SoroEpi MSP Phase 2

Household Survey to Estimate the Seroprevalence of SARS-CoV-2 Infection in Adults in the City of São Paulo, Brazil. Serial Cross-sectional Studies with Probabilistic Samplings

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I - JUSTIFICATION AND PILOT STUDY

The SARS-CoV-2 virus, which causes the disease COVID-19, has been spreading in the city of São Paulo since the end of February 2020 and has led government authorities to implement social isolation measures. Due to a large number of asymptomatic and oligosymptomatic infected people, and the small number of laboratory tests available, the actual percentage of infected people in the general population is still unclear, and so is how the pandemic is progressing in the municipality of São Paulo (MSP).

It is fundamental to know and monitor the percentage of the general population that has been infected during the pandemic period to support public policy for controlling the COVID-19 pandemic. The percentage, or prevalence, of infection in the population is essential data that must be taken into account when deciding when and how the easing of social isolation should occur (Goudsmith, 2020).

During May 2020, the SARS-CoV-2 Monitoring Group from the MSP devised, planned, and conducted a probabilistic sampling household serosurvey in six MSP districts. A representative sample of the adult population living in the Pari, Belém, Água Rasa, Jardim Paulista, Bela Vista, and Morumbi districts was randomly selected, and the chosen people were invited to participate in the study. This pilot project had two objectives: i) to estimate the prevalence of SARS-CoV-2 infection in the adult population of the MSP by detecting specific antibodies against the virus, and ii) to test the instruments and procedures for data collection in the fieldwork to conduct a series of household serosurveys to monitor the extent and evolution of novel coronavirus infection in the MSP. A questionnaire was used to collect socio-demographic information and to investigate the occurrence of COVID-19-related symptoms; then, venous blood samples were taken for serology tests.

The preliminary results of the pilot project, based on 299 adult participants, showed that the surveyed regions had a weighted seroprevalence of SARS-CoV-2 infection of 4.8% (95% CI 2.6-7.0%) considering complex sampling. The data collection procedures proved to be adequate, and the results of the fieldwork and the response rates are shown in Figure 1. The results of the statistical analyses are in progress and will be part of the concluding report and the scientific manuscript, being made available shortly.

The pilot project achieved the expected objectives. Given its success, we propose to follow prospective cross-sectional serial serosurveys. These surveys have a target population of all adult inhabitants of the entire MSP.

II - OBJECTIVES

Main objective

To monitor the progress and extent of the SARS-CoV-2 pandemic in the adult general population of MSP periodically.

Specific objectives

- ⇒ To estimate the percentage of adults infected with SARS-CoV-2 residing in the MSP, in six consecutive cross-sectional serosurveys during the pandemic period.
- ⇒ To describe COVID-19-related symptoms in the study population.
- ⇒ To investigate serostatus patterns among household contacts.

III - METHODS

All the methodological procedures detailed below will be repeated in each of the six planned surveys.

1. Target population and study design

Household seroepidemiological surveys will be performed to answer the objectives described above. There will be six studies conducted in series, with a methodology similar to that used in the pilot project. These are cross-sectional prospective studies, the target population is the adult inhabitants (18 years and over) of permanent private households in the MSP. The surveys are expected to occur monthly, but this can be changed based on the results found in each closed survey.

Legally incapable people, those who cannot consent to participate in the study, and those with health problems that make venipuncture impossible, will not be included in the survey.

2. Sampling plan

The MSP has an estimated population of 11,869,660 inhabitants, 8,407,202 of whom are 18 years of age or older, according to 2020 projections by the Statewide System for Data Analysis (SEADE) Foundation (https://perfil.seade.gov.br/?#). Administratively, the municipality is organized into 96 districts, distributed in six regions: central, west, south, southeast, east, and north.

The adult population will be divided into two strata of equal size, which will constitute study categories. The average income of the MSP districts will be used as a stratification variable. Thus, the first stratum will consist of the adult population residing in the higher-income districts and the second in the lower-income districts.

Each category is expected to have a sample size of 580 people. The calculation was made using the algebraic expression (Silva, 2015):

$$n = \frac{P.(1-P)}{(d/z)^2} \cdot deff$$

P=0.05 being the parameter to be estimated, z=1.96 is the value of the normal curve corresponding to a 95% confidence interval, *deff*=2 is the effect of the design, and d=0.025 is considered the tolerable sampling error.

The expected total sample size is 1,160 people. Three thousand (3,000) people will be drawn, considering a 40% response rate.

We will use probabilistic sampling for those selected to be tested, by clusters, in two stages: the census sector and household.

In the first stage, 120 census sectors will be drawn by systematic sampling with probability proportional to size, with the number of households according to the 2010 IBGE Census being used as a measure of size. The districts will be arranged by income average to conduct the drawing to obtain an implicit stratification by income.

In the second stage, ten (10) private households will be selected by systematic drawing in each census sector in the sample, from the list of households obtained by “plotting out the sector.” This activity will establish a complete and updated register of every household, occupied or not, that exists within each sector.

There will be no drawing within the household. All residents in the selected households over the age of 18 will be included in the sample. There should be 2.33 people, on average, found per household.

The sampling fraction corresponding to the sampling process (United Nations, 2005) described above is:

$\mathrm{f} = \frac{120 \cdot M_i}{M} \cdot \frac{10}{M_i'} \cdot \frac{2.33}{2.33}$, in which M_i and *M* are the numbers of households in the sector *i* and in the total study area, according to data from the 2010 Census, M_i' is the updated number of households in the sector *i* obtained in the “plotting of the sector.”

The switching of randomly selected sampling units (sectors, households, or residents) has not been considered during this study. If the interview is not conducted because the selected household was unable to be visited or the selected resident was unavailable for interviewing/testing, the corresponding situation will be recorded. The percentages of non-responsive households and residents will be recorded by the census sector, as will the reasons why.

Three visits are scheduled at different times and days to each household in the sample to reduce the non-responsive percentages. Other strategies will be adopted with this same objective, such as: distributing pamphlets (Annex I) while "plotting the sector," media disclosure, making telephone calls and sending letters printed and signed by the institutions participating in the studies (Annex II).

3. Data collection

Data can only be collected after all relevant research information that the potential participants provided at the time of the home visit is clarified. All selected-household residents, 18 years or older on the day of the interview, will be invited to participate in the study. The blood samples will only be collected after the participant explicitly consents by signing the Free and Informed Consent Form (FICF – Annex III). All ethical aspects involved in the consecutive studies are detailed below in item 5, “Ethical Aspects of Research.”

As mentioned earlier, the data collection procedures will be similar to those of the pilot project. We will conduct face-to-face interviews using a questionnaire (Annex IV) on mobile devices to obtain socio-demographic information and record the occurrence of clinical symptoms suggestive of COVID-19. Professionals from IBOPE Inteligência will approach the home and conduct the questionnaire with the residents.

A venous puncture will be performed after the interview to collect a blood sample from the respondent, which will be sent to the laboratory where tests will be run to detect antibodies against SARS-CoV-2. The blood sample will be taken by a trained health professional who will accompany the interviewer during the approach to the households. The team of health professionals will be made available by Grupo Fleury.

The study participants’ contact information (address and telephone number) will be obtained while conducting the interviews, so the result of the test can later be made available. This personal information will be under the sole responsibility of the research coordinator.

Quality control

All research will be governed by ethical standards of the Brazilian Association of Research Companies (ABEP) and the World Research Association (ESOMAR). The procedures are also following the international quality standard in Market Research and Opinion of ISO 20.252 and the international standard of Quality Management ISO 9001.

The interviews will be conducted by a team of properly trained, supervised, and identified interviewers.

All interviewers and health professionals will go to the field with the appropriate Personal Protective Equipment, following the guidelines listed in the Standardized Operating Procedure released by the Brazilian Ministry of Health. This is to protect research participants, and it minimizes the risk of coronavirus infection. It will also protect the professionals who will collect data and biological materials from individuals who agree to participate in the research.

• At least 20% of the interviewers' material will be verified.

• 100% of the questionnaires will be submitted to an electronic consistency test to verify the coherence of the answers.

Laboratory testing

The blood analysis for detecting IgM and IgG antibodies will be performed in Grupo Fleury laboratories according to the manufacturer's guidelines using the CLIA methodology (chemiluminescence), MAGLUMI 2000 PLUS equipment, and the "MAGLUMI IgM 2019-nCoV (CLIA)" and "MAGLUMI IgG 2019-nCoV (CLIA)" kits, all from Snibe Diagnostic. The test was validated according to protocols based on recommendations from the Institute of Clinical and Laboratory Standards Institute (CSLI) and the American College of Pathology.

The tests will be conducted by mixing and incubating the study participants' serum samples with buffer solution and magnetic microspheres coated with IgM monoclonal antibodies and with the recombinant SARS-CoV-2 antigen (IgG test), separately forming immune complexes. After precipitation in a magnetic field, the supernatant is decanted and washed. Then, ABEI (non-enzymatic nano molecule) labeling is performed with the recombinant SARS-CoV-2 antigen in the anti-IgM test and anti-IgG human antibodies test, followed by incubation to form complexes. After precipitation in a magnetic field, the supernatant is decanted and washed. Subsequently, *starters 1+2* are added to initiate a chemiluminescent reaction. The light signal is then measured by a photomultiplier as relative light units (RLUs), which are proportional to the concentration of anti-SARS-CoV-2 IgM and IgG in the sample. The samples will be analyzed in a single batch to minimize experimental variations

Samples from patients diagnosed with the COVID-19 RT-PCR test and samples from a control group (blood donors from 2018, employees without flu symptoms vaccinated in the 2020 campaign, a panel of positive samples for other non-SARS-CoV-2 respiratory viruses, and samples from carriers of other infectious diseases) were used to determine the reference values. The results of the analyses of these samples led to the following reference values:

IgG	Reagent >1.4 UA/mL
	Indeterminate 0.8 to 1.4 UA/mL
	Non-reagents <0.8 UA/mL
IgM	Reagent >1.0 UA/mL
	Indeterminate 0.8 to 1.0 UA/mL
	Non-reagents <0.8 UA/mL

Detecting IgM and IgG antibodies against SARS-CoV-2 depends on the number of days after the onset of symptoms, and IgM approaches 100% from the seventh day, and IgG approaches 100% from the fourteenth day.

Individuals who present at least one of the positive serologic results (IgG or IgM) will be considered positive. Those who present indeterminate results will be offered to have a new sample taken 7 to 15 days after the date the sample was taken by the research team. However, the result of this new test will not be used to calculate prevalence.

4. Data analysis

The data obtained in the research is what should be considered since the current sector sizes differ from those in the 2010 Census. The individuals in the sample will be selected with unequal probabilities, and these differences should be adjusted. The weights will be given by inverting the sampling fractions used in each selection stage. They will also be adjusted by response rates and post-stratification according to age and sex. The seroprevalence of populations living in the two strata will be compared. The population subgroups of both strata will be compared and defined according to socio-demographic variables: gender, age, self-reported race/color, education, work in the healthcare area, and according to self-reported COVID-19 symptoms and previous diagnosis of SARS-CoV-2 infection.

The estimates will be obtained, taking into account the complex aspects of the sampling plan (drawing of clusters, stratification, and classification). Chi-square tests will be used to make comparisons with the Rao-Scott adjustment (Pessoa, 1998).

5. Ethical Aspects of Research

The project will be developed based on information and laboratory examinations of a sample of the adult population residing in the MSP. When invited to participate in the study, they will be duly informed by the research team that participation is voluntary and confidential, and the purpose of the research, the interview, and of the venous blood collection by puncture, including its risks, will be explained. The risks involve two aspects: i) venipuncture for collecting the sample may generate hematoma or phlebitis at the puncture site or some transitory mark on the skin at the point of collection, and ii) the participant will be visited by an interviewer and a healthcare professional who will take their blood sample. These professionals will be appropriately attired with a face shield, mask, disposable long-sleeved apron, foot protection, and disposable gloves. They will follow all the procedures recommended by the Brazilian Ministry of Health to guarantee biological safety. Thus, the risk of the research participants becoming contaminated by SARS-CoV-2 will be minimized, promoting the protection of

fieldworkers who will collect the data and blood samples. The cited precautions are already adopted in the home collection procedures carried out by Grupo Fleury's teams and are detailed in the "Annex_V_Mobile_Cornoavirus_Testing_Service_Flow" document.

The test result will inform the participants will know if they have ever had contact with the SARS-CoV-2 virus. This result is the only direct benefit to the participant. Still, the study results may help health authorities to plan measures to control the pandemic in the city of São Paulo, Brazil. Potential risks and benefits related to participating in the research are explained in the FICF.

Participants will also be informed they are free to refuse or withdraw their consent at any stage of the research without causing any type of penalty. The FICF includes information on a participant's right to free full assistance, for as long as necessary, in case of harm resulting from this research. They will also be entitled to legally established damages in case of personal injury directly caused by the procedures proposed in the study.

The biological material and information will only be collected after the participant has signed the FICF, which should sufficiently detail all the possible benefits, risks, and procedures that will be performed. The data will be analyzed together and coded without any possibility of compromising the identity of the participant.

All individuals tested in the field will have their contact information registered so that they can receive their test results. Each participant will have an identification number in the research, and the identification data will be in the exclusive possession of the project coordinator for the sole purpose of informing each participant of the laboratory test result. The participants will receive an email with the login and password to access their results online. The communication channel with the researcher responsible for the study will also be available, as described in the FICF.

The project has no commercial ends and aims to bring information to government agencies. Instituto Semeia and Grupo Fleury will partially finance the project. The study participants and researchers listed above will receive no payment of any kind.

The present study complies with the Brazilian Norms and Guidelines that mandate research involving human beings, including Resolutions 466/12 and 510/16 of Brazil's National Health Council.

The amendment to the project will be entered into the CEP/CONEP system by the Grupo Fleury researcher, and fieldwork will only start after its approval. The pilot project was approved on May 2, 2020, CAAE nº 31032620.0.0000.5474.

Storing samples and creating a biorepository (biobank)

Serological tests will be performed using the currently available methodology for detecting antibodies against SARS-CoV-2. However, as they are recently developed tests, their accuracy needs to be evaluated in different contexts and compared with possible new tests that are being developed. This allows the collected serum samples to be stored in a biorepository for one year for possible future testing. The information is described in the FICF.

6. Financing source

Grupo Fleury, Instituto Semeia and Todos pela Saúde are funding the project.

7. Chronogram

The estimated duration of each of the serial surveys is four weeks, according to the following schedule:

Activities	**Week**			
	1	**2**	**3**	**4**
Organization of fieldwork	**X**			
Data collection	X	X		
Database creation and curation		X	X	
Preliminary statistical analyses			X	X
Preparation of materials and documents for disseminating the results			X	X

IV. EXPECTED OUTCOME AND CONTRIBUTION TO FACING THE SARS-CoV-2 PANDEMIC

We expect to achieve a proportional estimate of adult inhabitants of the MSP that have been infected with SARS-CoV-2 since it was first introduced to the city up to the survey date (of the six, monthly data collections).

The present study will provide information fundamental to understanding what stage of the pandemic the MSP is in, and how the virus is spreading in the general

population of the city. This will permit public managers to make decisions based on consistent and updated information on which measures to take to face the SARS-CoV-2 pandemic.

V. DISCLOSING THE RESULTS

All data obtained will be made widely available after the study is completed and will be published in scientific journals.

VI. REFERENCES

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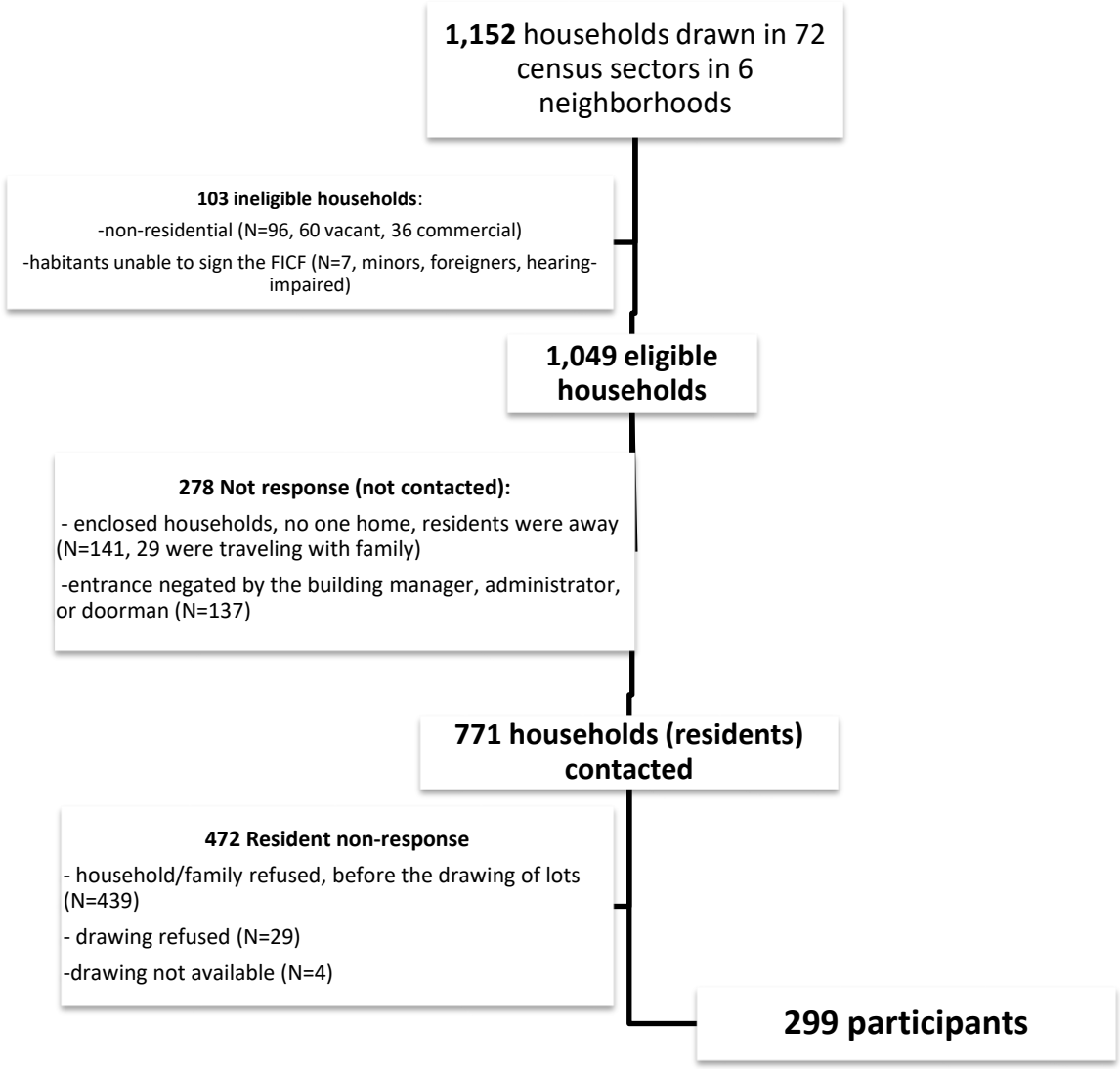
São Paulo, Brazil

May 26, 2020

Figure1. Pilot Project: Summary of Data Collection Steps and Response Rates



Household response rate: 771/1049 = 73.5%

Response rate of contacted residents: 299/771 = 38.8%

Total response rate: 0.735 X 0.388 = 28.5%

ANNEX I: Disclosure Leaflet

Scientific Research on the Novel Coronavirus: Your Participation is Very Important!

Many scientists believe that the number of people already infected by SARS-CoV-2 is much higher than that detected in hospitals. The reason for this suspicion is that there are many people who, after being infected, have no symptoms or have symptoms so mild that they can be mistaken for the flu.

This study proposes to identify the fraction of people living in the region that have been infected by the virus and are probably already resistant to it.

Who is conducting this research?

This project is being conducted by a group of renowned scientists and doctors who have joined forces with Grupo Fleury, IBOPE Inteligência, and Instituto Semeia. They are a group of specialists and substantiated institutions with a solid reputation in healthcare.

Research Participants

To begin the study, IBOPE Inteligência will draw one of the household residents (18 or over). In all, 720 households will participate.

After receiving information about the study and signing a Free and Informed Consent Form, the resident will answer a straightforward questionnaire and agree to the collection of a venous blood sample taken by a+ Medicina Diagnóstica from Grupo Fleury, to ascertain the presence of antibodies against the new Coronavirus (SARS-CoV-2) in the participant's blood.

The resident who participates in the study will receive the exam result by mail and an exclusive login and password to access the result online. There is no cost to participate.

Safety

For their safety, the entire project team is properly accredited and uses Personal Protective Equipment according to the guidelines of the Brazilian Ministry of Health. Blood samples will be exclusively taken by a trained healthcare professional from a+ Medicina Diagnóstica, of Grupo Fleury.

IBOPE Inteligência and Grupo Fleury guarantee that the information provided by participants is confidential and will be treated anonymously. Respondents will not be identified, following all international ethical standards on healthcare research. The study results will always be treated together and never individually and, subsequently, will be widely disseminated and published in scientific journals.

This research project was approved by the Research Ethics Committee (CEP) under CASE number: 31032620.0.0000.5474.

Doubts?

Your participation is crucial in combating the COVID-19 pandemic. We thank you in advance for your cooperation and, for any doubts, contact us at the following phone numbers:

- Dr. Celso Granato – **Research Coordinator** – (11) 3179-0820 (Medical CAC, option 3)
- Grupo Fleury Ethics Committee – (11) 5014-7771 (Monday to Friday 8 am to 11 am)
- Erivaldo de Pietri – **IBOPE Inteligência** – (11) 3335-8583 / (19) 99773-1811
- Gisele Oliveira – **IBOPE Inteligência** – (11) 3335-8606

ANNEX II: Letter of Clarification to Condominiums and Households

Scientific Research on the Novel Coronavirus

Clarification to condominiums:

São Paulo, Brazil, April 2020.

As you may know, we are in the middle of a pandemic. A novel coronavirus called SARS-CoV-2 is spreading among us.

Many scientists believe that the number of people who have been infected by this virus is higher than that detected in hospitals. The reason for this suspicion is that there are many people who, after being infected, have no symptoms or have symptoms so mild that they can be mistaken for the flu.

It was for this reason that a group of renowned scientists and doctors joined forces with Grupo Fleury, IBOPE Inteligência, and Instituto Semeia to try to discover which fraction of the people in this region have already been infected by the virus and who may already be resistant to the virus.

The households located in the areas selected to participate in the survey were previously registered, and a part of them was drawn to conduct personal interviews. Some of the selected households are in this condominium and, therefore, we would like to ask that you allow the IBOPE Inteligência interviewer to approach the selected households. He will be duly identified and will invite residents to participate in the study.

Only 720 households were randomly selected in São Paulo. The results of the survey could help authorities determine the deadline for ending social isolation.

A resident aged 18 or over will be randomly drawn from each of the selected households to conduct the survey. After receiving information about the study and signing a Free and Informed Consent Form, the resident will answer a straightforward questionnaire and agree to the collection of a venous blood sample to ascertain the presence of antibodies against the new Coronavirus (SARS-CoV-2) in the participant's blood. This test does not indicate you have the virus, but whether your body has been exposed to it.

Residents over 18 years of age who live with the research participant (the selected individual) who wish to take the test to know their serological status regarding SARS-CoV-2 infection will be attended by the research team. The same data collection procedures adopted for the randomly selected householder will be adopted. However, the coinhabitants' test results will not be made available immediately. We will wait for the new exam kits to arrive to evaluate those tests.

The resident who participates in the study will receive the exam result by mail and an exclusive login and password to access the result online. Residents of the same household will also receive a login and password as well as the results by mail, but those exams will take longer to be released.

For everyone's safety, the entire project team is properly accredited and uses Personal Protective Equipment according to the guidelines of the Brazilian Ministry of Health. Blood samples will be exclusively taken by a trained healthcare professional from a+ Medicina Diagnóstica, of Grupo Fleury.

IBOPE Inteligência and Grupo Fleury guarantee that the information provided by participants is confidential, will be treated anonymously, and respondents will not be identified, following all international ethical standards on healthcare research. The study results will always be treated together and never individually and, subsequently, will be widely disseminated and published in scientific journals.

It is important to know that this research project was approved by the Research Ethics Committee (CEP) under CASE number: 31032620.0.0000.5474.

Your participation is crucial in combating the COVID-19 pandemic. We thank you in advance for your cooperation and, for any doubts, contact us at the following phone numbers:

- Dr. Celso Granato – **Managing Researcher** – (11) 3179 0820 (Medical CAC, option 3)
- Grupo Fleury Ethics Committee – (11) 5014-7771 (service from Monday to Friday from 8 am to 11 am)
- Erivaldo de Pietri – **IBOPE Inteligência** – (11) 3335-8583 / (19) 99773-1811
- Umberto Pereira – **IBOPE Inteligência** – (11) 3335-8645/ (11) 99185-9995
- Gisele Oliveira – **IBOPE Inteligência** – (11) 3335-8606

Scientific Research on the Novel Coronavirus

São Paulo, Brazil, June 2020.

As you may know, we are in the middle of a pandemic. A novel coronavirus called SARS-CoV-2 is spreading among us.

Many scientists believe that the number of people who have already been infected by this virus is much higher than that detected in hospitals. The reason for this suspicion is that there are many people who, after being infected, either have no symptoms or have symptoms so mild that they can be mistaken for the flu.

It was for this reason that a group of renowned scientists and doctors joined forces with Grupo Fleury, IBOPE Inteligência, and Instituto Semeia to try to discover which fraction of the people in this region have already been infected by the virus and who may already be resistant to it.

Your residence was chosen to participate in this research, and we would like you to collaborate with these researchers and scientists also participating in the research.

Only 1,380 households were randomly selected in São Paulo. If you decide to participate, at no cost to you, Grupo Fleury will inform you of the results.

This information can also help authorities determine when to end social isolation.

All residents of your household aged 18 or over will be invited to participate in the survey. After receiving information about the study and signing a Free and Informed Consent Form, each participating resident will answer a straightforward questionnaire and agree to provide a venous blood sample to ascertain the presence of antibodies against the novel coronavirus (SARS-CoV-2) in their blood. This test does not indicate you have the virus, whether your body has already been exposed to it.

The resident who participates in the study will receive the exam result by mail and an exclusive login and password to access the result online.

For your safety, the entire project team is properly accredited and uses Personal Protective Equipment according to the guidelines of the Brazilian Ministry of Health. Blood samples will be exclusively taken by a trained healthcare professional from a+ Medicina Diagnóstica, of Grupo Fleury.

IBOPE Inteligência and Grupo Fleury guarantee that the information provided by participants is confidential, will be treated anonymously, and respondents will not be identified, following all international ethical standards on healthcare research. The study results will always be treated together and never individually and, subsequently, will be widely disseminated and published in scientific journals.

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ANNEX III: Free and Informed Consent Form

FREE AND INFORMED CONSENT FORM

Project: SoroEpi MSP. Household Survey to Estimate the Seroprevalence of SARS-CoV-2 Infection in Adults in the City of São Paulo, Brazil, A Serial Cross-sectional Study with Probabilistic Samplings

You are being invited to participate in the **"SoroEpi MSP. Household Survey to Estimate the Seroprevalence of SARS-CoV-2 Infection in Adults in the City of São Paulo, Brazil, A Serial Cross-Sectional Study with Probabilistic Samplings"** survey.

This study aims to assess the percentage of the population that has been infected by the novel coronavirus. It determines how many people have produced immunity to the virus and, therefore, are already totally or partially protected. This study will be conducted under the responsibility of researcher, Dr. Celso Granato, who can be found at Rua General Valdomiro de Lima 508 – Térreo, CEP: 04344-070 or at telephone (11) 3179-0820 (option 3).

If you agree to participate in this study, we will ask you to answer a short questionnaire with questions about you and if you have had any flu-like symptoms recently. In addition to the interview, we will need to puncture the vein in your arm to collect 5 ml of blood, which will be used to run tests that will detect antibodies against the coronavirus. Antibodies are defense proteins that are formed when our body has contact with an external element. The presence of antibodies against the coronavirus, for example, suggests that you had contact with it, and your body has formed memory since contact.

At no time will you be identified. The information obtained in this study will be analyzed together with that of other participants, and no personal information or identification will be disclosed. You will have no financial gain or expense for participating in the survey.

Risks consist of a hematoma or phlebitis (inflammation) at the puncture site or a transitory mark on the skin where the collection is made. You will also receive a visit from an interviewer and a healthcare professional who will take their blood sample. These professionals will be appropriately dressed in gloves, aprons, and disposable masks. They will follow all the procedures recommended by the Brazilian Ministry of Health and have already performed in-home collections for Grupo Fleury, so the risk of contamination is minimal.

You will receive the test result, which will look for the presence of antibodies against the coronavirus. You will receive an email with a login and password to access your result online at

the website "https://resultados.amaissaude.com.br/cliente/," and the communication channel for the researcher responsible for the study – mentioned at the beginning and the end of the document – will also be available. If you feel uncomfortable with a question, you can refuse to answer it with no penalty. The mentioned communication channels will be open to help you clarify any doubts about the result of your exam. This result is the only direct benefit to the participant, but the results may help health officials to plan measures to control the pandemic in the city of São Paulo. Even if the result of the exam is positive, indicating you have had contact with the coronavirus, you should continue following the recommendations of the Brazilian Ministry of Health and the Office of the São Paulo State Government regarding measures to protect the population. This is because there is still a lot of clear information needed on the tests to detect antibodies against the coronavirus and the disease. The researchers responsible for the study will be available to answer any questions you have on the subject.

The spare sample will be stored under suitable conditions for one (1) year at Grupo Fleury. Its sole purpose is to have other serological tests performed to determine the presence of antibodies against the SARS-CoV-2 virus (coronavirus) when, and if, new tests arise. This is because we know that even the traditional serological tests that are already in use, like the one that will be used in this study, may have limited sensitivity. The spare sample will not be subjected to any type of test other than serology for COVID-19 and will be discarded after one year. If there is any new information about your exam, you will be contacted by the study researchers.

Your participation in this research is voluntary. You are free to refuse to participate or withdraw your consent at any stage of the survey without any prejudice or penalty, and your sample will be discarded. An original copy of this Free and Informed Consent Form will remain with you.

Your right to full and free assistance will be guaranteed for as long as necessary if any injury results from participating in this survey. You will also be entitled to legally established damages in case of personal injury directly caused by the procedures proposed in the study.

You will have access to the professionals responsible for the research to clarify any doubts at any stage of the study. The Research Coordinator is Dr. Celso Granato, who can be found at Rua General Valdomiro de Lima 508 – Térreo, CEP: 04344-070, or at the telephone number (11) 3179-0820 (option 3).

If you have any concerns or doubts about the research ethics, please contact the Grupo Fleury Research Ethics Committee – Rua General Valdomiro de Lima 508 – Térreo. CEP: 04344-070. Phone (11) 5014-7771. Email: instituto.fleury@grupofleury.com.br. The service hours are from Monday to Friday from 8 am to 11 am. The Research Ethics Committee is an independent

group of people that exists to defend the interests of research participants in its integrity and dignity and to contribute to ethically developed research standards.

This research project was registered together with the Grupo Fleury Research Ethics Committee under CAAE number: 31032620.0.0000.5474

I, _____,

CPF: _____ certify that I have read, understood, and discussed the content of this Free and Informed Consent Form and **freely agree to participate in this study in an informed manner**, authorizing the procedures listed above:

Participant's Signature	Project Representative's Signature
_____	_____
Date:	Date: