

## CONSENT DOCUMENT FOR SURVEILLANCE PROGRAM

Georgia Institute of Technology

**Project Title:** SARS-Cov-2 Surveillance Testing at Georgia Tech

**Principal Investigator:** Greg Gibson, PhD

**Protocol and Consent Number:** H20195

**What am I Being Asked to Do?** You are being asked to participate in a voluntary study to evaluate the incidence of the SARS-Cov-2 virus on campus. We are asking you to participate as a member of the campus community as part of our efforts to reduce transmission of the virus.

**What Is This Study About?** This is a surveillance study. It will help us identify “silent carriers” who do not know they have the virus, but may be transmitting it. If your results are positive, you may be infected. Students will be referred to STAMPS and staff will be recommended to seek immediate medical care, while the Institute will require a period of quarantine and is required to inform the State of Georgia Department of Public Health. If your results are negative, you can carry on with your business as normal. The results will help you and your colleagues continue to work and study on campus while reducing the risk of a new outbreak.

**What Procedures Will I be Asked to Follow?** You will sign the consent online, fill in a brief survey regarding exposure to COVID-19, and then provide a saliva sample. We will then test for the presence of virus with a “PCR test” that has also been certified by the FDA as a clinical diagnostic test. You will be informed by email within 24 hours that your results are available through our secure online portal, where you may access them. You will be given the option to approve anonymous “tagging” that you have tested positive to the CoEPI contact tracing app.

### **Are There Any Risks or Discomforts you Might Experience by Being in this Study?**

As this is only a survey with provision of a saliva sample, there are minimal risks to participation and no physical discomfort is expected. The results of the test may however cause some anxiety if they are positive, and potentially lead to a requirement for a week or more of self-quarantine according to policies that will be determined by the University System of Georgia and Georgia Tech governance. Being positive does not mean that you will necessarily develop COVID-19 symptoms, and does not predict how severe the disease may be.

### **What Are the Reasons You Might Want to Volunteer For This Study?**

For your own peace of mind in knowing that you are probably not infected. To be allowed to return to work knowing you are unlikely to infect others around you. As a service to fellow staff and students in preventing transmission of the virus.

## **Do I Have to Take Part in the This Study?**

You do not have to participate, it is your voluntary decision to do so. Failure to participate may delay your ability to return to campus, but you are free to decide. There will be no financial or academic consequences of not participating.

## **You are being asked to be a volunteer in a survey.**

**Purpose:** Georgia Tech has authorized the use of a test for presence of the SARS-Cov-2 virus in saliva samples for the purpose of surveillance. This test is based on the CDC-approved polymerase chain reaction (PCR) diagnostic assay, and is "CLIA" certified as a clinical diagnostic test. The results will be used to identify individuals who have the virus but may not know that they are "silent carriers" capable of transmitting it to others. Your voluntary participation is greatly valued as a contribution to maintaining a safe yet active campus.

This document provides basic information on how you will go about giving a saliva sample and what we will do with it. If you have any questions, please ask the coordinator where you donate your sample. Your participation is voluntary and has no impact on your participation in Georgia Tech activities as a student, faculty or staff member.

SARS-Cov-2 is a respiratory virus that often leads to the infectious disease, COVID-19, which starts with mild flu-like symptoms, but in a minority of cases may cause pneumonia, hospitalization and possible death. Unlike most other coronaviruses, it seems to be spread efficiently from infected individuals who either are not yet sick or will not get sick. This is the reason that social distancing is required and people are requested to wear masks in public. It may also live for many hours on surfaces, which is why people are asked to be careful about touching in public. Droplets from a cough or sneeze or possibly even normal breathing can travel a short distance through the air and land on the mouth, nose, or eyes of persons who are nearby. The virus also can spread when a person touches a surface or object with infectious droplets and then touches his or her mouth, nose, or eye(s). If we can identify individuals who have the virus early in their infection cycle, in particular before they start feeling sick, we can stop transmission and hopefully slow or prevent new surges of infection. In that case, most people can confidently continue at work and study and avoid contracting COVID-19.

**Inclusion criteria:** You must be an enrolled Georgia Tech student or an employee of the University, 18 years or older. There are five general categories of inclusion:

1. Self-request
2. Random sampling
3. Likely exposure identified by contact tracing
4. Student athletes
5. Follow-up testing

**Exclusion criteria:** Under 18 years of age, or unwillingness to sign consent

**Procedures:**

Prior to participating in the study, you will be asked to sign this informed consent. You will have two options for doing so:

- (i) Online, by signing with secure DocuSign prior to arriving at the collection site, while also filling in a brief Qualtrics survey regarding potential exposures. You will register as a participant in the study and receive a unique “Barcode Key”, which you will show to the staff at the collection site who will scan it and link it to the alphanumeric key on a saliva sampling tube they will give you.
- (ii) Directly at the collection site by signing the consent, and entering your data and survey answers onto a dedicated laptop computer at the site.

You will then self-collect the saliva sample into a cup, and transfer it to a small plastic tube pre-loaded with a lysis solution that inactivates the virus. The collection site in most cases will be located near the entrance of the EBB1 Building adjacent to green space where you can find the space to safely spit into the vessel. You will dispose of the cup in a Biohazard bag.

The sample will be stored temporarily at the collection site, before being transferred inside EBB where RNA will be extracted and PCR testing for presence of the virus will take place.

After the test is complete, usually within 24 hours, the results will be uploaded to a website, *GT COVID on Campus* (<https://covid19.biosci.gatech.edu/>) where you may log in securely with your GTID to access your result, which in the vast majority of cases is expected to be negative. In the event of a positive, you should immediately go to STAMPS for medical advice and possibly to get a second diagnostic test performed. You will be required to follow Institutional instructions on whether and when you may return to work and being quarantined in set-aside student housing for 2 weeks.

For volunteers who may have been exposed, we expect to conduct two tests between three and six days after the likely exposure. If you have a positive result, we will also be able to provide follow-up testing after a certain period of time to evaluate whether you may no longer be carrying the virus. In both of these situations, you will need to reregister on the website each time you are retested.

**Risks or Discomforts:** As this is only a survey with provision of a saliva sample, there are minimal risks to participation and no physical discomfort is expected. The results of the test may however cause some anxiety if they are positive, and potentially lead to a requirement for two or more weeks of self-quarantine according to policies that will be determined by the University System of Georgia and Georgia Tech governance. This risk needs to be judged relative to the consequences of not knowing whether you have the virus after a possible exposure, as well as relative to existing policies set by the above-mentioned authorities. We will ask you to maintain social distancing and to wear a mask if there is a need to wait while giving your saliva sample

**Potential Benefits:** This study will benefit subjects by generating an accurate daily understanding of the incidence of SARS-Cov-2 in the Georgia Tech community, by identifying likely “silent carriers” who are positive and potentially transmitting virus, and through follow-up sampling defining when an

individual is no longer positive. By being tested and found negative, you may be free to circulate freely earlier than might otherwise occur, and will have peace-of-mind that you are not infected.

The survey complements efforts also proposed by others on campus to trace exposure, and to test for the presence of serum antibodies.

**Compensation:** You will not be compensated for participation.

**Costs to you:** There are no costs to you for participating, other than your time.

**Storing and Sharing your Information:**

Your saliva sample will be destroyed as soon as RNA has been extracted. We will store the RNA only for one month after first generating a PCR test for the presence of virus, in case we need to re-run the test in that time. At that point the RNA sample will also be destroyed.

Your survey data will be stored on a secure server maintained by the Georgia Institute of Technology under security protocols put in place by the Office of Information Technology. It will be stored for a period of up to 5 years following conclusion of the study.

Only summary information on the incidence of the virus according to the criteria set out in the survey will be reported. This will happen by nightly updates of the online website. Positive results will be shared with the team performing contact tracing so that they can inform other individuals potentially exposed by the individual. These reports will be de-identified (time and place only), that is to say, your name or GTID will not be given to anyone other than responsible health personnel.

We may also draft a scientific paper describing our findings, but in no case will an individual's data be reported in a publication.

**Confidentiality:** Your survey results will be kept confidential and not shared with anyone other than the study coordinator and Professor Gibson. Your biological samples will only be associated with the Barcode Key, so no-one performing the diagnostic tests will be able to identify you. Only the study coordinator or Professor Gibson may be able to identify you, but we will use your GT-ID to report positives to STAMPS since by law positive results must be reported to the GA Department of Public Health. The test results will be stored on a secure data portal linked to your Qualtrics survey results. We will comply with any applicable laws and regulations regarding confidentiality.

**Do I Have to Take Part in the This Study?**

You do not have to participate, it is your voluntary decision to do so.

- You have the right to leave the study at any time without giving any reason, and without penalty, before the project is completed. In that case we will delete your survey results from the system.

- Your decision whether or not to participate in this study will have no impact on you as a student or staff member. It will not affect your grade in any courses that you may be taking, or your employment status.
- However, you should be aware that not being tested in the case of likely exposure may also have consequences in the form of regulations that will be decided upon by the USG and Institute governance and periodically updated as the course of the epidemic progresses.
- You do not have to answer all of the questions on the Qualtrics survey
- You do not waive any of your legal rights by signing this consent form.

**In Case of Injury or Harm:**

If you are injured as a result of being in this study, please contact Greg Gibson, Ph.D., at telephone (404) 385-2343. Neither Dr. Gibson nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

**Voluntary Participation and Withdrawal:**

Your participation in this study is completely voluntary, and you have the right to refuse to be in it. You can stop at any time before the study is complete after giving your consent. You may withdraw from the study if you wish.

**Clinically Relevant Information:**

The default assumption of this study is that your result is negative, which we expect to be the case most of the time. However, in a few percent of cases, a positive result will trigger consequences mandated by the Institute with everyone's safety in mind. Please be aware that since we are conducting a biological test on your saliva sample, it has been certified as a clinical diagnostic test, but you may wish to get a second test performed through STAMPS or elsewhere. We will not be testing your own genes in any way.

**Questions about the Study:**

If you have any questions about the study, you may contact Prof. Greg Gibson by email at [Greg.Gibson@biology.gatech.edu](mailto:Greg.Gibson@biology.gatech.edu).