

**AGREEMENT FOR
SPONSORED COVID-19 ANTIBODY STUDY**

THIS AGREEMENT ("Agreement") is made and entered into as of the date of execution by both parties, by and between Lee County, a political subdivision of the State of Florida, hereinafter referred to as the "County" and Florida Gulf Coast University Board of Trustees (FGCU), a public body corporate of the State of Florida, whose address is 10501 FGCU Blvd. S., Fort Myers, FL and whose federal tax identification number is 65-0753801, hereinafter referred to as "Vendor."

WITNESSETH

WHEREAS, the County intends to utilize Federal CARES Act dollars to help fund a FGCU COVID-19 Comprehensive Antibody Public Health Study; and,

WHEREAS, the County evaluated the COVID-19 Comprehensive Antibody Public Health Study Proposal received and found the Vendor qualified to provide the necessary services; and,

WHEREAS, the Vendor has reviewed the services to be supplied pursuant to this Agreement and is qualified, willing and able to provide all such services in accordance with its terms.

NOW, THEREFORE, the County and the Vendor, in consideration of the mutual covenants contained herein, do agree as follows:

I. SERVICES

The Vendor agrees to diligently provide all services in accordance with the project Scope of Services made part of this Agreement as Exhibit A, attached hereto and incorporated herein. Vendor shall comply strictly with all of the terms and conditions of Vendor's proposal for Sponsored COVID-19 Antibody Study, a copy of which is attached as Exhibit B and is deemed incorporated into this Agreement.

II. TERM AND DELIVERY

A. This Agreement shall commence immediately upon execution by both the County and the Vendor, and shall continue for one (1) year. Outcome assessment, presentation and publication are expected to continue beyond the term of this contract. Vendor will provide County with a report six months after full payment on the contract. Vendor may request an extension of time for the report.

B. A purchase order not to exceed \$450,000.00 (Four Hundred Fifty Thousand Dollars and 00/100) must be issued by the County before commencement of any work or purchase of any goods related to this Agreement. The County will pay the Vendor within 15 days of the amount invoiced.

III. COMPENSATION AND PAYMENT

- A. The County shall pay the Vendor in accordance with the terms and conditions of this Agreement for providing all services as set forth in Exhibit A attached hereto and incorporated herein. Said total amount to be all inclusive of costs necessary to provide all services as outlined in this Agreement, and as supported by the Vendor's proposal for Sponsored COVID-19 Comprehensive Antibody Public Health Study.
- B. Notwithstanding the preceding, Vendor shall not make any deliveries or perform any work under this Agreement until receipt of a purchase order from the County. Vendor acknowledges and agrees that no minimum order or work is guaranteed under this Agreement and County may elect to issue no purchase orders. If a purchase order is issued, the County reserves the right to amend, reduce, or cancel the purchase order in its sole discretion.
- C. All funds for payment by the County under this Agreement are subject to the availability of CARES Act funding. In the event CARES Act funding is unavailable, the County will terminate the contract, without termination charge or other liability. If at any time funds are not appropriated for the continuance of this Agreement, cancellation shall be accepted by the Vendor on thirty days' prior written notice, but failure to give such notice shall be of no effect and the County shall not be obligated under this Agreement beyond the date of termination.

IV. METHOD OF PAYMENT

- A. The County shall pay the Vendor in accordance with the Local Government Prompt Payment Act, Section 218.70, Florida Statutes, upon receipt of the Vendor's invoice and written approval of same by the County indicating that the services have been provided in conformity with this Agreement.
- B. The Vendor shall submit an invoice for payment to the address indicated on the purchase order on a monthly basis and provide an activity report for the month for those specific services as described in Exhibit A that were provided during that invoicing period.
- C. For partial shipments or deliveries, progress payments shall be paid monthly in proportion to the percentage of services delivered on those specific line items as approved in writing by the County.

V. ADDITIONAL PURCHASES

- A. No changes to this Agreement or the performance contemplated hereunder shall be made unless the same are in writing and signed by both the Vendor and the County.
- B. If the County requires the Vendor to perform additional services or provide additional product(s) related to this Agreement, then the Vendor shall be entitled to additional compensation based on the Fee Schedule as amended to the extent necessary to accommodate such additional work or product(s). The

additional compensation shall be agreed upon before commencement of any additional services or provision of additional product(s) and shall be incorporated into this Agreement by written amendment. The County shall not pay for any additional service, work performed, or product provided before a written amendment to this Agreement.

Notwithstanding the preceding, in the event additional services are required as a result of error, omission or negligence of the Vendor, the Vendor shall not be entitled to additional compensation.

VI. LIABILITY OF VENDOR

- A. To the extent provided under Section 768.28 of the Florida Statutes, Vendor assumes any and all risks of personal injury and property damage, deprivation, or infringement (including, but not limited to, intellectual property) attributable to the negligent acts or omissions of the Vendor and its officers, employees, servants, and agents while acting within the scope of their employment by Vendor. Nothing contained herein shall be construed or interpreted as (1) denying to the Vendor any remedy or defense available to it under the laws of the State of Florida; (2) the consent of FGCU, its affiliates, the Board of Governors, the State of Florida or its officers, employees, servants, agents, agencies, political subdivisions, or public bodies corporate to be sued; (3) a waiver of sovereign immunity of FGCU, its affiliates, the Board of Governors, the State of Florida or its officers, employees, servants, agents, agencies, political subdivisions, or public bodies corporate beyond the waiver provided in Section 768.28, Florida Statutes; or (4) constituting a hold harmless agreement on the part of the Vendor.
- B. This section shall survive the termination or expiration of this Agreement.

VII. RESPONSIBILITIES OF THE VENDOR

- A. The Vendor shall be responsible for the quality and functionality of all products supplied and services performed by or at the behest of the Vendor under this Agreement.
- B. The Vendor warrants that it has not employed or retained any company or person (other than a bona fide employee working solely for the Vendor), to solicit or secure this Agreement and that it has not paid or agreed to pay any person, company, corporation, individual, or firm other than a bona fide employee working solely for the Vendor, any fee, commission, percentage, gift, or any other consideration, contingent upon or resulting from the award of this Agreement.
- C. The Vendor shall comply with all federal, state, and local laws, regulations and ordinances applicable to the work or payment for work thereof, and shall not discriminate on the grounds of race, color, religion, sex, or national origin in the performance of work under this Agreement.

D. Vendor specifically acknowledges its obligations to comply with Section 119.0701, Florida Statutes, with regard to public records, and shall:

- 1) keep and maintain public records that ordinarily and necessarily would be required by the County in order to perform the services required under this Agreement;
- 2) upon request from the County's custodian of public records, provide the County with a copy of the requested records or allow the records to be inspected or copied within a reasonable time at a cost that does not exceed the cost provided in Chapter 119, Florida Statutes, or as otherwise provided by law;
- 3) ensure that public records that are exempt or confidential and exempt from public records disclosure requirements are not disclosed, except as authorized by law; and
- 4) meet all requirements for retaining public records and transfer, at no cost to the County, all public records in possession of Vendor upon termination of this Agreement and destroy any duplicate public records that are exempt or confidential and exempt from public records disclosure requirements. All records stored electronically must be provided to the County in a format that is compatible with the information technology system of the County.

IF THE VENDOR HAS QUESTIONS REGARDING THE APPLICATION OF CHAPTER 119, FLORIDA STATUTES, TO THE VENDOR'S DUTY TO PROVIDE PUBLIC RECORDS RELATING TO THE CONTRACT, CONTACT THE CUSTODIAN OF PUBLIC RECORDS AT 239-533-2221, 2115 SECOND STREET, FORT MYERS, FL 33901, publicrecords@leegov.com; <http://www.leegov.com/publicrecords>.

E. The Vendor is, and shall be, in the performance of all work, services and activities under this Agreement, an independent contractor. Vendor is not an employee, agent or servant of the County and shall not represent itself as such. All persons engaged in any work or services performed pursuant to this Agreement shall at all times, and in all places, be subject to the Vendor's sole direction, supervision and control. The Vendor shall exercise control over the means and manner in which it and its employees perform the work, and in all respects the Vendor's relationship and the relationship of its employees to the County shall be that of an independent contractor and not as employees of the County. The Vendor shall be solely responsible for providing benefits and insurance to its employees.

VIII. OWNERSHIP OF PRODUCTS

- A. Vendor agrees to notify sponsor of any invention made by Vendor hereunder within thirty (30) days after receipt of an invention disclosure from the inventor.
- B. Vendor shall retain all rights to inventions or discoveries, patentable or not, conceived solely by Vendor and shall prepare and prosecute all related patent applications. County shall retain all rights to inventions or discoveries, patentable or not, conceived solely by County. Inventions or discoveries, patentable or not, made jointly by County and Vendor shall be jointly owned by County and Vendor, and Vendor shall prepare and prosecute all related patent applications and County shall reimburse Vendor for one-half of the expense of all filing, prosecution and maintenance costs for all such patent applications and all issued patents. Vendor grants County an option to secure an exclusive license to Vendor's rights to said jointly owned inventions and discoveries. The provisions of article C, D, E, F and G shall apply to such an option.
- C. County shall indicate to Vendor in writing, within thirty (30) days of receipt of invention disclosure, whether it wishes Vendor to file a patent application on the invention, if applicable, or whether it wishes Vendor to register a copyrightable material.
- D. Vendor agrees to grant and hereby grants County an option to secure a royalty-bearing license under reasonable terms, with the right to make, use and sell, have made and have used, the claimed invention of any patent which is based on any invention conceived and reduced to practice during the term of this Agreement. Such option shall be in effect and exercisable for ninety (90) days from the date of filing of a U.S. patent application under this Agreement or for ninety (90) days from the date of receipt of notice of such a filing by County whichever date is earlier.
- E. The license, which will be exclusive, will include a royalty rate in an amount to be negotiated in good faith by both Vendor and County at the time County decides to exercise its option. County shall have the rights under the license to sublicense and shall have the sole right to designate the terms of any sublicense, provided that Vendor shall receive, at a minimum, the royalty rate expressed in the license between Vendor and County, and fifty percent (50%) of any other remuneration received by County from sub- licensees.
- F. At the time of exercise of the option, County shall indicate in which foreign countries it wants a patent application filed. Rights to such foreign countries shall be included in the patent rights under any license between Vendor and County.
- G. County shall reimburse Vendor for all filing, prosecution and maintenance costs for all patent applications and all issued patents filed at the request of County. Any such patent applications shall become part of the patent rights in any license between Vendor and County. County shall also reimburse Vendor for all filing, prosecution and maintenance costs for all other patent applications and issued patents which become part of the patent rights in any license Agreement between Vendor and County.

The County recognizes that under the Vendor's policy, the project results are non-confidential and agrees that personnel engaging in the project shall be permitted to present or publish at their own choosing, methods and results of the project, provided, however, that the County shall have been furnished copies of any proposal presentation or publication thirty (30) days in advance for review for patentable items or items deemed confidential. If the County believes that any planned publication contains a patentable development and wishes Vendor to file a patent application, upon written notice to Vendor, submission of such manuscript for publication shall be delayed for a reasonable time, not to exceed sixty (60) days, to permit the filing of a patent application(s) by Vendor. Nothing in this Agreement shall entitle Vendor to disclose to others or publish any information disclosed to Vendor by the County which is confidential without the prior written approval of the County. The County will have no editorial role in presentations or publications. The Vendor and associated personnel will be solely responsible for the content and scientific merit of any presentations or publications. The County will be acknowledged as a Sponsor, if deemed appropriate by the County in presentations or publications.

IX. TIMELY DELIVERY OF PRODUCTS AND PERFORMANCE OF SERVICES

- A. The Vendor shall ensure that all its staff, contractors and suppliers involved in the production or delivery of the products are fully qualified and capable to perform their assigned tasks.
- B. The personnel assigned by the Vendor to perform the services pursuant to this Agreement shall comply with the terms set forth in this Agreement. Any change or substitution to the Vendor's key personnel must receive the County's written approval before said changes or substitution can become effective.
- C. The Vendor specifically agrees that all products shall be delivered within the time limits as set forth in this Agreement, subject only to delays caused by force majeure, or as otherwise defined herein. "Force majeure" shall be deemed to be any unforeseeable and unavoidable cause affecting the performance of this Agreement arising from or attributable to acts, events, omissions, or accidents beyond the control of the parties.

X. COMPLIANCE WITH APPLICABLE LAW

This Agreement shall be governed by the laws of the State of Florida. Vendor shall promptly comply with all applicable federal, state, county and municipal laws, ordinances, regulations, and rules relating to the services to be performed hereunder and in effect at the time of performance. Vendor shall conduct no activity or provide any service that is unlawful or offensive.

XI. TERMINATION

- A. The County shall have the right at any time upon thirty (30) days' written notice to the Vendor to terminate this Agreement in whole or in part for failure to conduct the proposed work or just cause. In the event of such termination, the County shall be responsible to Vendor only for fees and

compensation earned by the Vendor, in accordance with Section III, prior to the effective date of said termination, including non-cancelable obligations for the term of the Agreement, which shall include all appointments of research staff incurred prior to the effective date of the termination. In no event shall the County be responsible for lost profits of Vendor or any other elements of breach of contract.

- B. After receipt of a notice of termination, except as otherwise directed, the Vendor shall stop work on the date of receipt of the notice of termination or other date specified in the notice; place no further orders or sub- contracts for materials, services, or facilities except as necessary for completion of such portion of the work not terminated; terminate all vendors and subcontracts; and settle all outstanding liabilities and claims.
- C. The County's rights under this Agreement shall survive the termination or expiration of this Agreement and are not waived by final payment or acceptance and are in addition to the Vendor's obligations under this Agreement.

XII. DISPUTE RESOLUTION

- A. In the event of a dispute or claim arising out of this Agreement, the parties agree first to try in good faith to settle the dispute by direct discussion. If this is unsuccessful, the parties may enter into mediation in Lee County, Florida, with the parties sharing equally in the cost of such mediation.
- B. In the event mediation, if attempted, is unsuccessful in resolving a dispute, the parties may proceed to litigation as set forth below.
- C. Any dispute, action or proceeding arising out of or related to this Agreement will be exclusively commenced in the state courts of Lee County, Florida, or where proper subject matter jurisdiction exists, in the United States District Court for the Middle District of Florida. Each party irrevocably submits and waives any objections to the exclusive personal jurisdiction and venue of such courts, including any objection based on forum non convenience.
- D. This Agreement and the rights and obligations of the parties shall be governed by the laws of the State of Florida without regard to its conflict of laws principles.

XIII. STOP WORK ORDER

The County may, at any time, by written order to the Vendor, require the Vendor to stop all or any part of the work called for by this Agreement for failure to conduct the proposed work or just cause. Any order shall be identified specifically as a stop work order issued pursuant to this clause. This order shall be effective as of the date the order is delivered to the Vendor. Upon receipt of such an order, the Vendor shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. The Vendor shall not resume work unless specifically so directed

in writing by the County. The County may take one of the following actions:

1. Cancel the stop work order; or
2. Terminate the work covered by the order; or
3. Terminate the Agreement in accordance with provisions contained in Section XI.

In the event the County does not direct the Vendor to resume work, the stop work order may be converted into a notice of termination for convenience pursuant to Section XI. The notice period for such termination shall be deemed to commence on the date of issuance of the stop work order. In the event the County does not direct the Vendor to resume work within ninety (90) days, the Vendor may terminate this Agreement.

XIV. VENDOR WARRANTY

- A. All products provided under this Agreement shall be new and of the most suitable grade for the purpose intended.
- B. If any product delivered does not meet performance representations or other quality assurance representations as published by manufacturers, producers or distributors of the products or the specifications listed in this Agreement, the Vendor shall pick up the product from the County at no expense to the County. The County reserves the right to reject any or all materials if, in its judgment, the item reflects unsatisfactory workmanship or manufacturing or shipping damage. In such case, the Vendor shall refund to the County any money which has been paid for same.

XV. MISCELLANEOUS

- A. This Agreement constitutes the sole and complete understanding between the parties and supersedes all other contracts between them, whether oral or written, with respect to the subject matter. No amendment change or addendum to this Agreement is enforceable unless agreed to in writing by both parties and incorporated into this Agreement.
- B. The Vendor shall not assign any interest in this Agreement and shall not transfer any interest in same (whether by assignment or novation) without the prior written consent of the County, except that claims for the money due or to become due to the Vendor from the County under this Agreement may be assigned to a financial institution or to a trustee in bankruptcy without such approval from the County. Notice of any such transfer or assignment due to bankruptcy shall be promptly given to the County.
- C. The exercise by either party of any rights or remedies provided herein shall not constitute a waiver of any other rights or remedies available under this Agreement or any applicable law.

- D. The failure of the County to enforce one or more of the provisions of the Agreement shall not be construed to be and shall not be a waiver of any such provision or provisions or of its right thereafter to enforce each and every such provision.
- E. The parties covenant and agree that each is duly authorized to enter into and perform this Agreement and those executing this Agreement have all requisite power and authority to bind the parties.
- F. Neither the County's review, approval or acceptance of, nor payment for, the services required under this Agreement shall be construed to operate as a waiver of any rights under this Agreement or of any cause of action arising out of the performance of this Agreement.
- G. If the Vendor is comprised of more than one legal entity, each entity shall be jointly and severally liable hereunder.
- H. Any notices of default or termination shall be sufficient if sent by the parties via United States certified mail, postage paid, or via a nationally recognized delivery service, to the addresses listed below:

Vendor's Representative:

County's Representatives:

Name: Donna Gilmore
Title: Director,
Research &
Sponsored
Programs

Names: Roger Desjarlais Mary Tucker
Titles: County Manager Director of
Procurement
Management

Address: Florida Gulf Coast
University
10501 FGCU
Blvd. S.

Fort Myers, FL 33965

Address: P.O. Box 398

Fort Myers, FL 33902

Telephone: 239-590-7582
Facsimile: _____

Telephone: 239-533-2221 239-533-8881
Facsimile: 239-485-2262 239-485-8383

E-mail: dgilmore@fgcu.edu

E-Mail: rdesjarlais@leegov.com mtucker@leegov.com

- I. Any change in the County's or the Vendor's Representative will be promptly communicated by the party making the change.
- J. Paragraph headings are for the convenience of the parties and for reference purposes only and shall be given no legal effect.
- K. In the event of conflicts or inconsistencies, the documents shall be given precedence in the following order:
 - 1. Agreement
 - 2. County's Purchase Order
 - 3. Vendor's proposal for Sponsored COVID-19 Antibody Study

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date last below written.

WITNESS:

Florida Gulf Coast University Board of Trustees

Signed By: Donna Gilmore

Signed By: *Tachung Yih* 07/02/2020

Print Name: Donna Gilmore

Print Name: Tachung Yih, Ph.D.

Title: Associate Vice President for Research

Approved as to Form and Legality
Lisa R. Jones
Associate General Counsel
Florida Gulf Coast University Board of Trustees

07/02/2020

Date: 07/07/2020

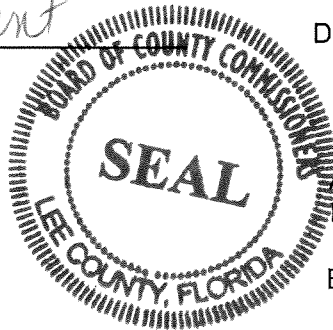
LEE COUNTY BOARD OF COUNTY COMMISSIONERS

ATTEST:
LINDA DOGGETT, CLERK
LEE COUNTY CLERK OF COURTS

BY: *Brian Hamman*
BRIAN HAMMAN, CHAIR
Frank Mann V. Chr

BY: *Missy Flint*
DEPUTY CLERK

DATE: 7-7-20



APPROVED AS TO FORM FOR THE RELIANCE OF LEE COUNTY ONLY:

BY: *Linda Doggett*
OFFICE OF THE COUNTY ATTORNEY

Sponsored COVID-19 Antibody Study

EXHIBIT A SCOPE OF SERVICE

Principal Investigator: Krista Casazza PhD, RD

Co-Investigators: Anne Harner, EdD, MSN, RN; Scott Michael PhD

Tasks to be Performed by Vendor:

1. Phase 1

- 1.1 Collect, analyze and interpret Point of Care (POC) COVID-19 assay tests of a cross-section (n=4000) of Lee County Residents – lateral flow tests (LFT). Tests must be performed using a process that allows the data to be reflected in the Florida Department of Health's Serology Report. These tests must also be done using the Florida Department of Health's preferred test, the CELLEX™ qSARS-CoV-2 rapid IgG/IgM antibody test, unless written approval for a substitute test is provided by the County Manager's Office.

2. Phase 2

- 2.1 Collect, analyze and interpret COVID assay tests for first-responders and Health Care providers – both LFT and neutralization assay (n=300).
- 2.2 Collect, analyze and interpret a sub sample from the population (n=40) of the POC tests to analyze and correlate sensitivity and specificity of POC tests – via the "gold-standard" neutralization assay.
- 2.3 Collect, analyze and interpret a comprehensive assessment of the inflammatory response and/or immune cascade in First-responders and Health Care Workers – endothelial function (flow-mediated dilatation) and inflammatory marker tests (Human Th1, Th2, Th9, Th17 Cytokine 18-plex ProcartaPlex, Human Atherosclerosis 9-plex ProcartaPlex Panel 1, Human Ferritin Simplex ProcartaPlex, Vitamin D).
- 2.4 Prepare quarterly written progress reports to County.
- 2.5 Prepare and present final report to Lee County Administration and Board of County Commissioners.
- 2.6 Provide an accounting of all expenditures for the entire project at the conclusion of Phase 2.

3. Phase 3

- 3.1 Analyze sewage sludge for COVID-19 virus genetic material. Report normalized COVID-19 virus levels over time.

Deliverables:

1. Vendor will provide County results from quantitative reverse transcriptase polymerase chain (qRT-PCR) reaction testing from wastewater treatment sites in Lee County in a timely manner.

Residual COVID-19 virus genetic material remains intact in waste water far longer than infectious virus particles and can be quantitated using the same qRT-PCR test that is used for detecting active infections in humans. We propose to run such tests on wastewater sludge samples provided by Lee County waste water treatment plants. The results of this testing will provide a quantitative measure of the levels of COVID-19 virus in the community that is served by each plant. To provide continual information on the state of the pandemic in Lee County, sequential testing over time will reveal if infection incidence is increasing, decreasing or remaining the same. Other studies have shown that wastewater COVID-19 virus levels precede symptoms by approximately one week and can predict future hospital admissions. To adjust for variations caused by usage patterns and precipitation, the tests will be internally controlled using the human gene control reaction that is currently built into the CDC COVID-19 virus testing protocol. We will test samples provided to the FGCU laboratory from up to five different sites on a weekly basis and report the

results to the county within five days. We will continuously evaluate the collection and sampling protocol and refine as necessary.

Deliverables:

1. Vendor will provide County results from POC testing in a timely manner with the expectation that the County will cross-reference results and population identifiers to provide individual results. The Vendor will be blinded to the identity of POC tests.
2. All de-identified raw data contained in comprehensive assessment across measures will be made available to the County.
3. Comprehensive final report that includes results from the Tasks to be performed by Vendor in the list above.
4. Delivery of PowerPoint presentations to the Lee County Administration and County Commission outlining the work completed, key results, and suggested future direction.

Not-To-Exceed Budget

The County shall pay the Vendor for all actual work performed as described in this Agreement. The total cost of all work shall not exceed \$450,000. The Vendor shall provide itemized monthly invoices to the County stating the hourly rate and number of hours worked for each of Vendor's personnel during that month, travel costs for that month, supply costs for that month, analytical costs for that months, and indirect costs for that month. The total costs shall not surpass the not-to- exceed budget amounts described as follows:

HBOI/FGCU	Not-To-Exceed Budget
Personnel	\$87000
Supplies/Equipment	\$325,000
Analytical Costs	\$38000
Indirect Costs	Not allowed
TOTAL NOT-TO-EXCEED BUDGET	\$450,000

Exhibit B – Vendor's Proposal for Sponsored COVID-19 Antibody Study

Exhibit B
Vendor's Proposal for Sponsored COVID-19 Antibody Study

COVID-19 represents the most significant medical challenge in decades as the clinical course, its comorbidities, and mechanistic considerations require comprehensive evaluation for future therapies. Understanding the prevalence of COVID immunity in the SW Florida community, especially among groups such as healthcare workers, is critical for understanding how we should proceed with re-opening our economy and culture. As we approach higher levels of immunity, we can be more confident that herd immunity will slow the spread of future infections. Conversely, lower levels of immunity present a clear risk for additional rapid spread and potential spikes in COVID-related deaths.

Our proposal involves collecting antibody tests and inflammatory markers from a cross-section of the population in Lee County. Since there is a portion of the population who experience no symptoms, it is critical to randomly select from the population, preferably from people who have not experienced symptoms.

Much uncertainty exists regarding COVID-19. We have learned a wide range of how the disease affects people, ranging from asymptomatic carriers to people who suffer from severe sepsis. Due to limitations in understanding the disease and limited availability of testing, we have mostly collected tests from people experiencing symptoms, which gives us some idea of the Case Fatality Rate (CFR). While we have some idea of this CFR, the results are likely flawed because people are afraid to seek medical treatment, and there is likely a more significant portion of the population who are infected without realizing it.

A better assessment of COVID-19 effects on the community must include an investigation of the Infection Mortality Rate (IMR). The IMR includes an evaluation of a randomly selected sample of individuals who include asymptomatic individuals.

Lee County has a population of 750,000 people. A power analysis of the population indicated an evaluation of approximately 4000 people is a representative sample.

Having an idea of the IMR using an accurate cross-section of Lee County residence will help us understand more about the spread of the disease, the death rate, and the percentage of the population who must show some level of immunity to approach herd immunity.

Herd immunity refers to the percentage of the population who have antibodies for a particular infection. The more significant percentage of the population who have immunity severely reduces the R_0 , which is the number of people that each infected person passes the infection on to, creating a compounding effect, resulting in the rapid spread of the COVID virus. To highlight the idea of herd immunity, the measles requires a population of people who have antibodies at the rate of approximately 90% of the population to achieve herd immunity. The high rate of immunity in the population is why it is critical to have a vaccine available. This is further evidenced by the recent outbreak of measles, which correlated with decreasing immunizations.

Public health officials at Johns Hopkins School of Public Health anticipate a need to have antibodies present in at least 70% of the population to achieve herd immunity. A vaccine will likely be necessary to achieve herd immunity.

The details of conducting a large-scale immunity trial are not trivial. There are several ways to test for anti-COVID antibodies. Some of these tests are faster and easier to use than others, but the previous testing has shown that these rapid tests are often unreliable. Other tests are slower but much more accurate and reliable.

We plan to use a rapid test to conduct the bulk of the sample testing and follow up with a reliable, gold standard test on a smaller subset of the samples to ensure that our larger test results are valid.

An additional consideration is the timing of sampling. Two main types of blood antibodies develop after a viral infection. IgM antibodies develop first, and more powerful and specific IgG antibodies develop later. Testing for IgG antibodies has been shown to be more reliable, but sampling timing is essential, as these antibodies do not develop fully until approximately two weeks after infection.

Lateral flow tests (like a pregnancy test) require only a few drops of blood to be applied to a test strip, which then shows results as the development of a colored band on the test strip in a matter of minutes to hours. There are commercially available test strips from several different manufacturers. However, some are more accurate than others and these test strips are in high demand and can be expensive. From head to head testing results conducted in other laboratories, we have identified a preferred test strip manufacturer as well as two highly regarded backups in case the preferred test strips are not available.

Results from lateral flow test strip testing will be compared to a gold standard antibody test called a neutralization assay. In a neutralization assay, a dilution series of serum will be mixed directly with the COVID virus and the mixture will be allowed to infect cells in the laboratory. A decrease in infection caused by anti-COVID antibodies in the serum is called neutralization and is the gold standard for defining the presence or absence of immunity. In our testing at FGCU, we will use a technique called virus pseudotyping to avoid growing and working with the live COVID virus in the laboratory, while still maintaining the ability to conduct this gold standard testing.

Using both a rapid, lateral flow test strip on a large number of samples and a more accurate neutralization test on a smaller number of samples will allow us to quickly estimate the overall prevalence of COVID immunity in Lee County and to understand precisely the strengths and limitations of our estimate.

Testing for a variety of stress-related markers will also be conducted in a subset of serum samples to compare disease severity and antibody responses to stress levels.

Additionally, we would like to evaluate the stress response, specifically in the first responder population. While COVID-19 primarily affects the lungs, it also affects multiple organs, particularly the cardiovascular system. Risk of severe infection and mortality increase with advancing age and male sex. Mortality is increased by comorbidities (e.g., cardiovascular disease, diabetes, obesity). An overlapping mechanism is the inflammatory cascade associated with chronic disease and vastly elevated in COVID. Mechanistically, the bindings to the transmembrane angiotensin-converting enzyme 2 (ACE2) allows entrance into immune cells activating the inflammatory cascade. Initial immune and inflammatory responses induce a severe cytokine storm [interleukin (IL)-6, IL-7, IL-22, IL-17, etc.] during the rapid progression phase of COVID.

The pathophysiology and disease severity in patients is due to not only the viral infection but also the host response. The mechanisms by which COVID subverts the body's innate antiviral cytokine responses are yet to be studied, but research indicates various stages in the inflammatory cytokine signaling pathway. Unrestrained inflammatory cell infiltration can itself mediate damage in the lung through excessive secretion of proteases and reactive oxygen species, in addition to the direct damage resulting from the virus.

In addition to local damage, cytokine storm also has ripple effects across the body. These may result in myocardial damage and circulatory failure observed in some patients. Further, while initially children appeared not to develop severe disease with more than 50% of children experiencing mild symptoms or were asymptomatic, the emerging Kawasaki's syndrome presentation suggests an inflammatory response that is manifesting. It is highly likely that lack of vitamin D and physical inactivity are promulgating the inflammatory

cascade and generating this idiopathic symptomology. A comprehensive investigation is essential, with less than 6% of children developing severe symptoms. Thus, while the rapid testing represents significant inroads, a full picture of the critical host immune factors that underlie the development of severer inflammatory responses in some patients remains poorly defined and warrant investigation.

As an aside, COVID also shows a difference in fatality rate between males (2.8%) and females (1.7%). As ACE2 is located on the X chromosome, there may be alleles that confer resistance to COVID-19, explaining the lower fatality rate in females. Alternatively, the estrogen and testosterone sex hormones have different immunoregulatory functions, which could influence immune protection or disease severity