State of New Jersey

DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

MEMORANDUM OF AGREEMENT
BETWEEN
NEW JERSEY DEPARTMENT OF HEALTH
AND
RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY
FOR
SARS-CoV-2 ANTIBODY PREVALENCE IN THE PEDIATRIC POPULATION OF NEW JERSEY

WHEREAS, pursuant to N.J.S.A. App.A:9-45(i) and Executive Order 102, Governor Murphy declared that COVID-19 was a serious public health threat and declared the necessity to work closely with Federal, State, and Local agencies and authorities to protect the health and well-being of New Jersey residents, and

WHEREAS antibody testing studies for prior SARS-CoV-2 infections have focused on adults and little is known about seroprevalence in pediatric populations within the state of New Jersey; and

WHEREAS, an antibody testing study among pediatric populations in New Jersey will help estimate seroprevalence of COVID-19, assess risk factors for SARS-CoV-2 infections, and aid in the understanding of associated individual, household, and community-level risk factors among children; and

WHEREAS, an understanding of the risk factors associated with pediatric seroprevalence may influence vaccination decisions and inform prevention and control efforts; and

WHEREAS, pursuant to N.J.S.A. 26:1A-15 and N.J.S.A. 26:1A-37, the New Jersey Department of Health (NJDOH) is authorized to maintain liaison with State agencies and authorities to carry out its public health functions, including the prevention of disease within the State; and

WHEREAS, pursuant to Compliance with Circular 05-14-OMB, the NJDOH is authorized to establish the proper procedure to procure and account for the purchase of goods or services from the state colleges and universities; and

WHEREAS, pursuant to N.J.S.A. 18A:64M-1 et seq., Rutgers, The State University of New Jersey (Rutgers), a body corporate and politic of the State of New Jersey, is a comprehensive public university authorized to engage in medical research to benefit public health; and

WHEREAS, pursuant to N.J.AC 17:44-2.2, the NJDOH is authorized to audit or review contract records; and

WHEREAS, funding was awarded to the NJDOH from the Centers for Disease Control and Prevention (CDC) continuation of funds for Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) through the ELC Enhancing Detection grant, ending November 30, 2022, and the ELC Enhancing Detection Expansion grant, ending July 31, 2023 (CFDA No: 93.323), for the purpose of strengthening the capacity of public health systems to effectively prepare for and respond to public health threats and emergencies; and

WHEREAS, NJDOH seeks to engage the professional services of Rutgers to provide oversight of the coordination and implementation of a pediatric SARS-CoV-2 antibody prevalence study and aid in an emergent public health investigation of COVID-19.

NOW, THEREFORE, THE NJDOH AND RUTGERS (COLLECTIVELY THE "PARTIES") AGREE AS FOLLOWS:

I. Under this Memorandum of Agreement (MOA), the NJDOH is hereafter referred to as the "Funding Agency" and Rutgers is hereafter referred to as the "Service Provider Agency."

II. OBLIGATIONS AND RIGHTS OF FUNDING AGENCY

A. Obligations

1. Funding Agency will provide funding in an amount not to exceed: $352,110.98, $30,000 of which will be allocated towards incentives.
   a. Payment is contingent upon the satisfactory delivery of services by the Service Provider Agency as described herein at Section III.A., "Service Provider Obligations."
   b. Payment obligations, reporting and monitoring requirements, and other special conditions to this MOA, are set forth at Attachment A, incorporated herein by reference.
   c. Payments will be made in accordance with the provisions of Attachment A, Section I. Payments will be made for approved budget costs, set forth at Attachment B, incorporated herein by reference.

2. Funding Agency will monitor the progress of this project to ensure services are provided in accordance with the schedule of work in Section III. A. for which payment will be made. The financial and performance monitoring requirements are set forth at Attachment A, Sections I and II.

B. Rights

1. Audit
   a. Funding Agency has the right to audit all accounts and/or records maintained by the Service Provider Agency for this project.
   b. Funding Agency has the right, during normal business hours, to access all records and/or data pertaining to this MOA.
   c. The provisions of this subparagraph shall continue for a period of seven years after the submission and acceptance of the financial and programmatic reports required under this MOA.

2. Work Product
   a. Funding Agency owns all data originated, developed, prepared, used, obtained, created, and maintained in the performance of services set forth herein.
      i. All written work produced pursuant to this MOA shall bear an acknowledgment of the support of the Funding Agency.
   b. Funding Agency must grant prior written consent before the Service Provider Agency may release any written work produced utilizing funds or data obtained pursuant to this MOA.
   c. Funding Agency has the right to edit all written work produced pursuant to this MOA and to add co-authorship or disclaimers as it, in its sole discretion, deems appropriate.
   d. Funding Agency assumes all responsibilities relative to determining compliance and effect of the Open Public Records Act (N.J.S.A. 47:1A-1 et seq.) as it pertains to any work performed by the Service Provider Agency pursuant to this MOA.

3. Purchases
   Any purchases made using funds from this MOA are the property of the Funding Agency, which Service Provider Agency agrees to return upon request at the expiration or termination of this MOA.

III. OBLIGATIONS AND RIGHTS OF SERVICE PROVIDER AGENCY

A. Obligations

1. Service Provider Agency shall deliver work established in the budget at Attachment B.

2. Service Provider Agency shall submit expenditure, progress, and final reports, and State invoices as set forth at Attachment A.

3. Service Provider Agency shall maintain all records related to this MOA for a period of seven years from the date of expiration or termination of this MOA.

4. Schedule of Work. Service Provider Agency agrees to deliver the following work in the expressed timeframe as follows:

Deliverables	Completion Date
1. Identification and outreach to state-affiliated physician practices to participate in the pediatric SARS-CoV-2 antibody study meeting criteria outlined in Attachment D.	To be completed within two weeks of the execution of this MOA.
2. Ensure all Institutional Review Board (IRB) processes and approvals are in compliance with federal regulations governing the protection of human subjects (45 CFR 46) and are obtained, completed, and maintained for the duration of the SARS-CoV-2 pediatric survey project.	Prior to implementation of the study and for the duration of the study.
3. Implementation of the SARS-CoV-2 antibody study meeting criteria outlined in Attachment D.	After agreement has been signed and all necessary approvals have been obtained (see Deliverable #1).
4. Biweekly Progress Report and antibody results submission to NJDOH via spreadsheet.	On a biweekly basis from the start of project implementation.
5. Ensure full dataset is complete and accurate upon project culmination.	To be completed by October 31, 2022.

5. Whistleblower Protection Notice.
Service Provider Agency agrees to comply with and provide adequate notice of available whistleblower rights and remedies, pursuant to 41 U.S.C. 4712, as follows:
   a. Informing employees and independent contractors working on this MOA of their entitlement to the rights and remedies of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections", which cannot be waived by any MOA, policy, form or condition of employment, and includes the following:
      i. The right not to be discharged, demoted, or otherwise discriminated against as a reprisal for whistleblowing, which is defined as "making a disclosure that the employee reasonably believes is evidence of," any of the following:
         1. Gross mismanagement of federal contract or grant.
         2. A gross waste of federal funds:
         3. An abuse of authority relating to federal contract or grant;
         4. A substantial and specific danger to public health or safety;
         5. A violation of law, rule or regulation related to a federal contract or grant (including the competition for, or negotiation of a contract of grant); and
      ii. This benefit applies when the employee's disclosure is made to one of the following individuals or entities:
         1. A member of Congress, or representative of Congressional Committee.
         2. An Inspector General;
         3. The Government Accountability Office;

4. A federal employee responsible for contract or grant oversight or management at the relevant agency;
5. An official from the Department of Justice or other law enforcement agency;
6. A court or grand jury; or
7. A management official or other employee of the contractor, subcontractor, grantee, or subgrantee with responsibility to investigate, discover, or address misconduct.
    a. Providing such written notice in the predominant native language of the workforce; and
    b. Including such requirements in any subsequent MOA with another party to carry out its obligations under the MOA.

6. Data Privacy and Data Security
Service Provider Agency agrees to protect NJDOH data collected, used, and maintained through the professional services provided pursuant to this MOA pursuant to applicable federal and State law, standards and policies of the State of New Jersey Office of Information Technology, as amended and supplemented, and accessed at https://www.nj.gov/it/. Service Provider Agency agrees to comply with the data privacy and security standards set forth at Attachment C, incorporated herein by reference.

7. Compliance with Circular 05-14-OMB
Service Provider Agency shall provide the majority of the services required to complete the schedule of work identified above as directed by Circular 05-14-OMB, which directs that when State colleges or universities are engaged by a State Department, the majority of the services should be directly provided by the university. (https://www.nj.gov/infobank/circular/cir0514b.htm).

8. Compliance with N.J.A.C. 17:44-2.2
In addition to the provisions of Sections II.B.1.c and III.A.3 of this MOA, Service Provider Agency shall maintain all documentation related to products, transactions or services under this MOA for a period of five years from the date of final payment in compliance with N.J.A.C. 17:44-2.2. Such records shall be made available to the New Jersey Office of the State Comptroller upon request.

B. Rights

Service Provider Agency has the rights set forth at Sections III, IV, and V of this MOA and Attachment A.

IV. GENERAL PROVISIONS

A. During the term of this MOA, each Party shall comply with all federal, State and municipal laws, rules and regulations generally applicable to the activities performed pursuant to this MOA. The award of funds is based on the Service Provider Agency's submission, and the Funding Agency's acceptance, of a Cost Proposal/budget, which is incorporated herein by reference.

B. Each Party shall maintain accurate books and records of all disbursements, funds received, funds spent and funds available because of this MOA.

C. Each Party is an independent entity and neither Party shall hold itself out as an agent, partner, or representative of the other.

D. Failure by either Party to exercise any right or demand performance of any obligation under this MOA shall not be deemed a waiver of such right or obligation.

E. If any terms and conditions of this MOA are held to be invalid or unenforceable as a matter of law, the other terms and conditions hereof shall not be affected thereby and shall remain in full force and effect. To this end, the terms and conditions of this MOA are declared severable.

F. This MOA may not be assigned or delegated without the prior written consent of NJDOH.

G. The laws of the State of New Jersey govern this MOA.

H. This MOA may be modified in accordance with the provisions of Attachment A, Section III.

I. The Parties recognize and agree that this MOA is expressly dependent upon the availability to the NJDOH of funds appropriated from applicable federal or state funding sources. The NJDOH shall not be held liable for any termination of this MOA due to the absence of available funding appropriations.

J. Funding Agency reserves the right to reproduce, publish or otherwise use, and to authorize others to use, any work developed under this MOA.

K. The Parties agree that all data resulting from this MOA is to be considered confidential and shall be used solely for the purposes outlined above. The Parties are required to use reasonable care to protect the confidentiality of the data.

L. The Parties acknowledge that the Service Provider Agency shall obtain Institutional Review Board approval for this study and that any research resulting from this MOA shall be confidential. Each Party is responsible for adhering to the rules of the Institutional Review Board.

V. TERMS AND TERMINATION

A. Subject to any rights of termination hereinafter set forth, this MOA shall become effective on March 1, 2022, and shall remain in effect through December 31, 2022

1. A portion of this MOA is retroactive.
2. Neither Party will incur any penalty because of the retroactive period.

B. This MOA may be terminated by either Party with or without cause upon 30 days' advance written notice.

C. Notice of termination shall be addressed to the contact persons identified at Section VI and delivered via U.S. Certified Mail, return receipt requested, and shall be effective upon receipt.

D. Upon the expiration of the term of this MOA or upon the issuance of a notice of termination, all unexpended funds appropriated by the Funding Agency to the Service Provider Agency, in any account whatsoever, shall be immediately returned to the Funding Agency through the contact person identified at Section VI without any further assessment or expenditure except as specifically approved by the Funding Agency in writing.

VI. PRINCIPAL CONTACTS

The principal contacts for all notifications required or otherwise necessary under this MOA are as follows:

For the New Jersey Department of Health:

Program Management Officer
Edward Lifshitz, MD, FACP
Medical Director
Infectious and Zoonotic Disease Program
Division of Epidemiology, Environmental and Occupational Health
New Jersey Department of Health
P.O. Box 369
Trenton, New Jersey 08625-0369
Phone: [redacted]
Fax: 609-292-5811
Email: [redacted]

Fiscal Officer
Kathleen Dieal
Contract Administrator II
ELC COVID-19 Response
New Jersey Department of Health
P.O. Box 369
Trenton, New Jersey 08625-0369
Phone: [redacted]
Email:
[redacted]

For Rutgers, The State University of New Jersey:

Program Officer
Pauline Thomas, MD
Director, Preventive Medicine Residency
Department of Medicine
Rutgers New Jersey Medical School 185 South
Orange Avenue
Newark, New Jersey 07103
Phone [redacted]

Fiscal Officer
Lamar Oglesby, Director
Rutgers, The State University of NJ
Research Financial Services
33 Knightsbridge Road, 2nd Floor East
Piscataway, NJ 08854
Phone: [redacted]
Fax: 732-932-0182
Email: [redacted]

VII. WE, THE UNDERSIGNED, CONSENT TO THE CONTENTS OF THIS AGREEMENT.

New Jersey Department of Health:

Signature: David Adinaro — 4/26/2022

David Adinaro, MD, FACEP
Deputy Commissioner
Public Health Services

Date

Rutgers, The State University of New Jersey

Signature: DocuSigned by: Letitia Dean DBF6294CC52C44C... — 5/25/2022

Letitia Dean, MPA, CRA
Assistant Director
Research and Sponsored Programs

Date

(mct/DR00019720)

ATTACHMENT A

This Attachment A is hereby incorporated into the Memorandum of Agreement (MOA) between the New Jersey Department of Health (NJDOH) and Rutgers, The State University of New Jersey (Rutgers), entitled, " SARS-CoV-2 Antibody Prevalence in the Pediatric Population of New Jersey."

I. METHOD OF PAYMENT

A. NJDOH will make quarterly cost reimbursement payments based upon receipt of approved financial reports and State invoices, as follows:
   1. For purchased items:
      a. Purchase orders;
      b. Invoices; and
      c. Payments made.
   2. For In-State travel:
      a. Itemized list of travel expenses.
      b. Copies of tolls and parking receipts; and
      c. Beginning and ending addresses travelled.
   3. For Out-of-State travel:
      a. Itemized list of travel expenses; and
      b. Copies of airfare, ground transportation, and hotel fees.
   4. For conference fee reimbursement:
      a. Completed attendance sign-in sheet indicating the numbers of:
         i. State employees;
         ii. Rutgers employees; and
         iii. Non-state employees.

B. Quarters shall be defined as follows:

   First Quarter: January 1, 2022-March 31, 2022
   Second Quarter: April 1, 2022-June 30, 22
   Third Quarter: July 1, 2022-September 30, 2022
   Fourth Quarter: October 1, 2022-December 31, 2022

C. NJDOH may withhold final payment pending receipt and acceptance of final reports.

II. FINANCIAL AND PERFORMANCE REPORTING AND MOA MONITORING

A. **Expenditure Reports.**
   Rutgers shall submit a final expenditure report to NJDOH, within 30 days after the end of each quarter. A final expenditure report shall be due no later than 30 days after the end of the project period.

B. **Progress Reports.**
   Rutgers shall submit the required progress reports as set forth at Section III.A of the MOA.

C. **Meetings.**
   Rutgers is required to attend monthly technical assistance meetings with NJDOH, or as needed.

D. **Monitoring Requirements.**
NJDOH will monitor progress on a bi-weekly basis to ensure the timely progression of the project and, if needed, will initiate improvement plans to overcome any barrier to completion.

III. MODIFICATIONS TO THE AGREEMENT

The MOA and any attachments thereto represent the entire Agreement between the parties and shall not be amended except by the express written consent of both parties, except as stated herein:

A. **Extensions of Time**
May be granted in writing by the NJDOH Program Management Officer and NJDOH Fiscal Officer identified in the MOA at Section VI.

B. **Budget Revisions**
May be granted in writing by the NJDOH Program Management Officer and NJDOH Fiscal Officer identified in the MOA at Section VI.

C. **Modifications to Service Deliverables**
May be made to Section III of the MOA with the approval of the NJDOH Program Management Officer identified in the MOA at Section VI.

IV. SPECIAL CONDITIONS

The MOA has no special conditions.

V. MULTI-YEAR AGREEMENTS

A. The MOA is for the period of March 1, 2022, through December 31, 2022, and authorization is approved for that time.

ATTACHMENT B

This Attachment B is hereby incorporated into the Memorandum of Agreement between the New Jersey Department of Health (NJDOH) and Rutgers, The State University of New Jersey, "SARS-CoV-2 Antibody Prevalence in the Pediatric Population of New Jersey."

See attached Budget.

Budget for SARS-CoV-2 Antibody Prevalence in the Pediatric Population of New Jersey

Rutgers Team								
Name	Title	Salary	Hours	% time	salary	Fringe (@53.61%)	Total Requested	
Manisha Gurumurthy	Project Director	$125/hour	520				65,000.00	
Stephen Friedman	Science Director	$125/hour	390				48,750.00	
Pauline Thomas	Administration	$196,202		5% 8 mo%	$2,452.53	$1,314.80	3,767.32	
Laptop for Dr. Gurumurthy							1,000.00	
Translation of consent into Spanish							1,000.00	
Translation services (e.g.language line)							1,000.00	
Printing of fliers							500.00	
							121,017.32	121,017.32

NJMS Pediatrics								
Joseph Schwab	Director	$150,000/year		5.00% 6 months	7500	4020.75	11,520.75	
TBN	Research Nurse	$35/hour	496				17,360.00	
	lab tech/research assistant * 20							
TBN	hours/week	$35/hour	160				5,600.00	
	incentive: 20x250						included	
	test kits: 350*15						5,250.00	
	2 Ipads @329 each						658.00	
	PPE						500.00	
							40,888.75	40,888.75

Atlantic Health Systems					
Maria Ceceila Di Pentima	Director				11,500.00
	research nurses, 3 sites * 0.6/site *				
	40 hours/week * 8 weeks	$40/hour			23,040.00
	lab tech/research assistant	$35/hour	160		5,600.00
	incentive: 20x250				included
	test kits: 350*15				5,250.00
	2 Ipads @329 each				658.00
	PPE				500.00
					46,548.00
					46,548.00

Summit Health					
TBN	Director				11,500.00
	research nurse				17,360.00
	lab tech/research assistant				5,600.00
	incentive: 20x250				included
	test kits: 350*15				5,250.00
	2 Ipads @329 each				658.00
	PPE				500.00
					40,868.00
					40,868.00

RWJMS and Chandler					
	Director				11,500.00
	research nurse				17,360.00
	lab tech/reseach assistant				5,600.00
	incentive: 20x250				included
	test kits: 275*15				5,250.00
	2 Ipads @329 each				658.00
	PPE				500.00
					40,868.00
					40,868.00

Total Requested		290,190.07
Overhead	11%	31,920.91
Grand Total		**322,110.98**
Incentives		**30,000.00**

ATTACHMENT C

Secure Protection and Handling of DOH Data by Rutgers

The Attachment C is hereby incorporated into and provides for additional provisions and conditions between the New Jersey Department of Health (NJDOH) and Rutgers, The State University of New Jersey (Rutgers), for a Memorandum of Agreement entitled " SARS-CoV-2 Antibody Prevalence in the Pediatric Population of New Jersey."

1. **Data Classification and Confidentiality:** Data shall mean Personally Identifiable Information (PII) and other data or information to which Rutgers receives or otherwise has access pursuant to the provision of services under this MOA and shall be classified as confidential and secured as such, as defined by the New Jersey Statewide Information Security Manual, (effective 2/21/2021) https://www.nj.gov/it/docs/ps/NJ_Statewide_Information_Security_Manual.pdf (SISM).

2. **Compliance with the Law for the Use and Disclosure of Confidential Information:** Rutgers agrees to preserve the confidentiality, integrity and accessibility of Data collected, accessed or obtained pursuant to this MOA. Rutgers agrees that any and all Data exchanged shall be used expressly and solely for the purpose of performing services set forth in the MOA. Rutgers agrees that beyond Rutgers performance of the services in the MOA, Rutgers shall not share, disclose, distribute, repurpose, or share across other applications, environments, or business units of Rutgers any Data collected, accessed or obtained under this MOA. Rutgers agrees that Data is confidential and subject to requirements as defined by the New Jersey Statewide Information Security Manual, (effective 2/21/2021) https://www.nj.gov/it/docs/ps/NJ_Statewide_Information_Security_Manual.pdf (SISM. Rutgers further agrees that Data shall not be re-used, shared, disclosed, distributed, transmitted, exchanged or otherwise passed to other 3rd parties except on a case-by-case basis as specifically authorized in writing through a modification to the MOA.

3. **Information Security, Privacy and Generally recognized Industry Standards:** The Rutgers agrees to ensure the security and privacy of State information systems is aligned with the administrative, physical, and technical controls and objectives, as documented in the SISM, including but not limited to secure Data storage and encryption. The SISM is derived from applicable State and federal laws; industry best practices including, but not limited to National Institute of Standards and Technology (NIST) Cybersecurity Framework for Improving Critical Infrastructure; NIST Special Publication 800-53, the international security and privacy practices aligned with ISO 27001 series, Center for Internet Security (CIS) Top 20 Critical Security Controls; the Cloud Security Alliance, (CSA) Cloud Controls Matrix (CCM); lessons learned; and other New Jersey State Government applicable laws and standards.

4. **End of Agreement Data Handling.** Rutgers agrees that upon termination of the Agreement, Rutgers shall upon receipt of written instructions from DOH, return Data to DOH in accordance with SISM requirements for secure Media Transport MP-06 and/or securely and permanently destroy all Data in accordance with the SISM requirements for secure Media Sanitization MP-09 which are based upon NIST Special Publication 800-88, rev. 1, Guidelines for Media Sanitization.

5. **Security Breach Notification.** Rutgers agrees to comply with all applicable laws that require the notification of individuals in the event of unauthorized release of Data, personally identifiable information, or other event requiring notification required by applicable law as determined by DOH. In the event of a breach of any of Rutgers' security obligations, or other event requiring notification under applicable law, Rutgers agrees to:
   a. Notify DOH of such an event immediately upon discovery the DOH privacy officer at privacy.officer@doh.nj.gov and DOH Information Security Office at iso@doh.nj.gov, and
   b. Assume responsibility for informing all such individuals in accordance with applicable law, and
   c. Indemnify, hold harmless and defend DOH and its employees from and against any claims, damages, or other harm related to such notification event.

6. **Right to Audit.** DOH or an appointed audit firm (Auditors) has the right to audit Rutgers and any affiliates that provide a service for the processing, transport or storage of DOH's data. DOH will announce its intent to audit Rutgers by providing at a minimum two weeks (10 business days) notice to Rutgers. This notice will go to the signatory of this MOA. A scope document along with a request for deliverables will be provided at the time of notification of an audit. If the documentation requested cannot be removed from Rutgers' premises, Rutgers will allow the Auditors access to their site. Where necessary, Rutgers will provide a personal site guide for the Auditors while on site. Rutgers will provide a private accommodation on site for data analysis and meetings; the accommodation will allow for a reasonable workspace, with appropriate lighting, electrical, a printer and Internet connectivity. Rutgers will make necessary employees or contractors available for interviews in person or on the phone during the time frame of the audit. In lieu of DOH or its appointed audit firm performing their own audit, if Rutgers has an external audit firm that performs a Statement on Standards for Attestation Engagements no. *18* (*SSAE 18*) report and certification, Rutgers shall submit the report and certification to DOH. DOH has the right to request additional controls to be added to Rutgers's environment for testing the controls that have an impact on DOH data. Audits will be at DOH's sole expense, except where the audit reveals material noncompliance with contract specifications, in which case the cost will be borne by Rutgers.

7. **DOH Data.** DOH Data shall mean any Personally Identifiable Information (PII), as defined by the New Jersey Statewide Information Security Manual https://www.nj.gov/itidocs/ps/NJ Statewide Information Security Manual.pdf, or other data or information which Rutgers receives or to which Rutgers otherwise has access pursuant to the provision of services under the MOA.

8. **Network Security.** Rutgers agrees at all times to maintain network security that - at a minimum - includes: network firewall provisioning, intrusion detection, and regular (three or more annually) third party vulnerability assessments. Likewise, Rutgers agrees to maintain network security that conforms to generally recognized industry standards and best practices that Rutgers then applies to its own network.

9. **Application Security.** Rutgers agrees at all times to provide, maintain and support MOA and subsequent updates, upgrades, and bug fixes such that the MOA is and remains secure from those vulnerabilities as described in generally recognized and comparable industry practices or standards. User access will be controlled through a user id and password and privileges within the system will be restricted based on user role.

10. **Data Security.** Rutgers agrees to preserve the confidentiality, integrity and accessibility of DOH data with administrative, technical and physical measures that conform to generally recognized industry standards and best practices that Rutgers then applies to its own processing environment. Maintenance of a secure processing environment includes but is not limited to the timely application of patches, fixes and updates to operating systems and applications as provided by Rutgers or open-source support.

11. **Data Storage.** Rutgers agrees that any and all DOH data will be stored, processed, and maintained solely on designated target servers and that no DOH data at any time will be processed on or transferred to any portable or laptop computing device or any portable storage medium, unless that device or storage medium is in use as part of Rutgers' designated backup and recovery processes and encrypted in accordance with "7. Data Encryption."

12. **Data Transmission.** Rutgers agrees that any and all electronic transmission or exchange of system and application data with DOH and/or any other parties expressly designated by DOH shall take place via secure means (using HTTPS or SFTP or equivalent) and solely in accordance with "8. Data Re-Use."

13. **Data Encryption.** Rutgers agrees to store all DOH backup data as part of its designated backup and recovery processes in encrypted form, using a commercially supported encryption solution. Rutgers further agrees that any and all DOH data defined as personally identifiable information under current legislation or regulations stored on any portable or laptop computing device or any portable storage medium likewise be encrypted.

14. **Data Re-Use.** Rutgers agrees that any and all DOH data exchanged shall be used expressly and solely for the purposes enumerated in this MOA and this Addendum. DOH data shall not be distributed, repurposed, or shared across other applications, environments, or business units of Rutgers. Rutgers further agrees that no DOH data of any kind shall be transmitted, exchanged or otherwise passed to other interested parties except on a case-by-case basis as specifically agreed to in writing by DOH.

15. **Industry Standards.** Generally recognized industry standards include but are not limited to the current standards and benchmarks set forth and maintained by the:

    a. Center for Internet Security - see http://www.cisecurity.org
    b. Payment Card Industry/Data Security Standards (PCIIDSS) see http://www.pcisecuritystandards.org
    c. National Institute for Standards and Technology - see http://csrc.nist.gov
    d. Federal Information Security Management Act (FISMA) - see http://csrc.nist.gov
    e. ISOIIEC 27000-series - see http://www.is027001security.com/
    f. Organization for the Advancement of Structured Information Standards (OASIS) - see http://www.oasis-open.org/
    g. New Jersey Office of Homeland Security and Preparedness, Statewide Information Security Manual - see https://www.cyber.nj.gov/governmentl

ATTACHMENT D

This Attachment D is hereby incorporated into the Memorandum of Agreement between the New Jersey Department of Health (NJDOH) and Rutgers, The State University of New Jersey, "SARS-CoV-2 Antibody Prevalence in the Pediatric Population of New Jersey."

See attached Study Protocol.

Title of Project: SARS-CoV-2 Antibody Prevalence in the Pediatric Population of New Jersey.

Funding Source: N/A

1. Background and Significance

With increasing vaccinations among the NJ population, much is still not understood about natural COVID-19 immunity. New Jersey in particular has experienced higher than average spread of SARS-CoV-2; estimates of natural seropositivity have been as high as 23% at the height of the pandemic.[1] While there is ample serological data on adults through commercial testing, children are less likely to be tested and antibody prevalence data in the pediatric population is lacking.

Since May 2021, COVID-19 vaccines have been recommended to all individuals 12 years of age and older.[2] While vaccines are not yet available for use in younger children, emergency use authorization for those between 5-11 years old was issued on Nov 2, 2021. [3] Most all K-12 schools in New Jersey, however, have returned to fully in-person learning environments since September 2021. While the protective effect of naturally acquired antibodies is not known, it is likely that such antibodies play a role in preventing or blunting disease severity. A better understanding of SARS-CoV2 antibody prevalence as well as potential symptoms among the pediatric population in NJ is needed to inform the urgency of vaccine uptake among this population and to help better understand the risk of contracting from COVID-19 from school-based and childcare-based exposures.

1.1 Primary Objectives

- Estimate population-level SARS-CoV-2 antibody prevalence among New Jersey children 18 months to 11 years of age.
- Assess how antibody prevalence differs across clinical, household and community-based exposures

1.2 Secondary Objectives

- Describe the symptom profile of diagnosed and undiagnosed SARS-CoV2 infection among children.
- Explore caregiver vaccination status and better understand knowledge/attitudes toward pediatric vaccinations

2. Purpose/Specific Aims

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[1] https://www.the-scientist.com/news-opinion/largest-seroprevalence-study-in-us-shows-vast-covid-19-undercount-67762

[2] CDC, June 11, 2021, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html?s_cid=10493:covid%2019%20vaccine:sem.ga:p:RG:GM:gen:PTN:FY21

[3] https://www.usatoday.com/story/news/health/2021/11/02/covid-vaccine-kids-children-approved/6233927001/

The purpose of this survey is to conduct epidemiologic surveillance to estimate the antibody prevalence of COVID-19 among pediatric patients, assess risk factors for SARS-CoV-2 infection, and better understand the individual, household and community-level factors that influence antibody prevalence among the pediatric population. We also aim to better understand the household-level factors that may influence vaccination decisions going forward. The survey findings intend to gain a better understanding of antibody prevalence estimates among this population to inform school/child-care based COVID-19 prevention and vaccination efforts.

This surveillance survey falls under revised 2018 Common Rule requirements which allow for public health surveillance activities to be conducted by public health authorities to "identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases)"[4]

3. Research Design and Methods

In accordance with CDC's broader COVID-19 serologic surveillance strategy (4), NJDOH Communicable Disease Service (CDS) will conduct a survey to assess the prevalence of antibodies to SARS-CoV-2 among 18 month to 11 year-olds presenting to physician practices. The survey aims to ascertain the prior incidence of infection among this population and to determine how antibody prevalence differs given risk factors/exposures.

Testing for SARS-CoV-2 antibodies will be conducted in partnership with physician practices across the state using point-of-care testing of oral fluid samples. In addition to biospecimen collection, a one-time electronic survey will be administered to participants and/or their guardians to query them on:

Household-level information including county of residence, highest level of education of primary caregivers, vaccination status of household members, history of COVID-19 or COVID-19 symptoms in the past 12 months amongst all household members.

Individual-level information including COVID-19 exposure history, current and planned activities, and preventative practices.

Aggregate survey results will be made available to participants and stakeholders to guide COVID-19 control measures, and antibody test results will be provided to participants.

Collection of diagnostic samples and laboratory testing:

[4] https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html

Individuals who agree to provide an oral fluid sample for testing using the Diabetomics CovAb platform. Although this test has not yet been FDA cleared, it has been authorized for emergency use under an EUA.

The Diabetomics CovAb SARS-CoV-2 Ab test is a point-of-care lateral flow test for antibodies to the SARS-CoV-2 spike protein. FDA reports estimates of sensitivity for detecting total (IgG, IgA, IgM) antibodies of 97.1% (95% CI 90.0% ; 99.2%) and 97.4 % (95% CI 91.1% ; 99.3%) respectively (5).

Sample collection and testing will follow the below protocol:

1) Participants will be asked to not eat or drink 30 minutes before test.
2) Oral fluid will be obtained by swabbing participants at the upper and lower gum lines using a collection swab.
3) Staff will not perform more than 3 attempts to obtain oral fluid sample
4) The swab head with oral fluid sample will be introduced into the sample solution and transferred to a clean and unused test cartridge (6).
5) Test results (positive, negative, or invalid) will be read in 15 minutes.

All human oral fluid specimens will be handled as potentially infectious material.

3.1. Duration of Survey

We plan to conduct the survey until optimal sample size is obtained at each site (for a maximum of 6 months).

As part of the consent for the survey we will ask for permission to retain contact information for each child/family, in case of possible follow-up investigation.

Fall 2021	Finalize protocol/funding, purchase and distribute testing supplies
February 2022	Conduct survey, data entry
April 2022	Debrief with partners, finish data entry
Summer 2022	Surveillance results with data analysis and preliminary report

3.2 Sites

Primary data collection will occur at five (5) physician practices universities across north, central and south New Jersey : 1.) Summit Health, Department of Pediatrics (Florham Park, NJ) 2.) New Jersey Medical School (Newark, NJ) 3.) Atlantic Health Department of Pediatrics (Morristown, NJ) 4.) Robert Wood Johnson Medical School Faculty Practice (New Brunswick, NJ) and 5.) Cooper University Healthcare (Camden, NJ). Survey questionnaire analysis will occur at NJDOH-CDS (Trenton, NJ).

3.3 Sample Size Justification

While much is not known about antibodies to SARS-CoV2 infection among children, available literature from other multi-site samples suggests that antibody levels are lower in children than adults.[5] Children are also generally more likely to present with asymptomatic or mild infection when compared to adults, which may result in lower IgG/IgM/IgA levels. We created a range of antibody prevalence values for the N.J. pediatric population given what is known about antibodies in asymptomatic/mild populations and the higher (unvaccinated) antibody prevalence rates in the N.J. area.

Assuming antibody prevalence will be higher if the child was diagnosed with COVID (as opposed to being undiagnosed) a one-tailed test of 90% power (α= 0.10) and a 0.2 or 0.1 allocation ratio (0.2/0.1) between samples (for every 10/5 children diagnosed with COVID, 50/50 are not), we calculated a range of sample sizes corresponding to different effect sizes in SARS-CoV-2 antibody prevalence given COVID undiagnosed vs COVID diagnosed patient sample over the investigation period across all sites. Sample size estimates for each group decrease with larger effect sizes and greater allocation ratios. Any additional stratified analyses will increase the effective sample size. Calculations were conducted with G*Power 3.1.9.4. See appendix A for sample size calculation examples.

Allocation Ratio (dx:undx)	***p1* (seropostivity undx)**	***p2* (seropositivity dx)**	**Effect Size**	***n1***	***n2***	***Total sample size***
10:50	0.10	0.20	10	492	98	590
10:100	0.10	0.20	10	895	90	985
10:50	0.08	0.16	8	638	127	765
10:100	0.08	0.16	8	1161	116	1277
10:50	0.10	0.15	5	1713	342	2055

[5] Burkhard Tönshoff, MD1; Barbara Müller, PhD2; Roland Elling, MD3,4; et al. Seroprevalence of SARS-CoV2 infection of children and their parents in Southwest Germany. JAMA Pediatr. 2021;175(6):586-593. doi:10.1001/jamapediatrics.2021.0001

10:100	0.10	0.15	5	3132	313	3445

3.4 Subject Selection and Enrollment Considerations

The approximate potential survey populations of each site are described below:

	Atlantic Health	**Summit Medical**	**Cooper, (Camden)**	**RWJMS/Chandler (New Brunswick)**	**NJMS (Newark)**
Approximate daily pediatric patient flow	20 ped. patients/day	10 ped patients/ day	15 ped. patients/ day	5 ped. patients/day, 25 per week	5 ped patients/day, 24 per week

Enrollment will be open to all pediatric patients at each of the sites who meet the below inclusion criteria.

3.5.1 Inclusion Criteria

Patients 18 months to 11 years of age without acute illness consistent with COVID-19 or symptoms of COVID-19 in the past 15 days.

3.5.2 *Exclusion Criteria*

Individuals less than 18 months of age or greater than 11 years of age will be excluded. Additionally, individuals with symptoms consistent with COVID-19 in the past 15 days should be excluded. This is in line with FDA recommendations for the oral fluid test.

See screening form (Appendix B)

3.5.3 Subject Recruitment

The households of potentially eligible participants will be approached either: 1) by phone or letter prior to their scheduled visit or 2) at the time of their visit, according to site preference, to assess interest in the survey. Recruitment materials are available in appendix F. Interested participants will be screened (screening tool described in appendix B). Further examples of recruitment protocols are included in Appendix C.

Each site will aim to recruit an approximately equal number of participants from each age group: 18 mos-3 years, 4-5, 6-7, 8-9, and 10-11 years. The need for recruitment of under-represented age groups will be assessed on a regular basis and emphasized once a site has reached 50% of their proposed sample size.

3.5.4 Consent Procedures

All participants and their legal guardians will receive information regarding the study's purpose, procedures, and risks/benefits prior to agreeing to participating in the study. Written or electronic consent will be solicited from a participant's guardian on behalf of the child before administration of the questionnaire and any specimen collection. The interviewer will answer any questions the participant and/or guardian may have and inform them of their rights to participate before consent is obtained. Interviewing staff will be required to answer all questions individuals may have on a level they understand. A sample consent form is provided in Appendix E.

3.6 Chart Review Selection

<N/A>

4. Study Variables

4.1 Independent Variables or Interventions

A main independent variable is a history of diagnosed COVID infection. Refer to attached survey instrument for a description of all exposure data to be collected. (Appendix D).

4.1.1 Drug or Device Interventions

<N/A>

4.2 Dependent Variables or Outcome Measures

Our primary outcome is SARS CoV-2 antibody prevalence as measured by presence of total Immunoglobulin G (IgG/IgM/IgA)

4.3 Risk of Harm

There is a minimal risk of discomfort with collection of oral fluid, however all staff collecting samples will be supervised by trained medical professionals.

4.4 Potential for Benefit

The prevalence of COVID-19 in the population 18 mos-11 years old is unknown. Additional surveillance data could be used to inform the importance of vaccine uptake in this population as well as the impact of preventative measures and educational exposures on the risk of developing COVID-19. This information could be used to develop public health and clinical guidance for this vulnerable age group.

. Data Handling and Statistical Analysis

Data Confidentiality

Test results will be maintained by NJDOH and stored in the Communicable Disease Reporting Surveillance System (CDRSS), a secure data repository behind a state-secured firewall. CDRSS data exists on network servers that are separate from web-facing servers and requires usernames and passwords for access. CDRSS data cannot be stored on laptops and is accessed only by state and local health officials. Any paper data containing personally identifiable information will be stored in a locked office and filing cabinet at participating sites. Biospecimens will be processed at point of care and will not require storage or transportation. All data collection will adhere fully to HIPAA standards and regulations.

Confidentiality of survey data will be assured against disclosure through tiered process of securing personal health identifiers. Identifiers will be collected separately from the survey questionnaire and linked to participant data only through a coded ID number. Lastly, all data reporting would be on an aggregate basis and fully PHI-protected.

Statistical Analyses

Overall antibody prevalence will be determined by the proportion of all samples that are SARS-COV-2 IgG positive. Using information obtained from the electronic survey instrument, antibody prevalence may be further stratified by sociodemographic factors (e.g., age, sex, race/ethnicity), exposure behaviors, clinical history, and household environment.

6. Data and Safety Monitoring

<N/A>

7. Reporting Results

7.1 Individual Results

Results from antibody tests will be made available to all study participants by the administering site.

7.2 Aggregate Results

Aggregate serosurvey results will be shared with participating healthcare partners and other public health stakeholders include NJDOH, CDC, and local health departments.

7.3 Professional Reporting

Results have the potential to be published in a peer-reviewed journal. Any data reporting will be done on an aggregate level, and no participant identifiers will be included.

8. Bibliography

1. https://www.the-scientist.com/news-opinion/largest-seroprevalence-study-in-us-shows-vast-covid-19-undercount-67762

2. CDC, June 11, 2021, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html?s_cid=10493:covid%2019%20vaccine:sem.ga:p:RG:GM:gen:PTN:FY21

3. https://www.usatoday.com/story/news/health/2021/11/02/covid-vaccine-kids-children-approved/6233927001/

4. https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html

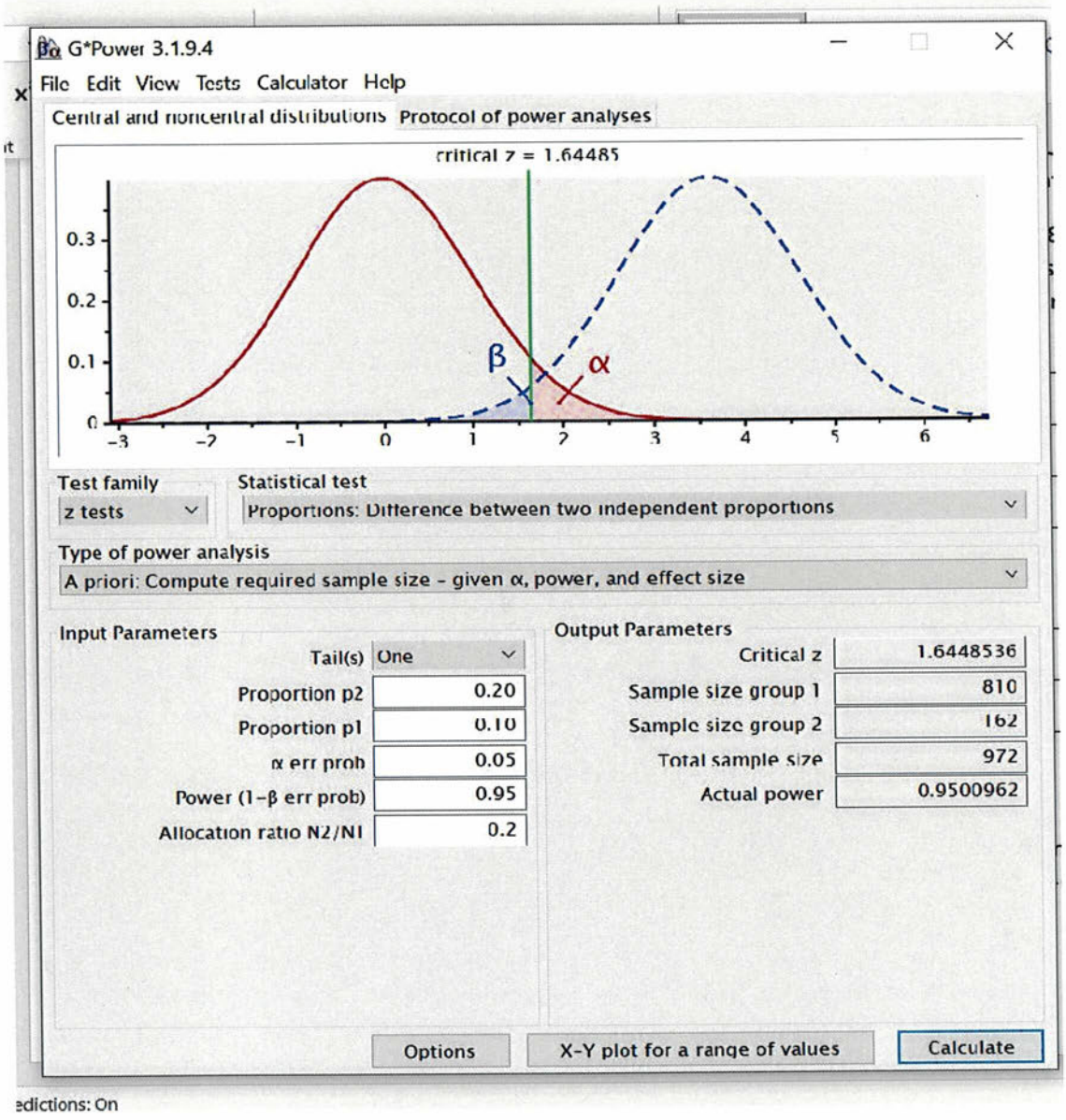
5. Burkhard Tönshoff, MD1; Barbara Müller, PhD2; Roland Elling, MD3,4; et al. Seroprevalence of SARS-CoV2 infection of children and their parents in Southwest Germany. JAMA Pediatr. 2021;175(6):586-593. doi:10.1001/jamapediatrics.2021.0001

6. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html

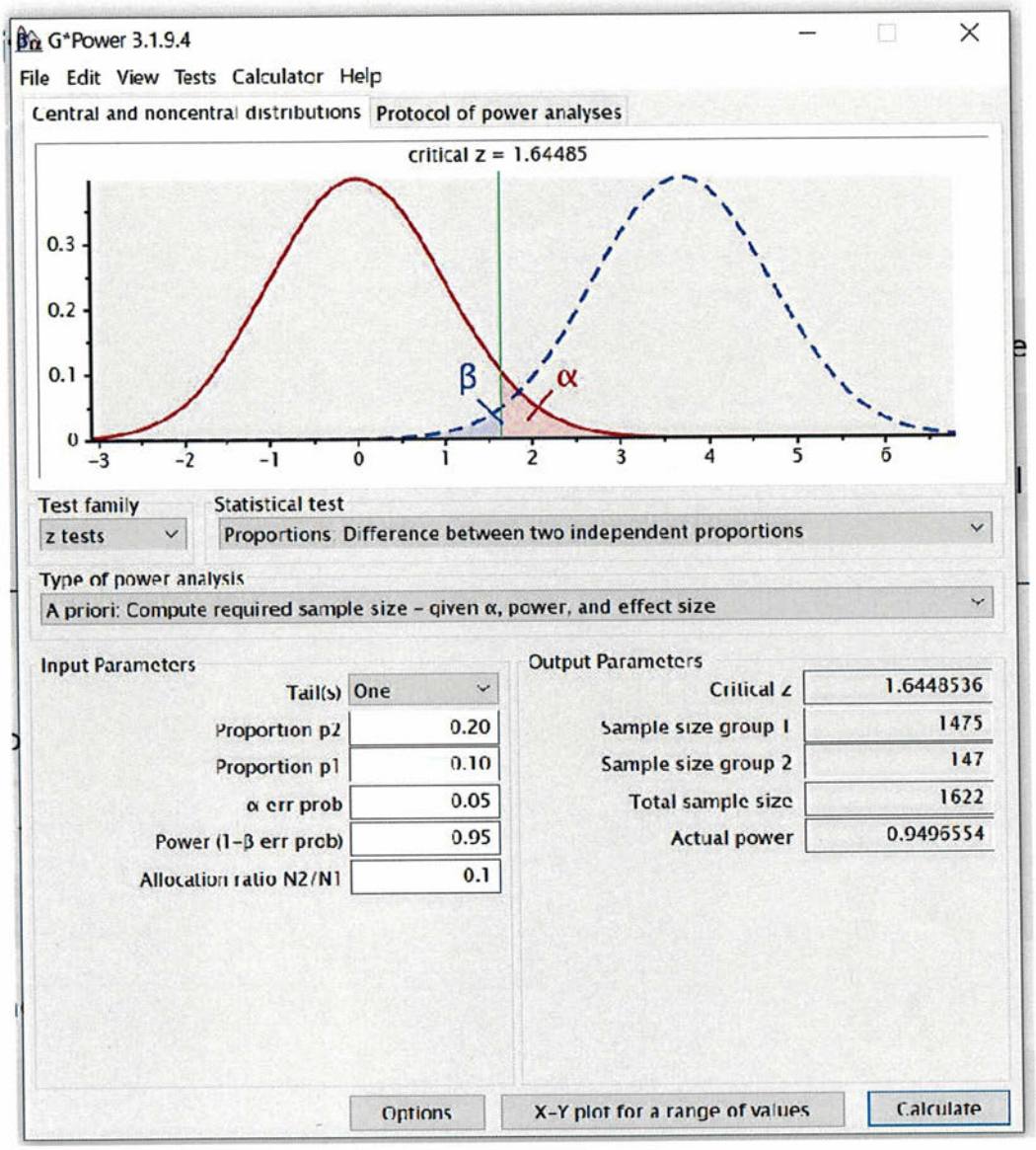
7. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance

8. https://www.fda.gov/media/149943/download

Appendix A: Sample Size calculation estimates



Assuming allocation ratio of 0.2, for every 10 dxd, there are 50 who are not.



Assuming allocation ratio of 0.1, for every 10 children ever diagnosed with COVID, there are 100 who are not Dxd. (or for every 5 dxd, 50 are not).

Appendix B:

Survey Screening form

1) Is patient aged 18 mos -11 years? ☐ No ☐ Yes

2.) Has participant been vaccinated against SARS-CoV-2?

a. Yes
b. No

3) Do you have any COVID symptoms today or in the past 15 days? (this might or might not already be asked in advance of routine physical)

Appendix C: Example site recruitment practices

Option A:

- Patients between 18 months and 11 years old will receive a flyer/brochure from front desk staff upon check in at the office.
- Patients will be pre-screened by clinicians for inclusion/exclusion criteria and willingness to participate in study during the physician visit in the exam room.
- Research assistant will obtain informed consent and administer questionnaire for interested and eligible patients in exam room after physician visit.

Option B:

- The survey team at each site will contact families by phone prior to their scheduled routine and/or vaccine visits to discuss the survey and assess their interest in participating.
- Households interested in participating will meet with the survey team at the time of their visits to assess inclusion/exclusion criteria obtain consent, complete the survey and perform the testing (including obtaining the specimen and running the test).

Appendix D: Survey instrument

1. Clinic Identifier:
   - ☐ Atlantic: Florham Park
   - ☐ Atlantic: Madison
   - ☐ Atlantic: Morristown
   - ☐ Atlantic: Scotch Plains
   - ☐ RWJMS: New Brunswick
   - ☐ RWJMS: Somerset
   - ☐ Summit
   - ☐ NJMS
   - ☐ Cooper
2. Today's Date: MM / DD / YYYY

Provided by Study Staff:

3. Household ID # (1-1000):
4. Household Member ID (A-Z):

I. Demographic Information About The Child: The following questions are used to let us get to know the participating child better. As a reminder, the results of all questions in this survey are strictly confidential.

1. What is the child's date of birth: MM / DD / YYYY
2. Is the child Hispanic or non-Hispanic?
   - ☐ Hispanic
   - ☐ Non-Hispanic/Latino
3. What is the child's race?
   - ☐ White
   - ☐ Black
   - ☐ Asian
   - ☐ American Indian/Alaskan Native
   - ☐ Native Hawaiian/Other Pacific Islander
   - ☐ Other
4. What is the child's sex?
   - ☐ Male
   - ☐ Female
5. What is the primary reason for today's visit?
   - ☐ Routine Visit (i.e. well visit, vaccine visit)
   - ☐ Visit for New Illness (i.e. sick visit)
   - ☐ Other: _____

II. Household Questions: The following questions help us find out more information about the household that the child is living in. These questions only need to be answered once for each household. *You do not need to answer these questions for every child and may skip to the next section if you have already answered these questions.*

6. On average, how many nights per week does the child spend in the household?
   - ☐ Every Night
   - ☐ Most Nights
   - ☐ Less Than Half of Nights
   - ☐ No Nights
7. How many members are in your household* (including all participants)?
   **We define a household member as anyone who has shared a living space (such as your home) with the child for at least a week in the past 6 months.*

   _____
8. What county does the household live in?

☐ Atlantic	☐ Bergen	☐ Burlington
☐ Camden	☐ Cape May	☐ Cumberland
☐ Essex	☐ Gloucester	☐ Hudson
☐ Hunterdon	☐ Mercer	☐ Middlesex
☐ Monmouth	☐ Morris	☐ Ocean
☐ Passaic	☐ Salem	☐ Somerset
☐ Sussex	☐ Union	☐ Warren

9. How many members of your household* are in each age group below? Within these age groups, how many members have been fully vaccinated** and how many members have been boosted?

**We define a household member as anyone who has shared a living space (such as your home) with the child for at least a week in the past 6 months.*
***Fully vaccinated means at least two doses of Pfizer/Moderna or one dose of Johnson & Johnson*

	How many household* members?	How many are fully vaccinated**?	How many have received boosters?	How many have been diagnosed with COVID-19 in the past 12 months?
Adults (>18 years old)	☐	☐	☐	☐
Children (12-17 years old)	☐	☐	☐	☐
Children (5-11 years old)	☐	☐	☐	☐
Children (18 months to 5 years old)	☐	☐	☐	☐
Children (<18 months old)	☐	☐	☐	☐

10. About when was the last person diagnosed with COVID-19: MM / DD / YYYY

III. Clinical History/COVID Exposure History: The next few questions will ask about any health problems the child has and whether they have been exposed to or had COVID-19.

11. Has a doctor ever said the child has any of the following health problems?
Select all that apply.
    - ☐ Asthma/Reactive Airway Disease
    - ☐ Other Chronic Lung Disease (i.e. cystic fibrosis, sleep apnea): _____
    - ☐ Diabetes
    - ☐ Hypertension (high blood pressure)
    - ☐ Chronic Cardiovascular or Heart Disease
    - ☐ Chronic Kidney Problems
    - ☐ Liver Problems
    - ☐ Cancer (current, in-treatment, or diagnosed in last 12 months)
    - ☐ Immunosuppressive Condition or Therapy/Medications
    - ☐ Obesity/Overweight
    - ☐ ADHD
    - ☐ Autism
    - ☐ Other Neurologic Conditions (i.e. cerebral palsy, Down's syndrome, seizure disorder, etc.)
    - ☐ Any Other Medical Conditions: _____

12. In the last 12 months, has your child been in close contact* with someone who was confirmed to have COVID-19?

**This question is about being in contact with someone with COVID-19. Close contact means being within 6 feet of someone with COVID-19 for 15 minutes or more. Confirmed COVID-19 means that the person has had a positive test or been told by a doctor that they had the disease.*

☐ Yes ☐ No ☐ I Don't Know

13. Please give an estimate on the date of the most recent COVID-19 exposure:
Leave blank if unknown.
MM / YYYY
14. Please specify the relations of any known COVID-19 close contacts.
Check all that apply.
    - ☐ Relative/Friend Within Household
    - ☐ Relative/Friend Outside Household
    - ☐ Classmate or Teacher
    - ☐ Other Relation (Please Specify If Known): _____
15. Please specify the locations where you think the exposures may have occurred.
Check all that apply.
    - ☐ At Home (Among Household Members)
    - ☐ At Home (Among Guests)
    - ☐ Another Home Outside of Your Household
    - ☐ Workplace
    - ☐ School Classroom
    - ☐ School Extracurricular Activity (including sports)
    - ☐ Daycare
    - ☐ Hospital/Clinic
    - ☐ Church/Temple/Mosque/Other Religious Gathering
    - ☐ Other Public Place (shopping centers, restaurants, etc.)
    - ☐ Other (Please Specify): _____
16. Has the child been diagnosed with COVID-19 since January 2020?
    - ☐ Yes ☐ No
17. How many times has the child been diagnosed with COVID-19 since January 2020? _____
18. What was the approximate date of the child's most recent positive COVID-19 test?
MM / YYYY
19. Did the child have any symptoms during the last time the child was diagnosed with COVID-19?
    - ☐ Yes ☐ No

20. Which symptoms did the child have?

	At diagnosis?		Lasted more than 4 weeks?	
	Yes	No	Yes	No
Fever > 100.4F (38C)	○	○	○	○
Felt Feverish	○	○	○	○
Chills	○	○	○	○
Muscle Aches	○	○	○	○
Runny Nose	○	○	○	○
Sore Throat	○	○	○	○
New Cough	○	○	○	○
Shortness of Breath	○	○	○	○
Nausea/Vomiting	○	○	○	○
Headache	○	○	○	○
Abdominal Pain	○	○	○	○
Diarrhea	○	○	○	○
Change In or Loss of Taste	○	○	○	○
Change In or Loss of Smell	○	○	○	○
Fatigue	○	○	○	○
Seizures/Neurologic Issues	○	○	○	○
Other (Specify Below)	○	○	○	○

21. Specify other symptoms: _____
22. Was medical care sought for the child's illness?

☐ Yes ☐ No

23. If yes, where was medical care received?

☐ Doctor's Office or Clinic
☐ Urgent Care
☐ Emergency Department
☐ Admitted To (Stayed In) The Hospital for Greater Than 24 Hours
☐ Admitted To (Stayed In) The ICU (Intensive Care Unit)

24. Has the child had any illnesses accompanied by fever (either measured with temperature >100.4 or felt feverish) in the past 12 months?

☐ Yes ☐ No ☐ I Don't Know

25. What were the approximate dates of illness and for each illness, was the child tested for COVID-19?

	Approximate Date of Illness		Tested for COVID-19?	
	Month	Year	Yes	No
Illness #1			○	○
Illness #2			○	○
Illness #3			○	○
Illness #4			○	○

26. Which symptoms did the child have during the most recent illness with fever?

Select all that apply and whether symptoms occurred at diagnosis and lasted for more than 4 weeks.

	At diagnosis?		Lasted more than 4 weeks?	
	Yes	No	Yes	No
Fever > 100.4F (38C)	○	○	○	○
Felt Feverish	○	○	○	○
Chills	○	○	○	○
Muscle Aches	○	○	○	○
Runny Nose	○	○	○	○
Sore Throat	○	○	○	○
New Cough	○	○	○	○
Shortness of Breath	○	○	○	○
Nausea/Vomiting	○	○	○	○
Headache	○	○	○	○
Abdominal Pain	○	○	○	○
Diarrhea	○	○	○	○
Change In or Loss of Taste	○	○	○	○
Change In or Loss of Smell	○	○	○	○
Fatigue	○	○	○	○
Seizures/Neurologic Issues	○	○	○	○
Other (Specify Below)	○	○	○	○

27. Specify other symptoms: _____
28. Was medical care sought for the child's most recent respiratory illness?

☐ Yes ☐ No

29. If yes, where was medical care received?

Check all that apply.

☐ Doctor's Office or Clinic
☐ Urgent Care
☐ Emergency Department
☐ Admitted To (Stayed In) The Hospital for Greater Than 24 Hours
☐ Admitted To (Stayed In) The ICU (Intensive Care Unit)

IV. Activities/Preventative Measures: We would like to ask you a few questions about activities that your child has done and measures that your child takes to protect themselves against COVID-19.

30. Has the child travelled outside of the state in the past 12 months (not including New York, Pennsylvania, Delaware)?

    ☐ Yes ☐ No

31. Where has the child travelled?

    ☐ A State Other Than New Jersey (not including NY, PA, DE)

    ☐ Outside of the Country

32. Which state? _____

33. Which country? _____

34. Please indicate which of the following in-person activities the child has attended in the past 12 months.

    ☐ Daycare
    ☐ Summer Camp
    ☐ Indoor Sports Team: _____
    ☐ Outdoor Sports Team: _____
    ☐ Theater/Music
    ☐ Indoor Religious Services
    ☐ Other School-Based Activity (i.e. extracurricular activities, clubs, etc.)
    ☐ Other Non-School-Based Activity: _____

35. On average, in the past 12 months, in which situations has the child worn a mask?
    Please mark N/A if you were never in this situation.

	How often has the child worn a mask in this situation? Please mark N/A if you were never in this situation.					
	Never	**Rarely**	**Sometimes**	**Often**	**Always**	**N/A**
Situation:						
At Home	○	○	○	○	○	○
Indoor Dining Outside of the Home (While Not Eating)	○	○	○	○	○	○
Outdoor Dining Outside of the Home (While Not Eating)	○	○	○	○	○	○
Indoor Sports	○	○	○	○	○	○
Outdoor Sports	○	○	○	○	○	○
Indoor Social Gathering with Non-Household Members	○	○	○	○	○	○
Outdoor Social Gathering with Non-Household Members	○	○	○	○	○	○
School Classroom	○	○	○	○	○	○
Indoor School Extracurricular Activities	○	○	○	○	○	○
Outdoor School Extracurricular Activities	○	○	○	○	○	○
Daycare	○	○	○	○	○	○
Indoor Religious Services	○	○	○	○	○	○
Other Public Indoor Venues (stores, malls, post office)	○	○	○	○	○	○

V. Health Attitudes of Parent/Guardian: The next set of questions will ask about sources of health information, use of masks and opinions about vaccines. For each question, if you prefer not to answer, please select that option.

These questions only need to be answered once for each household (not needed for every child in the family) and should be independently answered by a direct guardian or parent.

36. Where do you obtain the majority of your health information?
Select up to three.

- ☐ NJ State Website (ex: NJ.gov)
- ☐ Federal Website (ex: CDC.gov)
- ☐ Local Health Department Website or Bulleting
- ☐ Non-Governmental Medical Website (i.e. WebMD)
- ☐ Personal Physician
- ☐ Friends/Family/Colleagues
- ☐ Social Media
- ☐ TV News Outlet (ex: NBC, CBS, Fox)
- ☐ Newspaper (Online or Print)
- ☐ Other: _____
- ☐ Prefer Not to Answer

37. On a scale of 0-3, how worried are you about becoming infected with the virus that causes COVID-19?
0 being not risky at all, 3 being extremely risky.

Not Worried At All			Extremely Worried	
0	1	2	3	Prefer Not to Answer
○	○	○	○	○

38. On a scale of 0-3, please indicate how risky you believe the following situations/activities are:
0 being not risky at all, 3 being extremely risky.

	Not Risky At All			Extremely Risky	
	0	1	2	3	Prefer Not to Answer
Indoor Dining (Outside of the Home)	○	○	○	○	○
Outdoor dining (Outside of the Home)	○	○	○	○	○
Indoor Sports	○	○	○	○	○
Outdoor Sports	○	○	○	○	○
Indoor Gathering With Non-Household Members	○	○	○	○	○
Outdoor Gathering With Non-Household Members	○	○	○	○	○
School Classroom	○	○	○	○	○
Daycare	○	○	○	○	○
Indoor Religious Services	○	○	○	○	○
Other Public Indoor Venues (stores, malls, post office)	○	○	○	○	○

39. How effective do you think wearing a mask is for preventing COVID-19?

- ☐ Very Effective
- ☐ Somewhat Effective
- ☐ Somewhat Ineffective
- ☐ Not At All Effective
- ☐ I Am Not Sure
- ☐ Prefer Not to Answer

40. How effective do you think vaccination is for preventing COVID-19?

- ☐ Very Effective
- ☐ Somewhat Effective
- ☐ Somewhat Ineffective
- ☐ Not At All Ineffective
- ☐ I Am Not Sure
- ☐ Prefer Not to Answer

41. Do you plan to get your child(ren) vaccinated against COVID-19 in the next 6 months?

☐ Yes ☐ No ☐ Unsure ☐ Prefer Not to Answer

42. If no or unsure, why not?

- ☐ I am worried about side effects.
- ☐ My child has a medical condition that might be affected by the vaccine.
- ☐ Religious reasons.
- ☐ I am concerned that vaccines will make fighting future strains more complicated.
- ☐ My child already had COVID-19.
- ☐ I prefer to wait until more children have been vaccinated.
- ☐ It is too difficult to obtain a COVID-19 vaccination for my child.
- ☐ I have seen/heard of someone who had the vaccine and was still diagnosed with COVID-19.
- ☐ Prefer not to answer.
- ☐ Other: _____

43. The next few questions ask about your level of agreement to the following statements about vaccines. Please answer these questions on a scale of 0-5, where 0 represents strongly disagree and 5 is strongly agree.

	Strongly Disagree					Strongly Agree	
	0	1	2	3	4	5	Prefer Not to Answer
COVID-19 vaccines are safe for adults	○	○	○	○	○	○	○
COVID-19 vaccines are effective for adults	○	○	○	○	○	○	○
COVID-19 vaccines are safe for children	○	○	○	○	○	○	○
COVID-19 vaccines are effective for children	○	○	○	○	○	○	○
There's not enough known about the COVID-19 vaccine in children	○	○	○	○	○	○	○
COVID-19 vaccinations are unnecessary for children because it's a mild illness	○	○	○	○	○	○	○
I agree with my pediatrician's medical advice most times	○	○	○	○	○	○	○
In general, childhood vaccinations (for example against measles or chicken pox) are important	○	○	○	○	○	○	○

Appendix E: Consent Form

Site Letterhead

Site Address here

Site Contact information here
Phone:
Fax:
Email:

CONSENT TO TAKE PART IN AN ANTIBODY SURVEY

Title of Survey: **SARS-CoV2 Antibody Prevalence in the Pediatric Population of New Jerseyy.**

Principal Investigator: [Site-specific PI here]

SURVEY SUMMARY: [name of site] and New Jersey Department of Health are working together to investigate the impact of SARS-CoV-2, the virus that causes the disease named COVID-19, on children in New Jersey. To do this, we are approaching the caregivers of unvaccinated children between ages 2-11 to participate in an investigation about the presence of antibodies to SARS-CoV-2 and potential exposures to the virus. The purpose of this consent form is to help you understand this investigation so that you can decide whether you and your child want to take part.

The **purpose of the investigation** is to identify whether children have been previously infected with SARS CoV-2. We will do this by testing for antibodies to the virus in a sample of fluid collected from the mouth. Antibodies tell us whether a person has been infected in the past even when their infection has not made them sick. Antibodies usually mean that a person is protected against a second infection from a virus, but the duration of this protection is not yet known for COVID-19. If you take part in the survey, you will be asked to allow us to collect fluid from your mouth which we will test for antibodies to the virus. You will have the results of your test within 15-30 minutes. We will also ask your permission to take a short (10-15 minute survey) about your child's prior COVID-19 testing, potential exposures to COVID-19, symptoms, and information about your health. We will also ask about whether other members of the household have ever had COVID-19 and have been vaccinated against the virus that causes COVID-19.

Only [name of site] and New Jersey Department of Health will have access to identifying information; all data will be stripped of all personal information (identifiers) prior to sharing with New Jersey Department of Health and other partners. Your results will be kept confidential within our survey team and your physician's office.

Your total time in the investigation will take 30 minutes (a half hour).

Possible benefits of taking part may be that you will find out whether you have antibodies to COVID-19 even if you have not been ill from the virus, and possibly, whether you are less likely to get infected in the future.

Possible harms or burdens of taking part in the survey may be slight discomfort when we swab your child's mouth for oral fluid.

An alternative to taking part in the survey is not to take part in it. Non-participation in this survey will not affect the medical care you receive.

We may also try to figure out how many children get sick with COVID-19, develop antibodies and/or continue to have antibodies after a few months. To do this, we would ask you, in a few months, for permission to collect

another sample of oral fluid and/or repeat the questionnaire. You do not have to decide now whether you want to participate again later.

Do we have your permission to contact you again in 6-8 months? Yes_____ No_____

AGREEMENT TO PARTICIPATE

Signature of Participant' Caregiver

I have read this entire consent form, or it has been read to me, and I understand what has been discussed. My questions about this form and this survey have been answered. I agree to take part in this survey.

Participant/Child Name (Print): _____

Caregiver Name (Print):_____

Caregiver Signature:_____ Date: _____

Appendix F: Recruitment materials

Do you know if your child has ever had COVID-19?

Your chid may have already had COVID-19, even if they only had mild or no symptoms at all. New Jersey Department of Health is testing unvaccinated children for antibodies to the virus that causes COVID-19 and collecting information about symptoms, exposures and family health.

We are looking for unvaccinated chidren to participate in:

- A saliva test for antibodies to the virus that causes COVID-19
- A 10-15 minute electronic survey

Is your child eligible?

- 2-11 years old
- English or Spanish speaking
- **Has not been vaccinated** against COVID-19

Participants will receive:

- $20.00 Visa E-Gift Card

Location:

- Discuss with your physician *to find out more information*
  OR
- Call or email xxxxxxx

For general questions, please contact:

xxxx xxxx
xxxxx@xxxxxxx

or

Bozena Katic
bozena.katic@doh.nj.gov

Reed Magleby
Reed.magleby@doh.nj.gov

With your help, we can better understand how coronavirus is affecting the health of children in New Jersey!

[LETTER TO SEND TO POTENTIALLY ELIGIBLE FAMILIES]

[DATE]

[Site Stationery, e.g., Summit Health]

Dear [name of parent or guardian]

The New Jersey Department of Health [NJDOH] and the [name of site] Department of Pediatrics are working together to find out how many children in New Jersey have already had Covid 19. Many children have had mild illness or no symptoms and may not have had a test during their illness. NJDOH is going to test a sample of children across the state, to find out how many have antibodies to the virus that causes Covid. Even children who had no symptoms would have antibodies, if they had the infection.

Children who take part in the study will have a saliva test for antibodies, and there will also be a 10–15-minute electronic survey.

Your child is eligible if he or she is a patient of [.....], is 18 months to 11 years old, is English or Spanish speaking, and has not received the Covid vaccine.

[Name of site] will be reaching out to children who have upcoming doctor visits at [list of locations for each site]. If you are contacted, we hope you will participate.

With your help we can better understand how corona virus is affecting the health of children in New Jersey!

For more information please call [ ] or email [ ].

Sincerely,

[name of person at each site who is in charge]