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**Q001 - VBR: Intro Study** **Text**

**Not back**

Dear Panel Member,

We invite you today for the CON-VINCE study. This study is not comparable to the studies, you've participated to, in the past. This is a clinical study for collecting information regarding Covid-19. The primary goal is understanding the prevalence, dynamics and penetrance of the virus infection within the Luxembourgish population.
Due to the importance, sensibility and complexity of this study, we ask you to go through a 2-step information and consent process, before getting into the main questionnaire.
But first things first, this is the Participant Information. Please read carefully and thoroughly the information describing the aims and procedures on the following pages. Take your time. Ask questions.
You will get information about scope and conduct of study, use of samples, future genetic analysis, risks and drawbacks, benefits of participating, confidentiality and protection of personal data, costs associated with participation and insurance.
The principal investigator of this study is Prof. Dr. Rejko Krüger. In case of questions, you can write an email to con-vince@lih.lu.
About 6 hours after you've completed the Participant Information Questionnaire, you will receive a link for the second part of this process, the Informed Consent Questionnaire.
Thanks a lot for your interest in this study.

**Q002 - VBC: Scope of Study** **Single coded**

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**Scope of the Study:**

The Luxembourg Institute of Health (LIH) and the Luxembourg Centre for Systems Biomedicine (LCSB)/University of Luxembourg (UL) carry out a national survey on the prevalence of COVID-19 in healthy (asymptomatic) or oligosymptomatic (with few mild symptoms) carriers in Luxembourg. This study, together with other national efforts currently being put in place, will provide a statistical study on the prevalence, evolution, impact and spread of the COVID-19 pandemic caused by the SARS-CoV-2 virus in Luxembourg. The main goal of the study is the assessment of the prevalence, dynamics, and penetrance of the SARS-CoV2 infection within the Luxembourgish population. Secondary analyses include focus on epidemiological, socio-economic and psychological aspects of the confinement during the pandemic.
This information will make it possible, in particular, to carry out simulations and short- and medium-term projections to facilitate decision-making on the restrictions to be put in place or lifted. In a second phase, the samples and data collected in the framework of this study may, with your consent, be used for other research projects in the field of infectious diseases and immunology duly authorized by the Comité National d'Ethique de Recherche (CNER) and the Ministry of Health.
In order to identify a representative sample of the adult population of Luxembourg, a selection of persons was made by an epidemiologist and statistician to include adults of all ages, sexes, geographical areas and nationalities. You have been selected, among more than 1500 other panelists, to ask you if you wish to participate in this study.
The purpose of this Participant Information Questionnaire is to inform you about this study, including what you will need to do if you decide to participate in this study. Thanks to this information, you will be able to decide whether or not you wish to participate. Your participation is entirely voluntary. If you decide to participate in this study, you may withdraw at any time. This study has been authorized by the Ministry of Health and has received a favorable opinion from the National Research Ethics Committee on 9th of March 2020.

**Main objectives of this Study:**

• Understanding the **prevalence**, **dynamics** and **penetrance** of the SARS-CoV-2 infection within the Luxembourgish population
• Providing information for **evidence-based responses** to the pandemic
• Providing relevant information on the **emerging immunity**
• Tracking the **psychological burden** of long-term containment on the general population
• Identifying **protective factors** preventing COVID-19 in carriers

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**Q003 - VBK: Conduct of Study** **Single coded**

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**Conduct of the Study:**

The national CON-VINCE survey, referred to as the "study" in the rest of the document, is based on your voluntary participation. It has several levels of participation: if you wish to participate in the study, **the collection of certain data and samples is mandatory**. If you wish, you can also participate in the optional part, as explained below.
Your participation in this study involves **one visit** (questionnaire and sample collection) **every 14 days for 2 months** after your inclusion in the study, for a **total of 5 visits**. A final visit, one year after your inclusion, will also be made.
At each visit you will be asked to provide mandatory data and samples for the study and you will be able to decide whether or not to participate in the optional part of the study.

**Mandatory part:**
During this Participant Information Questionnaire, the study will be explained to you and you will have the opportunity to ask any questions you may have about the study and your involvement (con-vince@lih.lu). You will then receive the Informed Consent Questionnaire and your consent will be requested, before getting into the main questionnaire.
If you agree to take part in this study, you will be asked to complete a health questionnaire. An account will be created specifically for you and answers will be treated confidentially and separate from your personal information:
* Epidemiological factors and travel history
* Demographics and socio-economic questions
* Symptoms onset and initial clinical signs of infection by SARS-CoV-2
* Current clinical symptoms
After the health questionnaire, you will be asked to go to a laboratory near you in order to take the following samples:
* Blood (up to 45 mL)
* A nasal swab
* An oropharyngeal swab (if possible)

**Optional part:**
You will have the opportunity, if you wish, to answer the following questionnaire modules, which will provide researchers with important information on the impact of containment on the mental and physical health of the population.
* Compliance to government recommendations during COVID-19 pandemic
* Home and social contact + socio-economic status
* Environmental conditions at home with a diagnosis of COVID-19
* Psychological questionnaire
You will have the possibility, if you wish, to donate the following samples for research:
* A stool sample (you will receive a special collection kit to take home, and you will take a small amount of stool in the days following your visit. You should then send the kit by post)
Your samples will be stored in the LIH's biobank, the Integrated Biobank of Luxembourg (IBBL) for research purposes

**Long-term follow-up:**
In order to study the impact of the pandemic on the population over the long term, you will be contacted to complete a questionnaire and give samples as indicated one year after your inclusion in this study.

**Important :**
At any time during your participation in this study, if you develop symptoms similar to COVID-19 (cough and fever), you are asked to contact your treating physician and keep us informed by calling the following number: +352 26 970 800 (during working hours: 8-17h).
If you develop symptoms and test positive for COVID-19, you will have to leave this study but you will have the option of participating in another study, dedicated to patients with clinical symptoms and a positive COVID-19 test.

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| Q004 - VBL: Use of samples | Single coded |
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**The use of your samples:**

You are invited to **donate** samples for this study (primary use) and to **authorize further use** (secondary use) of your samples for future research on infectious diseases and immunology.
As part of this research project, specific tests are foreseen on your samples, e.g., virology (to check if the virus is present) and serology (analysis of your blood antibodies that indicate if your immune system encountered and reacted against the coronavirus). The stool may be used to check for the presence of the new coronavirus in your stool.
New knowledge about the SARS-CoV-2 infection is gained daily through the efforts of researchers at the international level. For this reason, it is currently impossible to list precisely which tests will be performed on the samples you donate.
If you give consent for other research as well, your samples may be used for other medical research conducted by the LIH or other duly authorized national or international research organizations or biobanks, for academic and/or commercial purposes, whether in the field of COVID-19 research or in the field of infectious diseases and immunology, depending on the options you choose in the Informed Consent Questionnaire.
The principles described will apply to future medical research projects to the extent that they are relevant, except that for future third party research projects:
* Information on such future medical research may not be available, and the Data Controller, Principal Investigator, sponsor and approving authority may be different;
* In case of withdrawal of consent, you will no longer be able to request the destruction of your samples or data already transferred to biomedical research projects.
Your samples and data will only be used for research projects that have received the formal approval from the Comité National d'Ethique de Recherche (CNER) and the Ministry of Health, and that do not contradict the choices you have expressed in this informed consent form. In any case, the recipients of the data will not have access to the key that allows your identity to be associated with these samples and data.

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**Q005 - VBM: Genetic Analyses** **Single coded**

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**What are the Genetic Analysis?**

Genes are present in every cell of the body. They give the body the instructions it needs to function and repair itself, and they are passed from parents to children and from cell to cell as new cells are created in the body. Sometimes the genes in the body can change, and if this change can be passed from parents to children, it is called a germ line mutation.
Researchers want to understand how diseases can be linked to the genes we all carry. In this case, the question is to understand whether the course of COVID-19 disease can be influenced by the genetic make-up of individuals. Understanding these links may lead to the development of more effective and personalized tests and treatments for each patient. For this type of research to be carried out, it is necessary to analyse and compare the genes of healthy and sick people. In this context, the use of Next Generation Sequencing (NGS) techniques allows a precise and exhaustive analysis of the genome that will contribute to the discovery of genetic modifications, even subtle ones.
If you agree, genetic analyses may be carried out in the framework of secondary use of your samples. Therefore, you are asked to authorize the genetic analysis of your samples.
In this context, a fortuitous discovery of a germline mutation (mutations or aberrations that could not only affect my future health, but also that of my children, siblings, parents) could also be discovered. Therefore, you are asked to authorize the genetic analysis of your samples.
In this context, it's possible that we encounter incidental findings. An Incidental Finding (IF) can be defined as a "finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study." Genetic and clinical IFs can be of potential importance for the health of the participant. IFs are not specifically targeted and there is no obligation of the researcher to search for such findings actively. It is also important to stress, that methods used in the research study are intended for the research questions of the study.
In case of an IF, we follow the guidelines published by the Comité National d'Ethique de Recherche (CNER) of Luxembourg, where, if the researcher discovers an IF, he/she will inform the principal investigator (PI) of the study, who will act according to your preference "to be informed" or "not to be informed". If you indicate in the consent form that you prefer "to be informed", the PI (who in this case is the study physician) will communicate the finding to you within 15 working days. If you indicate that you prefer "not to be informed", no action is required. Your decision is fully respected. Finally, at any time during the study, you can change your mind and communicate the decision to the study team.

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**Q006 - VBN: Risks and Drawbacks** **Single coded**

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**What are the Possible Risks and Drawbacks?**

There are no major risks associated with this study. The table below lists all of the risks associated with the collection procedures associated with taking your samples, but these risks are **RARE**.

**Procedure – Collection of samples Associated risks.**
Blood sampling --> Pain, bruising, tiredness or fainting, infection
Nasal swab --> Discomfort while brushing, bleeding, infection
Oropharyngeal swab --> Discomfort while brushing, bleeding, infection
Stool sampling --> No known risks
Entering data on an online application --> Minimal risks * associated by entering data in an online questionnaire * there are risks associated with the fact that the study involves the recording of data online (hacking, risk of endangering the confidentiality of health and other personal data). This risk is low, but there is no such thing as zero risk. The LIH has implemented extensive data protection measures to minimize this risk. These measures are explained in the section "Confidentiality and Protection of Personal Data".

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| Q007 - VBP: Benefits of Participating | Single coded |
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**What are the Benefits of Participating in the Study?**

You will not benefit directly from participating in this study. However, in case you were tested positive for the coronavirus, we will inform you and advise regular diagnostic confirmation and appropriate sanitary and healthcare measures. In this case, our study will inform you about your immune status, which can inform about your personal risk to be (re)infected by coronavirus.
Your participation in this study is voluntary. You will not receive any compensation for your participation in this study, apart from the normal payment incentive linked to the length of the questionnaire, nor for further developments resulting from this study. Your participation is important because you are the source of the information we need to improve our understanding of infectious diseases such as the current COVID-19.

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| 1 | I have read and understood this information |

| Q008 - VBQ: Confidentiality and Protection of Personal Data | Single coded |
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**Confidentiality and Protection of Personal Data:**

As part of this study, your personal data will be collected and analysed in order to achieve the scientific objectives of the study.
The LIH and LCSB/UL are responsible for the collection, analysis and more generally the processing of your personal data and ensure their protection, in accordance with the General Data Protection Regulation (EU) 2016/679 of 27 April 2016, applicable as of 25 May 2018 known as the "GDPR" and any subsequent text replacing or supplementing this text (in particular the law of 1 August 2018 on the organisation of the National Commission for Data Protection and the implementation of the GDPR).

**What data do we collect?**
Your participation in the study involves only the collection of personal data that are really necessary for answering the objectives of this scientific study.
In particular:
* At the time of your registration the following data will be collected to verify that you meet the criteria to participate in the study: **date of birth, contact details: name, first name, telephone number**. The personal identification information will be collected only for the purpose of recontacting you in case you were tested coronavirus positive. In this case, we will refer you for a diagnostic validation of the results by an accredited laboratory. We have the legal obligation to inform the competent authorities of any coronavirus-positive tests for taking the necessary procedures.
* You will be asked to answer questionnaires every 2 weeks for 2 months. They will focus on:
your health: **weight, height and in general your clinical situation and medical history, current treatments**
your personal life: **lifestyle and consumption habits, family situation, level of education, socio-professional category, participation in other research or studies, tobacco/alcohol consumption, level of stress/anxiety/depression, physical activity, quality of life, pain, travel and social contacts**
You will be able to choose whether or not to answer some of the different questionnaires.

**On what legal basis do we process your data?**
The use of your personal data is necessary to achieve the objectives of the study, which we are conducting in the public interest and for the purposes of scientific research (art. 6.1e and art. 9.2j of the GDPR.).

**Who has access to your data?**
Only the following categories of people will be able to access your data:
* the investigating physician involved in the study and authorized members of his team acting under his responsibility,
* the scientific leader of the study at LIH/IBBL and LCSB/UL, and the team acting under his responsibility,
* other researchers or research organizations in the private or public sector to meet the objectives of the study or for future scientific research purposes if you have consented to this (under no circumstances do we provide them with data revealing your identity).
* we may also provide access to your pseudonymised data to service providers who perform services on our behalf.
* finally, in the context of certain controls or audits, the competent authorities may also have access to your personal data for the purpose of controlling the quality of data.

**What are your rights?**
You have the right to access and rectify your personal data. In certain cases (according to the conditions laid down by law), you have additional rights to object to the way your data is used, to request the deletion of your data, to request the restriction of certain aspects of the processing of your data, to retrieve your data with a view to passing it on to a third party (right of portability). If you wish to exercise your rights, you may contact the investigating doctor or his designated representative.
Finally, you have the right to lodge a complaint with the National Commission for Data Protection (CNPD) concerning the processing of your personal data.
For any request for information concerning the processing of your personal data by the LIH or LCSB/UL, you can contact the Data Protection Officer by e-mail at dpo@lih.lu or sandrine.munoz@uni.lu, or by post at the following address:
LUXEMBOURG INSTITUTE OF HEALTH
Protection des données
1A-B, rue Thomas Edison
L-1445 Strassen
Luxembourg
Or
UNIVERSITÉ DU LUXEMBOURG
Protection des données
Maison du Savoir
2, Avenue de l'Université
L-4365 Esch-sur-Alzette

**How do we protect your personal data?**

LIH and LCSB/UL implement appropriate security measures, depending on the sensitivity of the data concerned, in order to protect your data against the risk of unauthorised access, loss, fraudulent use, disclosure, alteration or destruction of your data.
Your data will be treated in a strictly confidential manner. They will be pseudonymised, i.e. a confidential reference code will be used instead of your name. This code alone does not allow you to be directly identified and will only be used for the scientific processing of your data. At no time will your identity appear in a document intended for the public or other institutions. The correspondence table establishing the link between the reference code and your name will be kept by the Principal Investigator in a confidential manner.
The LIH and LCSB/UL also apply the principle of data segregation, i.e., identification data on the one hand and research data on the other hand are stored on different secure servers in order to minimize the potential risks of re-identification. Despite all security efforts, the risk of data breach is not zero but can be described as very low.

**How long do we keep your data?**
Your personal data will be kept for a period of 15 years from the end of the study and subjected to revisiting of the study and storage of data and biosamples with the CNER after this period. After a period of 5 years after the end of the study, the table of correspondence between your code in the study and your login ID will be deleted. In the event that you no longer wish to participate in the study, your samples and data collected prior to the withdrawal of your consent may be retained and used in the study, unless you object. In this case, they will be destroyed. However, if some of your samples and data have already been used in the study, they can no longer be removed from the study.

**Data transfers outside the European Union.**
Your data may be transferred outside the European Union when this is necessary for the implementation of the research or the exploitation of its results. Only anonymous data will be transmitted outside the European Union. It is possible that certain countries outside the European Union/European Economic Area do not offer the same level of privacy protection as your country. In such cases, LIH and LCSB/UL will put in place appropriate measures to ensure the protection of your personal data (for example, by including standard data protection clauses in its contracts, by complying with codes of conduct or by complying with a certification scheme) or will rely on your explicit consent.

For more detailed information on the appropriate measures implemented by the LIH, you can send a written request to the LIH Data Protection Officer by e-mail to **dpo@lih.lu**.
For more detailed information on the appropriate measures implemented by the LCSB/UL, you can send a written request to the UL Data Protection Officer by e-mail to sandrine.munoz@uni.lu.

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**Q009 - VBS: Costs associated with participation + Insurance** — **Single coded**

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**Costs associated with your Participation:**

If you decide to participate in this study, there will be no cost to you or your insurance company. Visits and procedures identified as being specific to the study are the responsibility of the promoters.

**Insurance:**

As the promoter, the Luxembourg Institute of Health (LIH) has taken out civil liability insurance for this study (Zurich Insurance plc, Belgium Branch, Da Vincilaan 5, B-1930 Zaventem).

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| 1 | I have read and understood this information |

**Q010 - VBT: Your decision to participate** **Single coded**

**Not back**

**Your Decision to Participate:**

Your decision whether or not to participate in this study will not affect the quality of care you receive. If you decide to take part in this study, you may end your participation at any time, and you will not be required to give reasons for your decision.
In order to participate in the study, we are seeking your consent online. Please read the consent form and tick the boxes that correspond to your wishes. You can download this document at any time.
If you decide to participate in this clinical study, we ask that you:
*** Cooperate fully in the conduct of this study.**
*** Not withhold any information about your health condition, the medications you are taking or any symptoms you may have.**
If you would like more information about the study, you can contact the research team at CON-VINCE@lih.lu or the following number: +352 26 970 800 (during working hours: 8-17h).

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| 1 | I have read and understood this information |

**Q011 - VBY: Continue to Informed Consent Questionnaire** **Single coded**

**Not back**

We hope that you got all the information necessary to assess what this study is about and what is expected from you, if you participate in this study. In about 6 hours, you will receive a link to the Informed Consent Questionnaire.
Thanks for your participation.

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| 1 | Yes, send me the link for the Informed Consent Questionnaire |
| 2 | No, I prefer not to participate in this study |