CORONA IMMUNITAS Canton of Zurich:

Multi-center observational study to determine the spread of coronavirus and development of immunity in Switzerland

Sponsor: Foundation Swiss School of Public Health (SSPH+), Prof. Dr. med. et PhD Nino Künzli

Project management: Prof. Dr. med. Milo Puhan, Prof. Dr. med. Jan Fehr, PD Dr. Anja Frei

Dear Madam / Dear Sir,

We would like to ask if you wish to participate in a research project. In the following form, the planned research project will be presented to you: first in a short summary as a table of contents, then in a detailed version.

Summary

1	**Aim of the project** The research project investigates the extent of the spread of the new coronavirus and the immunity of the population in the canton of Zurich. We do this by conducting antibody blood tests in different population groups.
2	**Selection** You are being asked to participate in the study because you either 1) have been randomly selected by the Swiss Federal Statistical Office from the population register of the Canton of Zurich; 2) belong to a population group that is particularly at risk for infection with the coronavirus due to work or living conditions; or 3) have requested an antibody blood test at the COVID-19 test centre of the University of Zurich.
3	**General information about the project** The results should provide important insights into the course of the epidemic, the properties of the coronavirus and antibodies, and for supporting policymakers in future decisions.
4	**Procedure** Participation in the study includes filling out a questionnaire (approx. 30 min.) and taking a blood sample at our study centre or at your home for the antibody test against the coronavirus (approx. 20-30 min.). Separately, we will ask you to fill in a short (approx. 2 min.) weekly and a longer (approx. 15 min.) monthly questionnaire online for 6 to a maximum of 12 months. If you belong to a certain subgroup, we will ask you to take one or more blood samples again for testing at a later time or to fill in additional questionnaires.
5	**Benefits** The results of this study are particularly beneficial to society. We will inform you about your antibody test result. Because of the limited accuracy of the currently available tests, your result may be incorrect. We will inform you exactly what this means.

6	**Rights** You decide voluntarily whether you want to participate in this project or not. Your decision has no influence on your medical treatment/care and you do not have to justify this decision.
7	**Recommendations** If you take part, we ask you to comply with certain requirements: to answer the questions asked honestly, to keep to scheduled blood collection appointments, to follow the official FOPH protective measures and, if you are one of the particularly vulnerable persons, to wear a protective mask on your way to and from the study centre.
8	**Risks** Through the project, you are exposed to minimal risks associated with blood collection. Any additional, close contact between two persons carries the risk of infection with the coronavirus. We minimise this risk by observing all hygiene and protective regulations during your study visit and when taking blood samples.
9	**Results** If new results emerge during this project, you will be informed accordingly.
10	**Confidentiality of data and samples** We collect your personal and medical data and collect biological material/samples (blood) from you. The data and samples will be used for other projects if you give separate consent for same. We comply with all legal regulations of data protection. All parties involved are subject to the obligation of secrecy.
11	**Resignation** You can withdraw from the project at any time and no longer participate. The data and samples collected until then will still be evaluated.
12	**Compensation** You will not receive any compensation. We will reimburse your travel expenses per study visit at a flat rate of Fr. 20.
13	**Liability** The liability insurance of the University of Zurich will pay for any damages incurred during the course of the project.
14	**Funding** The project is financed by the fundraising of SSPH+ (funds from the Federal Office of Public Health and private donors), by the Health Department of the Canton of Zurich and by the Pandemic Fund of the University of Zurich.
15	**Contact person:** PD Dr. Anja Frei, Institute for Epidemiology, Biostatistics and Prevention (EBPI), University of Zurich, Hirschengraben 84, 8001 Zurich. Contact: Phone number: 044 634 46 11 E-mail: corona-immunitas@ebpi.uzh.ch

More detailed information

1. Aim of the project

With this project we want to investigate the extent of the spread of the new coronavirus (SARS-CoV-2) in the canton of Zurich. For this purpose, individuals from the population and from specific population groups will be randomly selected. Using an antibody blood test, we will check whether their body has already produced specific antibodies against the virus. This will provide information about the spread of the virus and the immunity of the population. The results of this project should serve as a basis for future policy decisions.

2. Selection

All persons who are invited to participate and who are at least 20 years old can take part in this study. Specifically, we are asking two groups of people: 1) women and men, randomly selected by the Federal Statistical Office from the population register of the Canton of Zurich; 2) people from specific population groups. These are people who, because of their work or living conditions, are particularly at risk of infection to the coronavirus; and 3) people who have requested the COVID-19 test centre of the University of Zurich to carry out an antibody blood test.

3. General information about the project

Background information

It is currently not known how many inhabitants in Switzerland and in the canton of Zurich have already been infected with the coronavirus and are therefore most likely immune to it. It is suspected that the infection goes unnoticed by many people or, in the case of mild symptoms, is confused with a cold. For politicians, it is crucial that future decisions are based on a solid database. This requires knowledge of the infection rate with the coronavirus throughout Switzerland. Since antibodies are formed only after a few days, antibody tests are not suitable for determining an acute infection. But they can detect cases in which infection with the coronavirus has occurred with no or only slight symptoms.

In a national collaboration of experts, studies on antibody blood tests in the population are currently being carried out in various cantons (CORONA IMMUNITAS initiative, initiated and coordinated by the Swiss School of Public Health SSPH+). The first study started in the canton of Geneva in April 2020, followed by the canton of Zurich together with other cantons in a second phase starting in May/June 2020. A third survey phase is planned in all cantons, including the canton of Zurich, in September 2020. The results of these studies should provide clarity about the spread of the coronavirus in Switzerland, deepen understanding of the virus and support politicians in their decisions. Detailed information can be found at www.corona-immunitas.ch.

Structure and duration of the project and number of participants

This is a so-called observational study, which means that we will collect information from you but will not intervene.

In the canton of Zurich, we will ask people to participate, selected at random from the population, at two different time points in 2020: 800 people in May/June and 400 people in September. In addition, we will ask 200 people from each of four specific population groups to participate, as well as about 500 people who have asked the COVID-19 test centre of the University of Zurich to perform an antibody blood test. At the national level, a total of about 25,000 people will be invited to participate and, depending on how the corona epidemic develops, more people from the population will be invited at a later date.

Participation in the study includes filling out a questionnaire and taking a blood sample at our study centre or at your home (in a minibus in front of your apartment/house or at your home). Subsequently, we will ask you to fill out a short questionnaire online every week for 6 to 12 months (see below for a detailed description of the procedure).

If you are one of the 800 people **randomly selected** from the **population** in May/June 2020, we will invite you again in September 2020 to take a blood sample for antibody blood testing.

If you are one of the approximately 500 people who have **requested an antibody blood test at the COVID-19 Test Center** of the University of Zurich, you will be asked to complete additional questionnaires before the study visit and about one month after receiving the test results (duration: about 30 minutes each).

In addition, for every 100 people in the population sample with both positive and negative antibody test results from the first survey, we will invite them to take three additional blood tests, approximately 2, 4 and 8 months after the first test. The 100 persons with negative test results are randomly selected from the population sample. For the other group we ask all persons with a positive result from the population sample as well as persons from the other groups until 100 persons are reached. If you have been selected for one of these groups, we will contact you personally after receiving your test result.

This project will be carried out in accordance with the laws in Switzerland. The competent ethics committee has examined and approved this project.

4. Procedure

If you participate in the study, this means the following for you:

Appointment

As a first step, we ask you to make an appointment for the blood tests by phone or via an electronic booking system. This takes place either at the study centre in Zurich (COVID-19 test centre of the University of Zurich) or in Winterthur. If you belong to a risk group for a severe course of corona infection or prefer not to travel, you can choose whether you come to a study centre for the blood collection or whether we should visit you at home (in a specially equipped minibus or at your home). Following are risk factors for a severe course according to the recommendations of the Federal Office of Public Health: Age of 65 years or more; a chronic disease (diabetes, cardiovascular or respiratory diseases, immune deficiency due to a specific disease or therapy, active cancer); and overweight (body mass index >30 kg/m2).

Questionnaire and first electronic consent

After making an appointment, you will receive an e-mail from us with the confirmation of the appointment, directions, this study information and a personal link to a questionnaire. We will ask you to complete the questionnaire via the Internet the day before the blood sample is taken. We encourage you to complete the questionnaire online. If you do not wish to do so, you will have the option of completing it on paper during your visit to the study centre. Completing the questionnaire takes about **30 minutes**. You will answer questions about yourself, your state of health, coronavirus symptoms and diagnoses in you and your personal environment, your behaviour in the pandemic situation and your well-being.

Study visit and blood collection

For the blood collection you will either come to our study centre on the agreed date or the study team will visit you at home. You will be welcomed by a study officer who will explain the exact study procedures to you and answer your questions. Together you will sign the consent form. A nurse will take 30 ml of blood from a vein in your arm for the antibody test and for storage in the biobank at the Institute for Epidemiology, Biostatistics and Prevention at the University of Zurich (EBPI). This is less than a tenth of a normal blood donation and corresponds to about two tablespoons. The entire study visit with blood collection takes about **20-30 minutes**. We only take the blood sample if you are healthy and do not suffer from flu-like symptoms.

Online survey in the further course

You will be invited to complete a short questionnaire online every week for 6 to a maximum of 12 months. You will receive a link to the questionnaire. It takes about **2 minutes to** complete the

questionnaire and we will ask you about any symptoms, hospitalization, test results and your behavior. Once a month we will add further questions about your mental health (takes about **15 minutes**). The online surveys are optional and separate from the in person visits.

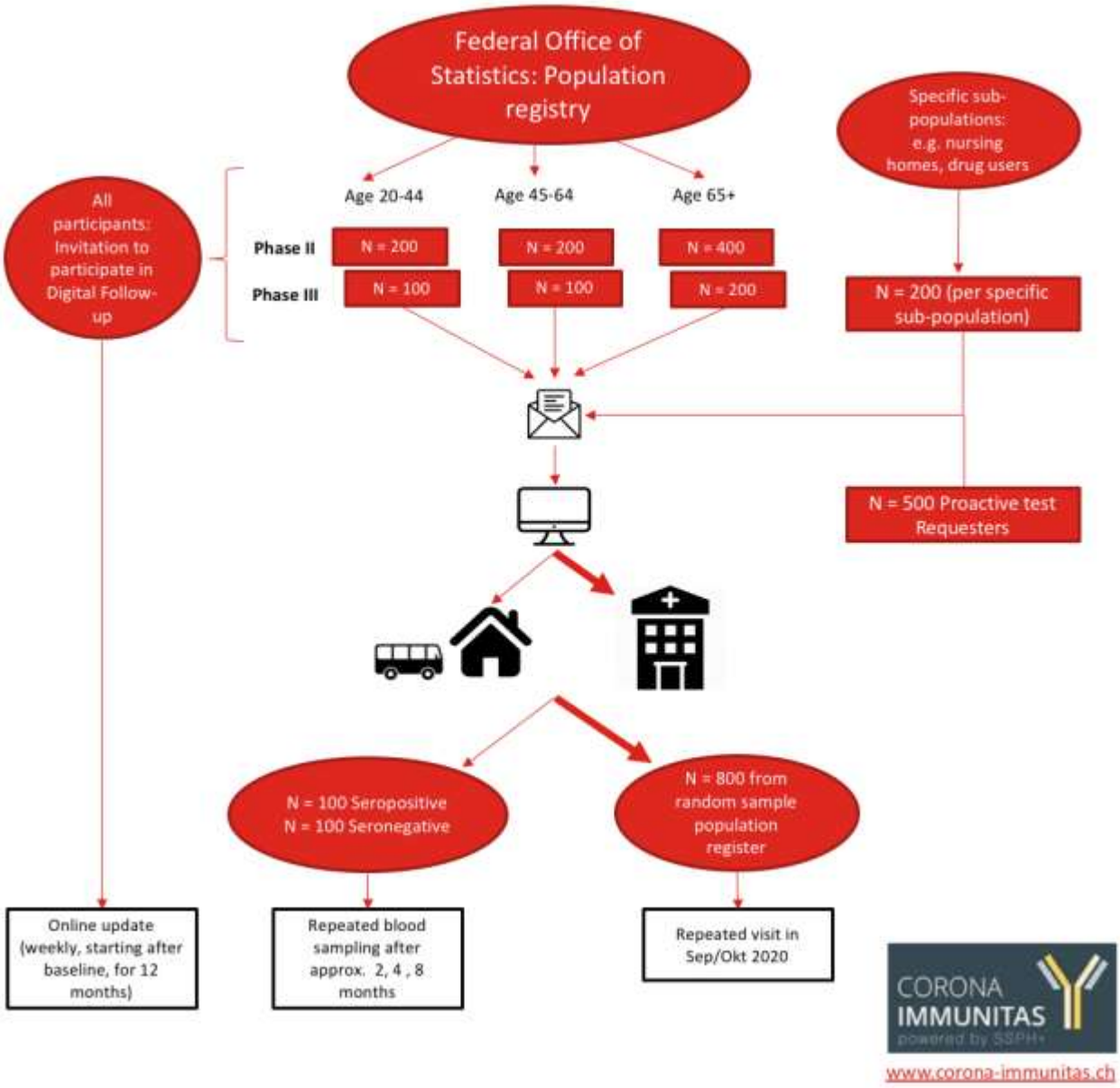

Figure 1: Overview of the course of the study and the groups included

Further study visits to persons with repeated blood tests

If you are one of the 800 people selected from the population, we will invite you again in in September 2020 to come to our centre for, or provide in your home, a second blood collection (duration: approx. **20-30 minutes**).

If you belong to the 100 people with a first positive antibody blood test or to the randomly selected 100 people with a first negative antibody blood test, we will invite you to take three more blood samples at our centre or at your home, which will take place about 2, 4 and 8 months after the first collection (duration: about **20-30 minutes** each).

Figure 1 gives an overview of the course of the study and the groups included.

5. Benefits

The results of this study are particularly beneficial to society. They help to control the corona epidemic and to understand whether a past infection protects against a new disease.

You will be informed about your own test result, i.e. whether the test detected antibodies against the coronavirus (SARS-CoV-2 antibody) in your blood or not (if you do not wish to be informed, we will not inform you). In this context, it is important that you can correctly classify the result. Currently, the common tests used to detect antibodies are good, but not yet perfect. If you get a positive test result, it is possible that the test result is wrong and that you have not actually developed antibodies against the new coronavirus. A negative test result is most likely correct. According to the current state of knowledge, at least temporary immunity is likely after an initial infection with the coronavirus, but scientific knowledge is still limited. Even if you have antibodies in your blood, there is a possibility that you will be infected again during the course of the epidemic. For these reasons, it is essential that you continue to follow the precautions and recommendations of the Federal Office of Public Health and the Federal Council, regardless of the test result.

6. Rights

You participate voluntarily. If you do not want to participate or later withdraw your participation, you do not need to give reasons for this. Your medical treatment/care is guaranteed regardless of your decision. You may ask questions about participation and the project at any time. Please contact the person named at the end of this information.

7. Recommendations

As a participant it is important that you

- answer frankly and truthfully the questions asked
- keep to the agreed date for blood collection as closely as possible
- inform us if you have to postpone the agreed appointment
- follow the official FOPH protective measures and, if you are one of the particularly endangered persons, wear a protective mask also on your way to and from the study centre

8. Risks

Through the project you are exposed to the minor risks associated with blood collection. Taking blood from the arm vein can be somewhat painful and may temporarily discolor the skin blue locally.

Any additional, close contact between two people carries the risk of infection with the coronavirus. We minimize this risk by observing all hygiene and protective measures during your study visit and when taking blood samples. Both the study staff and you will wear a mask. The study personnel also wears disposable gloves. In addition, we offer visits at home to persons at particular risk. We will take the blood sample either in a minibus or at your home and will follow the same hygiene and protective measures as in the study centre. If you travel to the study centre, we recommend that you respect the social distance (2 metres between people) and, if this is not possible, wear a mask.

9. Results

The project management will inform you during the project about any new findings that may affect the benefits or your safety and thus your consent to participate.

10. Confidentiality of data and samples

For this project, your personal and medical data will be collected. Very few professionals will see your unencrypted data, and view this only to perform tasks within the project. When data is collected for study purposes, the data is encrypted. Encryption means that all reference data that could identify you (name, date of birth) will be deleted and replaced by a key as soon as the data

collection is completed. The list of keys always remains in the institution. Those persons who do not know the key can therefore not draw any conclusions about your person. In the case of a publication, the summarised data cannot be traced back to you as an individual. Your name will never appear on the Internet or in any publication. Sometimes there is a requirement in a journal for publication that individual data (so-called «raw data») must be transmitted. If individual data has to be transmitted, the data is always encrypted and therefore also not traceable to you as an individual. All persons who have access to your data within the framework of the project are subject to confidentiality. The data protection regulations are observed and you as a participating person have the right to view your data at any time.

If data/ samples are stored on site, it is a database/ biobank for research purposes. These data and samples can be encrypted and sent to another database/ biobank in Switzerland within the framework of this project. It is possible that your data and samples will be used for other investigations at a later date or that they will be sent to another database/biobank in Switzerland for investigations that have not yet been defined in detail. This other database/biobank must comply with the same standards as the database/biobank for this project. For this further use, we ask you to sign a further declaration of consent at the very end of this document.

It is possible that this project will be reviewed by the competent ethics committee or by the institution that initiated the project. The project leader may need to disclose your personal and medical information for such reviews.

11. Resignation
You can stop and withdraw from the project at any time if you wish. The data and samples collected until then will still be evaluated in encrypted form, otherwise the whole project will lose its value. The encryption code for your data and samples will be deleted when you graduate. Your data and samples are then anonymous and cannot be traced back to you. If you wish, you can also request the destruction of your stored samples.

12. Compensation
If you take part in this project, you will not receive any compensation. We will reimburse your travel expenses per study visit at a flat rate of Fr. 20. There will be no costs for you or your health insurance company.

13. Liability
If you suffer damage as a result of the project, the liability insurance of the University of Zurich is liable. If you have suffered damage, please contact the project manager.

14. Funding
CORONA IMMUNITAS is financed from various sources: Through the fundraising of SSPH+, which includes funds from the Federal Office of Public Health and private donors (ethical guidelines for financing are observed), through cantonal funds and through institutional funds from the universities. For the Canton of Zurich, financing is provided by the SSPH+ funds, the Health Directorate of the Canton of Zurich and the UZH pandemic fund.

15. Contact person(s)
In case of any uncertainties, fears or emergencies that may arise during or after the project, you can always get in touch with the following contact:

PD Dr. Anja Frei, Institute for Epidemiology, Biostatistics and Prevention (EBPI), University of Zurich, Hirschengraben 84, 8001 Zurich. Contact:
Phone number: 044 634 46 11
E-mail: corona-immunitas@ebpi.uzh.ch

Declaration of consent

Written declaration of consent to participate in a study project
Please read this form carefully. Please ask if you do not understand or do not want to know something.

BASEC number (after submission):	
Title of the project (scientific and lay language):	CORONA IMMUNITAS Canton of Zurich: Multi-center observational study to determine the spread of coronavirus and development of immunity in Switzerland
Responsible institution (project management with address):	Foundation Swiss School of Public Health (SSPH+), Prof. Dr. med. et PhD Nino Künzli Hirschengraben 82, 8001 Zürich
Place of implementation:	At the study centre (EBPI) Zurich, in Winterthur or in minibuses at the participants' place of residence / at home
Examiner at the place of study: Name and first name in block letters:	Prof. Dr. Jan Fehr
Participant: Name and first name in block letters: Date of birth:	☐ female ☐ male

- I was informed orally and in writing by the undersigned examiner about the purpose, the course of the project, possible advantages and disadvantages as well as possible risks.
- I am participating in this project voluntarily and accept the content of the written information provided on the above mentioned project. I had enough time to make my decision.
- My questions in connection with the participation in this project have been answered. I keep the written information and will receive a copy of my written consent upon request.
- I agree that the responsible experts of the project management/the client of the project and the ethics committee responsible for this project may inspect my unencrypted data for testing and control purposes, but in strict compliance with confidentiality.
- I will be informed about the result of the antibody test, i.e. whether the test has detected antibodies against the coronavirus (SARS-CoV-2 antibody) in my blood or not. If I do not wish to be informed, I will inform my examiner.
- I understand that my health-related and personal data (and samples) can only be passed on in encrypted form for research purposes **for this project.**
- I can withdraw from the participation at any time and without giving reasons without any disadvantages. The data and samples collected until then will still be used for the evaluation of the project.
- The liability insurance of the University of Zurich will pay for any damage.

Place, Date	Signature of participant

Confirmation by the investigator: I hereby confirm that I have explained the nature, significance and scope of the project to this participant. I confirm that I have fulfilled all obligations in connection with this project in accordance with applicable law. If at any time during the implementation of the project I learn of any aspect that might influence the participant's willingness to participate in the project, I will inform him/her immediately.

Place, Date	Name and first name of the informing investigator in block letters Signature of the investigator

Declaration of consent for further use of (genetic) data and biological material in encrypted form

BASEC number (after submission):	
Title of the project (scientific and layman's terms):	CORONA IMMUNITAS Canton of Zurich: Multi-center observational study to determine the spread of coronavirus and development of immunity in Switzerland
Participant: Name and first name in block letters:	
Date of birth:	☐ female ☐ male

- I allow that my (genetic) data and samples from this project may be used in encrypted form for medical research. This means that the samples may be stored in a biobank and used for future, not yet further defined research projects for an indefinite period of time. This consent is valid for an unlimited period of time.
- I decide voluntarily and can revoke this decision at any time. If I resign, my (genetic) data will be made anonymous and my samples will be destroyed. I only inform my investigator/project management and do not have to justify this decision.
- I understand that the data and samples are encrypted and the key linking document is kept safe. The data and samples can be sent to other data and biobanks for analysis if they comply with the same standards as in Switzerland. All legal requirements regarding data protection are complied with.
- Normally, all data and samples are evaluated as a whole and the results are published in summary form. If a result that is relevant for me is found, it is possible that I will be contacted via my investigator. If I do not wish to be contacted, I will inform my investigator/the project management.
- If results from the data and samples are commercialized, I am not entitled to a share of the commercial use.

Place, Date	Signature of participant

Confirmation by the investigator: I hereby confirm that I have explained to this participant the nature, significance and implications of the further use of samples and/or genetic data.

Place, Date	Name and first name of the informing investigator in block letters Signature of the investigator