PROTOCOL TITLE:
A novel device to collect droplets generated from the lung of COVID-19 patients

PRINCIPAL INVESTIGATOR:
Larry J. Anderson, MD and Evan J Anderson, MD.
Emory University School of Medicine
Department of Pediatrics

NCT NUMBER:
NCT04912895

VERSION: v3.0: September 10, 2021

FUNDING SOURCE: Internal funding in addition to Georgia Tech grant

REVISION HISTORY

Revision #	Version Date	Summary of Changes
AM1	v 2.0: 01JUL2020	Recruitment materials Oral consent and phone screen questionnaire for prescreening Language in protocol to reflect the recruitment process and consenting process
AM2	V3.0 10SEP2021	Increased COVID sample population from 30 to 75 and decreased minimum time between collections to 15 min.

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1. Study Summary

Study Title	Detection of SARS-CoV-2 RNA and Biomarkers in Coughed Droplets from Patients with COVID-19 and Controls
Study Design	Single Center comparative trial with controls
Primary Objective	Determine the sensitivity and specificity of detecting SARS-CoV-2 RNA in cough-generated droplets captured with the PneumoCheck™
Secondary Objective(s)	Determine the value of detecting inflammatory cytokines and chemokines and other biomarkers in cough-generated droplets with PneumoniaCheck in evaluating disease in COVID-19 patients.
Research Intervention(s)/Interactions	Determine the value of PneumoniaCheck specimens for diagnosing SARS-CoV-2 infection and assessing disease state and understanding pathogenesis of disease.
Study Population	We will to enroll up to 30 SARS-CoV-2 PCR positive patients and up to 30 patients with a non-COVID-19 acute respiratory illness being treated either as inpatients or outpatients to participate in the study. We will also enroll up to 30 healthy controls.
Sample Size	Up to 135 across all cohorts
Study Duration for individual participants	Those who consent to participate will have a cough specimen collected over the following 24 hours and asked to do 4 additional sets of 10 coughs into the same device
Study Specific Abbreviations/ Definitions	NA
Funding Source (if any)	Internal funding in addition to Georgia Tech grant

2. Objectives

Goal: Determine the value of PneumoniaCheck specimens for diagnosing SARS-CoV-2 infection and assessing disease state and understanding pathogenesis of disease.

Aim 1: Determine the sensitivity and specificity of detecting SARS-CoV-2 RNA in cough-generated droplets captured with the PneumoCheck™

Aim 2: Determine the value of detecting inflammatory cytokines and chemokines and other biomarkers in cough-generated droplets with PneumoniaCheck in evaluating disease in COVID-19 patients.

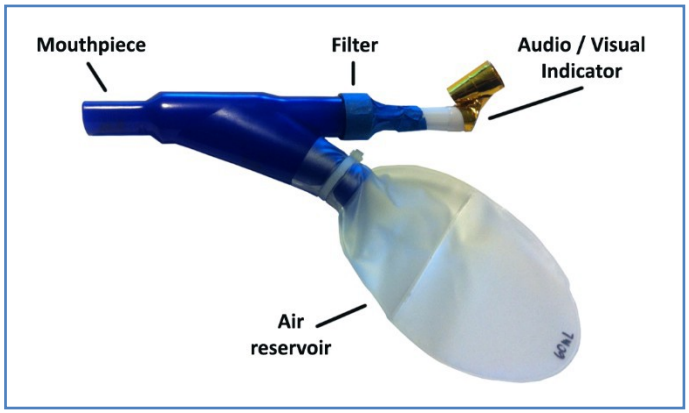
3. Background

A novel coronavirus (SARS-CoV-2) was detected in association with cases of severe respiratory illness and pneumonia (COVID-19) in Wuhan City, Hubei Province, China in December 2019(1). The virus

subsequently spread widely throughout China and globally. As of June 2 2020, over 6,000,000 cases and 375,000 deaths have been reported globally and over 1,700,000 cases and 100,000 deaths in the United States(2). Addressing this unprecedented global pandemic is requiring all available tools to diagnose infection, manage ill patients, understand disease pathogenesis and virus transmission to guide efforts to decrease transmission and rapidly develop anti-viral drugs and vaccines. We propose to use the PneumoniaCheck™, a device developed collaboratively by investigators at Georgia Institute of Technology (GA Tech) and the Centers for Disease Control and Prevention (CDC), to help address these issues. This device, non-invasively, captures coughed droplets onto a filter with minimal contamination from upper airway secretions(3, 4). In preliminary studies in cystic fibrosis, mycobacterium tuberculosis (TB) patients and control patients, we detected bacterial DNA by PCR, inflammatory cytokines and chemokines by multiplex Luminex assays, surfactant by enzyme immunoassay (EIA), and amylase by enzymatic assay. These data show that this device can provide high quality specimens from the lung with minimal risk to the patient and healthcare provider and much lower risk than invasive procedures such as bronchioloalveolar lavage. In addition, with this device, we can acquire specimens from patients who do not have a productive cough (dry cough), a commonly reported symptom for COVID-19, and specimens with minimal upper respiratory contamination unlike a sputum specimen. Thus, this device can provide lung secretion specimens to improve detection of SARS-CoV-2 RNA (lung specimens are better for detecting virus than upper respiratory tract specimens) and detect inflammatory and other biomarkers to explore pathogenesis of disease, identify inflammatory processes that might be amenable to intervention, and identify biomarkers of disease severity for patient management and evaluation of vaccines and anti-viral drugs. We propose to determine how PneumoniaCheck™ can help diagnose, manage, and understand pathogenesis of disease and transmission risk of COVID-19.

The PneumoniaCheck uses fluid mechanics to preferentially eliminate upper respiratory contaminants while capturing cough-generated droplets from the lung onto a filter. The device, illustrated in Figure 1, is designed to prevent upper respiratory tract fluids from entering the device, to direct residual upper airway (dead space) that may contain upper respiratory tract contaminants to a balloon, and to direct coughed air from the lung through a filter. Once the balloon is filled with dead space air, air from the lung is diverted through the filter and the droplets captured onto the filter. DNA or RNA from bacteria, viruses, *etc.*, or proteins and other molecules present in these droplets can be detected by real time PCR for DNA or RNA or by enzyme immunoassays (EIAs) for cytokines, chemokines, or other molecules. The ability to detect SARS-CoV-2 RNA and biomarkers indicative of inflammation and active disease should help physicians manage COVID-19 patients and researchers understand the disease process and possibly transmission risk. This study will develop data on detection of SARS-CoV-2 RNA and lung biomarkers with this device in COVID-19 patients.

Figure 1. PneumoniaCheck.



4. Study Endpoints

Aim 1. Determine the sensitivity and specificity of detecting SARS-CoV-2 RNA in cough-generated droplets captured with the PneumoCheck™. We have captured real time PCR detectable bacterial DNA from the lung with PneumoCheck™ in the lung of adults with cystic fibrosis at a rate similar to that reported for detecting bacteria in bronchoalveolar lavage fluid (BALF) specimens by culture(3). Since high levels of SARS-CoV-2 RNA can be detected in sputum specimens, the coughed specimens are a promising specimen to detect SARS-CoV-2 RNA for diagnosis, monitoring course of disease, and possibly indicating risk of transmitting virus to others.

Aim 2. Determine the value of detecting inflammatory cytokines and chemokines and other biomarkers in cough-generated droplets with PneumoniaCheck in evaluating disease in COVID-19 patients. We previously demonstrated that with PneumoniaCheck that we can detect inflammatory biomarkers in patients with acute respiratory illness as illustrated in **Figure 2**. Using the amylase to indicate upper respiratory origin and surfactant A to indicate lower respiratory tract origin, we demonstrate that PneumoniaCheck specimens come primarily from the lower respiratory tract (**Table**). We now propose to detect biomarkers of inflammation in coughed specimens from patient with COVID-19. We hypothesize that biomarkers of inflammation from the lung will indicate disease activity, inform pathogenesis of COVID-19 disease.

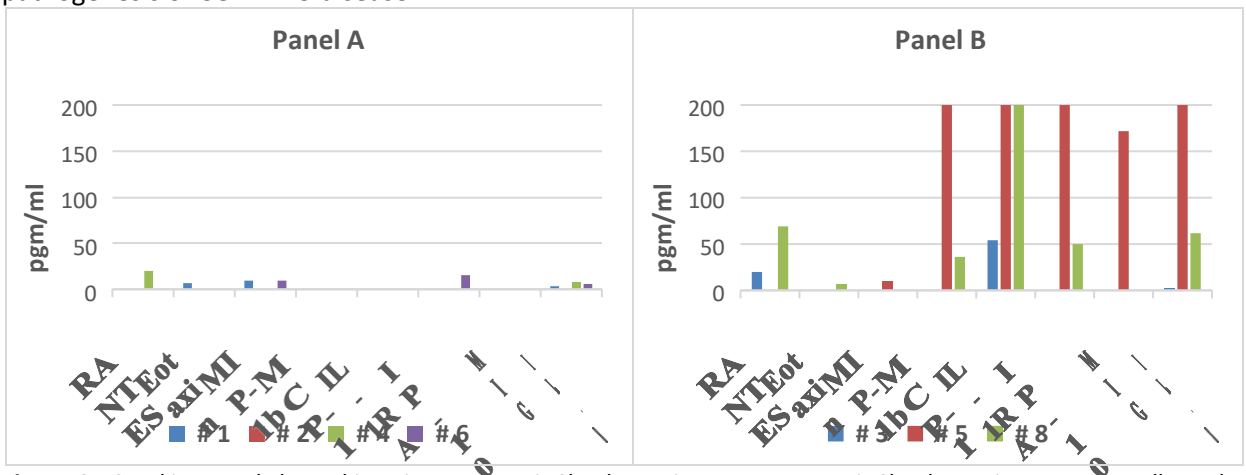


Figure 2. Cytokines and chemokines in PneumoniaCheck specimens. PneumoniaCheck specimens were collected in 4 subjects without respiratory symptoms (Panel 2.A) and 3 subjects (Panel 2.B) with respiratory symptoms. The PneumoniaCheck specimen was collected with 5 different collections of 10 coughs with each collection separated by > 1 hour. The device was stored at -80°C until processing. The specimen was eluted from the filter and tested by multiplex Luminex assay for cytokines and chemokines. Note the marked difference in level of cytokines and chemokines detected in patients with respiratory symptoms compared to those without.

Specimen	Staph A	Pseud A	Strep Pn	Amyl/SurfA
PneuCk 1	neg	neg	neg	0.24
PneuCk 2	neg	38.68	neg	0.03
PneuCk 3	37.17	37.9	neg	23.6
PneuCk 4	neg	37	neg	0.02
PneuCk 5	neg	38.58	41.96	3.49
PneuCk 6	neg	37.12	neg	0.30

PneuCk 7	neg	30.08	neg	517.6
PneuCk 8	neg	neg	neg	3.92
PneuCk 9	neg	neg	neg	0.04
Sputm 1	neg	36.89	35	1293
Sputm 2	neg	27.62	neg	6494

Table 1. Pathogen detection and specimen quality determination. PneumoniaCheck specimens were collected in 9 CF patients and 2 non-CF control patients by 5 different collections of 10 coughs with each collection separated by > 1 hour. The device was stored at -80°C until processing. The specimen was eluted from the filter and tested for *Staphylococcus aureus* (Staph A), *Pseudomonas aeruginosa* (Pseud A), and *Streptococcus pneumoniae* (Strep Pn) DNA by PCR, surfactant A (Surf A) by EIA, and amylase (Amyl) by an enzymatic assay. Neg = negative by PCR. Values are PCR CT values except for Amyl/SurfA which is the ratio of Amylase concentration over surfactant A concentration. Note the much higher Amyl/SurfA ratio for the sputum compare to PneumoniaCheck specimens indicating much lower or negligible levels of upper respiratory tract secretions in the specimen.

5. Study Intervention/Investigational Agent

Description: The PneumoniaCheck is a device uses fluid mechanics to preferentially eliminate upper respiratory contaminants while capturing cough-generated droplets from the lung onto a filter. The device, illustrated in Figure 1 above.

Device Handling: The patient will be given the PneumoniaCheck device with a sterile ziplock bag and cooler with cold packs to keep the device, shown a video, given verbal guidance for collecting the first set of coughed specimens, and asked to do 4 additional sets of 10 coughs into the same device. The device will be stored in the ziplock bag in the cooler betweencollections.

6. Procedures Involved:

Patients seen at Emory COVID-19 testing centers will be asked to participate in the study. Those who consent to participate will have a cough specimen collected over the following 24 hours and their medical record will be reviewed for age, sex, race/ethnicity, underlying medical conditions, their SARS-CoV-2 PCR test results, and other diagnostic test results if being seen for a COVID exposure or illness or other acute respiratory illness. The patient will be given the PneumoniaCheck device with a sterile ziplock bag and cooler with cold packs to keep the device, shown a video, given verbal guidance for collecting the first set of coughed specimens, and asked to do 4 additional sets of 10 coughs into the same device. The device will be stored in the ziplock bag in a cooler between collections. After the specimen is collected, the specimen will be collected by study personnel and transported using standard operating procedures for specimen transportation to the laboratory. In the laboratory, in a BSL2 biosafety cabinet with BSL2+ conditions, the PneumoniaCheck will be double bagged for storage at -80°C. Later the specimen is processed and tested for SARS-CoV-2 RNA by real time PCR and biomarkers by a multiplex Luminex assay and mass spectrometry. Each specimen will be given an identification number, without personal identifying information, which will be used to link laboratory results to clinical and epidemiologic data.

Specimen Processing

In the laboratory, in a BSL2 biosafety cabinet, with BSL2+ conditions, the PneumoniaCheck will be processed according to Biosafety approved processes.

For processing, the filter is removed from the device (see **Figure 1** for location of the filter) and captured coughed droplets eluted from the filter as described in Attachment 1. The 300ul of specimen containing elution buffer will be divided in 3 aliquots (RNAZol will be added to one aliquot) for storage at -80°C until

testing. The Spin-X column and filter will also be stored at -80°C. The vials will be sprayed with 70% alcohol to inactivate any contaminating virus before storage.

Specimen testing. The RNAZol containing specimen will be tested with the CDC SARS-CoV-2 N1 and N2 primers according to the CDC online protocol. One of the other aliquots will be thawed and tested by multiplex Luminex or Simoa Quanterix system assays for cytokines and chemokines (e.g., the Inflammation 20-Plex Human ProcartaPlex™ Panel, Invitrogen™, Waltham, MA, USA) and enzyme immune assay for surfactant A (Human surfactant Protein A ELISA Kit, Abbexa Ltd UK) according to the manufacturer's instructions. The specimens will also be tested for amylase by an enzymatic assay according to the manufacturer's instructions. Before biomarker testing, SARS-CoV-2 will be inactivated with an Environmental, Health and Safety Office approved method (e.g., heat-inactivation at 56°C for 30 min. protocol) and for novel biomarkers by mass spectrometry.

7. Data and Specimen Banking

Data will be analyzed based on specimen identification number and group (e.g., COVID-19 patient, non-COVID-19 acute respiratory illness patient, control). Participants will be consented for future contact and use of data and/or specimens. At the completion of this study, we will store any remaining samples for possible future use. The remaining samples may be stored indefinitely and may be used for future studies of genetic causes of the disease. The samples will be stored at Emory Children's Center and Emory Labs.

The sample will be given a unique identification number and stored without participant name or other identifiers. Only the investigator will have a list to know which sample is linked to which patient and this list will be kept confidential in a secure location. If the investigator distributes these samples for research into the causes of the disease, it will be released with the unique identifier, but without any names or medical record numbers.

8. Sharing of Results with Participants

In general, we will not give any individual results from the study of the samples. If we find something of urgent medical importance, we will inform the participant or the participant's primary care physician, although we expect that this will be a very rare occurrence.

9. Study Timelines

Patients who consent to participate in the study will be instructed on method of collection and asked to collect 5 sets of 10 cough specimens over the next 24 hours with the same PneumoniaCheck device. In some cases, participants may be asked to collect additional samples at a later time period.

10. Inclusion and Exclusion Criteria

We will to enroll up to 75 adult SARS-CoV-2 PCR positive patients and up to 30 adult patients with a non-COVID-19 acute respiratory illness being treated either as inpatients or outpatients to participate in the study. We will also enroll up to 30 adult healthy controls. We will collect coughed specimens during 5 sessions of 10 or more coughs separated by at least 15 minutes. Patients who consent to participate in the study will be instructed on method of collection and asked to collect 5 sets of 10 cough specimens over the next 24 hours with the same PneumoniaCheck device. After specimen collection is completed, the device is transferred to the laboratory and stored for processing. For processing, the filter (see **Figure 1**) with the captured coughed droplets is removed from the device, captured droplets eluted from the filter, and the eluate and filter are stored at -80°C for later testing, PCR for SARS-CoV-2 RNA, multiplex Luminex and Simoa Quanterix system assays for biomarkers of inflammation, enzyme immunoassay (EIA) for surfactant A, and an enzymatic assay for amylase. The PCR results, positivity and CT values, in

COVID-19 patients will indicate the sensitivity of this specimen for detecting SARS-CoV-2 RNA and in non-COVID-19 patients and controls the specificity. The ratio of surfactant A to amylase indicate lung and upper respiratory contributions to the specimen for all groups. The multiplex Luminex and Simoa Quanterix system data will give biomarkers of inflammation for each group and differences between groups biomarkers associated with COVID-19. We will also test some specimens with mass spectrometry to identify novel biomarkers associated with COVID-19 lung disease.

11. Vulnerable Populations

The population group for this study is adults age 18 and up. The study will initially be inclusive to English as a primary spoken language. At a later point, inclusion to other primary languages will be considered with available resources to that population group.

12. Local Number of Participants

Up to 90 total participants will be accrued locally; taking into consideration those that consent but are not able are to provide specimens. Those that consent and are unable to provide specimens will be considered screen failures and not counted toward overall enrollment.

13. Recruitment Methods

Once the ECC-VRC staff learn of a potential participant, they may contact the patient's physician to determine whether the patient is suitable for participation in a research study. The study staff may contact the potential participant and the LAR to determine their interest in participating in the study. The staff may learn of potential participants either by reviewing test results in the medical records (for example, a positive diagnostic test) or from physician colleagues.

In the case of hospitalized patients, the patients' physician must be willing to act as the liaison between the patient, the patient's LAR and the research team. For outpatients, the primary physician may be asked to serve as the contact person for the patient. If the patient is ambulatory and has recovered from the illness, such patients may be asked to visit the ECC-VRC if they are interested in participating in the study. There will be no monetary incentive for the patient's physicians to refer patients to this study.

In the case of healthy volunteers, ECC staff will utilize the adult participant database for those who agreed to be contacted for future studies.

Research staff will utilize the Emory IRB approved Oral Consent form to prescreen interested participants. If the subject/LAR provides oral consent, the research staff will proceed with a prescreening telephone questionnaire to exchange relevant study information with the subject. Research staff will collect the participant's name, phone number, email, age, COVID history, respiratory history and medical history and offer time for questions and study information. If the subject/LAR is interested in participation, the first clinic visit will be made at which time full written consent or full oral consent (as stated in the consent section of this document) will be obtained prior to the initiation of any research activities.

14. Withdrawal of Participants

Subjects may withdraw from the study at any time by contacting the principle investigator. Subjects may also be withdrawn from the study at the investigators' discretion, for example if the investigator thinks this may affect the subjects' wellbeing. If a subject withdraws, no further data will be collected. If data has been collected, it will not be destroyed.

15. Risks to Participants

The most common risks and discomforts expected in this study are:

- Participants may feel a slight discomfort from coughing repeatedly into the device.

The less common risks and discomforts expected are:

- Loss of confidentiality, all necessary precautions will be in place to reduce breach of confidentiality.

16. Potential Benefits to Participants

Taking part in this research study will not benefit participants personally but the research may help learn new things that may help others in the future.

17. Data Management and Confidentiality

Data Analysis. Data will be analyzed based on specimen identification number and group (e.g., COVID-19 patient, non-COVID-19 acute respiratory illness patient, control).

The quality of the specimen captured on the filter, i.e. from the lung or upper respiratory or both will be indicated by surfactant A (lung) and amylase (upper respiratory).

The PCR results will be analyzed as positive or negative and by CT value. The PCR results in COVID-19 patients will indicate the sensitivity of this specimen for detecting SARS-CoV-2 RNA and PCR results in non-COVID-19 patients and controls the specificity. The ratio of surfactant A to amylase indicate lung and upper respiratory contributions to the specimen for all groups. The multiplex Luminex data or Simoa Quanterix system will give biomarkers of inflammation for each group. We will also test some specimens with mass spectrometry to identify novel biomarkers associated with COVID-19 lung disease. Specimens will be saved for additional future research testing.

Attachment 1. Cough specimen processing

Reagents and Materials required

1. Sterile forceps
2. 15ml tubes
3. Ethanol
4. Assay diluent (Provided in Millipore luminex kit)
5. Spin-X centrifuge tube filter (0.45um)-Costar 8162
6. Table top centrifuge

Procedure

1. Procedure is done in a BSL2 biosafety cabinet under BSL2+ conditions, i.e. gowns, gloves, face mask or face shield.
2. Carefully remove the filter from cough device under the hood using a disposable sterile forceps.
3. Transfer the filter to a 15ml tube.

4. Add 200ul Assay diluent to the 15ml tube with filter.
5. Mix well by vortexing for 2 min.
6. Transfer the filter and 200 ul of assay diluent carefully into the insert of a 2.0 ml spin-Xcolumns using the sterile forceps.
7. Add 100ul assay diluent to 15ml tube to remove any residual specimen. After vortexing for ~5 seconds, transfer the 100ul to the spin-X column containing the 200ul diluent andfilter.
8. Centrifuge the filter and diluent at 14,000rpm for 15 min.
9. Collect the clear flow through below the insert and divide into three aliquots. Add RNAZol to one the aliquots for PCR testing and store -80 freezer the 3 aliquots and the spin-X column with filter insert at -80^{o}C until testing.

18. Provisions to Monitor the Data to Ensure the Safety of Participants

There is no product being administered in this study. The study is no more than minimal risk, so there is not a specific Data Monitoring and Participant Safety plan.

19. Provisions to Protect the Privacy Interests of Participants

The privacy of the participants health information is important. As part of this study, we will be consenting the participants prior to the conduct of any research activities . During this process, health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) will be identified. The participant will be informed that the researchers who obtain IIHI ("individually identifiable health information" or "IIHI") from the health care entities are not covered by HIPAA. Once they receive the IIHI from the health care entities, they will put it in a separate research record that is not a part of the medical record and that IIHI placed in the separate research record is not be covered by HIPAA.

We will also inform them of their ability to provide research staff consent to access their IIHI for the purpose or research. Data and specimen collection will not be linked to individual participants for privacy interest as described in section 7.

Participants are informed that they do not have to sign the consent form. If they do not sign this consent form, then they may not participate in the research study.

20. Economic Burden to Participants

There will be no cost to participants for participating in the study, other than basic expenses like transportation. Participants will not be charged for any of the research activities.

21. Consent Process

Once a potential participant is identified and confirms interest in the study, the study staff will initiate the informed consent process. The consent process may be initiated by the research team through a prescreening process utilizing an oral consent and phone screen document as described in the recruitment section of this document. In cases where the consent process begins in person, the study coordinator will discuss the study with a potential participant or LAR in a private room within the hospital/clinic. The subject may be referred by a healthcare provider or may request information independent of a provider's referral about the cough droplet specimen collection COVID 19 study and the purpose of the study will be shared. The subject will be given ample time to review the consent and ask questions. The consent will be signed in the presence of the coordinator. A signed copy will be given to the participant/LAR. The participant/LAR will have the option to retain consent, discuss with family members, and sign the consent at a future date in the presence of a member of the study staff. In the case of a hospitalized participant, a copy of the consent will be made for the medical record.

In some scenarios, informed consent will be obtained verbally without signature through a waiver of documentation. This would be done in situations where it is important to minimize in-person exposure time to protect study staff and reduce risk of disease transmission in general or the potential participant's LAR is not allowed to visit them (the potential participant) per containment policies. In this situation, hospital staff will provide the consent, or an emailed copy of the consent form will be made available to the participant/LAR from contact information provided by the hospital staff. The research staff will contact the individual by phone and proceed with the informed consent process. An informed consent progress note will be used to source document the consent process, date, name of research staff conducting the process, and relationship to participant. The consent process will be the same as written consent (as described above) the only element missing will be the written signature, as the process is oral and not in person, from the participant/LAR.

In the case of the adult SARS-CoV-2 PCR positive patients or the adult patients with a non-COVID-19 acute respiratory illness being treated as either inpatients or outpatients, the ability to consent will be made in conjunction with the study team and the advice of the primary care physician. For all cohorts, the appropriate time will be allowed for consenting, including questions and answers, as well as steps to reduce the risk of coercion or undue influence.

Within the consent process, participants will be able to indicate optional consent for participation in future studies and genetic testing of samples. Currently there are no plans for genetic testing.

Non-English-Speaking Participants

At this time due to resource restraints we will not be seeking non-English speaking participants, however will seek amendment if this becomes available.

Participants who are not yet adults (infants, children, teenagers)

At this time, our target population will be adults ages 18 and up.

Cognitively Impaired Adults

Prior to and during the consenting process steps will be made to assure that consent is being received by cognitively intact participants and/or the LAR.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

A partial HIPAA waiver for identification and recruitment may be utilized. Additionally, a waiver of written signature for cases where as described above in section 10 when oral consent will be obtained in lieu of written consent.

22. Setting

The research will be done at Emory Healthcare facilities either as an inpatient or outpatient, and Emory Children's Center for Healthy Volunteers and follow up visits.

23. Resources Available

- The research group at ECC has its own recruitment staff and utilizes research databases to satisfy recruitment goals.
- This research will be ongoing until the goals for recruitment have been satisfied.
- We are a research facility in which all staff members have been adequately trained on the protocol and appropriate training credentials are on record.

24. Multi-Site Research when Emory is the Lead Site

NA Single site study

25. References

1. Zhu N, Zhang D, Wang W, Li X, Yang B, Song J, Zhao X, Huang B, Shi W, Lu R, Niu P, Zhan F, Ma X, Wang D, Xu W, Wu G, Gao GF, Tan W, China Novel Coronavirus I, Research T. 2020. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med 382:727-733.
2. WHO. 2020. Coronavirus disease 2019 (COVID-19): Situation Report – 134, June 2, 2020.
3. Ku DN, Ku SK, Helfman B, McCarty NA, Wolff BJ, Winchell JM, Anderson LJ. 2016. Ability of device to collect bacteria from cough aerosols generated by adults with cystic fibrosis. F1000Res 5:1920.
4. Scholz TL, Midha PA, Anderson LJ, Ku DN. 2010. PneumoniaCheck: A device for sampling lower airway aerosols. J Medical Devices.