study.

6. **How long will your participation in this study last?**
   The overall project duration is four years. If you agree to participate in the experimental-clinical healthy lifestyle study, you will attend the study center twice at scheduled times. During your first visit, you will sign the informed consent form and undergo a health check. After 7 days, you will return for a second visit. Each visit will last up to 60 minutes.
7. **In which countries is this study being conducted?**
   This study is being conducted in the following countries: Germany, Italy, the USA, Lithuania, Serbia, Cyprus, Luxembourg, Finland, Denmark, and Switzerland, across a total of 15 centers.
8. **How many participants will be involved in this study?**
   The study will include several million residents in Denmark and Switzerland. In Lithuania, approximately 1000 individuals in Kaunas participated in the anonymous online survey on air pollution and health. From this group, 180 participants will be selected for the in-depth clinical healthy lifestyle study.
9. **What will be required of you?**
   Upon agreeing to participate and providing your contact details, the researchers will invite you two times to attend the Family Medicine Clinic of Kaunas Clinics at a scheduled time. During your first visit, you will receive detailed information about the study and be asked to arrive having fasted for at least 2 hours, as a blood sample (up to 20 ml) will be taken. You will also be informed that a second blood sample will be taken on Day 8, also after fasting for at least 2 hours. During your first visit, you will sign the informed consent form and be informed of your group assignment and 7-day behavioral expectations. During the first visit, a health check will include measurements of blood pressure, height, weight, waist circumference, body composition, and blood collection. You will receive behavioral recommendations and be equipped with a smartwatch to monitor physical activity, heart function, and sleep quality. During the second visit (Day 8), the same health checks will be repeated, the smartwatch will be collected, and a blood sample taken to analyze metabolic markers. Each visit will take up to 60 minutes.
10. **What are the potential benefits of participating in this study?**
    Participants will not receive direct health benefits. However, indirect benefits include receiving information about their body composition and metabolic health, which are indicative of CVD risk. Additionally, your anonymized data will contribute to developing preventive measures to improve public health and reduce the burden of cardiovascular diseases.
11. **What are the risks and inconveniences of participating in this study?**
    Participation may involve minor inconveniences such as slight alterations to daily routine, limited time investment (up to 2 hours), and temporary discomfort from blood draws. All data

will be anonymized and coded in accordance with data protection regulations to ensure participant confidentiality.

12. **What if something goes wrong? (Insurance information)**
    Venous blood sampling is considered safe and not harmful to health; therefore, adverse effects are not expected, and no insurance coverage applies. In case of an unexpected health issue (adverse reaction), the study physician will provide immediate assistance and, upon completing an adverse event report, will inform your general practitioner. Since the study procedures do not pose health risks, this biomedical study is not covered by civil liability insurance for either the sponsor or the principal investigators.
13. **What are your options if you decline or withdraw your consent?**
    Participation is entirely voluntary. You have the right to refuse or withdraw from the study at any time by submitting a written request. Your decision will not affect your standard medical care in any way.
14. **Can you terminate your participation in the study?**
    If you decide to withdraw from the study before its completion, the investigator will request a written withdrawal statement. You have the right to withdraw your informed consent at any time without providing a reason. Upon withdrawal, data collection will cease, but previously collected data will not be destroyed.
15. **Under what circumstances may your participation be terminated?**
    Your participation may be terminated if you fail to follow the investigator's instructions, experience unexpected health deterioration, or develop an acute infectious illness during the study.
16. **Will you incur any costs for participating in the study?**
    Participation is voluntary and short-term, requiring minimal time and financial commitment and only minor adjustments to your daily routine. No financial compensation will be provided for participation.
17. **Will your personal data remain confidential?**
    Health information collected during the study that could identify you is confidential and will be shared only in accordance with the General Data Protection Regulation (GDPR), the Law on the Rights of Patients and Compensation for Health Damage of the Republic of Lithuania, and other applicable legal acts. The data controller is the Research Center of Vytautas Magnus University (VMU). To protect confidentiality, a unique code will be assigned to you and used in all documents except the consent form. The electronic database linking your name to the code will be stored on a password-protected computer accessible only to the principal investigator and authorized researchers. Health and personal data will be entered into an electronic system. A separate coded and anonymized data set will be stored on the principal investigator’s computer. Data collected during the study will be transferred every 10 days via USB to the principal investigator’s security computer using your assigned code. Anonymized and aggregated health data will not be considered confidential and may be published without requiring your consent, your identity cannot be directly or indirectly revealed.
18. **Who will have access to your personal data and for what purpose?**
    Researchers will process your personal data to ensure study reliability and participant safety. The sponsor must also process your data for research purposes. Your consent is the legal basis for this data processing. By signing this form, you agree that researchers, oversight bodies (ethics committees, VMU representatives), and those providing your medical care may access

the data collected about you for this study. All personnel with access to your data are bound by confidentiality under GDPR and national data protection laws. Other parties will receive only coded data that do not allow direct personal identification. Your coded blood samples may be sent to laboratories in other EU countries. You have the right to know what data have been collected and to request corrections of inaccurate or incomplete data.

19. **How long will your data be stored, and who is responsible?**
    All information will be recorded in electronic documents prepared specifically for this study and stored for 10 years after study completion at the study center. This retention period complies with international agreements to support long-term EU environmental and health programs. Afterward, your personal data will be destroyed in accordance with the study center's procedures. The responsible parties for data storage are Prof. Regina Gražulevičienė and her designated representative, Dr. Sandra Andrušaitytė.
20. **Who has reviewed this biomedical study? Who can you contact for questions?**
    If you have questions about your rights as a research participant, contact the Kaunas Regional Biomedical Research Ethics Committee, Lithuanian University of Health Sciences, Mickevičiaus g. 9, LT-44307, Kaunas. Phone: (+370-37) 326889, Email: kaunorbtek@lsmuni.lt. For questions about your personal data, contact the principal investigator, Prof. Regina Gražulevičienė, at regina.grazuleviciene@vdu.lt. Your inquiry may be forwarded to the project's data protection officer: dap@vdu.lt. You also have the right to file a complaint with the State Data Protection Inspectorate: L. Sapiegos g. 17, 10312 Vilnius, or via their online system. Phone: (+370-5) 212 7532, Email: ada@ada.lt.
21. **Other relevant information that may influence your decision to participate**
    The study results will be published in scientific journals, presented at conferences, and used to prepare recommendations for the European Environment Agency, healthcare professionals, and patients to reduce cardiovascular disease risk.

## CONSENT TO PARTICIPATE IN A BIOMEDICAL / CLINICAL STUDY

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 may withdraw from the study at any time without providing any reason.
I understand that if I choose to withdraw my consent to participate in the biomedical study, I must inform the investigator or another authorized member of the research team in writing.
I understand that participation in this study is voluntary.
I confirm that I am giving my consent to participate in this biomedical study of my own free will.
I authorize the use of my 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 signed Informed Consent Form.

**PARTICIPANT**:

| | | | | _:_ |
|---|---|---|---|---|
| Name | Surname | signature | date | time |

I confirm that I have provided information about the biomedical study to the above-named individual.
I confirm that the individual was given sufficient time to decide whether to participate in the biomedical study, taking into account the nature of the study and other relevant circumstances that may influence their decision.
I encouraged the individual to ask questions and responded to them.

**RESEARHER:**

| | | | | _:_ |
|---|---|---|---|---|
| Name | Surname | signature | date | time |