Information for the participant and Informed Consent Form to participate in the research experiment

The information for the potential study participant and the informed consent form for participation in the study is addressed to men and women diagnosed with small cell lung cancer at the stage of extensive disease.

Title of the research experiment: "Evaluation of radiotherapy strategies used in combination treatment of small cell lung cancer at the stage of extensive disease - a research experiment"

Protocol: 22.05.2024, Version 1.1

Name of the Principal Investigator:

Details of the institution/center/hospital:

Sponsor: Regional Multi-Specialist Centre for Oncology and Traumatology Pabianicka 62, 93-513 Łódź

Participant's name:

This informed consent form consists of two parts:

- **Information for the participant (including information about the research experiment),**
- **Statement of consent to participate in the study (to be signed if you agree to participate in the study) with attachments.**

You will receive a full copy of the Informed Consent Form.

PART I: Information for the participant of the research experiment

Introduction

Dear Sir/Madam,

I kindly ask you to read the detailed information about the objectives presented below and the rules for conducting the research in which we would like to offer you participation. Your participation in this study is completely voluntary. The decision to participate is yours. Regardless of the decision you make, the hospital will continue to provide you with services – nothing will change in this regard. If you choose to participate in this research experiment, we will provide you with treatment in the same Healthcare Facility. You can change your mind and stop participating, even if you have now agreed to participate.

This form consists of two parts:

- Information for the participant (including information about the medical experiment),
- A statement of consent to participate in the study (to be signed if you agree to participate in the study) with attachments in the form of consent to the processing of personal data of the research experiment participant, consent to accept the terms and conditions of insurance and consent to genetic testing.

You will receive a full copy of the informed consent form.
If the document contains wording that you do not understand, your doctor will explain all the terms you do not understand. If you have any questions at a later date, you can ask the investigator or a member of the study team. The confidentiality of personal data will be maintained, personal data will be excluded from any study description. Each participant in the study is covered by insurance against damage caused in connection with participation in the study.

Each participant has the opportunity to participate in the scientific biobanking program of the Medical Research Agency. You will receive an additional informed consent form with all the necessary information. Please read it. Participation in the scientific program is voluntary. If you agree, an additional blood sample will be taken. The informed consent form in the Medical Research Agency's scientific biobanking program is also accompanied by a study participant questionnaire form, which is mandatory to fill in if consent to biobanking is given.

Purpose of the research experiment

In Poland, lung cancer is the most common malignant tumor and the main cause of cancer-related deaths. Small cell lung cancer accounts for about 15% of all lung cancer cases. It is characterized by aggressive growth and early dissemination to lymph nodes and distant organs. The medical experiment aims to evaluate radiotherapy strategies in the combination treatment of patients with histopathologically confirmed small cell lung cancer (DRP) at the stage of advanced extensive disease (ED) undergoing chemo-immunotherapy.

In patients with ED DRP who have responded to chemotherapy, palliative dose (30Gy/3Gy) has been shown to be able to consolidate the chest lesion area radiotherapy. However, the current standard of treatment for patients with ED stage is chemo-immunotherapy, and in this group of patients the legitimacy of this procedure has not been proven on the basis of clinical trials.

We are conducting a study to objectively assess whether the use of radiation therapy and what dose of radiation therapy is most appropriate to prolong the time to disease progression and survival with cancer. Similar clinical trials are underway in the United States and other European countries, but they do not evaluate the effect of increasing the dose of radiotherapy on the time to disease progression and survival. The designed study will evaluate the consolidation radiation strategy for residual lesions after chemo-immunotherapy (during immunotherapy) for progression-free time (time to disease progression) as the primary endpoint. In addition, the following will be assessed: overall survival, treatment toxicity, area of progression (primary lesions/new lesions).

As part of the study, you will be randomly assigned to one of the study arms:

- arm I continuation of standard treatment - PDL1/PD1 immunotherapy (durvalumab or atezolozumab) after platinum-based chemo-immunotherapy;
- arm II standard of treatment with radiotherapy to consolidate the chest area and possibly metastatic lesions in doses and for palliative indications (total dose 30Gy in 10 daily doses of 3Gy each);
- arm III standard of treatment with radiotherapy attached in radical/ablative doses (total dose of 45Gy in 15 daily doses of 3Gy-chest area and total dose of 24Gy administered in single doses every 2-3 days 8Gy-area of metastatic lesions) of the chest area and all metastatic lesions.

Responsibilities related to participation in a research experiment

The participant will be required to: report to appointments and undergo all procedures related to the study, inform the study staff about their well-being, observed symptoms, and not participate in any other study. It is important that when you decide to participate in the study, you accept the course and purpose of the study and are ready to participate until the study is completed or you withdraw your consent to participate. Until you complete and sign the informed consent form below, none of the study procedures can be performed on your premises.

Selection and number of participants and conditions of participation in the research experiment

The study will involve 165 participants. If, during the course of the research experiment, it is determined that a potential participant will experience events/factors that prevent further participation in the study, or the risk to the participant associated with participation in the study increases, the principal investigator may exclude the participant from the study, despite prior eligibility.

Voluntary participation in a research experiment

Your participation in this study is completely voluntary. The decision to participate is yours. Regardless of the decision you make, the hospital will continue to provide you with services – nothing will change in this regard. You can change your mind and stop participating, even if you have now agreed to participate.

Types of research interventions

The study will consist of randomly assigning you to one of the three study arms, implementing radiotherapy and treatment strategy. Before the study begins, you will undergo a number of medical procedures listed below that are necessary to conduct the medical experiment.
Procedures/tests performed as part of a medical experiment:

- signing an informed consent form,
- to collect general information about your health condition,
- filling in the form on the assessment of the quality of life,
- full physical examination,
- blood sample collection,

- computed tomography used to plan radiotherapy including real-time tracking of tumor mobility. Tomography can be performed with or without the administration of a contrast agent, depending on medical indications,
- radiotherapy – before each fraction of radiotherapy, a cone beam tomography will be performed to verify your position on the therapeutic device or imaging using X-rays (Kv),
- follow-up visits during radiotherapy to assess the presence of possible complications of treatment,
- monitoring of safety and assessment of your fitness.

Procedures and protocol of the research experiment

Description of the process and duration of the research experiment

Radiation therapy is a treatment method that uses high-energy external radiation that kills cancer cells. In order to be treated with radiation, you will need to come to the study center every day for about 3-4 weeks. Detailed information on the type and frequency of radiation will be provided to you after the radiation treatment plan has been completed.

During weekly follow-up visits, you will have your blood drawn to determine the following laboratory tests:

- 1 time before starting radiotherapy,
- up to 3 times during radiotherapy,
- 1 time when a possible progression is detected.

In addition, an additional volume of blood will be collected during each routine collection – a total of 5 samples of 10 ml of blood. This blood will be collected for storage and later use to determine the free tumor DNA circulating in the blood. The data obtained from the analysis of this material will serve as a marker of the time to progression and a marker of the possible benefit of radiation treatment.
Once you meet the criteria for inclusion in a medical experiment, you will be randomly assigned to one of the three groups described in the previous section of the information sheet. The term 'randomly assigned' means that the treatment regimen will be assigned to you by chance by tossing a coin or drawing lots from a hat. You have the same chance to draw each of the three possible groups.
After being assigned to one of the groups, the doctor will talk to you about the treatment options and its continuation.

RISKS

As a result of adding radiotherapy to chemo-immunotherapy, additional toxicity may occur, i.e. an increase in the frequency and severity of adverse effects of radiotherapy and immunotherapy. The expected toxicity is lower than the expected benefit to the patient. The treatment strategy that is the subject of this study is used in clinical practice outside of clinical trials based on NCCN guidelines, which recognize it as a treatment option. There is little data on the toxicity of such a combination of chemotherapy, immunotherapy, radiotherapy in small cell lung cancer. Data from the treatment of non-small cell lung cancer (from the PACIFIC study), in which chemoradiotherapy was combined with subsequent immunotherapy, indicate an acceptable risk of toxicity from the combination of these methods.

Possible side effects of radiotherapy added after chemo-immunotherapy during immunotherapy:

Acute radiation reaction:	• swallowing disorders, • hoarseness • cough • dyspnea • pneumonia, mediastinum, myocarditis;
risk of the combined effect of radiation pneumonia and immunotherapy-associated pneumonia, possible cough, fever, shortness of breath	
Late complications:	• progressive pneumonia, • dyspnea • chronic cough, • narrowing of the esophagus, • tissue necrosis, fistulas in the irradiated area, • impairment of hematopoietic function of the bone marrow, • spinal cord injury;
Other rare complications caused by a reaction to ionizing radiation of connective tissue in the treated tissue block	
Secondary cancers (very low risk)	

It is no significant risk of adverse effects from the collection of the extra volume of blood in this experiment. Blood will be collected during routine blood collections.
Risks associated with blood collection from a vein may include, but are not limited to:

- temporary discomfort at the donor site, possibly bruising, redness and swelling around the donor site,
- bleeding from the donor site,
- dizziness felt during blood draws,
- in rare cases, infections at the blood donor site.

Benefits

Adding radiotherapy to chemo-immunotherapy can increase the time to disease progression and survival. Radiation therapy can help fight cancer by regulating the immune system. For non-small cell lung cancer, a combination of chemotherapy, radiotherapy with consolidating immunotherapy is already a standard treatment option. As a result of the additional blood draw, we do not anticipate direct personal benefits for the participating patients - the evaluation of circulating tumor DNA (ctDNA) is of a cognitive nature. The data obtained from ctDNA analysis will be used as a potential marker of the time to progression and benefit from radiotherapy.

Salary / Reimbursement

You will not incur any additional costs for participating in this study. You are not expected to pay for the procedures or tests required as part of this study. You will be responsible for the cost of your usual medical care, including non-study procedures and medications, that your study physician or primary care physician requires as part of your usual medical care. You will not receive any remuneration for your participation in this research experiment.

Data privacy

If you decide to take part in this survey, your personal data will be processed in a confidential manner and will not be made public, and the management and use of the information collected during the process is regulated by the principles contained in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27.04.2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). on data protection) – GDPR – and the Polish Act of 10 May 2018 on the protection of personal data. The processing of personal data related to the health condition is necessary for the study to be carried out.
We do not disclose the identity of the people participating in the study.
The information collected as part of the study will be confidential. The information collected about you as part of the study will not be available to anyone other than researchers.

Sharing of research results, including the sharing of a summary of the results of the research experiment in the European Union database

We will not share confidential information, and the identity of the study participants will remain anonymous even after the study has ended. After the study is completed, the results will be scientifically and statistically compiled, after which they will be published in medical journals and presented at scientific conferences. Participants will not be informed of the outcome of the study.

Right to refuse or withdraw participation in a research experiment

You don't have to participate in the study if you don't want to. Refusal to attend will not affect your previous treatment at this clinic in any way. You will still be able to use the services to which you are entitled at this clinic. You can stop participating in the study at any time and you will not lose the benefits to which you are entitled as a patient. Such a decision will in no way affect the treatment received at the clinic.

Source of study funding

The research will be financed from a grant from the Medical Research Agency.

Contact options

If you have any questions, you can ask them now or later, even after the study has started and at any time during the study.

If you want to ask about something later, you can contact:

Principal Investigator	dr n. med. Łukasz Kuncman
Phone number	42 689 55 55

You can also contact the indicated person if you want to withdraw from the study. In the event of any additional information about the research experiment that may affect the willingness to continue participating in the study, the doctor/researcher is obliged to immediately provide it to the participant. The design of this research experiment has been verified by the Bioethics Committee at the Medical University of Lodz and received a positive opinion. An ethics committee is a group of people whose task is to protect research participants from harm/damage that may be associated with the trial.
If you would like to obtain further information about the Bioethics Committee, please contact the Secretariat of the Bioethics Committee at (42) 272-52-43, (42) 272-52-44 or e-mail bioetyka@umed.lodz.pl.

In case of any adverse effects, contact the ambulance service at 112 or A&E 42 689 51 61, depending on the clinical symptoms present.

PART II: Statement of Voluntary Consent to Participate in the Study

Declaration of the person agreeing to participate in the study

I have read or have had the above information read to me. I had the opportunity to ask questions about this information and received satisfactory answers to all my questions. I voluntarily agree/do not agree to participate in this study as a participant.

I agree: **YES** **NO** (delete as appropriate)

Participant's name (in capital letters) _____
Participant's signature _____
Signature Date _____

INFORMATION CLAUSE REGARDING THE PROCESSING OF PERSONAL DATA participant in a research experiment

In accordance with Article 13(1) and (2) and Article 14(1) and (2) of 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, and repealing Directive 95/46/EC (the so-called General Data Protection Regulation) ("**GDPR**"),

The Administrator informs that:

1. The administrator of personal data is (contact details): Regional Multidisciplinary Center of Oncology and Traumatology of Nicolaus Copernicus in Łódź, 62 Pabianicka Street, 93-513 Łódź ("Administrator").
2. The Controller has appointed a Data Protection Officer ("DPO"). Contact with the DPO: 42 207 44 55.

We invite you to contact us in all matters related to the processing of your personal data.

1. Information on data processing in your case:

Participate in a research experiment:

Who is affected by data processing?	Participants in a research experiment. Your personal data has been obtained directly from you or has been shared with us by other medical entities in connection with the provision or intention to provide medical services or participate in a research experiment.
How we obtain your personal information	From you – the study participant.
Legal basis for processing personal data	• Article 6(1)(c) of the GDPR – compliance with a legal obligation, inter alia: Regulations on archiving, keeping medical records, Act on clinical trials of medicinal products for human use of 9 March 2023 • Article 6(1)(f) of the GDPR – implementation of the legitimate interest of the controller; • Article 6(1)(e) of the GDPR – a premise on which entities performing tasks in the public interest or in the exercise of public authority (e.g. a public entity) may rely on; • Article 9(2)(i) of the GDPR – implementation of tasks related to the public interest in the field of public health; • Article 9(2)(j) of the GDPR – processing of personal data necessary for the purposes of scientific research; • Article 9(2)(h) of the GDPR – provision of health care and processing for the purposes of preventive health care (research centre).
Personal data processed	Ordinary and special categories of personal data in the scope of identification data, contact data and study documentation – in the questionnaire, informed consent form, clinical case report and medical documentation. In particular, depending on the data provided by you, these may include: names and surname, address of residence, PESEL number (in the absence of such a number – series and number or type of identity document), other contact details (telephone number, e-mail), patient identification number (in certain cases).
Purpose of personal data processing	Implementation of the research experiment by Administrators who participate in the implementation of the research experiment – sponsor, researcher, research center. The participants' personal data will be processed only for the purpose of conducting research and to

	the extent necessary to achieve this purpose, as well as to conduct medical activities and medical documentation required by law.
Period of personal data processing	Your personal data will be stored for the period of storage of medical records required by law, in accordance with the law, in particular Article 29 of the Act of 6 November 2008 on Patients' Rights and the Ombudsman for Patients' Rights.

2. Providing data is necessary for the implementation of the research experiment. Failure to provide data will result in the inability of you to participate in the research experiment.
3. Entities carrying out the research experiment will have access to the personal data of the participants only to the extent necessary to perform their tasks. These entities guarantee the implementation of appropriate technical and organizational measures to ensure the security of personal data.
4. The Administrator may, in accordance with the law, transfer your data further, to other recipients. In the case of your medical records, the law specifies in detail who can have access to your medical records – Article 26 of the Act on Patients' Rights and the Ombudsman for Patients' Rights – and each time the Administrator should comply with these regulations.
   In addition to the issue of medical records, the recipients of your personal data may be:
   a) duly authorized associates of the Administrator or its service providers, to the extent necessary and justified, including, for example, providers of IT or software services;
   b) entities authorized to statutory or contractual control or supervision over the Administrator, including the competent minister;
   c) other entities authorized by law to supervise and control and other entities authorized by law;
   d) entities conducting scientific research and development works in the European Economic Area;
   e) entities providing maintenance or support for IT systems used by the Administrator, entities providing hosting or cloud services;
   f) companies providing specialized transport;
   g) courier and postal companies.
5. Your personal data will not be transferred to third countries or international organizations.
6. With regard to your personal data, decisions will not be made by automated means. There will also be no profiling based on them.
7. Regarding your rights, please contact the Administrator. You have the right to:

a) access to the personal data provided;
b) rectify the personal data provided;
c) request restriction of the processing of your personal data;
d) the right to object to processing;
e) lodge a complaint with the President of the Office for Personal Data Protection against the processing of data by the Administrator;
f) delete data (the right to be forgotten), in a situation where data processing does not take place in order to comply with an obligation resulting from a legal provision;

8. Pursuant to Article 8 of the Act on Clinical Trials of Medicinal Products for Human Use of 9 March 2023, the application of the provisions of Article 15, Article 16, Article 18 and Article 21 of the GDPR may be limited in the implementation of clinical trials that are scientific research if it is likely that the rights set out in these provisions will prevent or seriously hinder the achievement of the objectives of the research experiment that is scientific research and if these restrictions are necessary to achieve these objectives.
9. Your personal data is devoid of identification function for the sponsor using pseudonymization methods due to the obligation of confidentiality. Personal data is processed only in such a way that it cannot be attributed to a specific person without the use of additional information, which is stored separately as part of the research experiment.

I authorize the Sponsor and its representatives to access my medical records in all forms permitted by law and regardless of the time of requesting access.

Participant's name (in capital letters) _____
Participant's signature _____
Signature Date _____

- *Statement of acceptance of the terms and conditions of insurance in the event of damage sustained as a result of a research experiment*

I have been informed about the terms and conditions of the research experiment insurance in the event of damage sustained as a result of the study and about the possibility of inspecting the study's insurance policy.

Participant's name (in capital letters) _____
Participant's signature _____
Signature Date _____

Investigator/Consenter Statement

I declare that I have discussed the presented study with the potential study participant using understandable, possibly simple wording and provided explanations regarding the nature and importance of the study.
I confirm that the participant had the opportunity to ask questions about the study, and I answered the questions asked by the participant truthfully and to the best of my ability.
I confirm that the participant was not forced to give consent and the consent was freely and voluntarily.

You have been provided with a copy of this informed consent form

Name of the investigator/consent seeker (in capital letters) _____
Signature of the investigator/consenter _____
Signature Date _____

Declaration of a person consenting to the collection and securing of material for genetic testing as part of a research experiment

"Evaluation of radiotherapy strategies in combination treatment of small cell lung cancer in the stage of extensive disease – a research experiment.
Principal Investigator's data: Łukasz Kuncman, MD, PhD

I declare that I have been informed about the assumptions, method of implementation and objectives of the above-mentioned research experiment. I have read and understood the Study Participant Notice. I had the opportunity to ask questions and I understood the answers I received. I had enough time to decide to carry out molecular/genetic tests on the material collected from me and to preserve the remaining biological material for further scientific research. I understand that the confidentiality of my personal data will be maintained, and further use of the biological material will remain under the control of the Bioethics Committee. I am aware that participation in the research is voluntary, and the consent given can be withdrawn at any time. I have received a copy of the Patient Information Form and the Informed Consent Form for the participant.

Pursuant to Article 6(1)(a) of the GDPR, I consent to the processing of my ordinary personal data transferred together with the biological material only by the Biobank, for the purposes of scientific research and handling of the biological material donated by me, and pursuant to Article 9(2)(a) of the GDPR for the transfer and storage by the Biobank of my biological material – blood for broadly understood scientific research purposes, including projects, current and future research in the field of biomedicine and biological sciences aimed at searching for and improving medical prophylactic, diagnostic and therapeutic methods, which will comply with the requirements of Polish law, ethical standards in the field of scientific research and will be approved by the relevant bioethics committees.

Pursuant to Article 6(1)(a) of the GDPR and Article 9(2)(a) of the GDPR, I consent to the processing of my personal genetic and health data (including those resulting from medical records) for the purposes of scientific research by the Biobank including the provision of anonymized or pseudonymized data (information) to entities conducting scientific research and development works in the European Economic Area – to the same research purposes.

I declare that I give my informed consent to the collection of an additional volume of blood from me during routine blood collection up to a total of 5x10 ml for the purpose of blood banking (storage) and use for circulating tumor DNA (ctDNA) determination in accordance with the protocol. The data obtained from ctDNA analysis will be used as a potential marker of the time to progression and benefit from radiotherapy.
I am aware that banking and the use of ctDNA for the purpose of testing is cognitive and I will not benefit directly from blood collection.

Failure to consent to the processing of the blood sample and data for future re-analysis will result in the inability to participate in the research experiment.

I agree: **YES** **NO** (delete as appropriate)

Participant's name (in capital letters) _____
Participant's signature _____
Signature Date _____

INFORMATION CLAUSE REGARDING THE PROCESSING OF PERSONAL DATA
Biobanking for scientific purposes

Pursuant to Article 13(1) and (2) of 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, and repealing Directive 95/46/EC (the so-called General Data Protection Regulation) ("**GDPR"),**

The Administrator informs that:
1. The administrator of personal data is (contact details): Regional Multidisciplinary Center of Oncology and Traumatology of Nicolaus Copernicus in Łódź, 62 Pabianicka Street, 93-513 Łódź ("**Administrator**").
2. The Controller has appointed a Data Protection Officer ("**DPO**").
   Contact with the DPO: 42 207 44 55

We invite you to contact us in all matters related to the processing of your data.

3. Information on data processing in your case:

Use biological material for scientific research

Who is affected by the processing	Individuals who have knowingly and voluntarily consented through an informed consent form to the use of their biological material for scientific research.

How we obtain your personal information	From you – the study participant.
Legal basis for processing personal data	Article 6(1)(a) and Article 9(2)(a) of the GDPR – your consent.
Personal data processed	Ordinary and special category personal data provided by you and genetic and health data (data provided by you which makes the scientific value of your biological material greater by associating it with other factors such as age, sex, lifestyle, demographic data, etc.).
Purpose of personal data processing	Carrying out scientific activity by the Administrator and other entities to which the Administrator may transfer your biological material, as part of the exercise of the right to scientific freedom, on the terms set out in the informed consent form and accompanying information. Including in order to make them available to entities for scientific purposes.
Period of personal data processing	On the above-mentioned principles for medical documentation, or until the consent is revoked or until the time that is not longer than the achievement of the goal of scientific research.

4. If you consent to ongoing contact or repeated contact with you, we will process your e-mail address and telephone number for the purposes of scientific research and handling your donation of biological material for scientific research and providing information relevant to your health regarding your health that may arise in connection with the research, if it is clinically relevant (Article 6(1)(a) of the GDPR).
5. Your personal data may also be processed for the purposes and to the extent required by the provisions of generally applicable law, e.g. regulations on archiving or keeping medical records (Article 6(1)(c) of the GDPR).
6. Your data will be stored for the duration of the biobanking program or until you revoke your consent.
7. If the law provides for a longer period of data processing to any extent, this longer period shall apply.
8. Providing data is voluntary, but necessary for the implementation of a scientific study, ongoing contact or repeated contact with you, transfer of biological material to scientific research for the purposes of scientific research and handling your donation, and provision of information relevant to your health regarding your health that may arise in connection with the research, if it is of clinical significance.
9. The Administrator may, in accordance with the law, transfer your data further, to other recipients. In the case of your medical records, the law specifies in detail who can have access to your medical records – Article 26 of the Act on Patients' Rights and the Ombudsman for Patients' Rights – and each time the Administrator should comply with these regulations. In addition to the issue of medical records, the recipients of your personal data may be:
   a. duly authorized associates of the Administrator or its service providers, to the extent necessary and justified, including, for example, providers of IT or software services;
   b. entities authorized to statutory or contractual control or supervision over the Administrator, including the competent minister;

c. other entities authorized by law to supervise and control and other entities authorized by law;
d. entities conducting scientific research and development works in the European Economic Area;
e. entities providing maintenance or support for IT systems used by the Administrator, entities providing hosting or cloud services
f. companies providing specialized transport;
g. courier and postal companies.

10. Your personal data will not be transferred to third countries or international organizations.
11. With regard to your personal data, decisions will not be made by automated means. There will also be no profiling based on them.
12. In terms of your rights, please contact the Administrator by e-mail. You have the right to:
    a. access to the personal data provided;
    b. rectify the personal data provided;
    c. request restriction of the processing of your personal data;
    d. lodge a complaint with the President of the Office for Personal Data Protection against the processing of data by the Administrator;
    e. erasure of data (the right to be forgotten);
    f. transfer personal data;
    g. withdraw your voluntarily given consent to the processing at any time – if the processing is based on consent. The withdrawal of this consent does not affect the previous processing on this basis, before its withdrawal.

I hereby declare my participation in the above-mentioned scientific project.

Participant's name (in capital letters) _____
Participant's signature _____
Signature Date _____

Investigator/consent holder name (in capital letters) _____
Investigator signature/consent recipient _____
Data signature _____