

COVID-19 Testing Consent Form

General Description and Purpose of Test:

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 individuals who experience or display no symptoms. Georgia Institute of Technology (“Georgia Tech”) has developed a two-part community surveillance and testing program (collectively, the “Program”) that will utilize a saliva test to facilitate understanding of the incidence of the SARS-CoV-2 virus on campus.¹

Part One (Community Surveillance): Part One of the Program consists of community surveillance where Georgia Tech will collect saliva samples from the volunteer population in order to determine the incidence of COVID-19 utilizing a saliva test. The results of such surveillance testing will be aggregate, population-level data to provide Georgia Tech leaders with a high-level understanding of the effects of COVID-19 on the health and safety of the campus. The results of Part One will only include aggregate, population-level data.

After completion of Part One, volunteers will receive one of the following communications:

- Recommended for diagnostic testing
- Not recommended for diagnostic testing.²

Part Two (Testing): Part Two of the Program will include diagnostic testing by a CLIA-approved laboratory for samples that Georgia Tech recommends for additional diagnostic testing after the Part One. Such additional diagnostic testing will be performed at Georgia Tech using the original sample or, if necessary, a fresh sample provided by the volunteer. Note that applicable state and local laws regarding public health reporting will be followed for Part Two, and volunteers with a positive result will be encouraged to seek healthcare.

By signing this form, **you agree to both Part One and Part Two.** Your continued participation in the Program throughout the semester is greatly valued as a contribution to maintaining a safe yet active campus.

Key Information for You to Consider:

<p>Voluntary Consent. Participation in the Program is completely voluntary. You have the right to discontinue participation at any time without giving any reason, and without penalty, before the test is complete. If you discontinue participation, your information will be deleted from the system and your sample will be destroyed. Your voluntary consent authorizes Georgia Tech to test your sample during both Part One and Part Two.</p>
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<p>Risks or Discomforts. The Program uses a saliva sample, so there are minimal risks to participation and no physical discomfort is expected. Positive results from Part Two, for applicable volunteers, may cause some anxiety and potentially lead to follow-up procedures according to policies that will be determined by the University System of Georgia and Georgia Tech governance.</p>

¹ Georgia Tech’s Program is purely a public/Institute Health Surveillance Program and not a Human Subjects Research study.

² Neither communication should be interpreted as an indication of a volunteer’s status of COVID-19, and Georgia Tech recommends volunteers continue to take all appropriate precautions.

Costs. There are no costs to you for your voluntary participation in the Program.

Compensation. You will not be compensated for participation.

Confidentiality. Georgia Tech will disclose test results collected during Part Two to the county, state, or to any other governmental entity as may be required by law. The information disclosed may include, but is not limited to, your name, age, race, ethnicity, sex, address, zip code, and county. Georgia Tech will comply with all applicable laws and regulations regarding the storage and transmission of your confidential information.

Storing Information. Your saliva sample will be stored for up to one (1) week after Part One in case the test needs to be re-run. Your survey data will be stored on a secure server maintained by Georgia Tech under security protocols put in place by the Office of Information Technology.

Sharing Information. Positive and negative diagnostic test results from Part Two will be shared with the applicable government entity as required by law and the team performing contact tracing on campus so that individuals that may have been exposed can be informed to take precautions. Any information shared with these individuals will be maintained under confidentiality and security protections.

Procedures:

1. You will be asked to pre-register as a volunteer in the Program, fill-out a brief survey, and sign this consent form online or at the collection site.
2. Once registration is complete, you will receive a unique “Barcode Key”. You will show your assigned Barcode Key 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 provide to you.
3. You will then, under supervision, self-collect the saliva sample from your mouth into a small plastic cup and then into a vial pre-loaded with a solution that inactivates the virus, using a plastic bulb pipette that we will provide. The sample will be temporarily stored at the collection site before being transferred to the lab for testing.
4. Once processing is complete, usually within forty-eight (48) hours, the surveillance results will be uploaded to the website, GT COVID on Campus (<https://mytest.gatech.edu>), where aggregate data will be reported describing incidence on campus that day and cumulatively.
5. After surveillance results have been obtained in Part One, volunteers will receive one of two responses as outlined above (*i.e.*, not recommended for diagnostic testing or recommended for diagnostic testing). However, volunteers should not interpret this response as an indication of their status of COVID-19. Volunteers should continue practicing appropriate precautions and recommendations provided by Georgia Tech. If your sample was recommended for diagnostic testing, your original sample will be processed by a CLIA certified lab and diagnostic results will be provided.
6. If a positive diagnosis is obtained after diagnostic testing in Part Two, we recommend you seek immediate medical advice from either Stamps Health Services or a medical professional such as your primary care physician. If you are a student, Stamps Health Services will provide any Institutional instructions on next steps.

Contact Information:

For any questions or concerns, you may contact Greg Gibson, Ph.D. by telephone at 404-385-2343 or by email at Greg.Gibson@biology.gatech.edu.

Consent:

I acknowledge and agree that I have read, understood, and agreed to the statements contained within this form. I have been informed about the purpose of the Program, procedures to be performed, potential risks and benefits, and associated costs. I have been provided an opportunity to ask questions before proceeding with a test and I understand that if I do not wish to continue with the collection, testing, or analysis of a COVID-19 test, I may decline to receive continued services.

I have read the contents of this form in its entirety and voluntarily consent to participate the Program.

Participant Name (printed)

Participant Signature

Date