Dear Sir or Madam,

We would like to invite you to participate in the study "Serological population study of the coronavirus epidemic", which is examining the spread of the new coronavirus in Finland and the extent and properties of the antibody formation (immunological resistance) resulting from it.

This study is being carried out by the Finnish Institute for Health and Welfare (THL) in cooperation with selected hospital districts and universities. We are inviting people to participate in the study based on random sampling of the population, so no one else can participate on your behalf.

The study is voluntary, and you need to give written consent if you wish to participate.

The study involves taking one blood sample and carrying out register checks.

The main purpose of the study is to determine to what extent the new coronavirus infection has spread in the Finnish population. On the basis of the information contained, it will be possible to deduce the intensity and current stage of the epidemic and to make informed decisions on what measures are needed to manage it.

We request that you read carefully the accompanying information sheet, which provides detailed information on the study and what your participation would involve.

There is also a consent form that we will ask you to sign during your study visit if you choose to participate in the study.

If you would like further information, please contact the THL study personnel

- by phone on +358 800 98015 (open Mon–Fri 9.00–15.00, calls are free)
- by email at koronaserotutkimus@thl.fi
- Via the website at thl.fi/koronaserotutkimus

If you are interested in taking part in the study, we ask you to reserve an appointment to participate using the separate form for this (TIME RESERVATION INSTRUCTIONS).

Please take along all the material received with this letter when going for your study visit.

The time reservation instructions can also be found on our website at thl.fi/koronaserotutkimus

Tampere, 23 April 2020,

Arto Palmu, Principal investigator, Docent, Public Health Specialist,
Finnish Institute for Health and Welfare (THL), Department for Public Health Solutions
FinnMedi I, Biokatu 6, 33520 Tampere

Source of address information: Population Information System, Digital and Population Information Authority, P.O. Box 123, 00531 Helsinki
STUDY INFORMATION SHEET

Title of study: Serological population study of the coronavirus epidemic

Development of seroprevalence in Finland during the new coronavirus epidemic (SARS-CoV-2) – serological population survey

Person responsible for the study: Arto Palmu, Specialist, MD, PhD, Finnish Institute for Health and Welfare (THL)
Study sponsor: Finnish Institute for Health and Welfare (THL)

INVITATION TO PARTICIPATE IN THE STUDY

We would like to invite you to participate in a study which is examining the spread of the new coronavirus in Finland and the extent and properties of the antibody formation (immunological resistance) resulting from this spread. The focus is a SARS-CoV-2 virus that causes mostly mild but also serious and sometimes life-threatening respiratory infections (COVID-19). This generally infectious disease has spread to become a global pandemic and strong restrictive measures have been imposed in order to control it.

You are being invited to participate in the study because you are among the group that has been selected as a sample representing the Finnish population. This information sheet describes the study and your possible contribution to it.

PARTICIPATION IS VOLUNTARY

Participation in the study is voluntary. You have the right to refuse to participate in the study, and the right to terminate your participation or withdraw your consent at any time and without giving any reason. Such refusal will not affect your right to receive the treatment you need.

Please read this information leaflet carefully. If you have any questions, you can contact the personnel of the Finnish Institute for Health and Welfare (THL) who are responsible for carrying out the study. Contact information can be found at the end of this information sheet. If you decide to participate in the study, we request that you sign the consent form attached to this information sheet when you come for your study visit.

BODY IMPLEMENTING THE STUDY

This study is being carried out by THL together with selected partners. These partners include the University Hospitals and Universities of Helsinki, Turku, Tampere, Oulu and Kuopio. THL is the data controller for the study and is responsible for ensuring the legality of the data processing.

PURPOSE OF THE STUDY

The primary purpose of this study is to obtain up-to-date information on how large a proportion of the population among different age groups and regions have developed antibodies to coronavirus. These antibodies indicate previous contact with the virus, meaning either a symptomatic or non-symptomatic coronavirus infection (seroprevalence). On the basis of this information, it will be possible to deduce the intensity, direction, and current stage of the epidemic. This information will provide a well-reasoned foundation for decisions on what measures are needed to manage the epidemic at each stage. In addition, the study will examine how long the antibodies remain and how their development relates to the severity of the infection. The study will also involve development of laboratory methods for virus antibody research and preparations for responding to new research questions that may arise during the epidemic.

BACKGROUND

There are a number of different coronaviruses, and some of these cause mild respiratory infections each year. A new type of coronavirus (SARS-CoV-2) has now emerged, which has been able to spread rapidly around the world because the population does not even have a partial immunity to it. The new coronavirus mainly causes mild respiratory tract infections, but sometimes these can be serious and lead to intensive care treatment or even death. Currently, no preventive vaccine or proven medicine is available for the disease. So far, the only means of managing the situation are strong restrictions on mobility and social interaction and the promotion of hygiene measures. However, these restrictions cause significant interference to people's daily lives and to the functioning of society and the economy. Research data is needed to support decision-making so that the measures chosen are sufficiently strong and also well-timed.
SELECTION OF RESEARCH SUBJECTS
You may choose to take part in the study provided that 1) you have received a personal invitation to participate and therefore belong to the selected sample, 2) you understand the information received sufficiently well, 3) you do not reside in an institution or an enhanced service housing unit under 24-hour care.

STUDY PROCEDURES
The study involves one visit to the location in your area where the study is being carried out. You can book a time for your study visit by following the instructions at the end of this information sheet. If possible, please do this within a week of receiving this invitation. If you experience symptoms of a acute respiratory tract infection (for example, coughing, a head cold, throat pain, fever), you must wait until two days after the symptoms have ended before you make your study visit.

During the study visit, you will be asked to sign the attached consent form and answer a few questions about your experience of respiratory tract infections. One blood sample will then be taken from you (maximum 5 ml). The study visit takes less than half an hour.

The blood samples are analysed in the THL laboratories in order to identify the presence of any antibodies against the SARS-CoV-2 virus. For some samples, the number and subtypes of the antibodies and their functional characteristics are also examined. The blood sample may also be used to determine other factors related to the course of a COVID-19 infection. The test is not suitable for diagnosing a sudden infection.

Subjects with SARS-CoV-2 coronavirus antibodies in their blood sample may be invited for further monitoring and re-sampling in order to monitor the maintenance of the antibody level. The research subject’s consent to this sub-study will be requested separately.

COLLECTION OF DATA FROM HEALTH REGISTERS
The study involves collecting historical and future register data on diseases and treatment resources related to coronavirus. The registers used in the study include the THL Care Register for Health Care, the THL Register of Primary Health Care visits, the THL National Infectious Diseases Register, the benefit registers of the Social Insurance Institution of Finland, the Kanta database, Statistics Finland’s socioeconomic variables and the Population Information System of the Digital and Population Data Services Agency. These analyses are mainly carried out as a population survey, but your consent also covers cases where register data is combined with the data collected in this study using your personal identity code.

BENEFITS OF THE STUDY
Participation in this study is not expected to benefit you personally. However, you will be notified by letter if antibodies against SARS-CoV-2 coronavirus are found in your blood sample. If antibodies are found, this is a sign that the person has already had the infection. The presence of antibodies will not affect the treatment you need. The presence of antibodies may indicate your immunity to the disease, but it does not guarantee it. If antibodies are found in your blood, we will provide you and those living with you instructions on the need for isolation or quarantine. By participating in the study, you will be helping researchers to learn more about the disease caused by the new coronavirus and also helping decision-makers to take well-reasoned measures to control the epidemic.

POSSIBLE HARM AND DISCOMFORT CAUSED BY THE STUDY
Blood sampling is a common and routine procedure. It may cause swelling, pain or bruising at the location where the sample is taken from. To minimise adverse effects, samples are taken by highly-trained personnel.

DATA CONFIDENTIALITY AND DATA PROTECTION
During the study, your identity is only known to the THL study personnel and the sample-taking personnel of the partnering organisations, and these are all subject to a confidentiality obligation.

The data collection is based on a research plan approved by the Ethics Committee. Only personal data necessary for the purpose of the study is processed and stored in the research register. Your direct personal identifiers, such as your name, personal identity code or contact information, will not be disclosed to persons outside of THL. In the study documents, they will be replaced by your subject code, which effectively conceals your identity. Your personal identity code is stored separately from other research material in THL’s protected premises that can only
be accessed by those that need the material for their research tasks. THL needs to have your personal identity code in order to collect information from health registers and patient documents. The research register is stored in THL’s secure databases.

Your research data, marked with your subject code, may be disclosed to hospital district researchers participating in the implementation of the study and possibly to other parties with whom THL is carrying out research cooperation. Research agreements include an obligation to process research data in a confidential manner.

The Office of the Data Protection Ombudsman has the right to carry out data protection audits and, in connection with this, to access the personal data for the study. In this case, the data is processed under the supervision and responsibility of the study personnel. In all cases, your data will be treated confidentially.

The privacy notice from the Research Register can be found on the study’s website (www.thl.fi/koronaserotukimus) and you can request to view it. It provides more detailed information on the processing of personal data and your rights in relation to this. You have the right to receive information from THL about any of your personal data that has been collected for the study as well as the way it has been collected and the parties it has been disclosed to. Where needed, you may request that your personal data be corrected. THL has appointed a data protection officer, who is available to answer any data protection enquiries sent to privacy@thl.fi. If you believe that your personal data has been processed in violation of the General Data Protection Regulation, you can file a complaint with the Data Protection Ombudsman (www.tietosuoja.fi).

LEGAL BASIS FOR RESEARCH, PERMITS AND STATEMENTS

The sampling and data collection for the study is based on your consent (Medical Research Act, 488/1999). In addition to your explicit consent, the basis for the processing of personal data included in the study is scientific research of public interest that is in accordance with the European Union’s General Data Protection Regulation (679/2016) and the National Data Protection Act (1050/2018).

The study has received a favourable opinion from the Ethics Committee of the Hospital District of Helsinki and Uusimaa. The required register permits will be obtained from the controllers of the national registers used in the study.

DATA PROCESSING AND RETENTION

The study personnel of the research partners will process your samples and data related to the study in a confidential manner and then deliver them to THL. The study data will be stored in the THL research database. The study data is stored for at least 5 years after the end of the study.

RESEARCH COSTS AND FINANCIAL MATTERS

The study procedures are carried out without any cost to you. In addition, no compensation is paid for participating in the study. The study is being funded with the additional appropriation within the state’s supplementary budget allocated to THL for research relating to the coronavirus epidemic. THL signs an agreement with the partnering organisations participating in the research and compensate them for the costs of the research work.

INSURANCE COVER FOR RESEARCH SUBJECTS

The participants in the study are covered for any personal injury incurred through the insurance against treatment injury provided.

STUDY DURATION AND TERMINATION

The invitations to participate in the study will be sent in 2020. In most cases, the study involves only one visit, but some of those found to have antibodies are invited to follow-up visits that will take place within 2 years of when the original sample was taken. The register checks will cover the years 2019–2022. The results of the study will be communicated in the media and on the study’s website (www.thl.fi/koronaserotutkimus) once the study is complete.

FURTHER INFORMATION

If you have any questions about the study, you may contact the THL study personnel by telephone on +358 800 98015 (available Mon–Fri 9.00–15.00) or by email at koronaserotutkimus@thl.fi.
Alternatively, the THL Study Nurse can contact you by telephone and provide further information on the study. The telephone numbers have been retrieved from the service provider (LeadCloud) using the information provided by the Digital and Population Data Services Agency.

Further information on the study can also be found on the website: www.thl.fi/koronaserotutkimus.

If you wish to participate in the study, you are requested to book a time using the local instructions sent with the invitation letter. These instructions can also be found on the research website at: www.thl.fi/koronaserotutkimus.