SUBJECT INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Salvacion USA Inc. / "A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Ethyl Lauroyl Arginate Hydrochloride (LAEH) Formulation Versus a Matching Placebo Formulation Administered as a Nasal Spray to Reduce Viral Load From Nasal Area of Subjects With Coronavirus Disease 2019 (COVID-19)"**
Protocol Number:	**SLV-CV19-SPRAY**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to participate in a clinical research study.

Before you decide to participate or not, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives, and your family doctor if you wish. Ask us if there is anything that is not clear and/or if you would like more information. Take time to decide whether or not you wish to take part in this study. If you agree to take part, you will be asked to sign and date this form. You will be receiving a signed and dated copy for your reference. The decision to be a part of this study is your choice.

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On March 11, 2020, the Word Health Organization (WHO) declared this a pandemic. In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. Currently there are very limited treatment options for COVID-19.

This study will test a formulation, Ethyl Lauroyl Arginate Hydrochloride [LAEH], 0.1% concentration (referred to as the "study product") formulation in subjects having mild Coronavirus-19 (COVID-19) disease.

The purpose of this study is to compare the effect of study product and placebo (does not have any active ingredient) administered as a nasal spray for reducing viral load levels in nasal areas of mild COVID-19 positive subjects.

This study is not intended to be reported to the Food and Drug Administration (FDA) because the ingredients in the study product (nasal spray) are deemed "Generally Recognized as Safe (GRAS) by the FDA. The use of these ingredients in a nasal spray is investigational.

HOW DOES THIS STUDY WORK?

If you agree to take part in this study, you will be one of approximately 30 subjects anticipated to be part of this study. The study will take place at multiple sites in the United States of America (USA).

Eligible subjects will have 50% chance of either having the study product or matching placebo formulation and will be decided at random (by chance, like the flip of a coin). You or study doctor or the study staff would not know which study product has been given or taken. However, the study doctor can find out which study product you are using, for medical reasons, if it is necessary to know before the study is finished.

The study is open to male and female subjects greater than or equal to 18 to less than or equal to 65 years of age with laboratory confirmed diagnosis of COVID-19 using a Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) test, a test used to detect the presence of specific genetic material in any pathogen, including a virus.

During the screening visit, your study doctor will analyze your health status to see if you are eligible to take part in the study. Only the subjects that meet the eligibility criteria will be enrolled in the study.

After you sign and date this informed consent form, the following tests or procedures will be done to find out if you can be in the study:

- We will confirm that you have signed and dated the informed consent form. We will not perform any procedures without the signed and dated informed consent form.
- You will be asked questions about your medical history, including information about other medical problems, allergies to medications, and information about your COVID-19 infection.
- You will be asked questions about your date of birth, race, ethnic origin, and gender etc. (only for clinical purposes).
- You will be asked about medications that you are currently taking, including prescription and over-the-counter medications, herbal remedies, vitamins, and supplements.
- If you are female who could become pregnant, you will have a urine pregnancy test.
- You will undergo a physical examination (including nasal examination) and your height and weight would be measured.
- We will also measure your vital signs (heart rate, respiratory [breathing] rate, blood pressure, temperature, oxygen saturation).
- You will be asked to refrain from eating, drinking, or using any nasal gavage or nasal spray at least 30 minutes prior to nasal spraying. A nasal mid-turbinate specimen will be collected initially through nasal (nose) swab for enumerating viral load at baseline by swabbing for 30 seconds from each nostril. The study doctor may be required by law to report the result of this test to the local health authority.
- If you are eligible to take part in the study, you will be provided with a nasal spray device and a bottle of study product nasal solution that you will take home with you.
- You will be given instructions and training on how to use the nasal spray device. You are required to take 2 to 3 puffs in each nostril at a time, twice a day for 6 days (On Day 6, only morning study product will be taken). You should keep at least 6 hours gap between the first and the second study product daily. You need to record in the subject diary your initials and date and time you took the assigned study product on a daily basis.
- On Day 6th (end of study [EOS]), you will take the first daily study product(11th dose) (administered through nasal spray by themselves at home around 8:00 am) and record the same in the subject diary.
- After 11th dose on Day 6, you will visit the study site and the study staff will perform the viral load enumeration using RT-PCR within 3 and 6 hours post last dose (at end of 11th treatment). You will be asked to refrain from eating, drinking, or using any nasal gavage or nasal spray at least 30 minutes prior to nasal spraying. The study staff will collect a nasal mid-turbinate specimen will be collected for enumerating viral load at Day 6/EOS visit by swabbing for 30

seconds from each nostril. The study doctor may be required by law to report the result of this test to the local health authority.
- If you experience any side effect (adverse event [AE]), you are requested to kindly visit/inform the study site at your earliest possible convenience.
- The study staff will call you daily and collect AE information, if any, concomitant medications, check for study product compliance and completion of subject diary.
- If you are discontinued from study or withdraw consent from the study voluntarily before the Day 6 visit, then you will be encouraged to complete all procedures and assessments as applicable.
- You may be requested to visit the study site for an unscheduled visit at the study doctor's discretion to address any possible issues you may experience that are of concern.

HOW LONG WILL YOU BE IN THE STUDY?

The screening/baseline evaluation will be from Day-3 to Day 0 (maximum 3 days) followed by study product for 6 days (Day 1 to Day 6). The maximum study duration is 9 days.

If you are discontinued from study or withdraw voluntarily before the EOS (Day 6) visit, then you will be encouraged to complete all procedures and assessments as applicable.

The study doctor may stop you from taking part in this study at any time if they think it is best for you, or if you do not follow the study rules. Your study doctor, the institutional review board that oversees the study or Salvacion (the study Sponsor) may decide to stop this study for medical or other reasons at any time without your consent. Your study doctor will tell you if this happens and will talk to you about other treatment options.

You can stop participating at any time. However, any information collected prior to your decision to stop participation may be used as part of this study. If you decide to stop participating in this study, we encourage you to talk to the study doctor.

If there is new information available on the study product during the study which might make you change your mind about taking part in the study, you will be informed of this new information without delay.

WHAT ARE YOUR RESPONSIBILITIES?

- You are requested to provide information to your study doctor on any history of allergies, flu or have received any medication in past 30 days.
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.
- Based on laboratory test report, and other eligibility criteria, you will be randomized in a 1:1 fashion to either receive the study product through nasal spray (2 to 3 puffs in each nostril at a time) formulation twice-daily or matching placebo for 6 days.
- You are expected to administer spray with assigned study product through nasal spray twice a day for 6 days. The steps to use nasal spray are:
    1. Prior to administration of nasal spray, you should refrain from eating, drinking, or using any nasal gavage at least 30 minutes.
    2. Wash your hands thoroughly with soap and water.
    3. Blow your nose to clear your nostrils before using nasal spray (if needed).
    4. While keeping the bottle upright, simply shake, and remove the cap to spray into the air until a mist to comes out.
    5. Keep your head upright.
    6. Place the spray nozzle inside the nostril carefully and not too deep in the nose.
    7. Spray 2-3 puffs into one nostril and repeat into the other nostril.
    8. Put the protective cap back on after use.
    9. Avoid blowing your nose shortly after taking a dose of the study product
    10. Avoid contact with the eyes.
    11. Stop use and call your study doctor if you experience allergic reaction, swelling or irritation.
    12. Keep away from direct sunlight and heat source.
    13. Store at room temperature.
- You need to record in the subject diary your initials and date and time you administered performed nasal spray with the assigned study treatment on a daily basis (twice a day for 6 days).
- The study staff will call you daily and collect adverse effects information, concomitant medications, and check for study product compliance and completion of the subject diary.
- Your study doctor may call you for an unscheduled visit to address any possible issues you may have experienced that are of concern.
- On Day 6th /EOS, the subject will take the first daily study product (11th dose) (administered through nasal spray by themselves at home around 8:00 am) and record the same in the subject diary. After 11th dose at Day 6, you will visit the study site and the study staff will perform the viral load enumeration using RT-PCR within 3 and 6 hours post last dose (at end of 11th study product).
- You are advised to contact the study doctor if you experience any other symptoms for which you may want some other medicine (concomitant medicine). Medications that are prohibited by the study plan include, but are not limited to, antibiotics, antiviral drug, and hormonal drugs.
- You are advised not to participate in any other study while being on this study.
- You should report to the study doctor immediately if you get any adverse effects (including any allergic reactions).
- You must bring back study product or study materials (even if they are empty or used or unused) for accountability at EOS visit.

WHAT HAPPENS TO THE SAMPLES OBTAINED DURING THIS STUDY?

Nasal swab samples obtained during screening and post study product will be sent to a laboratory and will be analyzed.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

There are minimal physical risks and discomfort to you in this study. No blood tests or medical interventions will be performed as part of this research.

The study staff will collect swabs from nasal passages which at times cause some discomfort to you. You may experience discomfort, eyes watering, sneezing, or bleeding.

Allergic Reaction Risks
As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

The study product ingredients are considered Generally Recognized as Safe by the FDA for use as a food additive/preservative, because there is no marketed nasal spray that includes these ingredients there may be side effects that are unknown.

As with any new drug, extra care has to be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed on the first page of this form.

If you receive placebo (the inactive substance) as part of this study, your symptoms of your disease may not improve or may get worse.

You may have pain or bruising at the site where the blood is drawn. You may feel faint. An infection at the site of the blood draw is possible.

There is a risk of loss of confidentiality of your information. The risk of identity disclosure will be kept to a minimum as all collected information will be de-personalized and kept confidential. The information will only be accessed by the study staff. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The possible benefits to the subjects in the study are reduction in viral load in the nasal passages along with stopping viral transmission/spread to others. This may or may not decrease your symptoms or COVID-19 infection.

If you agree to take part in this study, there may not be a direct medical benefit to you. We hope the information learned from this study will benefit other patients diagnosed with COVID-19 in the future.

WHAT ARE YOUR OTHER TREATMENT OPTIONS?

Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

If you decide not to join this study, your treatment will be decided by your regular doctor. The treatment you receive will not be affected in anyway.

WHAT HAPPENS IF YOU NO LONGER WANT TO TAKE PART IN THE STUDY?

Your decision to take part in this study is voluntary. You can refuse to take part or stop taking part at any time without giving a reason. If you decide to stop the study at any time, your exit from this study will not affect your medical care which you otherwise may receive. There will be no penalty or loss of benefits to which you would otherwise be entitled. If you decide to leave the study, you are strongly urged to return to your study doctor for an EOS visit assessments if any. This visit is to ensure your safety as well as to collect important information.

HOW MUCH WILL STUDY PRODUCT COST YOU?

The study product used in this study will be given to you at no charge. All procedures which are part of this study will be provided at no cost to you.

WILL YOU BE PAID TO BE PART OF THIS STUDY?

«Compensation»

You will not be paid to take part in this study.

WHAT HAPPENS IF YOU ARE INJURED?

In the case of injury or illness resulting from this study, emergency medical treatment is available, but will be provided at the usual charge.

If you sustain injuries from your participation in this research study, you may not be compensated by Salvacion USA, Inc. You or your insurance company will be charged for continuing medical care and/or hospitalization.

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure, or prevent COVID-19. This includes the study product Ethyl Lauroyl Arginate hydrochloride [LAEH] 0.1% concentration dispensed through study device (spray bottle) used in this study. Subjects using the study product (Ethyl Lauroyl Arginate Hydrochloride [LAEH] 0.1% concentration) in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00054373.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

The study doctor, study staff and those working for or with them will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research.
- Records about your study visits
- Laboratory results

You will not be able to participate in this study if you do not authorize the collection of this information about you.

To ensure your privacy, your name and other identifying information will not be attached to records or samples released for research purposes. Instead, you will only be identified by a code. Only the study doctor and authorized study staff will be able to connect this code with your name.

Your date of birth may also be recorded to help identify your study records.

Your coded data will be forwarded to Sponsor and its service providers for activities related to the study. It will be transferred into a computer database and processed to allow the results of this study to be analyzed and reported. Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

- Checking your suitability to take part in the study,
- Monitoring your study treatment with the use of the study nasal spray,
- Comparing and pooling your study treatment results with those of other subjects in clinical studies,
- Establishing whether the use of the study nasal spray meets the appropriate standards of safety set by the authorities,
- Establishing whether the study product is effective,
- Supporting the development and use of the study nasal spray,
- Supporting the marketing, distribution, sale and use of the study product anywhere in the world, and/or
- As otherwise required or authorized by law.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future always relating to your disease or similar diseases and/or development of the study product (but in compliance with applicable law and regulation).

If necessary, for these purposes, Sponsor may communicate information to affiliates of Sponsor, people, and companies with whom Sponsor works, and regulatory or other governmental agencies. These people, companies, and agencies may be in your country, the United States of America (USA),

and other countries that are outside of your country. However, the Sponsor will keep any information it receives as confidential as possible within the limits of the law.

The Sponsor, either alone or together with other researchers, may publish or present the results of the study based on your records and the records of all subjects in this study; however, you will not be identified personally in any publication or presentation.

The Sponsor (Salvacion Inc.), regulatory bodies such as the FDA, Department of Health and Human Services (DHHS) and Office for Human Research Protections (OHRP), the Institutional Review Board, Quality assurance and/or quality control auditors from regulatory agencies and Sponsor's authorized representatives, may also need direct access to your original medical records and study records for the purpose of verification data collected for the study without violating your confidentiality. Those who receive your information may share it if they are required to do so by law. These other groups may not be required to obey the federal privacy rules that the study site and researchers must follow. By signing and dating this form, you authorize this access.

By signing and dating this authorization, you agree that you will not be able to have access to your personal health information (effects of the study product on your disease) related to this study until the study is over. This is done to maintain the scientific integrity of the study. After the study is complete, you can obtain access to your information through your study doctor.

As indicated above, your participation in this study is voluntary and you may withdraw from the study at any time by informing your study doctor. By signing and dating this authorization, you authorize the collection and use of information about you as described in this consent. This permission will not have an expiration date. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document. However, you may withdraw your permission to share your protected health information at any time. You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form.

Health Insurance Portability and Accountability Act (HIPAA) Regulations or applicable state law requires that you authorize the release of any health information that may reveal your identity. If you withdraw from the study or if you revoke your authorization for the collection and use of information about you, your participation in the study will end and the study personnel will stop collecting information from you. Sponsor will need to retain and use any research results that have already been collected. Sponsor must do this to comply with its legal obligations and to maintain the scientific integrity of the study. Your decision to withdraw from the study or to revoke your authorization for the collection and use of information about you will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

If you have any questions about the collection and use of information about you, you should ask your study doctor.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Subject's Signature Date / Time

Subject's Name: (please print)

INFORMED CONSENT FORM TO PARTICIPATE IN THE CLINICAL STUDY

My participation in this research study is completely voluntary. By signing and dating this form, I declare that I have read and understood the information here and the study doctor or study staff has talked with me about the study. I have voluntarily decided to be in the study. My signature and date also shows that I was able to ask questions and I am satisfied with answers to all my questions.

By signing and dating this form, I do not give up any of my legal rights. I will be given a copy of this signed and dated consent form to keep for my records.

_____

Subject's Signature Date / Time

_____

Subject's Name: (please print)

I have carefully explained the nature of this study to the subject. I hereby certify that, to the best of my knowledge, the person signing and dating this consent form clearly understands the risks and benefits involved in participating in this study.

_____

Signature of Person Obtaining Consent Date / Time

_____

Name of Person Obtaining Consent