A Comparative Evaluation of Specimen Adequacy of a Traditional Nasopharyngeal Swab as Compared to Nasopharyngeal Saline Wash, Saliva, and Serum to Test for Respiratory Viruses and Antibody Response

NCT05864118

Study Protocol and Statistical Analysis Plan

2025-01-15

Human Biological Material Research
SECTION I

1. Title of Protocol:
A comparative evaluation of specimen adequacy of a traditional nasopharyngeal swab as compared to nasopharyngeal saline wash, saliva, and serum to test for respiratory viruses and antibody response

Is a OneChart/EPIC Subject Friendly Short Title needed?
No

2. Responsible Personnel:
A. Principal Investigator (PI):
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B. Secondary Investigator (SI):
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Brett-Major, David M - COPH Epidemiology - 402-559-8283 - david.brettmajor@unmc.edu - alt #: 202-618-0589 - degree: MD MPH - address: Eppley Science Hall 7007 UNMC Midtown (Zip 4395)

Broadhurst, Jana (Jana) J - Dept Of Path Home - 402-836-9775 - jana.broadhurst@unmc.edu - alt #: 541-521-1698 - degree: MD PhD - address: ESH 7032 UNMC Midtown (Zip 6819) - phone: 402-836-9775

Marx, Jared T - Emergency Medicine HOME - 402-559-5413 - jared.marx@unmc.edu - alt #: 402-559-4000 - degree: MD - address: UT 3287 UNMC Midtown (Zip 1150) - phone: 9-6638

Schnaubelt, Andy (Andy) T - Int Med Infectious Diseases - 402-559-4846 - andy.schnaubelt@unmc.edu - alt #: 402-960-3345 - degree: PhD, MS - address: Does not work on campus UT 3240 UNMC Midtown (Zip 1150) - phone: 9-5413

Wadman, Michael Charles - Emergency Medicine - 402-559-6948 - mwadman@unmc.edu - alt #: 402-559-6948 - degree: MD - address: UT 3291 UNMC Midtown (Zip 1150) - phone: 9-6948

Zeger, Wes (Wes) G - Emergency Medicine HOME - 402-559-6841 - wzeger@unmc.edu - alt #: 402-559-4000 - degree: MD - address: UT 3290 UNMC Midtown (Zip 1150) - phone: 9-6841

C. Participating Personnel:

Carstens, Julie M - Pathology, Microbiology & Immunolog - 402-559-4828 - jcarsten@unmc.edu - alt #: 402-559-4847 - degree: MS - address: ESH 7032 UNMC Midtown (Zip 6819) - phone: 9-4828

Williamson, Jan E - Pathology, Microbiology & Immunolog - 402-836-9775 - jwilliamson@unmc.edu - alt #: 402-559-4847 - degree: BS - address: ESH 7032 UNMC Midtown (Zip 6819) - phone: 402-836-9775

D. Lead Coordinator:

Zimmerman, Brooklin k - Emergency Medicine - 402-559-5237 - brooklin.zimmerman@unmc.edu - alt #: 402-836-9405 - degree: MSN, BA, RN - address: UT 3231 UNMC Midtown (Zip 1150) - phone: 9-5237

E. Coordinator(s):

Angell, Kathleen E - COPH Epidemiology - 402-559-4248 - kathleen.angell@unmc.edu - alt #: 402-559-8283 - degree: MPH

Longacre, Lauren Elizabeth - COPH Epidemiology - 402-813-6053 - lalongacre@unmc.edu - alt #: 402-813-6053 - degree: BS - address: No office assigned/w (Zip 5330) - phone: 402-559-1992

Are you adding a clinical trial management group?

No

F. Data/Administrative Personnel:

G. Are you a student or house officer?
No

3. Funding Source:
Check all that apply and provide the source of the funding.
Cooperative Group:
Center for Clinical and Translational Research (CCTR)
Federal (e.g., NIH) Grant - Provide source:
Other Grant:
♦ Departmental funding
Commercial - Provide company name:
Department of Defense
♦ Other - Provide source (e.g. personal funding): All study activities (supplies, interventions, testing) are funded by the UNMC - Dept of EM. University Medical Devices (UMD) is a start-up company that licensed the study device from UNeMED and are providing giftcards to support enrollment. UMD is not funding any other study related activities.

4. Deadline for IRB Approval
Yes - Explain and provide date:
♦ No

5. Contract
Is there a contract or agreement associated with this study?
No

6. Agreements
Is there a Material Transfer Agreement (MTA) associated with this study?
No

Is there a Data Use Agreement (DUA) associated with this study?
No

Is there a Data Transfer Agreement (DTA) associated with this study?
No

7. Study Sites:

A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the UNMC IRB or Joint Pediatric IRB.
Nebraska Medicine Emergency Department/UNMC Emerging Pathogens Laboratory

B. Will the research be conducted at external sites under the oversight of an external IRB?
No

C. Does UNMC, TNMC, CHMC or UNO serve as the lead site with responsibility for data and/or safety monitoring?
Yes

List the sites.
UNMC

D. Does this study involve any international sites where the PI will either; 1) conduct 2) supervise or 3) receive / ship HBM or data to / from UNMC?
No

E. Does this study involve face to face contact with subjects?
Yes

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:

- **All information in this application is complete and accurate.**
- **I will conduct the research as described in the application and the protocol.**
- **I will not initiate any change without IRB approval except when it is necessary to reduce or eliminate a risk to the subject.**
- **I will ensure that all research personnel are qualified and properly trained.**
- **I will fulfill my responsibilities as PI, described in** https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/126-pi-qualifications-and-responsibilities
- **I will follow all applicable HRPP and institutional polices, and all applicable laws, statutes and regulations.**

Nguyen, Thanh (Thanh) Thanh - 2024-12-24 06:39:01.537

9. Principal Investigator Financial Interest Disclosure

A. As the PI, I declare:

I have no financial interest in this research.

♦ I have a financial interest in this research.

B. As the PI, I understand

♦ I must disclose any change in my financial interest during the course of this research within five (5) business days from the time the change becomes known.

C. As the PI, I certify that:

No Responsible Personnel have a financial interest in this research.

♦ The Responsible Personnel listed below have informed me that they have a financial interest in this research.

Option chosen: The Responsible Personnel listed below have informed me that they have a financial interest in this research.

Each person selected below has completed the UNMC Disclosure of Potential Conflict of Interest Form and obtained all required signatures. The original disclosure form is attached as a document to this application.

Wadman, Michael Charles

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed within five (5) business days from the time the change becomes known.

Nguyen, Thanh (Thanh) Thanh - 2024-12-24 06:39:01.537

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief abstract of the research protocol. (2500 characters)
This summary should include: 1)) a brief description of the purpose of the study, 2) eligibility criteria, 3) interventions and evaluations and 4) follow-up.
Respiratory tract infections (RTIs) are prevalence community diseases and is the third leading cause of death worldwide [1, 2]. Rapid diagnosis of RTIs is essential as it drives decision points such as treatment, disposition, and containment. According to recent CDC (The Centers for Disease Control and Prevention) updates, nasopharyngeal swabbing is the preferred method of specimen collection for most RTIs such as SARS-COV-2 [4]. This process is invasive and traumatizing for patients as it requires probing (20 seconds) of the posterior nasopharynx with swab applicator. In some cases, this procedure has resulted in pain and injury. Because of the invasive nature of the procedure, patients often refuse testing or withdraw during the collection process resulting in inadequate specimen procurement. The study principle investigators (PI) have developed 2 novel specimen collection devices: 1) nasopharyngeal wash collection device (NP wash device) and 2) saliva collection device (the Oral Capsule). Both devices are designed for ease of use either by a healthcare professional or a patient. The benefits of such collection devices include 1) minimizing the invasive nature of the procedure because a swab applicator is not utilized and 2) minimizing infection risk to healthcare professional because the study devices can be self-administered when applicable. The study will enroll 1000 participants from a pool of patients presenting to the Nebraska Medicine Emergency Department (ED) who received a nasopharyngeal (NP) swab viral PCR test as part of their ED work up. Enrolled patients will be asked to provide four total specimens: 1) a saliva drool specimen, 2) a saliva Oral Capsule specimen, 3) a NP wash specimen, and 4) a finger stick serum specimen. Patients are able to opt out of any specimen collection method. Study specimens 1, 2, 3 will undergo a respiratory pathogen panel (RPP) PCR test and COVID-19 antibody testing. Study specimen 4 will undergo COVID-19 antibody testing and will function as a serum control for antibody detection.

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study
What are the specific scientific objectives of the research?
Objective 1: Evaluate for diagnostic efficacy between the nasopharyngeal swab (control) and a nasopharyngeal saline wash device (experimental) specimens when testing for respiratory pathogens and antibody response.
Objective 2: Evaluate for diagnostic efficacy between the nasopharyngeal swab (control) and a passive drool saliva (experimental) specimens when testing for respiratory pathogens

and antibody response. Finger stick blood is collected as a serum control for antibody detection.
Objective 3: Evaluate for diagnostic efficacy between the nasopharyngeal swab (control) and Oral Capsule saliva (experimental) specimens when testing for respiratory pathogens and antibody response.
Objective 4: Evaluate the patient's impression of the nasopharyngeal swab method vs the nasopharyngeal saline wash device vs saliva collection device regarding comfort level and acceptance.

3. Background and Rationale
Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill.
Respiratory tract infections (RTIs) are high prevalence community diseases and is the third leading cause of death worldwide [1, 2]. It is estimated that a new infectious disease emerges at a rate of one per year [3], making early disease detection critically important. Within the past few decades, we have seen an increase in cases of novel respiratory illnesses such as SARS (severe acute respiratory syndrome), H1N1 (Swine Influenza), MERS (Middle East respiratory syndrome), and SARS-COV-2 (severe acute respiratory syndrome coronavirus 2). Rapid diagnosis of RTIs is essential to the management of patients experiencing respiratory symptoms as it drives decision points such as treatment and disposition. There are currently millions of confirmed SARS-COV-2 cases globally. This number is likely underreported given the limitations and barriers to confirmatory testing. This problem is compounded by other RTIs such as influenza and rhinovirus, which are also tested via a nasopharyngeal swab specimen. According to recent updates from the CDC, nasopharyngeal swabbing is the preferred method of specimen collection for SARS-COV-2 [4]. The nasopharyngeal swab method is also commonly used in the testing of other viral pathogens such as influenza, respiratory syncytial virus (RSV), rhinovirus, and human parainfluenza. This process can be somewhat invasive and traumatizing for patients as it requires probing (10-20 seconds) of the posterior nasopharynx with a stiff swab applicator. In some cases, this procedure has been known to result in pain and injury. Because of the invasive nature of the procedure, patients often refuse testing or withdraw during the collection process resulting in inadequate specimen procurement. In our effort to streamline the specimen collection process, our team has developed working prototypes of two specimen devices (a NP wash collection device and an Oral Capsule saliva collection device).
- The NP wash device is designed to irrigate the patient's nasopharyngeal passage with 3 ml of sterile saline and recollect the solution for testing. In our preliminary testing, the study device was successful in collecting RNase P from the nasal passages 100% of the time while achieving a mean Cycle Threshold (CT) value of 29.5. Participants in early studies

also reported the study device to be more comfortable (0.3/10 pain) than the nasopharyngeal swab (8/10 pain).
- The Oral Capsule device is a soft-hollow device that is inserted into the mouth, overlying their molars. As the patient bites on the device, it generates an intermittent suction force which pulls saliva into the device's specimen chamber. In preliminary testing, the saliva collection device was successful in consistently collecting approximately 1 ml of saliva with 5-10 seconds of use.

The study design of this new protocol will allow the study investigators calculate the study devices' sensitivity and specificity for pathogen testing and test for antibody response from each respective specimen, along with improving enrollment rates. This study will enroll up to 1000 participants from a pool of ED patients who received a nasopharyngeal swab for PCR testing as part of their standard work up. Enrolled patients will provide four specimens 1) saliva drool specimen, 2) Oral Capsule saliva specimen, 3) NP wash specimen, and 4) finger stick serum specimen. Specimens 1, 2, 3 will undergo RPP PCR testing and COVID-19 antibody testing. Specimen 4 will undergo COVID-19 antibody testing. Patients can opt out of any of the four study specimen collection processes. Manufacturing of the NP Wash and the Oral Capsule devices is handled by the UNMC Department of Emergency Medicine fabrication lab. The NP wash study device is manufactured using fused deposition modeling (FDM) 3D printing technology with polylactic acid (PLA) printing material. The Oral Capsule device is manufactured using FDM 3D printing technology with polypropylene printing material. All study device will be sterilized via a cidex rinse, allowed to dry, then stored in a specimen bag. The NP wash device is designed to irrigate the user's nasopharyngeal cavity with 3 ml of sterile saline and recapture the irrigation solution into a specimen chamber as it drains back from their nose. The Oral Capsule device is designed to collect saliva via intermittent suction force generated within the device as the patient repeatedly bite on the device. With the implementation of our study devices we anticipate the following potential paradigm shifts in testing procedures: 1) minimizing the invasive nature of the procedure as a swab applicator is not utilized and 2) the procedure can be performed by a healthcare professional or solely by the patient, minimizing the risk of cross-infection to the healthcare professional. Nasopharyngeal irrigation is a common home remedy (neti-pots/bottles) for cold symptoms and is generally well tolerated by the user.

SAMPLE TYPES

4. What is the total number of samples to be collected?
The study will enroll up to 1000 participants who will each provide 4 study specimens: saliva passive drool, Oral Capsule saliva, NP saline wash by study device, and blood by standard finger stick method. All specimens are prospectively collected for study purposes only. Subjects can opt out of any specimen collection method. We anticipate 4000 samples

collected total.

5. What is the statistical or other justification for the total number of samples?
Industry guidance for the validation of investigational devices, and molecular (PCR) diagnostic assays.

The total sample size is variable, and dependent on the actual case-rate of SARS-CoV-2 (or other respiratory pathogen) infected participants who present to the emergency department for care. Due to this highly variable requirement, we estimate that as many as 97% of individuals who agree to participate in this study will be negative control cases. Consequently, we estimate the total number of enrolled participants will be at least 1000 at current case-rates. Study enrollment will continue until we reach 50 pathogen positive patients when tested by standard laboratory diagnostic methods, this allows 98% power to detect a change in sensitivity from 0.7 to 0.9 using a one-sided binomial test and 98% power to detect a change in specificity from 0.7 to 0.9 using a one-sided binomial test. The target significance level is 0.05.One-sided 95% confidence intervals will be determined for both sensitivity and specificity. The null hypothesis will be rejected if the lower bound of the CI is above the null performance level.

6. Prospective HBM
Will HBM be prospectively (i.e., does not already exist at the time of this IRB Application) collected?
Yes

A. Will any of the prospective HBM be obtained from a tissue bank or research study approved by the UNMC IRB/ Joint Pediatric IRB or external source?
No

B. Will excess (i.e., left-over after completion of a routine diagnostic or clinical procedure which would normally be discarded) HBM be collected?
No

C. Will Extra (e.g. an extra tube of blood taken when clinical labs are drawn or an extra sample of tissue taken at the time of a clinical biopsy) HBM be collected?
No

D. Will HBM be collected through a procedure/intervention (e.g., biopsy, blood draw, urine specimen, cheek swab, saliva collection) just for purposes of the research study/tissue bank?
Yes

1. List what types of HBM (e.g., blood, urine, tissue, DNA) will be obtained AND explain how (e.g. standard venipuncture) the material will be obtained.
Saliva Drool: Participants will provide a passive drool saliva specimen (up to 1 mL) which will receive RPP and COVID-19 antibody testing
Oral Capsule Saliva: Participants will chew on a soft hollow device that will collect saliva into the device as they repeatedly chew on the device which will receive RPP testing and COVID-19 antibody testing
Nasopharyngeal wash: Participants will receive a nasopharyngeal irrigation with 3 ml of sterile saline. The effluent saline is recollected by the study device and used for RPP testing and COVID-19 antibody testing
Serum: Participants will provide a blood specimen via capillary finger stick. Approximately 60 uL of blood will be collected by lancet which will receive COVID-19 antibody testing

2. How many samples will be obtained from each subject?
1 passive drool specimen per participant
1 Oral Capsule saliva specimen per participant
1 NP wash specimen per participant
1 finger stick per participant

3. What is the amount (e.g. 10 mLs of blood) of <u>each</u> sample that will be obtained?
Passive drool saliva: Approximately 1 ml of saliva
Oral Capsule saliva: Approximately 2 ml of saliva
NP wash device: Approximately 3 ml effluent saline
Finger stick: Approximately 60 uL of capillary whole blood

4. What is the frequency of the sample collection (e.g., one time only, twice/week)?
Once, at time of enrollment

7. Existing HBM
Will <u>existing</u> HBM (i.e., in a tissue bank or stored in a freezer at the time of this IRB application) be collected?
No

CHARACTERISTICS OF THE SUBJECT POPULATION

8. Accrual
A. Is this study conducted solely at sites under the oversight of the UNMC IRB (e.g. UNMC, Nebraska Medicine, CHMC, UNO)?
Yes

1. How many subjects will need to be consented (per group, as applicable) in order to achieve the scientific objectives of the research?
Up to 1000 subjects

2. What is the statistical or other justification for the total number of subjects described above?
The total sample size is variable, and dependent on the actual case-rate of SARS-CoV-2 (or other respiratory pathogen) infected participants who present to the emergency department for care. Due to this highly variable requirement, we estimate that as many as 97% of individuals who agree to participate in this study will be negative control cases. Consequently, we estimate the total number of enrolled participants will be at least 1000 at current case-rates. Study enrollment will continue until we reach 50 pathogen positive patients when tested by standard laboratory diagnostic methods, this allows 98% power to detect a change in sensitivity from 0.7 to 0.9 using a one-sided binomial test and 98% power to detect a change in specificity from 0.7 to 0.9 using a one-sided binomial test. The target significance level is 0.05.One-sided 95% confidence intervals will be determined for both sensitivity and specificity. The null hypothesis will be rejected if the lower bound of the CI is above the null performance level.

3. How long do you estimate it will take to accrue the required number of subjects?
2 years

9. Gender of the Subjects
A. Are there any enrollment restrictions based on gender?
No

10. Age Range of Subjects
A. Will adults be enrolled?
Yes

1. What is the age range of the adult subjects?
19 yrs or older

2. What is the rationale for selecting this age range?
Age of majority in Nebraska

B. Will children (18 years of age or younger) be included in this research?
No

1. What is the justification for excluding children from participating in this research?
Research is irrelevant to children (e.g. disease or condition rarely encountered in children).
Knowledge being sought in the research is already available for children or will be obtained from another ongoing study.
♦ A separate study in children is warranted and preferable.
Insufficient data are available in adults to judge the potential risk in children.
Other. Explain.

11. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
No

12. Vulnerable Subjects
A. Will prisoners be included in the research?
No

B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.
Decisionally-impaired persons
Critically ill patients
Students of the investigator
Employees of the investigator
Educationally disadvantaged individuals
Socially or economically disadvantaged individuals
Individuals with a stigmatizing illness or condition
Individuals from a marginalized social or ethnic group
Other.
♦ No vulnerable subjects will be specifically recruited

13. Inclusion Criteria
What are the specific inclusion criteria?
Age 19 years or older presenting to the ED, or admitted from the ED with a non-research nasopharyngeal swab ordered.

14. Exclusion Criteria
What are the specific exclusion criteria?
None, if the inclusion criterion is met.

15. Pregnancy and Contraception Requirements

A. Are women of child bearing potential (WOCBP) included in this research?
Yes

B. Are pregnant women included in this research?
Yes

C. Are breast feeding women included in this research?
Yes

1) Provide justification for the inclusion or exclusion of breast feeding women.
There is no study participation risk to pregnant or breast feeding women from the study interventions

METHODS AND PROCEDURES

16. Methods and Procedures Applied to Human Subjects
A. Describe the laboratory tests that will be done on the HBM.
Specimens will undergo COVID-19 and Influenza testing as soon as the lab is able to process them. This is a change from the original process of banking the specimens for 10 days. The COVID-19 and Influenza test assays are investigational and will not be reported to the patient's EMR. The results of the tests are also not to be used for diagnostic purposes. Remaining specimen volume will be frozen for RPP testing 10 or more days after collection.

1. The Nebraska COVID-19 Saliva PCR Test is a dual-plex, qualitative reverse transcription, real-time polymerase chain reaction (RT-PCR) assay that detects the presence of SARS-CoV-2 and human RNase P RNA in saliva.

2. The BioFire Respiratory Panel 2.1 (RP2.1) is a PCR-based multiplexed nucleic acid test intended for use with the BioFire® FilmArray® 2.0 System for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids obtained from individuals suspected of respiratory tract infections, including COVID-19.

3. The xMAP® SARS‑CoV‑2 Multi-Antigen IgG Assay (EUA) is a multiplex, microsphere-based, highly sensitive and specific assay that detects the presence or absence of antibodies against three different SARS‑CoV‑2 antigens. By using multiple antigens, this assay may provide earlier, more sensitive results.

B. Who will perform the testing?

The Emerging Pathogens Laboratory, UNMC.

C. Where will the testing be performed?
UNMC, Eppley Science Hall, 7th floor.

D. Does the study involve the use of surveys, questionnaires or focus groups?
Yes

1. Explain what will be done, including the frequency and describe each survey instrument/questionnaire.
Participants will be asked to complete two post-procedure surveys. Survey 1) regarding their experience with the NP wash device, the Oral Capsule device, and experience with nasopharyngeal swabs. Survey 2) regarding demographics, recent illness and vaccination status. Survey attached as study document

E. Describe briefly the statistical methods used to analyze the data (or reference the appropriate section of the detailed protocol or grant).
1. Survey data will be analyzed and reported using descriptive statistics.

2. We will use the methods described in the Clinical Laboratory Standards Institute's Molecular Diagnostic Methods for Infections Diseases, Chapter 7: Establishment and Evaluation of Performance Characteristics of Molecular Diagnostic Tests (MM03).

F. Does this research involve genetic testing including Genome Wide Association Studies (GWAS), Whole Genome Sequencing (WGS) or Whole Exome Sequencing (WES) ?
No

G. Does this study involve the creation of a tissue bank for future unspecified research? This includes un-used (excess) blood, urine, or tissue, obtained for clinical indication or for research, or additional human biological material collected specifically for future research.
No

DRUGS, BIOLOGIC DRUGS AND DEVICES

17. Devices
1. Does this research involve a medical device(s) (including an in vitro device [IVD] (assay), and medical software)?
Yes

A. Check all that apply:
FDA approved (or cleared) device
♦ FDA unapproved device
In Vitro Device (IVD)

1. Describe the device
- The NP wash study device is a Class I Exempted device manufactured in a clean room injection molding facility using high density polyethylene plastic. The NP wash study device is an adapter designed to fit on to a standard syringe. The device's tip is cone shaped, designed to be inserted into the nose while sealing against the nasal ala. 3ml of sterile saline is ejected from the syringe (by plunger force applied by the PI) and channeled into the patient's nose to perform the irrigation process. The device has a built-in reservoir designed to recollect the irrigation solution as it drains down the patient's nose. Only investigators and research staff listed on this protocol will have access to the study devices.
- The Oral Capsule device is a 3D printed device made REACH certified thermoplastic polyurethane material. The device is self-inserted into the patient's mouth overlying their molars. The patient is asked to repeatedly bite on the device. The bite force generates a gentle suction force within the device that pulls saliva into the device's hollow specimen chamber as the saliva drains down into a specimen reservoir. External drain channels were also added to the device to facilitate capture of saliva that is on the external walls of the Oral Capsule. After production, the study device will be sterilized via a cidex rinse, allowed to dry, then stored in a specimen bag. Only investigators and research staff listed on this protocol will have access to the study devices.

2. Specify the sponsor of the device
Thang Nguyen
Michael Wadman
Wesley Zeger
Abraham Campos
Aaron Barksdale
Jared Marx

3. Is the device a non-significant risk device?
Yes

i. Please provide rationale and/or documentation from the manufacturer or FDA
- The NP wash device is designed to channel sterile saline into the patient's nose and recollect the irrigation solution. Principles of fluid dynamics (ratio of fluid amount to device bore diameter) were taken into consideration during the engineering process to ensure the irrigation pressure does not exceed 30 pound-force per square inch (PSI). The core

mechanical principle of the device is similar to other nasal irrigation devices available on the market such as the Neti-Pot or the Neti-Bottle

Nasal irrigation systems are available as over-the-counter treatments and are widely considered consumer safe. Our device is designed to irrigate the nasal passage with 3 ml of sterile saline which is a fraction of the solution amount (240 ml) used in most consumer nasal irrigation systems currently on the market. Study participants will also receive usage instructions to ensure maximal drainage of the irrigation solution in a short period of time.

During our initial pilot study, we encountered zero adverse events related to the use of the study device. We anticipate minimal-to-no risk to the user of our device based on pilot study data and direct comparison to other nasal irrigation systems currently available on the market.

The study device have been reviewed by an FDA law firm and determined to be an FDA Class I device. 510K filing not required.

- Use of the Oral Capsule device will be self-administered by the user under direct supervision by the investigator to ensure proper use. The device was designed using Human Factor Engineering to ensure ease of use and safety. The investigator conducted quality control testing of the devices and did not observe any degradation of the device under repeated compression force (human bite and mechanical compression)

ii. Is the PI the holder of the IDE?
No

4. Indicate the stage or type of the investigation (choose one)
Nonclinical study
Early Feasibility Study
♦ Feasibility Study
Pivotal Study
Other

5. Describe where devices will be stored securely, how use will be limited to personnel listed on the protocol and for subjects participating in the research, and how usage of the devices will be tracked.
Each study device will be identified with a chronological number based on the order it was produced. Each study device will receive a cidex rinse to sterilize it, allowed to dry, then stored in separate sterile specimen bags. Only investigators and research staff listed on this protocol will have access to the study devices.

CONFIDENTIALITY AND PRIVACY

18. Confidentiality and Privacy
A. Describe where research data will be stored. Check all that apply.
Box@unmc.edu (secure UNMC or UNO designated cloud-based storage site)
♦ Microsoft Office 365 application (including SharePoint, OneDrive for Business, Teams or Streams) (UNMC, UNO or NU system instance) (secure UNMC or UNO designated cloud-based storage site)
Other secure UNMC or UNO designated cloud-based storage site - describe:
OnCor Clinical Trial Management System (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
CCORDA database (biostatistics) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
RITO-hosted databases (for example, REDCap, CV-QOR, Onchem Trials, XNAT) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
Nebraska Medicine PACS (for image files) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
Other secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO - describe:
On an NSRI or designated high security .gov storage site
On a VA-approved storage vehicle for a VA-approved study
On a remote secure server and/or database maintained by the sponsor accessible through the internet
On a secure server and/or database hosted and maintained by another institution accessible through the internet
On a device or mobile application provided by the sponsor to upload data to a coordinating center or central database
On a device or mobile application being developed by a sponsor or by a UNMC, CHMC or UNO investigator
On a device or mobile application that connects to the internet through UNMC or NM network (wired or wireless)
On an encrypted, password protected portable computer, or flash drive
Other - describe:
In hard copy (other than signed Consent Forms)

B. Will health information about the subject be obtained/provided for use in this research?
Yes

1. What is the specific information?
COVID-19 or respiratory virus panel PCR test results from the individual's paired NP Swab

sample collected at the time of research sample collection.

2. How will the information be obtained?
Medical record
Provided by a third party honest broker not involved with the research nor listed in section I of this application.
♦ Other Explain Provided to invesitgator by treatment team after consent.

C. Will the HBM be coded with a unique identifier?
Yes

a. Where will the key (that links the unique subject identification code to the subject's name or other identifier) be stored?
Collected specimens will be labeled with a chronological number based on order of enrollment with a letter prefix that indicates the type of specimen that was collected: S: drool saliva, OC: Oral Capsule, NP: NP wash, B: blood. This data will be documented on a study intake form that will include the patient's name, date of enrollment, MRN, and the specimen IDs for each specimen. Once the sample is returned to the lab with the study intake form, the information on the form (Name, MRN, date of collection, specimen IDs) is transcribed to an encrypted, secured, electronic master file and the paper record is destroyed.

b. Does the code number include the subject's initials or other subject identifier as part of the code?
No

c. Do any of the research personnel listed in section I of this application have access to the key linking the code number to the subject identifiers?
Yes

D. Will specific identifiers (e.g., ANY DATES, medical record numbers, email addresses etc) be recorded and linked with the HBM?
Yes

1. List the identifiers (ie., dates, medical record numbers) being provided with the HBM, recorded or indirectly associated by use of a coding system.
♦ Name
♦ DATES (e.g. date of study visit, date of sample collection, birth, admission, discharge)
Postal address information: street address, city, county, precinct, ZIP code
Telephone numbers

Fax numbers
Electronic mail addresses
Social Security numbers
♦ Medical Record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs) Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice print
Full face photographic images [and any comparable images]
No identifiers

2. What is the justification for recording the specific subject identifiers listed above? Check all that apply.
Schedule appointments
Collect continuous clinical information from the medical records
Follow-up with subjects
Link stored tissue with subject identification for it to be withdrawn in the future if requested
Compensation
♦ Other. Explain. Participants' name, MRN, and date of visit will be collected for the research team to perform a one-time chart review to collect the results of the participants' control COVID-19 or RPP results that was collected as part of their standard ER work-up.

3. How long will the subject identifiers be maintained in association with the research data?
Once the sample is returned to the lab with the study intake form, the information on the form (Name, MRN, date of collection, specimen IDs) is transcribed to an encrypted, secured, electronic master file and the paper record is destroyed.

4. Will research data that contain subject identifiers be disclosed to:
a. Other investigators at UNMC, NM, UNO or CHMC who are not listed in Section I of this application?
No

b. Investigators outside of UNMC, NM, UNO or CHMC?
No

c. Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO), or to any other external organization or entity (e.g., NCI cooperative groups)?
No

E. How will the research data be archived or destroyed when the data is no longer required?
Consent forms and intake forms will be destroyed using UNMC's confidential document disposal service

F. What provisions will be in place to protect the subject's privacy? Check all that apply.
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process.
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research.
♦ Ensuring that the research activities are performed in as private of a place as possible.
Other. Explain.

G. Does this research involve data banking at UNMC, NM, UNO or CHMC, or by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future research that is not related to this study?
No

RISK/BENEFIT ASSESSMENT

19. Potential Risks
What are the potential risks associated with research?
1) There is a small potential risk of aspirating the nasal irrigation saline.
2) There is a slight risk of infection
3) There is a potential risk of a nose bleed related to the saline irrigation process.
4) There is a small potential risk data breach.

The finger stick blood collection procedure can cause slight pain. It may also cause bleeding, irritation, bruising, and a rare chance of infection.

We anticipate minimal to no discomfort as part of the nasal irrigation process. We have conducted preliminary testing of the device as part of the engineering process and also conducted a pilot trial and currently enrolling in a prospective trial. We experienced zero

adverse events related to the use of the study device. Additionally, to mitigate potential discomfort we have incorporated safeguard elements such as ensuring the irrigation PSI does not exceed 30 PSI and we're only irrigating with 3 ml of sterile saline. Neti-Pots devices commonly irrigate with 240 ml of solution and is well tolerated by consumers.

20. Risk Classification
What is the overall risk classification of the research?
♦ Minimal risk
Greater than minimal risk

21. Minimization of Risk
A. Describe how the risks of the research will be minimized.
Loss of confidentiality:
--A paper record is collected at the time of sample collection and retained by a member of the study team (listed on this application). Once the sample is returned to the lab with the paper record, the information on the record (Name, MRN, date of collection) is transcribed to an encrypted, secured, electronic master file and the paper record is destroyed.
--Only individuals listed on this application will access the electronic file containing PII/PHI and only for the purpose of retrieving the viral PCR test result(s) for the paired NPS sample. The test result is recorded only on the master file.
--Aggregation and analysis from the data contained on the master file is only performed by an investigator listed in this study.
--Only anonymized data is provided to the FDA for the medical device evaluation application.
-- Extensive testing have been conducted on the NP wash device and Oral Capsule device to ensure device integrity when used. No adverse outcomes were observed in previous studies or internal QC checks.

B. Describe how the data collected will be monitored to ensure the safety of subjects. Identify who will perform the ongoing data and safety analysis, and describe the frequency of data analysis.
Analysis of the data is descriptive rather than inferential. Individuals who have provided samples have no ongoing study related activities, nor is there any follow-up with them. Data analysis is ongoing until final submission of data to the FDA.

The data will be analyzed every 50 enrolled subjects. If a collection method meets statistical significance, that collection method will be removed from the study. Emerging Pathogens Laboratory (Drs. Schnaubelt and Broadhurst) will perform this data monitor and analysis.

Participant discomfort for the Oral Capsule and NP wash collection methods (0-10 scale) is

collected as part of the study survey. If a mean pain rating of greater than 3 is observed, the research team will investigate the collection devices for potential pain points. Dept of EM (Dr. Nguyen) will perform this data monitor and analysis.

C. Describe the auditing plan for research conducted. Identify who will conduct the audits and specify the audit frequency.
The study investigators will continuously, in real-time, monitor and evaluate human research protections compliance and protocol effectiveness at achieving the study purpose.

D. Describe the specific subject withdrawal criteria.
There are no withdrawal criteria. This is a single point in time encounter for individuals providing samples.

E. Describe the stopping rules for the research (ie, the specific criteria for halting or early termination of the study.
- Statistical analysis is performed throughout the study enrollment period. If statistical significance is observed for a collection method, that collection method will be removed from the study. If all collection methods demonstrates statistical significance the study will terminate early.

- Our estimate of enrollment for up to 1000 participants considers that these individuals will not all be positive for viral respiratory pathogens. Only those who are positive by diagnostic testing in the Nebraska Medicine clinical laboratory are relevant for evaluating our collection devices/methods. Industry guidance for the evaluation of investigations devices, as well as the validation of diagnostic assays requires a minimum of 30 data points. In this case those data points are required for each device, pathogen, and test method. We will evaluate our data after each batch of sample testing, and when we have sufficient data (at least 30 cases with positive viral respiratory pathogen test results) to meet study objectives we will halt the study no matter how many subjects we've enrolled. If we cannot meet study objectives with 1000 subjects, we will present the data and request a modification to the application to increase our enrollment numbers.

F. Describe plans and resources available to promptly address any subject injury.
The study participants' emergency department or inpatient care provider will be notified of any injuries potentially related to the study procedures, although no injuries were observed in early studies.

22. Potential Benefits to the Subject
A. Is there the prospect for direct benefit (eg, research on diagnosis or treatment of disease)?

No

23. Potential Benefits to Society
Describe the potential benefits to society that may reasonably be expected to result from this research.
Respiratory pathogen specimen collection is traditionally performed using a nasal swab applicator which may be traumatizing for some and also has been known to result in injury. Some patients have refused testing due to the invasive nature of the nasopharyngeal swab technique. The nasopharyngeal swab technique required to obtain adequate sampling requires specific training and may prevent the widespread adoption, particularly for home testing. If the study devices are capable of demonstrating diagnostic agreement with the nasopharyngeal swab method, then there is potential for a less invasive process of collecting respiratory pathogen testing. The study device was designed for ease of use and could facilitate mass testing in endemic or pandemic scenarios.

FINANCIAL OBLIGATIONS AND COMPENSATION

25. Financial Obligations of the Subject
A. Who will pay for research procedures, evaluations and tests? Check all that apply.
Sponsor
Grant
CRC, CCTR
Costs or fees waived by Nebraska Medicine, UNMC- P, CHMC or CSP
♦ Department/Section funds
Other. Explain

B. Will any of these procedures, evaluations and tests will be charged to the Subject, the Subject's health insurance, or Medicare/Medicaid?
No

C. Are there any other financial obligations that the subject will incur as a result of participating in the study?
No

26. Compensation to the Subject for Participation
A. Will the subject receive any compensation for participation?
Yes

1. Describe the form of compensation, dollar amount (if applicable) and the prorated compensation plan (if applicable).

Study participants will receive a $20 Wal-mart gift card for participation in the study. Gift cards will be provided after completion of study intervention(s). Participants will provide at least 1 specimen but do not have to agree to all 4 specimen collection methods to receive the gift card.

PRIOR REVIEW

27. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the UNMC IRB (or the Joint Pediatric IRB) and then withdrawn by the investigator for any reason?
Yes

1. Describe why the study was withdrawn.
A study with a similar protocol is currently enrolling at UNMC (0587-21-FB) and has not yet been withdrawn. We intend to close 0587-21-FB when this new protocol is approved.

2. Describe changes made to the research plan prior to the current submission.
This new study design will increase enrollment numbers by allowing the PI to enroll any patient who have received a nasopharyngeal swab from the ED or admitted to inpatient from the ED. This revised study will also provide data to calculate the study device's sensitivity and specificity. This study will also provide data on antibody responses as applicable to each specimen type.

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and not granted approval?
No

SUBJECT IDENTIFICATION & RECRUITMENT

28. Method of Subject Identification and Recruitment
A. Will prospective subjects learn about the research and then contact the investigator about participation (for example, in response to a print, electronic, radio or television advertisement; referral by a clinician or other specifically for this research)?
No

B. Will the investigator make the initial contact with the potential subject to tell him/her about the research (for example, by contacting existing or past previous patients or research participants; or by contacting prospective subjects thru school records, or thru support groups or other Interest Groups; or thru use of the Hospital Opt-In Database)?

Yes

1. How will prospective subjects be identified?
Providers who are treating the prospective subjects will make the initial contact to ask them if the investigators can talk to them about the research. Researchers will not directly approach anyone prior to this permission.

2. Will potential subjects be screened for eligibility prior to informed consent?
Yes

a. What information will be collected prior to informed consent?
No PHI will be collected prior to consent.

b. By whom?
The patient's treating provider will notify the study investigators of a potential study candidate only after confirming with the patient that they are interested in the research opportunity. After receiving permission from the treating provider, the study investigator will approach the patient for the consenting process. Brooklin Zimmerman will not screen patients and will only engage with the patient after the treating provider has confirmed research interest.

c. Does that person have ethical access to information about potential subjects?
Yes

i. Describe
As ED clinicians, the study investigators has ethical access to the ED dash board. The study investigators will not access the patient's chart prior to consent.
Brooklin Zimmerman will not screen patients and will only engage with the patient after the treating provider has confirmed research interest.

3. How will potential subjects be approached and invited to participate?
- The treating provider (ED or inpatient) will confirm with the patient they are interested in speaking with the study investigators regarding the study opportunity.
- If they agree, the study investigators will approach the patient for consenting.
- The consent process will take place in the patient's private exam room.

a. Describe the process of initial contact
- The treating provider (ED or inpatient) will confirm with the patient they are interested in speaking with the study investigators regarding the study opportunity.

- If they agree, the study investigators will approach the patient for consenting.
- The consent process will take place in the patient's private exam room.

b. Who will make the initial contact?
The treating provider will make the initial contact, followed by the study investigators if the patient is agreeable to discuss the study opportunity.

c. Does that person have ethical access to information about potential subjects?
Yes

i. Describe
The treating provider has ethical access to the patient's chart

C. Will this study be listed in the clinical trial registry at www.clinicaltrials.gov?
Yes

i. Provide the NCT#.
NCT05864118

ii. Identify who holds the NCT#
♦ PI
Sponsor

OBTAINMENT OF INFORMED CONSENT

29. Waiver or Alteration of Informed Consent
A. Is a complete waiver or alteration of consent requested?
No

30. Waiver of Signed Consent
Is a waiver to obtain signed consent requested?
No

32. Process of Informed Consent
A. When will the prospective subject/parent(s)/guardian(s)/LAR be approached relative to their/the subject's actual participation in the study?
As an ED clinician, the study investigators has ethical access to the ED track board. Without accessing the patient's chart, the study investigators will be able to identify patients who have a RPP test ordered as part of their work-up. The study investigators will ask the

treating provider to ask the patient if they are willing to speak with the study investigators regarding the study opportunity. If the patient agrees with speak with the study investigators, they will be approached for consenting. If the patient is transported to their inpatient room prior to approach, the study investigators will obtain secondary confirmation of the patient's interest from their inpatient provider prior to approaching for consent.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
The consenting process will be conducted in a private (private ED or inpatient exam room) and quiet area for both cohorts in which the participant can speak with the investigator privately.

C. Who will be involved in the process of consent and what are their responsibilities?
Study investigators: study PI(s) and SI(s) will consent

D. Is there any limitation on the amount of time allotted to the process of consent?
No

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
--Request for consent sample collection is done with a "no pressure" approach. Individuals who are potentially more vulnerable to coercion or undue influence, will either not be approached, or if approached and decline, are thanked and we'll move on.
--Individual's who have questions are answered with patience and thoroughness in "lay" terms and language, and any requests to have family or friends present will be honored.
--We are not interested nor able to collect samples from individuals who request to take home study material, to "consider", or to consult others who are not present (except by phone). In this example, we will thank them and explain that sample collection needs to occur at the time of NPS sample collection.

F. Will non-English speaking subjects be enrolled in this research?
No

Provide justification for exclusion of non-English speaking subjects
--The diagnostic assay(s) performance does not distinguish between English and non-English speaking individuals, and there are no direct benefits to individuals providing samples for evaluation with these assay(s) (e.g., they are not provided the test result).
--This is a feasibility evaluation of a new specimen collection devices/methods that requires a specific level of understanding from the participant on how to use the devices safely. The investigators have developed verbal and visual instructions to help the participant

understand how the devices should be used. The investigators have not conducted any validity studies to ensure the verbal and visual instructions translates well to other languages. If data from this study is supportive of a particular specimen collection device/method, follow-up studies to include non-English speaking participants is warranted. The validation and translation of the study materials is not financially feasible in this early stage study.

G. How will it be determined that the subject/parent(s)/guardian(s)/LAR understood the information presented?
All elements of the consent will be discussed with them, and they will be asked to restate their understanding of all elements.

34. Information Purposely Withheld
Will any information be purposely withheld from the subject during the research or after completion of the research?
No

REFERENCES

36. Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.
[1] Brendish J., Malachira K., Armstrong L., et al. (2017).Routine molecular point-of-care testing for respiratory viruses in adults presenting to hospital with acute respiratory illness (ResPOC): a pragmatic, open-label, randomised controlled trial.Lancet Respiratory Medicine. 5(4). 111.
[2] Zumla A., Al-Tawfiq A., Enne I., et al. (2014)Rapid point of care diagnostic tests for viral and bacterial respiratory tract infectionsneeds, advances, and future prospects. Lancet Infectious Disease; 14(11), 2335.
[3] Abad, X. (2018).Biocontainment in low income countries: a short discussion. Medical Safety & Global Health. 7(1), 1-3. DOI: 10.4172/2574-0407/1000139.
[4] (2020).Interim guidelines for collecting, handling, and testing clinical specimens from persons for coronavirus disease 2019 (COVID-19). Center for Disease Control and Prevention. Retrieved from: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.
[5] Daley, P., Castriciano, S., Chernesky, M., & Smieja, M. (2006). Comparison of flocked and rayon swabs for collection of respiratory epithelial cells from uninfected volunteers and symptomatic patients. Journal of Clinical Microbiology. 44(6). 2265-2267. DOI:10.1128/JCM.02055-05.
[6] Fry, E. D. Pressure irrigation of surgical incisions and traumatic wounds. Surgical Infections. 2017. 18(4). 1-2.

[7] Ball, S. Optimal pressures and irrigation techniques in small-animal wound management. Veterinary Nursing Journal. 2017. 32(11). 325-328.
[8] Barnes, S., Spencer, M., Graham, D., & Johnson, B. H. Surgical wound irrigation: a call for evidence-based standardization of practice. American Journal of Infection Control. 2014. 42. 525-529.

SECTION III

SUBMISSION DEADLINE

A. FULL BOARD REVIEW:
The IRB meets twice monthly, on the first and third Thursday of the month, with the exception of January and July when the IRB meets only on the third Thursday of the month. No more than 15 applications (i.e., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. EXPEDITED REVIEW:
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

SUBMISSION CHECKLIST

Check all that apply.
Subject recruitment material
Performance site approval for all non-UNMC, TNMC, UNO and CH&MC sites
Grant Application
IRB Review Fee Form for all commercially sponsored research projects.
UNMC Disclosure of Potential Conflict of Interest Form for the Principal Investigator if a financial interest has been declared in Section I.11.
UNMC Disclosure of Potential Conflict of Interest Form for any responsible personnel with a financial interest declared in Section I.11.
♦ Other Study Survey 1, Study Survey 2, Saliva passive drool collection instructions
No attachments

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC and NM - Pharmacy & Therapeutics (P&T) Committee (Required for studies involving drugs)
Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) (Required for studies involving cancer)

Institutional Biosafety Committee (IBC) (Required for studies involving the use of gene transfer and vaccines)
♦ **Investigational Device Review Committee (IDRC)** Review by the IDRC is required for all protocols involving the use of investigational or marketed devices
Billing Grid (Required for all studies involving billing for hospital/clinic services)
Coverage Analysis (Departments requiring this analysis have been specified by the Organization)
Conflict of Interest (COI) Management Plan (Required for all studies with declared COI by study personnel)
Sponsored Programs Administration (SPA)/UNeHealth grants and contracts
Pathology approval for collection of tissue samples required for this study
Radiation Committee Approval
Other Review
None of the above organizational requirements apply to this study

SECTION IV

COVID-19

Human Subjects Research Safety Plan
For studies involving face-to-face encounters, the research team under the responsibility of the principal investigator will agree to comply with the following safety measures:

1. **Masking of the researcher(s) during a face-to-face encounter**
2. **Cleansing of any surface and/or equipment utilized before and after a subject encounter**
3. **The Biosafety Officer (jenna.mckenzie@unmc.edu) will be notified if obtaining saliva, nasal, sputum or stools samples to ensure safe collection, handling, and processing plan is in place**
4. **Suggest addressing the current health of the subject before commencing face-to-face research via questions below:**
    - **Have you or anyone in your household tested positive or had a fever, chills, cough, shortness of breath, diarrhea, nausea, vomiting, recent loss of taste or smell, tiredness or fatigue, or muscle aches? If yes, the monitor will not be allowed on campus.**
    - **Have you recently traveled to an area with a widespread outbreak or had close contact with a person known to have COVID-19, MERs-CoV or Ebola?**
    - **Have you traveled outside of the country within the past month? If so, where did you travel and when did you return?**
    - **Have you had a recent SARS-COV-2 antibody test or nasal swab and if so when and what were the results?**

♦ I acknowledge this requirement.

ADDENDUM B
Research Involving Pregnant Women, Fetuses and Neonates of Uncertain Viability or Non-Viable

Title of Protocol

A comparative evaluation of specimen adequacy of a traditional nasopharyngeal swab as compared to nasopharyngeal saline wash, saliva, and serum to test for respiratory viruses and antibody response

Principal Investigator

Nguyen, Thanh (Thanh) Thanh - Emergency Medicine - 402-559-7884 - thang.nguyen@unmc.edu

1. Preclinical Studies and Studies on Non-Pregnant Women [45 CFR 46.204(A)]
A. Will Pregnant women/fetuses be included in the research?
Yes

B. Have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted?
No

C. Do these studies provide data for assessing potential risks to pregnant women and fetuses?
No

2. Risks and Benefits to the Pregnant Woman or Fetus which are Associated with the Research [45 CFR 46.204(B)]
A. Is there *any prospect* of direct benefit for the woman or the fetus?
No

1) Describe any risks to the fetus.
No foreseeable risk to fetus

2) Describe how the research could lead to the development of important biomedical knowledge.
This research would provide insight on the specimen adequacy of a nasopharyngeal wash specimen when compared to a nasopharyngeal swab.

3) Could the research be conducted without involvement of pregnant women?
Yes

3. Minimization of Risks to the Pregnant Woman and Fetus [45 CFR 46.204(C)]
A. Describe how the risks to the pregnant woman and fetus are minimized to the greatest extent possible consistent with the objectives of the research.
There is no foreseeable risk to pregnant/fetus participants beyond the risk(s) identified for the general population.

4. Pregnancy Termination and Determination of Viability [45 CFR 46.204(H-J)]
A. Will the research involve termination of a pregnancy?
No

5. Consent of the Pregnant Woman and Father [46.204(B), 205(B), 205(C)]
Information Only

	BENEFITS				
RISK TO FETUS		**NONE**	**TO MOTHER ONLY**	**TO MOTHER & FETUS**	**TO FETUS ONLY**
	MINIMAL	**Consent of mother**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***
	GREATER THAN MINIMAL	**Not allowable**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***

***Except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence or temporary incapacity or the pregnancy resulted from rape or incest.**

6. Research Involving Neonates of Uncertain Viability [45 CFR 46.205]
A. Will the research involve neonates of uncertain viability?
No

7. Research Involvng Nonviable Neonates [45 CFR 46.205(c)]
A. Will the research involve nonviable neonates?

No