15. SAMPLE INFORMED CONSENT

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Study Title: A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing the Infection Rate and Progession to COVID-19 in Adults Exposed to SARS-CoV-2

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

WHAT SHOULD I KNOW ABOUT THIS RESEARCH?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you do not take part, it will not be held against you.
- You can take part now and later drop out, and it will not be held against you
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

HOW LONG WILL I BE IN THIS RESEARCH?

We expect that your taking part in this research will last for approximately 28 days. Your study doctor will inform you of how long you will be in the study and when study visits are required.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is try to see whether an experimental drug, PUL-042 Inhalation Solution (PUL-042), is effective in preventing infection with the COVID-19 virus (SARS-CoV-2) and reducing the severity of COVID-19 illness in particpants who become infected.

WHAT HAPPENS TO ME IF I AGREE TO TAKE PART IN THIS RESEARCH?

If you decide to take part in this research study, you will take the experimental drug, PUL-042 Inhalation Solution (PUL-042) or a placebo 4 times over a 10 day period. The study visits may involve collection of mouth/nasal swabs in addition to completion of physical examination, vital signs and lung function tests. Urine samples or blood samples will be required for females of child bearing potential.

COULD BEING IN THIS RESEARCH HURT ME?

The most important risks or discomforts that you may expect from taking part in this research may include irritation of the airways resulting in symptoms such as cough and tightness of the chest.

WILL BEING IN THIS RESEARCH BENEFIT ME?

There is no guarantee that you will receive personal benefit from participating in this study. The information gathered during this study could help develop treatments to prevent or reduce illness from SARS-CoV-2 virus infection in other patients.

WHAT OTHER CHOICES DO I HAVE BESIDES TAKING PART IN THIS RESEARCH?

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. The treatment being tested in this study is intended to be given in addition to any standard treatment needed, not as a replacement or alternative. If you choose not to take part, you will still receive the standard treatment that you would normally receive.

You are being asked to take part in this study because you have have had docoumented exposure to the SARS-CoV-2 virus.

DESCRIPTION OF RESEARCH

1. PURPOSE OF STUDY

This study will try to see whether an experimental drug, PUL-042 Inhalation Solution (PUL-042), is effective in preventing COVID-19 infection or reducing the severity of COVID-19 illness in participants who have been exposed to SARS-CoV-2, but have no documented infection of the virus at the time of enrollment.

2. DESCRIPTION OF STUDY

This is an investigational study. PUL-042 has not yet been approved by the U.S. Food and Drug Administration (FDA) or other Regulatory Authority to treat any medical condition and is not available for sale to the public or to be prescribed by a doctor. PUL-042 is a combination of two molecules (called Pam2 and ODN for short) mixed in sterile water. Previous studies in animals have shown that PUL-042 may help tissues in the lungs to resist infections better.

PUL-042 will be given through a nebulizer. This is a machine that uses a small motor to turn liquid into a mist, like a humidifier, so that you can breathe the drug into your lungs. You breathe in the mist through a plastic tube or facemask. Using a nebulizer is not painful or uncomfortable and is a common method of giving drugs during asthma attacks. It will take around 10 minutes to breathe in all of the study drug.

A total of up to approximately 200 participants will be enrolled in this study, all at up to 20 centers. Participants in the study will receive either PUL-042 or a placebo (an inactive agent that appears

identical to PUL-042). There is a 50% chance you will receive PUL-042 (like flipping a coin). Neither you or your doctor will know if you receive PUL-042 or placebo. However, your study doctor can find out which study group you are in if there is an emergency. All study procedures will be provided free of charge. If you decide to participate in this study, you will have assessments done over the course of approximately 28 days. The assessments performed at each Study Day are described below.

Study Day -2 to Study Day 1

- You will read this informed consent document and discuss any questions you have with the study staff. No other parts of this study will be performed until all your questions have been answered and you have signed this form, indicating that you want to take part in the study.
- The study doctor will collect information about your overall health and medical history, including documenting your exposure to SARS-CoV-2. You will be asked by study staff whether you have been diagnosed with COVID-19 illness.
- A physical examination will be performed.
- Your vital signs (blood pressure, pulse, temperature, and breathing rate) will be measured
- Your lung function will be measured by having you blow into a tube
- Women who can become pregnant will take a serum or urine pregnancy test. If a urine test is positive, the results will be confirmed with a blood pregnancy test. If you are pregnant, you will not be allowed to participate in the study.
- You will be asked about any recent health issues and medications you are taking.

Study Day 1

- A physical examination will be performed.
- Your vital signs (blood pressure, pulse, temperature, and breathing rate) will be measured
- Your lung function will be measured by having you blow into a tube
- A specimen will be taken by inserting a swab into your nasal passage or from the back of your mouth in order to test for the SARS-CoV-2 virus
- You will be asked about any recent health issues and medications you have taken.
- **You will be given the study treatment (PUL-042 or placebo) through the nebulizer.**
- Your vital signs (blood pressure, pulse, temperature, and breathing rate) and your lung function (by having you blow into a tube) will be measured at 30 minutes after you finish taking taking PUL-042.

If you are confirmed to have a SARS-CoV-2 infection at any time during the course of the study, you may continue to recieve further doses of PUL-042 if treatment has been well tolerated and at the discretion of the Principal Investigator.

Study Day 3

- A physical examination will be performed.
- Your vital signs (blood pressure, pulse, temperature, and breathing rate) will be measured.
- Your lung function will be measured by having you blow into a tube
- You will be asked about any recent health issues and medications you have taken since the assessment.
- **You will be given the study treatment (PUL-042 or placebo) through the nebulizer.**
- Your vital signs (blood pressure, pulse, temperature, and breathing rate) and your lung function (by having you blow into a tube) will be measured at 30 minutes after you finish taking PUL-042.

Study Day 6

Study Day 6 will have the same procedures as Study Day 3

Study Day 10

Study Day 10 will have the same procedures as Study Day 3.

Study Day 15

- A physical examination will be performed.
- Your vital signs (blood pressure, pulse, temperature, and breathing rate) will be measured.
- A specimen will be taken by inserting a swab into your nasal passage or from the back of your mouth in order to test for the SARS-CoV-2 virus.You will be asked about any recent health issues and medications you are taking.

Study Day 29

- You will be asked about any recent health issues and medications you are taking.
- A specimen will be taken by inserting a swab into your nasal passage or from the back of your mouth in order to test for the SARS-CoV-2 virus A
- Women who can become pregnant will take a urine pregnancy test. If the test is positive, the results will be confirmed with a blood pregnancy test.

This visit will end your participation in the study.

If dosing with experimental treatment is discontinued for any reason, you will be asked to complete all scheduled pre-treatment procedures but, will not receive further treatments or post-treatment measurements. It is still important that you complete all scheduled visits up to the Study Day 29 assessment.

If you withdraw from the study for any other reasons you will need to complete an Early Discontinuation Vist that will have the same procedures as Study Day 15 with the addition that women who can become pregnant will take a urine pregnancy test. If the test is positive, the results will be confirmed with a blood pregnancy test

3. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

Two previous studies in humans have been completed in which 49 people received PUL-042. The side effects noted in these 49 participants that were considered at least possibly related to PUL-042 administration included:

- a potential short term decrease in the ability of the lungs to transfer gas from inhaled air to red blood cells in 14 of 33 participants
- a short term increase in the number of white blood cells in 12 participants
- a short term decrease in the amount of air that can be forced out after a deep breath in 14 participants
- increased mucus in the nose or throat in 2 participants
- cough in 4 participants
- productive cough in 1 participant
- increased mucus in the lungs in 1 participant
- phlegm production in 1 participant
- aches in 1 participant
- chills in 1 participant
- viral symptoms in 1 participant
- chest pain, chest tightness, chest heaviness in 1 participant

Most of these side effects were mild and none were considered serious. As with any investigational study, the current study may involve unpredictable risks to the participants.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn.

You may be asked questions about your medical history that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about this, you are encouraged to contact your doctor or the study chairperson.

Pregnancy-Related Risks
Because taking part in this study can result in risks to an unborn or breastfeeding baby, you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications

If you are female, you must either have gone through menopause (at least one year since your last period) or be surgically sterilized (had a hysterectomy or your tubes tied). If you are capable of becoming pregnant and, if participating in sexual activity that may lead to pregnancy, you agree to use an effective dual method of birth control (acceptable methods include intrauterine device, spermicide, barrier, male partner surgical sterilization, and hormonal contraception) during the study and through 30 days after completion of the study.

If male, you must be surgically sterile (vasectomy) or, if not surgically sterile and if participating in sexual activities that may lead to pregnancy, you must be willing to practice two effective methods of birth control (acceptable methods include barrier, spermicide, or female partner surgical sterilization) during the study and through 30 days after completion of the study.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away. Getting pregnant may result in your removal from this study.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

If a pregnancy occurs during the study, you or your partner will be asked to report on the course of the pregnancy and birth of the child.

4. WHAT ARE MY RESPONSIBILITIES AS A RESEARCH PARTICIPANT

If you decide to participate in this medical research study, these are your responsibilities:

- Report all symptoms, side effects, injuries or medical treatments to your study doctor right away. Your safety depends on the prompt description of what you experience in the study. The quality of the safety information also depends on your prompt reporting.
- Attend all study visits.
- Report all medicines (including health supplements) taken. Safety and data quality depends telling your study doctor about everything you take.

Follow your study doctor's instructions about medicines and procedures you need to treat side effects.

5. POTENTIAL BENEFITS

There may be no medical benefits for you in this study. The information gathered during this study could help develop treatments to prevent or reduce the severity of COVID-19 illness in other patients.

6. ALTERNATIVE PROCEDURES OR TREATMENTS

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. The treatment being tested in this study is intended to be given in addition to any standard treatment needed, not as a replacement or alternative. If you choose not to take part, you will still receive the standard treatment that you would normally receive.

7. WHAT ABOUT CONFIDENTIALITY?

Your medical records will remain confidential. While you are part of the study, you may be asked that the investigators communicate with your other doctors.

For your protection and safety, your medical records may be reviewed by:

- The sponsor of this trial, Pulmotect or their designees
- The Institutional Review Board, or Ethics Committee (the agency that oversees human research at the Institution)
- The US Food and Drug Administration (FDA) or other Regulatory Authority
- Department of Health and Human Services (DHHS [US only])
- Department of Defense (US only)
- The Office for Human Research Protections (OHRP), the agency that oversees human research in the US (US only).

A description of this clinical trial will be available on http://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 Website at any time.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your name or identity will not be used for publication or publicity purposes.

Your name or the names of other participants will not be revealed in any data collected by the Sponsor. The United States Food and Drug Administration (FDA), Research Ethics Boards (REB), Institutional Review Boards (IRB), the Sponsor, or designee, or agents, may inspect and copy your medical records (without disclosing your identity) relating to this study. The results of this study will be reported to the FDA, and to other regulatory agencies. Absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

You have the right to see and copy your personal health information related to the research study to request information, rectification, erasure, restriction of your personal data processing as long as the study doctor holds the information or research institution. However, for the scientific validity of the study, you will not be able to review some of the study information until after the study has been completed.

8. REMOTE MONITORING

We will keep your study records private and confidential. Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential.

Due to the nature of this study, the sponsor of this study and affiliated contract research organization will not be able to review your study data while at your medical facility. The reviewing of your data may be required to be performed from an outside location.

If you sign and date this document, you give permission to the study's Sponsor (Pulmotect) or their designee who have been contracted to help in the conduct the study and the review of your data to use or disclose (release) your health information electronically outside of the clinical study site in a manner that is intended to protect the confidentiality of your data. In preparing copies of your medical records to be released electronically, the clinical study site staff will "de-identify"

the records, removing any directly identifiable data such as your name, initials, medical record number and full date of birth. The records will only be identifiable using the study number assigned to you by the study site. The disclosure is specific to this clinical study.

The only people who will be allowed to see these records are:

- The research team, including the study doctors and research staff, research nurses, and all other research staff as well as other doctors involved in your care.
- Certain government and university staff who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the country, state, provincial, or local government that regulates this research. This includes, Food and Drug Administration (FDA), State and Local Health Departments, the Department of Health and Human Services (DHHS), Department of Defense (DOD), and the Office for Human Research Protection (OHRP), European Medicines Agency (EMA)
- Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study and other offices who oversee this research.
- The sponsors of this study and any affiliated contract research organization.

The health information that we may use or disclose (release) for this research study may include:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests
- Health information related your Covid-19 infection

9. ADDITIONAL INFORMATION

You may ask the study chair any questions you have about this study. You may contact the study chair, Dr. *XX*, at *XXX-XXXX*. You may also contact the Chair of the Institutional Review Board or Ethics Committee (a committee that reviews research studies) at xxxxx with any questions that you have regarding this study and your rights as a study participant.

Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits.

If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated.

The study doctor or the Sponsor may remove you from the study without your consent for any of the following reasons:

- if it appears to be medically harmful to you,
- if you fail to follow directions for participating in the study,
- if it is discovered you do not meet the study requirements,
- at the discretion of the study doctor,
- if the study is canceled,
- or if you become pregnant.

If your participation in this study is stopped for any reason, you will be asked to complete the early discontinuation study procedures for your safety. An Early Discontinuation study visit, will be scheduled.

You will be asked to complete the assessments at Study Day 29.

If you agree to be in this study, you will be given a signed and dated copy of this consent form.

This study or your participation in it may be changed or stopped at any time by the study chair, Pulmotect, Inc., the U.S. Food and Drug Administration (FDA) or other Regulatory Authority, the Office for Human Research Protections (OHRP - a regulatory agency that oversees research in humans), or the IRB/Ethic Committee.

You will be informed of any new findings that might affect your willingness to continue taking part in the study.

The institution conducting the study may benefit from your participation and/or what is learned in this study.

This study is supported by Pulmotect, Inc. with funding from the Department of Defense.

In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s). If you have any questions about this, you may call the IRB.

10. STUDY COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, the institution's health providers will provide medical care. Pulmotect may pay for the treatment of the injury or illness. The institution cannot determine at this time what you may be reimbursed for. A financial counselor will be made available to you after the injury or illness is reported. You may also contact the Chair of the IRB or Ethics Committee at XXX-XXXX with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

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 treatment, PUL-042 used in this study. Participants using PUL-042 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.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

11. AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

A. During the course of this study, the research team will be collecting and using your protected health information. This information may include personal identifying information about you (such as your name, race, date of birth, gender, city, and zip code), your medical history, study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your doctor and the research team may share your study information with the parties named in Section D below.

B. Signing this consent and authorization form is optional However, if you refuse to provide authorization to use and disclose your protected health information for this study, you will not be able to participate in this research study.

C. The institution will take appropriate steps to keep your protected health information private when possible, and it will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point. Federal agencies (such as the FDA, other Regulatory Agencies, Office for Human Research Protections (OHRP)), Pulmotect or its designee, and the IRB/Ethics Committee might view or receive your record in order to collect data and/or meet legal, ethical, research, and safety-related obligations.

D. Your protected health information may be shared with the following parties:

- Pulmotect, Inc. (and/or any future sponsors of the study) and its designees

- CTI Clinical Trial & Consulting, a company Pulmotect has hired to help run this study and analyze its results
- Department of Defense (US)
- Federal agencies that require reporting of clinical study data (such as the FDA and OHRP)
- The governing IRB/Ethics Committee
- Officials of the institution
- Clinical study monitors who verify the accuracy of the information
- Individuals with medical backgrounds who determine the effect that the study procedures may have on the disease
- Individuals who put all the study information together in report form

E. There is no expiration date for the use of your protected health information. 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. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in XXXXXXX. You may contact the IRB/Ethics Committee questions. If you withdraw your authorization, you will be removed from the study and the study chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related protected health information to preserve the scientific value of the study. Data collected about you up to the time you withdrew will be used and included in the data analysis. The parties listed in Section D above may use and disclose any study data that were collected before you canceled your authorization.

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give XXXX permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

WITNESS TO CONSENT
I was present during the explanation of the research to be performed under Protocol PUL-042-501.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN) DATE

A witness signature is only required for vulnerable adult participants.

PERSON OBTAINING CONSENT

I have discussed this clinical research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
SIGNATURE of Person Authorized to Obtain Consent DATE