

ISRCTN11060415

Short name: Study of the spread of COVID-19 in St Petersburg, Russia

Full name: Population study of SARS-CoV-2 antibodies prevalence in residents of St. Petersburg, Russia based on blood serum tests; socioepidemiological study.

Protocol number: CDRU-001

Study sponsors:	Polymetal International PLC Independent not-for-profit educational organization of higher education "European University at St. Petersburg" OOO AVA-Peter
Study sites:	Scandinavia clinics: OOO AVA-Peter, Obvodny kanal branch, Moskovsky pr., 73, k.4 St. Petersburg
Protocol version:	2
Protocol date:	15 Jul 2020
Start of enrolment:	26 May 2020
End of enrolment:	20 Aug 2020
End of study:	31 Dec 2021
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Table of contents

1.	Introduction.....	3
2.	Study objectives.....	3
2.1.	Primary objective.....	3
2.2.	Secondary objectives.....	4
3.	Study procedures	4
3.1.	Study design	4
3.2.	Inclusion and exclusion criteria	5
3.2.1.	Study inclusion criteria:.....	5
3.2.2.	Study exclusion criteria:	5
3.3.	Data collection.....	5
3.4.	Ethical and legal aspects	5
4.	Laboratory diagnostics	6
5.	Statistical analysis.....	6
5.1.	Sample.....	6
5.2.	Encouragement design	7
5.3.	Data management and analysis	7
5.3.1.	Primary objective	7
5.3.2.	Secondary objectives	8
6.	Publication of the results	8
7.	References	8

List of Appendices

Appendix 1. Questionnaire for telephonic survey.

Appendix 2. Medical questionnaire.

Appendix 3. SARS-CoV-2 antibody test results.

Appendix 4. Participant Information Sheet and Informed Consent Form.

1. Introduction

Population analysis of infection spreading is one of the key methods of new epidemics control¹. The World Health Organization has included population serological surveys, which help to visualize the new virus distribution, into a list of essential assessments during the current epidemics, along with the vaccine development and search for effective treatments for severe disease². Such studies help understand real disease spread and a real proportion of fatal outcomes among the patients with a disease and infected persons. Initial studies have shown the presence of immune response to an earlier SARS-CoV-2 infection³.

Regarding the SARS-CoV-2 pandemic, the population assessment of immune response is recommended until the year 2024, as currently there is a discussion of a high risk of second and further peaks of new coronavirus epidemics⁴. Initial studies performed in the state of New York have shown that up to 14% state residents and 21.2% of New York City residents had had the infection and had developed antibodies⁵. In the states of Idaho and California, there were not more than 2% of such people^{6,7}.

To evaluate the proportion of people who have had the disease in a whole population (a city, a region, a country), the representativeness of a sample needs a strict approach. The methodology of a serological study is in many aspects similar to a sociological survey but is more complicated due to the use of serological test results. In addition, the population characteristics of these tests, i.e. sensitivity and specificity, are not always well-known². A serological study sample should be representative for the general population (age groups, gender, place of living, mobility during the epidemics)⁸.

In Russia, several studies have been performed to evaluate the proportion of antiviral antibody carriers, but many studies are probably biased in the direction of overestimation of positive results. This is caused by the selection of participants with higher probability of having antibodies. Thus, it is difficult to estimate how well these results reflect the real infection spread. In addition, such a study may help to identify objective social patterns of the epidemic spread in each specific region, i.e. correlation with the age, gender, occupation, mobility, and other factors. Also, some regions of Russia may have different stages of the epidemics, due to a geographical pattern of the viral spread. For example, in the Far East, there is high probability of viral spread from China, and in the European part of Russia from Europe.

Several designs exist to conduct blood antibody testing with the aim of studying the distribution of an infection. To evaluate a proportion of people who have had the infection up to the current moment, it is enough to assess the results of the tests performed in a representative sample in a short period of time. To evaluate the dynamics of the infection spread, similar testing in similar samples should be performed repeatedly, with specific time intervals at least of 4 weeks. There is also an option of a cohort study to evaluate the results of repetitive tests in the same sample defined at baseline. The latter design permits to define how the number of infected people in the population changes in time, evaluate the individual immune dynamics, and identify not only the distribution but also incidence of the infection.

2. Study objectives

2.1.Primary objective

Pilot study: to evaluate the proportion of people in St. Petersburg, Russia who have had the SARS-CoV-2 infection by means of analyzing the results of the blood serum tests for antiviral antibodies.

Cohort study: to evaluate the dynamics of the SARS-CoV-2 infection spread (incidence) by means of analyzing the results of blood serum tests for antiviral antibodies.

2.2.Secondary objectives

- To evaluate the incidence in the cohort study.
- To evaluate the relation between the risk of infection and several factors (mobility, social characteristics).
- To evaluate individual immune dynamics (seroconversion, seroreversion).
- To compare the proportion of participants with positive test results between age (<20, 20-29, 30-39, 40-49, 50-59, 60-69, >70) and gender groups.

3. Study procedures

3.1.Study design

This non-interventional observational socioepidemiological population study will be conducted in residents of St. Petersburg, Russia. Selection and invitation of participants will take place during telephonic survey. After giving signed informed consent, each participant will be subjected to a blood test for SARS-CoV-2 antibodies and will answer a questionnaire. The testing will be performed primarily using serological assays for serum IgG approved in the Russian Federation (Abbott Architect IgG and Genetico).

This study involves a telephonic sociological survey during which respondents will be invited to undergo a blood test for SARS-CoV-2 antibodies at the participating investigational sites in different cities and towns of Russia. The participants will undergo such a test, take part in an additional survey for those who plans or have already done such a test, and receive the results. A part of participants will be offered to use a taxi (see Section 5.2). Testing and questionnaire at the clinic will be repeated several times. It is planned to perform up to 10 visits which will include blood sampling, testing, and collection of additional information.

Table. Calculation of the study sample taking into account approximately 5% attrition at each visit

	First visit	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36
Telephone-based questionnaire; medical hypothesis; IgG tests	1000	950	902	857	815	774	735	698	663	630

Study participants will be asked to undergo multiple tests for SARS-CoV-2 antibodies with 4-week intervals to assess the immune response dynamics. If a participant agrees to repetitive tests, they will also complete questionnaires with the objective of collecting epidemiological information for the period since the first test. Time of each round of survey and information collection will not exceed 4 weeks.

If the test is not performed in the mentioned interval, delayed testing data may be used. If before the initial or a later test a participant shows signs of acute respiratory infection (see Section 3.2.2.3) or has been diagnosed with COVID-19, the study will use results of

a test performed at least 2 days after all symptoms resolved, or results of the last negative test for the virus.

3.2. Inclusion and exclusion criteria

3.2.1. Study inclusion criteria:

- 3.2.1.1. Residence in St. Petersburg, Russia.
- 3.2.1.2. Consent to participate in a telephonic survey and personal data collection.
- 3.2.1.3. Consent to an anti-SARS-CoV-2 antibodies test at an investigational site, and to management of the results of such a test with scientific objectives.
- 3.2.1.4. Consent to second and further surveys and tests with approximately 4-week intervals.

The participation in surveys and information collection should be based on a verbal (for telephonic surveys) and written (for surveys and information transfer from a clinic) informed consent. The participants will sign 2 copies of the informed consent form, one of which will be given to a participant, and another will stay at the investigational site. The participants will be also asked to agree to the transfer of additional medical data available at the clinic, for scientific analysis. The refusal to provide additional medical data is not an exclusion criterion.

3.2.2. Study exclusion criteria:

- 3.2.2.1. Refusal to take part in any of the study surveys.
- 3.2.2.2. Impossibility to perform an anti-SARS-CoV-2 antibody test.
- 3.2.2.3. Signs or symptoms of an acute respiratory infection at the moment of a survey or a test, based on the information provided by the participant or on the results of an examination at the investigational site. (The symptoms of an acute respiratory infection may include fever, cough, runny nose, loss of olfaction, marked weakness, dyspnea. A final decision on the presence or absence of the symptoms will be taken on the basis of analysis of observed and medical data).
- 3.2.2.4. Participants younger than 18 years old cannot take part in this study.
- 3.2.2.5. Residence in distant district of the city (Kronshdatsky, Kurortny, Petrodvortsovy, Krasnoselsky, Kolpinsky, Pushkinsky)

Participation in the study is not limited by a single blood draw and anti-SARS-CoV-2 antibody test. The consent to the information transfer maintains for similar repetitive tests and other medical information necessary in the frame of this study.

3.3. Data collection

During the study, the information will be collected from 3 sources:

- 1. Information collected via telephonic surveys (see Appendix 1);
- 2. Information collected during interviews at the clinical sites (see Appendix 2);

3.4. Ethical and legal aspects

Currently, results of the studies of SARS-CoV-2 infection prevalence in the population have key importance for public health in particular regions as well as at national and international levels. Conduction of such observational population studies is a key objective of scientific and practical medical institutions to be able to inform the society about the current epidemiological situation.

This observational study will involve blood sampling for the antibodies test; this procedure has minimal risks for the health. Participation in the study will not affect medical decisions

in any manner. The nature of participation is completely voluntary. The participants will be informed about the results, but it is not recommended to interpret these results from the point of view of protection from the infection.

This study will be conducted in adherence to applicable local, regional, and national laws and regulations. Non-interventional epidemiological observational studies without investigational drugs are not directly regulated by International Council on Harmonization (ICH) Good Clinical Practice (GCP), but before the start of the study, an ethics committee will perform a review, and the GCP principles will be applied as needed.

This study is being conducted at the territory of the Russian Federation, in accordance to the laws and regulations applicable to epidemiological observational studies. No personal data will be used in data analysis or transferred to the European University at St. Petersburg as well as to laboratories performing the tests.

Participation in the study is completely voluntary and is possible only after the familiarization with the Information Sheet (Appendix 3), study details explanation, and signing correspondent Informed Consent Forms (Appendix 3). The participants can withdraw their consent verbally or in written form at any moment. Withdrawal of consent applies to personal information and results of all tests and procedures which would follow the moment of withdrawal, as well as other personal data. Withdrawal of consent does not apply to already collected and analyzed, anonymized and aggregated data, as such data cannot be identified.

Results of this study cannot be the only reason for making decisions about the epidemics control measures, but they can be used in discussion of such measures.

4. Laboratory diagnostics

To measure IgG antibodies titer, Abbott Architect SARS-CoV-2 IgG (<https://www.fda.gov/media/137383/download>) assay will be used. According to the manufacturer, the sensitivity of the assay is 100%, and the specificity is 99.6%. With a scientific objective, Coronapass Total Ig assay (Genetico) will also be used, with the sensitivity of 96% and specificity of 100%, according to the manufacturer. Other point-of-care tests can be used to immediately inform participant but not for the research analysis.

5. Statistical analysis

5.1. Sample

In this study, a population of a region with the size of N is being looked at. Assuming that the number of infected (K) in the population is distributed binomially and the serological test is ideal, 2-sided 95% Wilson confidence interval for the prevalence (p) is:

$p' \pm z_{0,025} \sqrt{\frac{p'(1-p')}{n+4}}$, where $p' \equiv \frac{k+2}{n+4}$, and $z_{0,025}$ is the critical level of the standard normal distribution. In this case the sample size n , needed for the sample error to not exceed M , with a conservative assumption of hypothetical prevalence of 50%, is: $n > \left(\frac{1,96 \times 0,5}{M}\right)^2 - 4$. For the sample error to reach 2%, at least 2397 observations are needed.

If we assume that hypothetical prevalence is 10%, the sample size is less than 900 for the sample error of 2%. Taking into account possible attrition at the repetitive tests, it is planned to enroll at least 1000 participants.

During the study, it is planned to test at least 1000 participants with a highly sensitive (Se) and highly specific (Sp) test, to reach the sample error level of 2%. The calculations above are applicable to a cross-sectional study. In a cohort study, there is a problem of the sample attrition. We assume loss of 5% of participants at the repetitive blood sampling. If 1000 participants provide samples at the first visit, there will be 630 tested participants at Week 36.

5.2. Encouragement design

Even if random sample of potential participants (surveyed persons) is representative, the decision about the participation in the study may bias its results, as it is made (or rejected) by a potential participant. The assumption of ideal participation of all surveyed persons in the testing is unrealistic. The next step would be to assume self-selection based on the observed characteristics of the surveyed. But it is doubtful that during a telephonic interview all observed individual characteristics which may affect the decision about the participation may be identified and quantified. For this reason, the final assessment of the prevalence will be biased. To surpass the issue of non-observable decision about the voluntary participation, the encouragement design will be used in this study^{9,10}.

A randomly selected subgroup of the surveyed will be offered a benefit related to the study participation, free-of-charge taxi to the place of testing. This offer will be made during the interview. Such randomization will permit to assess the proportion of infected in the group of people whose decision to participate in the testing changes depending to this benefit. The prevalence assessed in this manner has higher external validity than the prevalence in the group of people who make the decision without external encouragement.

5.3. Data management and analysis

There are several endpoints in this study. All values will be presented with 95% confidence intervals which corresponds to type I error probability of 5%. Depending on the type of variables, correspondent statistical tests and models will be used.

The prevalence will be calculated using the GJRM library for R statistical software¹¹. The following parameters will be calculated:

- Uncorrected prevalence;
- Prevalence with a single imputation of results for non-tested participants;
- Prevalence corrected by self-selection of the participants based on observed characteristics (Heckman model);
- Prevalence corrected by self-selection of the participants based on unobserved characteristics;
- Coefficients of regression of the relation between the observed characteristics of the participants and test results.

5.3.1. Primary objective

Cross-sectional study: the main objective of this study is to calculate the proportion of participants with the presence of antibodies (taking into account the threshold recommended by manufacturer) in the total number of tested. Crude value will be equal to the proportion of positive-tested persons in the total number of enrolled. Additionally, standardized values and values in age or gender groups will be calculated as well as an adjusted value based on the total population in a region.

Cohort study: the main objective of the cohort study is to compare correspondent values of prevalence in different points in time. This comparison will be made using simple tests and models depending on the type of value (rough, standardized, adjusted).

5.3.2. Secondary objectives

Cross-sectional study:

- To evaluate the relation between different sociodemographic factors and presence of infection by means of calculation of the adjusted prevalence ratios in different groups¹².

Cohort study:

- To evaluate the incidence (number of new cases of infection by number of participants and observation time, i.e. incidence rates per person-days). Participants with positive result at the first testing will not be included in this assessment.
- To evaluate the relation between different sociodemographic factors and incidence (rate ratios).
- To evaluate the dynamics of immune response:
 - cumulative seropositivity, i.e. proportion of positive tests at each moment;
 - cumulative seroconversion, i.e. cumulative proportion of participants at all moments with at least 1 positive test;
 - cumulative seroreversion, i.e. cumulative proportion of participants at all moments with at least 1 negative test after at least 1 positive test.

6. Publication of the results

Results of this study will be published in forms of press-releases, preprints, and peer-reviewed scientific publications in Russian and English. Anonymized data will be publicly available for use in mathematical models of the epidemic dynamics and for the exchange of scientific information.

7. References

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Appendix 1

CATI: Study of the spread of COVID-19 in St Petersburg, Russia

Good afternoon! My name is _____. The European University at St. Petersburg together with Scandinavia clinics perform a study of coronavirus spread in St. Petersburg residents. It is a very important study which will help to make decisions on the duration of self-isolation, and it gives residents an opportunity of a free-of-charge test to discover if you have already had the infection, as it may be asymptomatic.

Please answer several questions of this survey; it will take about 10 minutes.

a) At the end of this survey, if you are interested in this testing, I will explain in which clinics you can do it and ask your contact information, for the reception contacting you and giving you an appointment at time which suits you.

b) At the end of this survey, if you are interested in this testing, I will explain in which clinics you can do it and ask your contact information, for the reception contacting you and giving you an appointment at time which suits you. In this study, the testing is free-of-charge, and the commuting to the clinic will be also covered: you will receive a personal promocode for a taxi.

CLARIFICATIONS FOR AN INTERVIEWER:

What does the test show: it's a test for antibodies. It shows if you have had a coronavirus infection earlier (as this infection is often asymptomatic or similar to other diseases). It does not show if you are currently infected. It is free of charge.

Results of the test will not be reported to state organizations.

What are Scandinavia clinics: it's the largest private clinics chain in St. Petersburg, one of the centers of urgent medical care in case of coronavirus infection.

Q1001 Single choice from 'Q1001 list'

We guarantee that your answers will be kept confidential. For the quality control of my work, this call will be recorded, and the record will be deleted after the end of the study. Do you agree to proceed to a survey?

How can I refer to you?

informationText('Respondent name: ' + Q.openValueTxt);

Q1

Sex

(DON'T READ THE QUESTION, REGISTER THE ANSWER BASED ON EARLIER ANSWERS)

Single choice from 'Q1 list'

1 Male

2 Female

Q2

Please tell me, do you live in St. Petersburg?

(DON'T READ ANSWERS)

(A SINGLE ANSWER) Single choice from 'Q2 list'

1 Yes

2 No

If Q2=2, terminate the interview

Q3 Single choice from 'Q3 list'

In which district of St. Petersburg do you live?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 admiralEiskiy

2 vasileostrOvskiy

3	vYborgskiy	
4	kAlininskiy	
5	kIrovskiy	
6	kOlpskiy	
7	krasnogvardEiskiy	
8	Krasnoselskiy	
9	KronshtAdtskiy (KronshtAdt)	
10	Kurortniy	
11	Lomonosovskiy	
12	Moskovskiy	
13	Nevskiy	
14	PetrogrAdskiy	
15	PetrodvortsOviy	
16	primOrskiy	
17	pUshkinskiy	
18	frUnzenskiy	
19	Centralniy	
998	OTHER (explain)	OpenValueTxt

Q4 Numeric

How old are you in full years?

If Q4(ValueInt<18), terminate the interview

Q5 Single choice from 'Q5 list'

Please tell me if since the beginning of February, you have been to somewhere outside of St. Petersburg and Leningrad region?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Yes

2 No

Q6 Single choice from 'Q6 list'

Q5=1

Have you traveled abroad since the beginning of February?

1 Yes

2 No

Q7 Single choice from 'Q7 list'

Among the people who you have met after the 1st of March, are there people who have traveled abroad in February or later?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Yes

2 No

999 (DON'T READ) Not sure

Q8

Have you exited your home during the last week (7 days)?

(DON'T READ ANSWERS)

(A SINGLE ANSWER) DisableReordering Single choice from 'Q8 list'

1 Yes

2 No

Q9 Single choice from 'Q9 list'

Q8=1

How often have you been outdoors during the last week (7 days)?

(A SINGLE ANSWER)

Q10 Single choice from 'Q10 list'

Q8=1

How much time have you spent out of your home when you went out most recently?

(IF THE ANSWER CONTAINS INTERVAL, REGISTER THE UPPER BORDER.

REGISTER HOURS OR MINUTES — 30 min, 20 min

IF THE ANSWER CONTAINS HOURS AND MINUTES, REGISTER AS IT IS: 1 h 10 min, 2 h 40 min)

999 (DON'T READ) Not sure

Q11 Multiple choice from 'Q11 list'

Q8=1

Which of the following places have you visited during the last week?

(ANY NUMBER OF ANSWERS)

1 Work

2 Metro and other public transport, including taxi

3 A pharmacy

4 A shop or a market

5 A post office, a bank, an ATM, a medical institution

6 I have not been to any of these places

Q12

Have you had any examination for coronavirus?

(DON'T READ ANSWERS)

(A SINGLE ANSWER) DisableReordering,

Blocking

Single choice from 'Q12 list'

1 Yes

2 No

Q121 Single choice from 'Q121 list'

Q12=1

The result of this examination was:

(A SINGLE ANSWER)

1 Positive

2 Negative

3 I don't know

999 (DON'T READ ANSWERS) Not sure

Q13 Single choice from 'Q13 list'

Do you or do you not follow information regarding coronavirus? If you follow, do you do it continuously or once in a while?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Follow continuously

2 Follow once in a while

999 (DON'T READ ANSWERS) Not sure DisableReordering

Q15 Single choice from 'Q15 list'

Q8=1

Were you wearing a mask when leaving your home during the last week?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Yes

2 No

Q16 Single choice from 'Q16 list'

Q8=1 and Q15=1

Were you wearing a mask while just outdoors?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Yes

2 No

Q17

Can you say that now you wash your hands more often than before the epidemics?

(DON'T READ ANSWERS)

(A SINGLE ANSWER) Single choice from 'Q17 list'

1 Yes

2 No

999 (DON'T READ) Not sure

Q19

In your opinion, should the limitations for public have been stricter or not?

(DON'T READ ANSWERS)

(A SINGLE ANSWER) DisableReordering Single choice from 'Q19 list'

1 Yes, they should have been

2 No, they should not have been

999 (DON'T READ) Not sure DisableReordering

Q20 Single choice from 'Q20 list'

Q19=2

In your opinion, should the limitations for public have been less strict or not?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Yes

2 No

999 (DON'T READ) Not sure

Q21

How would you evaluate your health?

(A SINGLE ANSWER) DisableReordering Single choice from 'Q21 list'

1 Very good

2 Good

3 Satisfactory

4 Bad

5 Very bad

Q22 Single choice from 'Q22 list'

Please remember how many times you have been ill since February. Answer about your own feelings, not only when you took a sick leave.

(IF THE ANSWER CONTAINS AN INTERVAL, REGISTER THE UPPER BORDER)

999 (DON'T READ) Not sure

Q23 Single choice from 'Q23 list'

Do you seek out preventative examinations in state or private clinics?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

1 Yes

2 No

999 (DON'T READ) Not sure DisableReordering

Q24 Single choice from 'Q24 list 1'

Do you live alone or with others?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

- 1 I live alone
- 2 I live with other people

Q241 Numeric

Q24=2

How many people live in your household (except you)?

Q242 Multiple choice from 'Q242 list'

Q24=2

Are there following categories among the people who live with you (except you)?

(ANY NUMBER OF ANSWERS)

(READ ANSWERS WITH PAUSES)

- 1 Minors (younger than 18 years)
 - 2 Elderly (older than 65 years)
 - 3 Your husband/wife, permanent partner
 - 4 (DON'T READ; REGISTER IF NO OTHER ANSWER HAS BEEN SELECTED) Nothing applies
- DisableReordering, Blocking

Q25 Single choice from 'Q25 list'

How would you define your income level before the start of pandemic?

(A SINGLE ANSWER)

- 1 It was very hard. We did not have enough money even for food
- 2 We had money for food, but buying clothes was a problem
- 3 We had money for food and clothes but buying a fridge, a TV set, furniture would be a problem
- 4 We could easily buy a fridge, a TV set, furniture, but did not have enough money for something bigger
- 5 We can easily buy a car, but we don't have enough money for bigger things, like a flat or a summer house
- 6 We can afford almost everything: a car, a flat, a summer house and many other things

Q26 Single choice from 'Q26 list (Yes No ДРУГОЕ)'

Tell me please if you were working at the moment of the February 1st.

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

IF A PERSON IS ON MATERNITY LEAVE, REGISTER AS UNEMPLOYED

998 Other (clarify)OpenValueTxt,
DisableReordering

Q27 Single choice from 'Q26 list (Yes No ДРУГОЕ)'

Were you studying at the moment of the February 1st?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

IF A PERSON CONSIDERS SOMETHING AS STUDYING, REGISTER ACCORDING TO THEIR WORDS

(DO NOT GUIDE TO ANSWER; ASK TO ANSWER ACCORDING TO THEIR OWN OPINION ABOUT IF IT IS OR IT IS NOT STUDYING)

998 Other (clarify)OpenValueTxt,
DisableReordering

Q28 Single choice from 'Q26 list (Yes No ДРУГОЕ)'

At the moment of the February 1st, were you receiving a pension, a welfare, a stipend from the state?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

998 Other (clarify)OpenValueTxt,
DisableReordering

Q29 Single choice from 'Q26 list (Yes No ДРУГОЕ)'

Q26=2 or Q26=998

Were you looking for a job during the last 12 months?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

The question implies the last 12 months until now.

998 Other (clarify)OpenValueTxt,
DisableReordering

Q30 Single choice from 'Q26 list (Yes No ДРУГОЕ)'

Q26=1

You said that you worked at the moment of the February 1st.

At that moment, were you managing others or no?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

998 Other (clarify)OpenValueTxt,
DisableReordering

Q31 Single choice from 'Q26 list (Yes No ДРУГОЕ)'

Q26=1 and Q27=2 and Q30=2

Did your job at that moment involve physical work?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

998 Other (clarify)OpenValueTxt,
DisableReordering

Q32 Single choice from 'Q32 list'

Q26=1

Currently, do you work as usual, or is your timetable/working organization different from those before the epidemics (remote work, coerced days off etc.)?

(DON'T READ ANSWERS)

998 OpenValueTxt,
DisableReordering

Q321 Single choice from 'Q321 list'

Q32=2

Which of the following situations is most similar to your timetable/working organization during the epidemics?

(A SINGLE ANSWER)

1 I work remotely

2 I am on paid leave

3 I've lost my job or on unpaid leave, I spend my savings or use help from friends and family.

4 I've lost my job or on unpaid leave, I have to do some casual jobs

Q33 Single choice from 'Q33 list'

What is your education level?

(DON'T READ ANSWERS)

(A SINGLE ANSWER)

- 1 Initial/ unfinished secondary education
- 2 Complete secondary education
- 3 Special secondary, technical secondary, initial professional education
- 4 University education

Q34

Do you have the Russian Federation nationality?

(DON'T READ ANSWERS)

(A SINGLE ANSWER) Single choice from 'Q34 list'

- 1 Yes
- 2 No

Q35 Numeric

Since what year have you been living in St. Petersburg?

Q36 Multiple choice from 'Q36 list'

let code = Q8001.getCheckedCode(); let texts = {

1: 'Thank you for your answers. You are offered free testing for anti-coronavirus antibodies

2: 'Thank you for your answers. You are offered free testing for anti-coronavirus antibodies

3: 'Thank you for your answers. You are offered free testing for anti-coronavirus antibodies 4: 'Thank you for your answers. You are offered free testing for anti-coronavirus antibodies

};

Q.text = code in texts ? texts[code] : 'Code text not found' + code;

Thank you for your answers!

You are offered free testing for anti-coronavirus antibodies at a Scandinavia clinic; it will show if you have or have not had the infection (or have it now). This is needed to evaluate the prevalence of this infection in our city, even if some people have had in in asymptomatic form.

a) If you agree, give me please your contact phone number, first and patronymic names (no last name). In the next 5 days, clinic representatives will contact you to discuss a moment for testing which suits you. Do you agree?

b) If you agree, give me please your contact phone number, first and patronymic names (no last name). In the next 5 days, clinic representatives will contact you to discuss a moment for testing which suits you and to explain how you can call for a free taxi to go to the clinic as a participant of this study. Do you agree?

CLARIFICATIONS FOR AN INTERVIEWER:

Any questions related to the testing results waiting time, its medical characteristics etc. might be asked to a clinic representative when they contact the respondent.

- 1 Name and patronymic name: OpenValueTxt
- 2 Contact phone number: OpenValueNum
- 3 No, do not agree Blocking

Appendix 2

Serological study of COVID-19 prevalence in St.Petersburg

PARTICIPANT QUESTIONNAIRE

ATTENTION! Please select most appropriate answers from your own point of view. If you have any doubt, select approximate answer. To avoid introducing bias into the study results, the clinic staff cannot give explanations. Your answers will not affect the decision about conducting the test and will be used in anonymized form.

1. Your body weight (may be approximated) is _____ (kg)

2. Your height (may be approximated) is _____ (cm)

3. Do you smoke?

<input type="checkbox"/> No	<input type="checkbox"/> Yes
Did you smoke before?	At what age did you start smoking? _____
<input type="checkbox"/> No <input type="checkbox"/> Yes	Usually, do/did you smoke cigarettes?
Go to Question 4	<input type="checkbox"/> No <input type="checkbox"/> Yes
Please answer when you quit smoking most recently and answer the questions on the right	Go to Question 4
I quit smoking in the year____.	How many cigarettes per day do/did you usually smoke?
	<input type="checkbox"/> Less than half a pack (10 cigarettes) per day
	<input type="checkbox"/> Approximately a pack (10-20 cigarettes) per day
	<input type="checkbox"/> More than a pack (20 cigarettes)

4. How often did you drink alcohol (including beer) in the last 30 days?

<input type="checkbox"/> Every day	<input type="checkbox"/> 4-6 times per week	<input type="checkbox"/> 2-3 times per week
<input type="checkbox"/> Once a week	<input type="checkbox"/> 2-3 times in the last 30 days	<input type="checkbox"/> Once in the last 30 days
<input type="checkbox"/> Never		

5. Have you visited a hospital or a clinic since the beginning of February?

<input type="checkbox"/> No	<input type="checkbox"/> Yes
-----------------------------	------------------------------

6. Have you had any common cold since February?

<input type="checkbox"/> No	<input type="checkbox"/> Yes
-----------------------------	------------------------------

7. For professional or other reasons, do you have to contact with people often?

<input type="checkbox"/> No	<input type="checkbox"/> Yes
-----------------------------	------------------------------

8. Have you used public transport in the last 2 weeks? If yes, how often?

- ☐ At least once a day per week ☐ Several times per week
- ☐ Once a week or less ☐ Never

9. Do you or your blood relatives (parents, children, siblings) have hereditary diseases?

- ☐ I don't know ☐ No ☐ Yes (which) _____

10. If you have any of the following chronic diseases, please, mark all applicable options

- ☐ Diabetes. If yes, do you receive insulin? ☐ No ☐ Yes
- ☐ Emphysema, chronic bronchitis, other respiratory diseases except asthma.
- ☐ Asthma. If yes, which of the following did you use during the last month (select all applicable options)?
- ☐ Manual inhalers
 - ☐ Oral medications
 - ☐ Oral steroids
 - ☐ Oral nebulizer at home
 - ☐ Other
- ☐ Renal failure
- ☐ Chronic hepatic diseases, for example, hepatitis or cirrhosis
- ☐ Cardiovascular diseases
- ☐ Hematological disorders, for example, chronic anemia
- ☐ Other chronic diseases or disorders not mentioned above. If yes, describe them:

What treatment do you receive? _____

11. Do you regularly (continuously) receive any medications not mentioned above?

- ☐ No ☐ Yes (please list all medications that you remember of)

12. Were you ever diagnosed with a cancer? ☐ No ☐ Yes

If yes, did you receive oncological treatment during the last year? ☐ No ☐ Yes

13. Do you have any known allergies? ☐ No ☐ Yes

QUESTIONS FOR WOMEN

14. Are you currently pregnant? ☐ No ☐ Yes (how many weeks)

15. Did you give birth during the last year? ☐ No ☐ Yes (when) _____

Completion date ____ May/June (underline the applicable option) 2020

Appendix 3

Subject Information Sheet and Informed Consent Form

Dear _____,

You are being offered to take part in the study named « Population study of SARS-CoV-2 antibodies prevalence in residents of St. Petersburg, Russia based on blood serum tests; socioepidemiological study», directed to the evaluation of prevalence of the novel coronavirus in St. Petersburg, Russia as well as to the assessment of immune reaction to this infection.

The main objective of this study conducted by the European University at St. Petersburg with the support of Polymetal International PLC, is to evaluate the scale of novel coronavirus infection. Results of this study will help to make conclusions about the stage of the epidemics. This study may also help to make rational decisions about the scale and duration of controlling measures needed to manage the epidemics. For this study, we need some information which will be collected by means of special questionnaires, as well as the results of anti-SARS-CoV-2 antibodies testing.

The study is dedicated to the assessment of the spread of novel SARS-CoV-2 coronavirus. Main symptoms of infection are usually mild and resemble those of common cold. Nevertheless, this virus may cause serious life-threatening complications related to respiratory organs damage. The novel virus has provoked a pandemic, and many countries has reacted with the introduction of different measures of infection control.

This invitation is directed to you personally. All participants have been selected randomly, so that results would reflect the objective image of the infection prevalence in residents of St. Petersburg. No other person may take part in this study in your place. Participation in the study is completely voluntary. To take part in the study, you will have to provide your written consent for data transfer. You have full right to refuse participation at any moment, without explaining the reason.

Please, read this Information Sheet thoroughly; it contains detailed information about the study and participation. In addition to this Information Sheet, we provide you with the Informed Consent Form. You can sign it at the clinic after receiving full information about the study, if you decide to take part.

You can always clarify any detail by asking study coordinators and investigators at the European University at St. Petersburg.

Study coordinator at the clinical site:

Name: _____

Phone: _____

Study coordinator, an employee of the European University at St. Petersburg:

Name: _____

Phone: _____

Why is this study being conducted?

The main objective of this study is to evaluate the scale of novel coronavirus infection. Results of this study will help to make conclusions about the stage of the epidemics. Presence of antibodies in blood permits to make a conclusion about a past SARS-CoV-2 infection with some certainty. Based on the number of people who have had the infection in a small investigative sample, we could evaluate its prevalence in a region. There is no vaccine or effective treatment for this disease yet, so it is very important to obtain information about its spread and presence of immunity. To make decisions on the scale and duration of controlling measures needed to manage the infection, it is essential to evaluate the scale of the epidemics and understand which stage of the infection spread is ongoing in each region.

How does the test for anti-novel coronavirus antibodies differ from other tests?

Unlike tests which detect presence of the virus in the body, this test permits to evaluate if a person has had SARS-CoV-2 infection before, and how their immune system has reacted. Thus, the antibody test does not provide information about the current presence of the virus in the body, and it cannot be used for diagnostics. As human body needs some time to develop antibodies, this test may rather reflect a past infection, symptomatic or asymptomatic.

If I have a positive result of the antibody test, does it mean that the novel coronavirus is not dangerous for me anymore?

Unfortunately, we don't know yet how much the immunity detected by this test is able to protect a person from a repeated infection with the same virus. One of additional objectives of this study is to attempt to answer this question exactly. Based on the experience of studying other infectious diseases, we know that such protection is possible, but there are still no exact data for the novel coronavirus. Thus, even a positive result of the antibody test cannot be a reason of refusing to use means of individual protection, which include personal hygiene and physical distancing.

Can anyone take part in the study instead of me?**A person I know has done a test already; can they be offered the study participation in my place?**

All potential participants of this study have been selected randomly, using methods which are being used, for example, in sociological surveys. By means of these methods, the investigators will be able to make conclusions about the infection spread in the whole region while having information only for a small amount of antibody tests. Participation of any other person who would like to or has already done the test may bias the results of this study, so that the result would not reflect the real spread of infection.

Does it make sense to repeat the test in case of positive result?

Currently, we don't know for how long the anti-novel coronavirus immunity maintains. To obtain this information, it is necessary to evaluate repeated testing results in same participants. Several persons are not enough to conclude about the immunity maintenance with certainty, but if there are enough people who agree to provide information about the repeated testing results, the investigators will be able to answer the question about the immunity durability.

Can this test give erroneous results?

Any test can give erroneous results. There is a small probability that a positive result will be obtained in a person who does not have antibodies, and vice versa, sometimes the test does not detect antibodies while a person has them. Errors in the anti-novel coronavirus antibody detection may be in part explained by the fact that these tests are pretty new. If

possible, tests made by different manufacturers will be used to detect antibodies; this will help to identify the most precise test.

I have symptoms of cold; can I participate in the study?

For safety reasons, to protect you and others, people with signs and symptoms possibly related to respiratory infections cannot take part in the study. If this is the case, you need to follow medical recommendations and self-isolation instructions if applicable. Nevertheless, if you have received this invitation, you will be able to take part in the study after your condition resolves, taking into account medical recommendations. Only results of the tests performed after your disease resolution will be collected in this study.

How much time will I spend in the study and what does it involve?

This study includes at least 2 questionnaires and at least 1 blood sampling for the testing. You can complete 1 questionnaire by phone, and the other at a clinical site. General duration of answering questions will be about 15 to 30 minutes. Answers are critically important to define if the study participants reflect a whole region population well enough, and which adjustments should be done during the calculation of the infection spread in this population. Some questions are needed to evaluate factors which may influence the probability of infection. A blood sampling is also planned in this study with the objective of performing a test.

The blood sampling will be performed as a service provided by the clinical sites, but for the participants of the study it will be free of charge. Laboratory tests will be performed later and do not require your presence. Blood sampling may be partly performed by means of a catheter which is a thin plastic tube, or a needle inserted in a vein on your forearm. During the blood sampling you may feel weakness or mild pain; at the place of the puncture, a bruise, irritation, or redness may appear. In very rare cases, an infection may develop. To perform tests, we will need 2 tubes of blood, 5 ml each. For another test, we will need several drops of blood collected by means of a fingertip puncture with a special thin needle; this procedure may bring minimal discomfort.

What tests will be used?

In this study, at the first stage we plan to use 1 or 2 types of coronavirus tests. They will be performed in laboratories and will answer the question about the presence of anti-coronavirus antibodies in blood. You will receive only results of the first test.

What personal benefits will participation in the study give me?

Participation in this study will not give you any personal benefits from the point of view of your health, except receiving information about a possible past infection. This information does not imply protection from the virus in the future. Nevertheless, by taking part in this study you will help to obtain information about the disease spread and characteristics of the immunity against the novel coronavirus at the population level. In the future, this may indirectly influence you, as means of epidemic control effect all aspects of life of a country population. No monetary compensation for the participation in this study is planned. But, in the frame of the second and later study stages, your transport expenses for commuting to the clinic may be compensated; we may also plan a compensation in the form of gift cards.

Personal data?

To perform analysis, the investigators do not need your personal data (like your name, contact phone number, address, passport data), so they will not be transferred from clinical sites. The alignment of completed questionnaires and test results will be performed at clinical sites, and later anonymized data will be used for analyses. Laboratory testing will not involve transfer of personal data to any other laboratories.

Where will I be able to see the study results?

Results of the study will be published in the form of press-releases and scientific articles in Russian and English. Detailed information may be followed at the European University at St. Petersburg webpage. All information about this sociological epidemiological study is open for general public.

When will the study end?

Timing of the study completion depends on its initial results. It is very important that the study continues while there are unanswered questions about the disease spread and immune system reaction with time. It is possible that the study will last at least for 1 year. For this reason, we cannot currently say how many times testing will be needed. We would like to perform at least 10 testing visits. We will be able to inform you about the timing and interval between the tests after your first visit. You have a right to refuse to take part in repeated tests when you decide.

May I be invited for blood sampling again?

This study includes several stages, and most probably we will ask you to come for testing again. It is necessary to answer the questions about the durability of immunity, its dynamics and changes in the disease spread. All these issues are very important to understand this novel disease, and this information can radically change our understanding of its nature and characteristics of the virus. In the Informed Consent Form, we have included a possibility of multiple testing.

Consent for the study participation

I have been offered to take part in the study « Population study of SARS-CoV-2 antibodies prevalence in residents of St. Petersburg, Russia based on blood serum tests; socioepidemiological study» (short name: Serological study of COVID-19 prevalence in St. Petersburg).

I have familiarized myself with clarifications and received exhaustive information about the study and related blood sampling, testing, data collection, management, and transfer. I have had enough time to consider my participation in this study. I understand that participation in this study is voluntary. I have a right to withdraw my consent to the study participation at any moment, without explaining the reasons. Withdrawal of consent will not have any negative consequences for me and will not affect my medical care at the clinical sites where the study is being conducted or at other medical institutions. Two copies of this Consent Form will be signed: one will be retained at the clinical site, and the other is intended for me.

By signing below, I confirm the following:

- I have read and understood the information provided in the Patient Information Sheet;
- I have had an opportunity to ask questions, and I have received exhaustive answers to all my questions;
- I voluntarily agree to take part in this study;
- I do not waive my legal rights by signing this document;
- My signature on this document means that I agree to take part in this study;
- I am aware that I may terminate my participation in the study at any moment;
- I voluntarily agree that my data collected during the study may be used with scientific objectives and published with the condition of confidentiality maintained;
- I agree that in case if I provide consent I will receive a signed and dated copy of this document;
- My signature on this document means that I agree to take part in the study described in the attached Information Sheet, and voluntarily give my consent to a single blood sampling, testing, using of the data provided by me during study-related surveys, and data collected by clinical site staff, including the results of testing for anti-SARS-CoV-2 antibodies.

First, second, last name (full) _____

Date: _____ / _____ / 2020 Signature: _____

Mесто: _____

My signature below means that I give my consent to multiple (up to 10 times) blood sampling, testing for anti-SARS-CoV-2 antibodies and transfer of the results of repeated tests for analysis within the objectives of this study.

First, second, last name (full) _____

Date: _____ / _____ / 2020 Signature: _____

Place: _____

I give my consent to contacting me again in relation to coronavirus epidemics studies:

Phone number: _____

email: _____@_____

Signature: _____

Study coordinator signature:

First, second, last name (full) _____

Date: _____ / _____ / 2020 Signature: _____

Place: _____