INFORMATION SHEET AND A FORM OF INFORMED CONSENT TO PARTICIPATE IN A STUDY AS PART OF THE PROJECT
"Sensors for rapid and non-invasive detection of SARS-CoV-2 at an early stage of infection" (acronym: CoVSens) funded by the Medical Research Agency (contract no. 2020/ABM/COVID19/0012)

This document comprises the following:

1. A participant information sheet about the scientific study,
2. A form of informed consent to having data and biological material taken and used for scientific purposes,
3. A personal data processing notice, and
4. A request for a laboratory test at the Medical Diagnostic Laboratory.

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1. A PARTICIPANT INFORMATION SHEET ABOUT THE CoVSens PROJECT

Dear Participant,

We are asking you for a voluntary consent to participate in a study as part of our scientific project to develop new tests for SARS-CoV-2, the virus causing COVID-19. The project will require collecting and testing swab samples taken from volunteers. The project is expected to develop SARS-CoV-2 screening tests that will allow for early, quick, non-invasive and relatively inexpensive diagnosis of people infected with the virus. They will help curb the spread of the virus and transmission of the disease among people. The CoVSens project is being publicly funded by the Medical Research Agency, contract no. 2020/ABM/COVID19/0012. Łukasiewicz-IMIF is a state-owned research institute carrying out the CoVSens project while Łukasiewicz-PORT is a research partner responsible for collecting swab samples, carrying out PCR tests and checking the efficacy of the newly-developed test.

Why your participation in the study is important?

To complete our study we need to collect nasal and throat swabs from at least 100 volunteers participating in the study – both healthy and infected with SARS-CoV-2. Participation in the study comes at no cost to the participant – PCR tests are free of charge. Half of the swab samples collected from each participant will be tested using the standard PCR procedure to obtain evidence on the presence or absence of SARS-CoV-2 in a participant who will receive the test result, certified by a diagnostic lab technician. The other half of the swab samples will be used to check the efficacy of the newly-developed test. As the PCR test and the new test are carried out in different conditions, it is necessary to collect swab samples using four swabs (sterile buds): one nasal swab and one throat swab will be used for the PCR test while the other nasal swab and the other throat swab will be used for the new test. Study participation criteria: you must be at least 18 years of age, express a voluntary and informed consent to take part in the study, and voluntarily come in for a swab test to one of the two collection points of Łukasiewicz-PORT.

What will the visit to a collection point look like? How will swab samples be taken?

The visit will be similar to a visit connected with taking a sample for a standard PCR test to detect whether you are infected with SARS-CoV-2 or not. A staff member taking a swab sample at Łukasiewicz-PORT will establish your identity on the basis of your identity card, give you this participant information sheet to read, a form of informed consent and a GDPR notice. If you need any clarification regarding your participation in the study, feel free to ask questions to obtain exhaustive answers. You will be asked to read this information sheet and fill out forms. Your informed and voluntary consent to take part in the study is required to take swab samples for a PCR test. The material for testing (swab samples) will be taken using four sterile swabs: two will be used to take samples from your nose and throat for a PCR test and the other two will be taken for the newly developed test. The swabs will be put in two test tubes: one with physiological saline and the other with a PBS buffer for further testing. The swab in the PBS buffer will be tested for electrochemical properties using the newly developed test.

Will the test cause discomfort?

Nasal swabbing is likely to cause minor discomfort because unlike in nasopharyngeal swabbing a swab is inserted shallowly into your nostrils. Discomfort may include eye watering and nasal discharge of serous secretion.

Throat swabbing involves inserting a swab into your throat through your mouth and may cause discomfort as the swab will touch the back of your throat to collect a sample. The swabbing procedure applied during the test in the CoVSens project is identical to the one in a typical PCR test for SARS-CoV-2. The increased discomfort may be due solely to the need for double throat and nasal swabbing.

What are the risks of taking part in the study?

Nasal swabbing may cause a minor or moderate nosebleed (extremely low incidence – one case per approx. 1,000 swab tests on average). Throat swabbing may, in rare cases, cause gagging (one case per 100 swab tests on average).

Personal data collection and storage entails a risk of breaching confidentiality. Łukasiewicz-IMIF and Łukasiewicz-PORT will take all appropriate technical measures to protect your personal data. Testing may reveal important information about your health status. Such information, if clinically relevant, may be passed on to you provided that you consent to this in an informed consent form.

Can I refuse to take part in the study?

You may refuse to take part in the study without giving any reason. You also have a right to withdraw your consent at any time, without giving any reason, by filling in a form "Withdrawal from the CoVSens project" and submitting it in person to the Medical Diagnostic Laboratory Łukasiewicz-PORT (your identity must be verified on the basis of your identity card). The form can be obtained at the collection point or by emailing joanna.jankowska.sliwinska@imif.lukasiewicz.gov.pl or kamil.kosiel@imif.lukasiewicz.gov.pl The CoVSens project staff will then process relevant documents and dispose of

your samples and remove your data. Test results obtained before you withdraw your consent may be used for scientific purposes. Your samples will be disposed of and your data will be removed permanently and irretrievably. Samples provided to other entities for scientific studies before you withdraw your consent cannot be disposed of.

What results will be obtained during the study? How will they be handed over to a participant?

The study will provide two results: a result of a standard PCR test indicating the presence or absence of SARS-CoV-2 and a result of an analysis carried out using our new test. The result of the PCR test provided by the Medical Diagnostic Laboratory Łukasiewicz-PORT will be an official result certified by a diagnostic lab technician. You will be able to download your result in a PDF document with a qualified electronic signature from the online results platform of Łukasiewicz-PORT (https://smart.diag.pl/SmartOrdersView/Account/Barcode/port) using your personal request number and date of birth within 36 hours of taking the test. The result of the analysis carried out using our newly developed test is experimental and scientific in nature – it has no diagnostic value and as such it will not be provided to you.

How will my samples and data be stored?

In accordance with applicable legal regulations and international guidelines on research on samples of human biological material, the staff members of the CoVSens project will be obligated to encrypt (pseudonymize) your samples. Research experiments conducted as part of the development of the new test in the CoVSens project will be carried out on samples labelled in such a way as to prevent identification of a participant whose personal data have been encrypted (pseudonymized). Your samples and data may be made available for other projects, if any, carried out by other research institutes than Łukasiewicz-IMIF also through pseudonymization – any data that can be used to link samples or medical data with a specific individual or participant will be encrypted and unavailable to researchers. Your personal data is required to carry out a diagnostic PCR test and to provide you a result. Data collected will include the following: your personal data (including your first name and surname, PESEL identification number, and address), age, sex, your result of a standard PCR test (indicating the presence or absence of infection) and the result of the efficacy of the newly developed test. All such data will be collected and available to Łukasiewicz-PORT, which is a standard procedure in the case of a PCR test. All the information related swab samples will be fed into an IT system ensuring secure storage of personal and medical data. Your personal data will be collected and stored for 20 years as medical records; after that period it may be stored for scientific research indefinitely.

The unused part of the swab sample collected for a PCR test following the completion of the test will be stored at -80□C for at least two weeks in accordance with the usual practice of diagnostic laboratories. The unused part of the swab sample following the completion of the newly developed test may be frozen and stored at -80□C to enable an identical experiment as part of the CoVSens project at a later date or be used for future scientific and research projects carried out by Łukasiewicz-IMiF or other research institutes, including projects carried out outside of Poland and the European Union.

Will participants be recontacted?

We do not foresee any need for recontacting study participants except for situations connected with the obtained diagnostic result of a PCR test or obtaining important information about your health – provided that you have consented to being contacted for this purpose.

Note for study participants on the conditions of civil liability insurance

The study carried out as part of the CoVSens project is covered by civil liability insurance for the conduct of a medical experiment pursuant to the Regulation of the Minister of Finance and Regional Policy of 23 December 2020 regarding the compulsory civil liability insurance of entities conducting medical experiments. The guaranteed insurance sum is equivalent to EUR 100,000.

Łukasiewicz-PORT, being an entity conducting medical activity, is covered by compulsory civil liability insurance for the conduct of medical activity.

I have read and understood the description of the project in which I am to take part.

……..

Date and legible signature of the study subject

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2. A FORM OF INFORMED CONSENT TO HAVING DATA AND BIOLOGICAL MATERIAL TAKEN AND USED FOR SCIENTIFIC PURPOSES

1. Consent relates to voluntary participation in the study as part of the scientific project to develop new tests for SARS-CoV-2 (the virus causing COVID-19). The CoVSens project is being publicly funded by the Medical Research Agency under contract no. 2020/ABM/COVID19/0012.
2. The study is being carried out by state-owned research institutes: Łukasiewicz-IMIF and Łukasiewicz-PORT.
3. Your informed and voluntary consent to take part in the study is required.
4. Study participation criteria: you must be at least 18 years of age, express a voluntary and informed consent to take part in the study, and voluntarily come in for a swab test to one of the two collection points of Łukasiewicz-PORT.
5. Please read the form below carefully. If you need any clarification about your participation in the study, feel free to ask questions to obtain exhaustive answers.
6. You may refuse to take part in the study without giving any reason. You also have a right to withdraw your consent at any time, without giving any reason.
7. Your consent is broad in nature and includes your consent to having your swab test samples frozen remaining after the study and used both in the CoVSens project and other scientific and research projects carried out by Łukasiewicz-IMiF or other research institutes in the future, including projects carried out outside of Poland and the European Union. If you wish to express a partial consent, please withdraw from taking part in the study.

Please insert an "X" as appropriate if you give an express, informed and voluntary consent:

YES ☐	**NO** ☐	**(CONSENT REQUIRED)** I hereby represent that I have been informed in detail of the testing method and my participation in tests. I understand what the tests are about and what my consent is needed for. I have been informed that I can refuse to participate in the tests during the research project.
YES ☐	**NO** ☐	**(CONSENT REQUIRED)** I consent to having my biological material taken in the form of swab samples, and to laboratory diagnostic tests and scientific studies carried out as part of the CoVSens project consisting in testing the sample for electrochemical properties using the newly developed test.
YES ☐	**NO** ☐	**(CONSENT REQUIRED)** I consent to having my biological material in the form of swab samples collected, stored, processed and used for the CoVSens project or other scientific and research projects, and having such samples and related data, including data in my medical records, made available. This consent includes making my biological material available for scientific and research purposes to third parties, including commercial entities, including for the reimbursement of the costs of making such material and data available. This consent includes transferring my biological material (swabs) outside of the Republic of Poland to other European Union member states and outside of the European Union. This consent also includes the use of the study results for commercialization purposes.
YES ☐	**NO** ☐	**(CONSENT REQUIRED)** I consent to having my personal data, provided together with my biological material, processed exclusively by Łukasiewicz-PORT and Łukasiewicz-IMiF for scientific purposes and handling the donation of my biological material (contacting me, documenting the origin of the material, etc.). I represent that have read the personal data processing notice, which was provided to me.

YES ☐	**NO** ☐	**(CONSENT REQUIRED)** I consent to having my personal medical data (including data resulting from my medical records concerning the health and diagnostic services provided by Łukasiewicz-PORT), survey or demographic data processed for scientific purposes, including having such data (information) transferred to third parties – always rendered anonymous or pseudonymized – for the same purposes of research, including to commercial entities, including outside of the Republic of Poland and the European Union. This consent includes the use of the study results for commercialization purposes.
YES ☐	**NO** ☐	I consent to being contacted by Łukasiewicz-IMIF so that I can be provided with relevant information about my health status that may be revealed during tests, provided such information is clinically relevant.
YES ☐	**NO** ☐	**(CONSENT REQUIRED)** I represent that I accept the conditions of the civil liability insurance outlined in the "The participant information sheet about the CoVSens project".

_____ _____

Place and date Legible signature of the study participant

_____

Signature of the person taking the biological material

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3. NOTICE ON PERSONAL DATA PROCESSING BY IMiF and ŁUKASIEWICZ-PORT

TAKING BIOLOGICAL MATERIAL FOR SCIENTIFIC PURPOSES AS PART OF THE CoVSens PROJECT and RELATED LABORATORY DIAGNOSTIC SERVICES

Also available at: https://www.port.org.pl/pl/dane-osobowe/ and https://imif.lukasiewicz.gov.pl/bip-2-2-2-2-2-2-2/

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 (General Data Protection Regulation – "**GDPR**"), we hereby inform you that:

1. The controllers of personal data in this procedure are: Łukasiewicz Research Network - Institute of Microelectronics and Photonics in Warsaw, Aleja Lotników 32/46, 02-668 Warsaw, KRS: 0000865821, NIP: 5213910680; sekretariat@imif.lukasiewicz.gov.pl, and Łukasiewicz Research Network-PORT Polish Center for Technology Development, with its registered office in Wrocław, ul. Stabłowicka 147, 54-066 Wrocław, KRS: 0000850580; NIP: 893140523; biuro@port.lukasiewicz.gov.pl ("**Controllers**").
2. In matters connected with personal data processing, please contact Data Protection Officers ("**DPO**") appointed by the Controllers. Contact data: iod@imif.lukasiewicz.gov.pl and iod@port.lukasiewicz.gov.pl.
3. Specific information on the processing of your personal data:

Laboratory diagnostic services (benefit for the participant resulting from participation in the study)

Who the processing applies to	Persons requesting the Controllers to carry out laboratory diagnostic tests on the biological material and voluntarily agreeing to donate their biological material and to it being used for scientific purposes
Method of obtaining personal data	From you – a study participant
Legal basis for personal data processing	Personal data are also processed by the Controllers to the extent necessary to protect the vital interests of the data subject (health protection) in accordance with point (d) of Article 6(1) 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 (further: "GDPR"). To the extent that the Controllers process sensitive data referred to in Article 9(1) of the GDPR, the basis for processing are points (h) and (i) of Article 9(2) of the GDPR. If you yourself request us to carry out a test, the provision of data for medical records is lawfully required to perform a medical service (point (b) of Article 6(1) of the GDPR). Failure to provide such data may partially or wholly prevent performance of a commercial medical service. Your provision of the required contact details is necessary to perform the service (make an appointment, etc.). To the extent required by the regulations on medical records and the content of the request for a test, the independent basis for processing is point (c) of Article 6(1) of the GDPR in conjunction with the provisions of the regulations of the minister for health on the types, extent and templates of medical records and the method of their processing, and on the quality standards for medical diagnostic and microbiological laboratories.

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Processed personal data	The Controllers process the health-related data (test results) and the personal data in your request form and medical records to the extent provided for in the law, including in particular in Article 25 of the Patients' Rights and the Patient Ombudsman Act.
Purpose of personal data processing	To deliver a health service (a diagnostic test) to you at your express request as a potential benefit to you of donating your biological material for scientific purposes.
Personal data processing period	Your personal data in your medical records will be processed for a period of 20 years from the end of the calendar year in which the last entry in such records is made, except for the cases specified in Article 29(1) of the Patients' Rights and the Patient Ombudsman Act of 6 November 2008.

Use of biological material for scientific research

Who the processing applies to	Persons who have granted an informed and voluntary consent in an informed consent form to having their biological material used for scientific research
Method of obtaining personal data	From you – a study participant
Legal basis for personal data processing	Point (b) of Article 6(1) of the GDPR – Your voluntary and informed consent
Processed personal data	Your personal data provided by you during the health services provided to you by the Controllers, and other environmental, clinical or demographic data, etc., provided by you directly (the data you provide increases the scientific value of your biological material as it can be linked to other factors such as age, sex, lifestyle, demographic data, etc.).
Purpose of personal data processing	To enable the Controllers and other entities that may receive your biological material from the Controllers to carry out scientific activity as part of exercising the right of scientific freedom, on the conditions specified in the informed consent form and explanatory notes, including for making it available to any other entities for scientific purposes and for using it in other projects in the future, including foreign projects.
Personal data processing period	As provided above for medical records or until the loss of its scientific value (becoming worthless from the point of view of the objective of the consent and scientific research).
IMPORTANT NOTE:	You should read this personal data notice in conjunction with the informed consent form and explanatory notes on scientific research. Your personal data for scientific activity will be pseudonymized or made anonymous so that you can never be identified by persons conducting research on your biological material.

4. If you request provision of your test result by electronic means, your e-mail address will be processed at your request to fulfill your request (point (b) of Article 6(1) of the GDPR).

5. Your personal data may also be processed for archiving purposes – when other legal bases have been exhausted – which is the legitimate interest pursued by a state-owned legal person using public funds to perform statutory public tasks referred to in point (f) of Article 6(1) of the GDPR; in such a case the further archiving period will not be longer than another 10 years.

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6. Data for the purposes of accounting and pursuing legal claims, including data in accounting documents, will be processed for the longer of: the period resulting from applicable legal regulations or for the period of limitation for legal claims.

7. If legal regulations, to any extent, provide for a longer period of data processing, the longer period will apply.

8. The Controllers may, by law, transfer your data to other recipients. As regards your medical records, legal regulations detail those permitted to access your medical records (Article 26 of the Patients' Rights and the Patient Ombudsman Act) and the Controllers shall, at all times, comply with such regulations. Recipients of your personal data, other than those specified in your medical records, may include:

   a) duly authorized contractors of the Controllers or their service providers, as required and justified, including without limitation IT and software providers;

   b) entities authorized to exercise statutory or contractual control or supervision over the Controllers, in particular the Łukasiewicz Center and the President of the Łukasiewicz Center, as well as the relevant minister;

   c) other entities authorized statutorily to exercise supervision and control and other legally authorized entities;

   d) if your relationship with the Controllers is established for the purposes of subsidized scientific projects or commercialization – the subsidizing, intermediating, funding or other institution, including in particular the Medical Research Agency (ABM), the National Center for Research and Development (NCBiR) or the National Science Center (NCN);

   e) entities providing maintenance and/or support for the Controller's IT systems, a hosting provider, etc.;

   f) courier companies, postal services, etc.

9. Your personal data may transferred to third countries or international organizations if this is compliant with the extent of your voluntary informed consent to the use of your biological material.

10. There will be no automated decision-making regarding your personal data. No profiling will be performed on the basis of your data.

11. To exercise your rights, you are requested to contact the Controllers. You have the right to:

   a) access your personal data;

   b) rectify your personal data;

   c) request restriction of personal data processing;

   d) file a complaint about the processing of your data by the Controllers with the President of the Personal Data Protection Office;

   e) erasure of your data (right to be forgotten);

   f) personal data portability;

   g) object to the processing of your personal data; and

   h) withdraw your voluntary consent to processing at any time where the processing is based on such consent without affecting the consent-based processing before its withdrawal.

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	A request for a laboratory test at the Medical Diagnostic Laboratory

Request number bar code:

Patient's data (please use **capital letters)**

First name:		Surname:															
Date of birth:		PESEL:*													Sex:	F	M

(day/month/year)

*If PESEL number is unavailable or there are other requirements, e.g. when crossing the border, please state the type and number of a different identity document:

Type of document:		No.:	
Citizenship:			

Residence address:	Postal code	_ _ - _ _ _ _	Locality:	
	Street and home/flat no.			
Contact details	Tel.:			

The above data must be provided for the request for a diagnostic test to be accepted. Prepared on the basis of the current Regulation of the Minister of Health on the quality standards for medical diagnostic and microbiological laboratories and other regulations on medical records.

1. Requesting party: ☐ patient / ☐ guardian ☐ employer ☐ health center/physician

(invoice data – business name, data of the requesting party being an individual)

Name:
NIP tax identification number:
Tel./email:

Name stamp of the physician requesting the test

2. Type of requested test (please insert an "X" as appropriate)

☐ **SARS-CoV-2 RT-qPCR test** – genetic PCR test

Testing offer - SARS-CoV-2 RT-qPCR test			
Individual ☐	Family 2+1 ☐	Family 2+2 ☐	Group of __ people ☐

3. Comments:

Procedure: ☐ **URGENT /** ☐ **STANDARD**	Result in English ☐ **YES /** ☐ **NO**	
VAT invoice** ☐	Invoice for an individual** ☐	Receipt ☐

**please provide your invoice data in item 1 of this form as the requesting party

4. Patient's important clinical data:

Chronic diseases: .....

.....

Drugs taken long-term: .....

.....

5. Test for infectious diseases:

Does the patient have symptoms of an infection? ☐ **YES /** ☐ **NO**

Types of symptoms, date the symptoms started: .....

.....

.....

Statements required for the test

☐ **YES /** ☐ **NO** I have read the notice on personal data protection required to request the test, provided to me by the Medical Diagnostic Laboratory upon its receipt of the request for a test. I affirm that I am aware that I can read the same notice at any time online at: www.port.org.pl/pl/dane-osobowe/

☐ **YES /** ☐ **NO/** ☐ **NOT APPLICABLE** In the case of a PCR test, I consent to having my genetic material isolated and tested as indicated in the request for a molecular test for diagnostic purposes. I have been informed of the diagnostic significance of the requested test. I understand that the lack of consent may prevent test performance.

☐ **YES /** ☐ **NO** I consent to having my material (swab, blood) taken for the indicated diagnostic test and I have been informed of the method of taking such material.

☐ **YES /** ☐ **NO** I consent to take part in the project "Sensors for rapid and non-invasive detection of SARS-CoV-2 at an early stage of infection" (acronym: CoVSens), funded by the Medical Research Agency (contract no. 2020/ABM/COVID19/0012) carried out by Łukasiewicz Research Network – Institute of Microelectronics and Photonics.

The patient has the right to file a complaint by email or telephone about the way the request is handled within 14 days of receiving a test report. For detailed information, please visit the website of Łukasiewicz-PORT: www.port.org.pl.
For a person aged less than 16 years, consent is to be provided by the person's statutory representative/actual guardian, for a person aged 16-18 – that person and/or that person's statutory representative/actual guardian, for a person aged 18 plus – by the patient.

Statutory representative / Actual guardian:

.....

(date, legible signature, first name and surname)

Patient:

.....

(date, legible signature, first name and surname)

To be filled in by a staff member of the Collection Point

Type of material taken:

☐ swab, place: Throat and nasal swab / nasopharyngeal swab

.....

☐ whole blood: ..... ☐ plasma ☐ serum

☐ other: .....

.....

Date and time of material taken for the test: _ _ /_ _ / _ _ _ _ _ _ : _ _

.....

First name and surname of the person taking the material: .....

To be filled in by a staff member of the Medical Diagnostic Laboratory

Material suitable for the test ☐ YES / ☐ NO because: .....

.....

Date and time of material accepted by the laboratory: _ _ /_ _ / _ _ _ _ _ _ : _ _

Comments: .....

Staff Member of the Laboratory: .....

.....

(signature)