COVER PAGE FOR CONSENT FORM

Official Study Title: Nicotinamide Riboside in SARS-CoV-2 (COVID-19) Patients for Renal Protection

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INFORMED CONSENT DOCUMENT

Project Title: **NIcotinamide Riboside in SARS-CoV-2 pAtients for reNAl protection (NIRVANA)**

Principal Investigator: Kumar Sharma, MD

Research Team Contact: Subrata Debnath, MPH, Ph.D., [redacted]

If you are the legally authorized representative of a person who is being invited to participate in this study, the word "you" in this document refers to the person you represent. As the legally authorized representative, you will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Kumar Sharma, MD having to do with acute kidney injury (AKI) due to COVID-19 infection. AKI is very common in COVID patients and associated with increased deaths, complications, and poor health outcomes. Unfortunately, there is no approved medicine for AKI. The human body makes a chemical substance called NAD+ and this substance supports energy production. NAD+ levels in kidney and in blood may be low in patients with AKI. We will test if increasing NAD+ levels with nicotinamide riboside will speed up recovery from kidney injury. In this study we will be testing if a form of vitamin B3 called nicotinamide riboside (NR) is (1) safe in COVID patients with AKI, (2) it increases blood NAD+ levels, and (3) it improves or protects kidney function.

HOW WILL THIS STUDY AFFECT ME?

- The purpose of this study is to determine if nicotinamide riboside is safe and whether it increases blood NAD+ levels and improves or protects kidney function.

- During your stay in the hospital, this research study will take a limited amount of your time. After discharge, you will need to spend no more than 30 to 60 minutes for the remaining visits.

- You were selected because you are diagnosed with COVID-19 infection and AKI.

- You will take study medicine only for 10 days and then come to clinic for two follow-up visits at 30 days and 90 days after taking your first dose of the study medicine
    - **While in the hospital, you will take study medicine twice daily for 10 days and all other study procedures are standard of care;**
    - **If you are discharged from hospital before completing 10 days, at home you will take study medicine, collect a daily urine sample, and perform a fingerstick blood test to measure your kidney function daily for the remaining days.**
- The main risks to you are an upset stomach, muscle soreness, itching, and your blood hemoglobin and blood cell count may drop. More detail about risks is provided below.

- You will not be paid for participating in this study. You will not have costs for participating in the study. Study medicine and research procedures will be paid by the research team.

- If you withdraw from the study, the research team may continue to use information already collected about you prior to your withdrawal.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you were admitted to hospital with a diagnosis of COVID-19 infection and your kidneys are affected with declining kidney function known as acute kidney injury or AKI. AKI is associated with high rates of death and poorer health outcomes compared to someone without AKI. Currently, there is no specific medicine to treat AKI and it is not known if available medicines or therapies for COVID-19 may help prevent or treat AKI.

The purpose of this research study is to test if nicotinamide riboside (NR, a form of vitamin B3 present in several foods such as milk) is safe in COVID patients who are hospitalized and developed AKI. The study also examines if taking NR increases blood NAD+ levels.

Nicotinamide riboside or NR (Niagen®) is a commercially available nutritional supplement. However, for this study, NR is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration for treatment of AKI in COVID patients. The safety and effects of Niagen on blood NAD+ levels will be compared against a placebo. A placebo is an inactive, harmless substance that looks like the other study drug.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to complete up to 12 visits with the research team. The study procedures for first 10 days (10 visits) may be completed during your hospital stay. Most of the study procedures will coincide with some standard of care or procedures and a few are research only. If you are discharged from the hospital before completing the first 10 days, you will receive all necessary information and materials to complete the procedures for the remaining days at home. Then you will need to return to clinic to see your study doctor t approximately at day 30 and day 90 from when you first started taking study drug The last two visits are research-only visits.

Baseline visit and Randomization (Treatment Visit 1):
After your eligibility is determined the study team will discuss the study with you. After obtaining consent from you, a baseline visit will be performed which will include a review and collection of following information from your medical records: medications during hospital stay, home medications, all concomitant medicines including dietary or nutritional supplements and over-the-counter medications, vitals and physical examinations including temperature, pulse rate, respiratory rate, and blood pressure, other clinical information to assess the severity of your condition, information of fluid intake and output, and routine laboratory test results. Some urine (about a cup) and blood (about 1 tablespoon) will be collected.

Note that a pregnancy test will be performed for women with childbearing potential after obtaining consent to the study. Positive pregnancy test will disqualify participation to this study.

After completing the above procedures, you will be assigned by chance (like flipping a coin) in a 1:1 ratio (or 50% chance) to one of two study groups:

- Placebo tablet 500 mg orally twice daily (Placebo)
  or
- Niagen 500 mg orally twice daily (Niagen)

Neither you nor the study doctor will know whether you are receiving Niagen or placebo. However, in the event of an emergency, there is a way for your study doctor to find out which one you are receiving.

If you are intubated (the insertion of a tube into your windpipe) and unable to take the study medicine orally, the pharmacist will provide the medicine via nasogastric tube (insertion of a plastic tube through the nose down into your stomach) if deemed safe by your hospital COVID care team.
Regardless of your assignment to either a placebo or Niagen, you will receive all the standard treatment for your health conditions including COVID-19 based on recommendations by your hospital COVID care team.

About half a teaspoon of blood will be collected from you at 3 hours and again at 6 hours after taking the first study pills.

Treatment Visits 2 to 10 (Day 2 to Day 10) while you are hospitalized:

You will be assessed daily by the study team for a total of 9 additional days while hospitalized. We will review your medical record daily to collect data about your vital signs, medications, treatments, and clinical course and the results of routinely performed laboratory tests. All these data will be collected

from the medical record and will not require additional time from you. You will continue to receive all standard of care for your health conditions.

You will be asked to provide the following on each day from days 2 to 10

- First morning void urine collection
- About one tablespoon of blood

Treatment Visits 2 to 10 (Day 2 to Day 10) if your hospital stay is less than 10 days from Visit 1:

If you are discharged from hospital to home before completing a total of 10 days of study medicine dosing, you will receive study medicine for the remaining days with instructions how to take the medicine and record taking the medicine on a paper form. In addition, you will also receive a device called StatSensor® Xpress™ to measure your kidney function. All necessary items will be provided to use the device – instructions, strips, alcohol swabs, lancets, and a biohazard waste container. The following information will be collected daily from you or your caregiver or family member using a phone visit:

- Any changes to your medications and treatment from previous day
- Any health complaints including changes to your health from previous day
- Your body weight, temperature, pulse rate, respiratory rate, and blood pressure (if available)
- Study drug administration and accountability log
- Your kidney function test results using the StatSensor® device

Each day you will collect first morning void urine in the provided container, which will be picked up daily until Day 9 by a courier service for delivery to the hospital laboratory. On Day 10 a study team member will visit your home to collect one tablespoon of blood, urine, the StatSensor® device, biohazard waste container, and any other left-over study items. All these procedures will be collected with all safety precautions in place.

Follow-up Visits 11 and 12 (Day 30 ± 3 and Day 90 ±3):

Two follow-up visits will be performed at the outpatient clinic with your study doctor. A study team member will call you well-ahead of the visit with instructions and clinic location. The following procedures will be performed at each follow-up visit at the clinic:

- Assess your overall health
- Collect any health complaints including new health issues or changes to your health from the last visit
- Record your current medications and treatment
- Collect body weight, temperature, pulse rate, respiratory rate, and blood pressure
- Perform physical examination
- Collect first morning void or random urine
- Draw about one tablespoon of blood

If a clinic visit is not possible for any valid reason, a phone visit will be conducted in conjunction with review of your medical records to complete the applicable procedures listed above. In addition, a

phlebotomist will visit your home to collect blood and urine with all safety measures in place.

If you do not or are unable to complete any of the visits described above after hospital discharge, the study team will take following measures:

- First, your family member who is listed in study file or in your medical records will be contacted via phone and e-mail daily for 3 consecutive days or weekly for 3 consecutive weeks (for each follow-up visit);
- Second, the study team will review your medical records to collect as much data as possible for each missed visit;
- Third, the study team will search public records and database to document your vital status.

Genetic Research

Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes. These differences may make us more or less likely to develop certain diseases or conditions or to have certain characteristics. Genetic research involves studying the differences in genes and DNA between individuals. This type of testing creates information that is as unique to you as your fingerprint.

As part of this study, we are obtaining urine and blood samples from you. These may be used for commercial profit (even if we remove your identifiable information). There are no plans to provide financial compensation to you should this occur. By allowing us to use your information including urine and blood data you give up any property rights you may have in the urine and blood.

Will you save my research information and/or biospecimens to use in future research studies?

We would like to use the urine and blood data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding AKI and its short- and long-term complications or prognosis, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your information including urine and blood data you give up any property rights you may have in the urine and blood data.

Some biosamples will or might be used to analyze your genetic information. You can think of genetic information as a large instruction book that your body reads to understand how it should be built and function. All humans have the same instruction book in their body but some words or letters may be different from one person to the other. Some of those differences have no effect on your health but others can influence the likelihood of developing a disease or affect how medicine to treat a disease will work. If genetic analyses are done, they may involve all or part of your genetic information, which will only be used for study/scientific research. There are no plans to provide this information to you or your physician.

We will share your information including urine and blood data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at UT Health San Antonio and University Health, at other research centers and institutions, or industry

sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your information including urine and blood data for future research you should contact the research team members identified at the top of this document. The information including urine and blood data will no longer be used for research purposes. However, if some research with your information including urine and blood data has already been completed, the information from that research may still be used. Also, if the information including urine and blood data has been shared with other researchers it might not be possible to withdraw the information including urine and blood data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My information including data and samples may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My information including data and samples may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Unless you agree to future use as described above, your private information including data/ blood collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 60 people will take part in this study conducted by investigators at UT Health San Antonio and University Health. A total of about 100 participants are expected to participate nationwide in this multi-center study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for:

- A total of 12 visits
    - Daily for 10 days
    - Two follow-up visits: at day 30 ± 3 and day 90 ± 3
- Duration for each daily visit for the first 10 visits depends on your hospital stay
    - If you are in the hospital for 10 consecutive days, then a small amount of time is needed from you because most of the study procedures listed above are review of your medical records.

The study team may contact you or your treating physician or family member to collect information which is not available in the medical records and or to collect additional information for accuracy and completeness
    - If your hospital stay is less than 10 days after receiving the first study medicine, you will spend approximately 30 to 45 minutes each day for up to 9 days to complete the visit procedures listed above including the phone visit.
- Duration for each follow-up visit will require about 60 to 90 minutes.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Nicotinamide riboside may produce drug interactions. Please inform the study team if you are taking any prescription or over-the-counter medications, including other nutritional or herbal supplements

Likely / Common

Mild

- Gastrointestinal disorders: nausea, heart burn (e.g., indigestion, gas, upper abdominal discomfort, and bloating), diarrhea, transient changes in stool;
- Musculoskeletal disorders: back soreness, muscle soreness;
- Skin disorders: pruritus (itching), flushing, hives;
- Other disorders: leg cramps, increased bruising, excessive sweating;

Less Likely / Less Common

Serious

- Allergic reaction or hypersensitivity

Mild

- Abnormal liver function tests
- Drop in blood hemoglobin and platelet (a type of blood cell) counts

Blood Collection
The physical risks that could arise from this study are related to finger prick to collect blood drop and blood draws. The risks for finger prick are bleeding and mild pain. The risks of a blood draw are minimal and may include pain, bruise at the site of the draw, and a rare risk of infection and fainting.

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn

child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Risks of Genetic Research
There may be information obtained from the genetic testing that indicates that you, or potentially a family member (since we inherit genes from our parents, and pass genes on to our children) are at risk for a particular disease or condition. For example, genetic sequencing may indicate that an individual is more prone to develop certain types of cancer or other types of diseases, (e.g. Alzheimer's or other inherited diseases).

If made available to persons or agencies outside of our research group, information about genetic test results could affect your employment or insurance. For instance, employers, insurers, or others may use this information when making decisions about you or your family members regarding employment, insurance, or other benefits.

Re-Identification from Genetic Sample
While the data developed for this study is being stored without traditional identifiers (stored only with coded ID numbers, no names), there may be ways of linking the genetic materials back to you. Because your DNA is unique to you, it is possible that someone could look at the information in the DNA database and compare it to information in another database, and use that to identify you. This is difficult to do and is very unlikely to happen.

Genetic Research
There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the study results may lead to additional research to gain better understanding if Niagen is beneficial to protect the kidneys and to minimize severity of AKI.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss other treatment options that are available to you. Instead of being in this study, you could be on currently available management or standard of care for AKI or or you may wish to purchase Niagen on your own, since it is a commercially available nutritional supplement.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.
If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

The study is providing Niagen, the device to measure kidney function at home, and items necessary to complete visit procedures at home at no cost to you.

You will not have any additional costs for being in this research study.

.WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that UT Health San Antonio and University Health is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor Kumar Sharma, MD, Phone # (210) 567-4706 and/or the Human Research Protection Office at 1-(800)-438-0445. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

The federal government has issued a declaration under a law known as the Public Readiness and Emergency Preparedness (PREP) Act to address the coronavirus (COVID-19) public health emergency. If you are injured or harmed as a result of participating in this study, that federal government declaration may limit your ability to obtain damages by filing a lawsuit against the study's researchers, health care providers, study site, study sponsor, and/or manufacturer or distributer of the drug. However, if you are injured or harmed as a result of participating in this study, the federal government has established a program that may provide compensation to you or your family. To find out more about this program, known as the "Countermeasures Injury Compensation Program" (CICP), go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427. The CICP is the payer of last resort, meaning that the CICP would generally only reimburse or pay for items or services to the extent such items or services are not covered by other third-party payers, such as your health insurance or workers' compensation you receive.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health and its delegated body such as the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the entities that they use to monitor, administer, or conduct the research
- Your primary care physician and or your treating physician team at the hospital if a medical condition that needs urgent attention is discovered
- Local or federal public health agencies to complete public health reporting requirements.
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The safety adjudication committee (SAC) and the data coordinating center of the NIRVANA Study

- The Institutional Review Board and the Compliance Office of UT Health San Antonio, and other groups that oversee how research studies are carried out; and
- The Research offices at UT Health San Antonio and University Health.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the NIRVANA study sites for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

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

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, “How will you keep my information confidential?”

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.
The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you

(de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact UT Health San Antonio's Compliance Officer at 210-567-2066.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- **appointment scheduling containing PHI.**

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.

- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

If you agree to allow us to contact you by email, we will ask that you sign a separate Email Authorization Agreement.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

If you withdraw from the study we will ask your permission to continue to collect information from your health care records. Should this occur we will ask you to sign a separate consent form before collecting this information.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Kumar Sharma, MD, Phone # (210) 567-4706. If you experience a research-related injury, please contact: Kumar Sharma, MD, Phone # (210) 567-4706.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

The University of Texas Health Science Center at San Antonio (UT Health San Antonio) is the local Institutional Review Board committee that reviews research on human subjects (Institutional Review Board) and can also answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy

of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 03/08/22.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Legally Authorized Representative's Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 03/08/22.

_____
(Participant's name – printed)

_____ _____
(Signature of Legally Authorized Representative) (Date)

_____ _____
(Name of Legally Authorized Representative - printed) (Relationship to Participant – printed)

Who should sign as the Legally Authorized Representative (LAR)?
If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
(2) Adult child;
(3) Parent;
(4) Brother or sister;
(5) Relative by blood or marriage.

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the

participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)

Witness to the subject's Signature

The witness should be someone not affiliated with the research: neither investigator nor study personnel. "Study personnel" means persons involved in carrying out the particular research protocol for which the subject is signing the consent. It is preferred that the witness not be associated with the subject. However, a family member or friend may serve as a witness if an impartial witness is not available.

_____ _____

(Signature of Witness) (Date)

_____

(Name of Witness - printed)