

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: **Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19**
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The COVID-19 virus has already been classified as a global pandemic by the World Health Organization (WHO) and many are attempting to understand more about how it works and causes disease.

We want to understand how the body's immune system reacts to the virus, the symptoms associated with the virus, and how the virus responds to different treatments.

If you agree to participate, we will ask you to do a **nasal swab** every 2 to 3 days at home. We will provide the supplies and strict instructions on how to do this. We will ask you to save these swab sample specimens in storage that we will provide (such as a container and bag or box). We will also keep these samples for future testing. This testing includes evaluating viral load, bacterial load, and host response. We will also ask that you complete a **temperature and symptom survey** each of those days. We ask that the nasal swab and survey be completed about 12 noon each of those days.

You will be randomly assigned by chance (like the flip of a coin) to a group to help us learn more about irrigation vs. no irrigation. If you are assigned to irrigation, it will be done twice a day during the study. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. You will have a 3 to 1 chance of being in one of the groups below:

1. No irrigation.
2. Nasal irrigation with saline every morning and evening throughout the study.
3. Nasal irrigation with saline and a surfactant (baby shampoo) every morning and evening throughout the study.

We will tell you which group you are in and provide the supplies you will need for that group.

*This box is for
IRB USE ONLY
Do not edit or delete*

Date of IRB Approval: 04/22/2020
Date of Expiration: 04/15/2021

Institutional Review Board



Study Title: **Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19**
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

Also, the **study staff will review your medical chart** at the completion of the study and collect information such as date of birth, medical conditions, and hospitalizations during study period.

Study staff will deliver all study materials to you and will pick them up on Day 21 or as soon as possible.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you have tested positive for COVID-19. The virus has already been classified as a global pandemic by the World Health Organization (WHO) and many are attempting to understand more about how it works and causes disease.

The information we learn about how the body's immune system reacts to COVID-19 can help us understand what is going on in patients with the virus and possibly help dictate future treatment options.

Only patients 18 years or older who live within 30 miles of Vanderbilt University Medical Center will be asked to participate in the study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Taking part in a research study involves some minor inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to the study doctor. The study involves the following risks:

Risks associated with medical record review:

As with any study that involves patient information, there is the risk of loss of confidentiality. Every effort will be made to protect your privacy and confidentiality. We will assign a study ID to your data to help protect your identity.

*This box is for
IRB USE ONLY
Do not edit or delete*

Date of IRB Approval: 04/22/2020
Date of Expiration: 04/15/2021

Institutional Review Board



Study Title: Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

Risks associated with nasal saline irrigations:

There is a risk of transient anosmia (loss of smell) when using nasal saline irrigations with surfactant (such as baby shampoo). This usually resolves once irrigations are discontinued. There is also a possible risk of infection involving household contacts by "aerosolizing" the virus while performing irrigations. This is why we will provide you with strict instructions on how to perform the irrigations in a separate bathroom from others in your household. There are very rare reports of brain inflammation, though any link to saline irrigations has not been established.

Risks of nasal swab:

The nose swab may include brief discomfort. Rarely, a nosebleed can occur. If this should happen, we will instruct that the swab be immediately removed, the head tilted forward, and pressure applied to the outside of the nostrils for 5 minutes.

Risks that are not known:

There are minimal risks involved in this study however, there may be risks that are not known yet.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: a) The benefits to science and humankind that might result from this study: This study might help researchers and doctors better understand how the virus functions and develop new treatment options. This information could lead to better treatment of those infected with COVID-19 and those at risk for infection.

b) There is no direct medical benefit to you.

Procedures to be followed:

Study staff has already talked to you by phone about the study and answered any questions you had. You decided that you would like to take part in the study. As part of this study, the following procedures will take place:

- Nasal swab. We will ask you to perform nasal swabs every 2-3 days at home.
- Saline Irrigations. For patients randomized to this treatment group, we will ask that you perform nasal saline irrigations every morning and evening. Instructions on proper technique will be provided.
- Saline Irrigations with shampoo. For patients randomized to this treatment group, we will ask that you perform nasal saline irrigations with ½ teaspoon of shampoo every morning and evening. Instructions on proper technique will be provided.

Study Title: Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

- Temperature and Symptom Questionnaire. We will ask you to record your temperature at the same time every 2-3 days and fill out a symptom questionnaire for that day.
- Medical record review. The study staff will review your medical chart at the completion of the study and collect information such as date of birth, medical conditions, and hospitalizations during study period.
- Save nasal samples. We will save swab sample specimens for future testing. This testing includes evaluating viral load, bacterial load, and host response.

| Study Procedures | Day 0 | Days 1 - 21 | Day 21 (or as soon as possible) |
|---|-------|-------------|---------------------------------|
| Telephone interview | X | | |
| Informed consent | X | | |
| Delivery of study materials by study staff | X | | |
| Saline Irrigations twice daily (in intervention group) | | X | |
| Nasal swabs (Days 1, 3, 5, 7, 10, 14 and 21) | | X | |
| Temperature and Symptom Survey (Days 1, 3, 5, 7, 10, 14 and 21) | | X | |
| Collection of swabs and questionnaire sheets by study staff | | | X |

Payments for your time spent taking part in this study or expenses:

We will give you a \$100 gift card for taking part in this study. The payment will be processed after we received the specimens. This process can take up to 3-6 weeks.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

*This box is for
 IRB USE ONLY
 Do not edit or delete*

Date of IRB Approval: 04/22/2020
 Date of Expiration: 04/15/2021

Institutional Review Board



Study Title: **Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19**
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Kyle Kimura at his research team office phone 615-322-0333 or pager 615-831-4638 or his Faculty Advisor, Dr. Justin Turner at 615-322-6180. If you cannot reach the research staff, please page the study doctor by calling **(615) 322-5000** and ask the operator to page him.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

The study doctor may take you off the study at any time if they feel it is necessary for your health or safety. You will be told if such a decision is made and the reason for it.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:

You will be assigned a study ID number that will be attached to your records and nasal swab samples to keep the information confidential. The data records will be kept in a password-protected database and in a locked office. The nasal swab samples will be kept in the Vanderbilt University Medical Center lab of Dr. Suman Das. His lab will process samples for this study.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

*This box is for
IRB USE ONLY
Do not edit or delete*

Date of IRB Approval: 04/22/2020
Date of Expiration: 04/15/2021

Institutional Review Board



Study Title: Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:

Study results will not be shared with you or your regular doctor.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by

*This box is for
IRB USE ONLY
Do not edit or delete*

Date of IRB Approval: 04/22/2020
Date of Expiration: 04/15/2021

Institutional Review Board



Study Title: **Impact of Nasal Saline Irrigations on Viral Load in Patients with COVID-19**
Version Date: April 21, 2020
PI: Kyle S. Kimura, MD

the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

| | |
|----------------------|--------------------------------|
| _____ | _____ |
| Date | Signature of patient/volunteer |
| Consent obtained by: | |
| _____ | _____ |
| Date | Signature |
| | _____ |
| | Printed Name and Title |

*This box is for
IRB USE ONLY
Do not edit or delete*

Date of IRB Approval: 04/22/2020
Date of Expiration: 04/15/2021