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

Sponsor / Study Title:	**Cellular Sciences, Inc. / Emphycorp / "Two Week Sub-Chronic Double-Blinded, Placebo Controlled Trial Designed to Determine if Sodium Pyruvate Nasal Spray Will Reduce the Symptoms, Duration and Replication of COVID-19 and Influenza Infections."**
Protocol Number:	**Pro00049340**
Principal Investigator:	**Christopher Lupfer, PhD**
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You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

1. This consent is being sought for research.
2. Participation in this research study is voluntary.
3. The duration of this study will be no longer than three hours on the first day, and then 30 minutes on the 7th and 14th days.
4. The purpose of this research is to evaluate the ability of N115 to reduce chronic symptoms in COVID-19 "Long Haulers."
5. You will be given a medical exam, and instructions. These are tests that do not cause any pain.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to study the effects of N115, a natural antioxidant of the human body that has been used to treat millions of people with sinus and lung diseases, to determine if this study drug can reduce the severity and duration of symptoms in people with chronic COVID-19 disease known as "Long Haulers." This study drug is believed to have the ability to improve lung function and inflammation in subjects who are COVID-19 "Long Haulers." The study drug is investigational and has not been approved by United States Food and Drug Administration (FDA). It has not previously been studied for the treatment of COVID-19.

About 50 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last approximately three hours on the first day and then 30 minutes on the 7th and 14th days.

If a subject withdraws from the study, the data collected on the subject to the point of withdrawal will remain part of the study database and will not be removed.

The study investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review and address the maintenance of privacy and confidentiality of the subject's information.

If a subject withdraws from the interventional portion of the study but agrees to continued follow-up of associated clinical outcome information as described in the previous paragraph, the study investigator must obtain the subject's informed consent for this limited participation in the study.

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the study investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, a study investigator may review study data related to

the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

What happens to me if I agree to take part in this research?

- You will be evaluated by a study investigator to see if you are healthy enough to participate. During this visit, any chronic COVID-19 "Long Hauler" symptoms will be noted, and your temperature, vital signs and blood pressure will be taken. The study investigator will ask about current medications you are taking.
- If you are a woman of child-bearing age, a urine sample will be collected and analyzed for pregnancy. You cannot participate in this study if you are pregnant.
- At the start of the study, you will report current symptoms associated with chronic COVID-19 disease. You will then record and rank your symptoms on a daily diary for 7 days without the use of any medication or study drug.
- After 7 days, you will be provided with the N115 study drug, which is a nasal spray, and asked to use the spray 3 times each day for an additional 7 days.
- Every other day, you will be contacted by a study investigator to check on your health status and verify compliance in using the N115 study drug.
- You will be given a "Subject Diary" in which you will be asked to record your body temperature and symptoms like headache, nausea, vomiting, muscle aches, tiredness. If you do not have a thermometer, we will provide one without charge.
- At this time, the study drug will not be available for sale. If you have determined that the N115 study drug relieved your symptoms, more of the N115 study drug will be provided to you upon conclusion of the study.
- Follow-up studies are not planned at this time.

What are my responsibilities if I take part in this research?

If you take part in this research:

- You should be truthful about your health with the study investigator enrolling you in the study. You must not participate in the study if you have used any of the following in the last week or plan to use them for the next two weeks: all nasal spray medications, nebulized medications or lavages, all antihistamines, steroids or anti-inflammatory medications of any kind. Subjects also may not currently be taking any antiviral or antibiotic medications.
- You should not participate in this research if you have any of the following:
    1. An infection other than COVID-19.
    2. Clinically significant cardiac disease including uncontrolled congestive heart failure and unstable angina.
    3. Pregnancy.
    4. Females of childbearing potential age not on adequate contraception or lactating.
    5. Subjects less than 18 years of age.
    6. Hospitalization within last 6 months due to acute exacerbation of airway disease like asthma.
    7. Subjects with a clinically significant abnormal chest x-ray within past 12 months.
    8. Medication changes within one month of study entry.
    9. Subjects who have participated in another investigation drug treatment study within the previous month.

10. Subjects with a current history of alcohol or recreational drug abuse.
11. Subjects who have taken dietary supplements containing pyruvate within 24 hours prior to the screening visit.

- The only study drug to be administered is the N115 nasal spray.
- Aside from visiting the study investigator, you should continue to limit contact with others and reduce the spread of COVID-19. This study drug has not been proven to work, so taking it does not mean that you are better, and you should continue follow CDC guidelines.
- Any self-perceived side effects should be immediately reported to the study investigator.
- You must agree to abstain from sexual intercourse or agree to use condoms or vaginal diaphragms or other devices designed to prevent conception, during the entire course of the study.

Could being in this research hurt me?

- Any experimental drug study has potential risks. In addition to these risks, taking part in this research may harm you in unknown ways.
- To date, no side effects have been reported with the use of Sodium Pyruvate.
- The research data will be coded before it is shared with individuals outside of the research. However, there is a small risk of a breach of confidentiality.
- You should seek urgent medical care if you experience significant worsening of your symptoms.

Will it cost me money to take part in this research?

It will not cost you any out-of-pocket money to take part in this research. Your insurance may be billed if you require any emergency treatment. Any out-of-pocket economic expenditures that may occur as a result of a serious study drug-related side-affect will be paid for by Cellular Sciences, Inc. (the study sponsor).

Alternatives to treatment:

You are in no way required to participate in this research study. There are FDA approved treatments for COVID-19 disease. If you are not interested in participating in this study, your study investigator can discuss other treatment options.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. If you receive the study drug and it is effective, possible benefits to you include improved lung function, allowing you to breath more easily; increased oxygen in your blood, allowing you to have more energy; and reduced inflammation which may lead to reduced coughing and nasal pain and a reduction of the severity, duration and symptoms of COVID-19 disease as a "Long Hauler."

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research Sponsor.
- People who work with the research sponsor.

- Government agencies, such as the Food and Drug Administration.
- The Institutional Review Board (IRB) that reviewed this research.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

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.

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 investigator 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: Pro00049340.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, call the study investigator immediately. The study investigator will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by an insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study investigator or sponsor.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

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 drug N115 sodium pyruvate nasal spray used in this study. Subjects using N115 sodium pyruvate nasal spray 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.

Can I be removed from this research without my approval?
The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest.
- You have a side effect that requires stopping the research.
- You need a treatment not allowed in this research.
- You become pregnant.
- The research is canceled by the FDA or the sponsor.
- You are unable to take the study drug.
- You are unable to keep your scheduled appointments.
- If tests suggest a condition that would adversely affect the outcome of the study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?
You may choose to leave the study at any time without any consequences and without any risks. If you decide to leave this research, contact the study team so that the study investigator can arrange for you to come to the clinic or have a Telehealth visit for a final exam and review of your documentation.

Will I be paid for taking part in this research?
Cellular Sciences, Inc. will pay each subject at the following rates:

Visit	**Subject Payment Rate**
First Visit	$50
Final Visit	$50

This payment is for the subject. Subjects will be paid for the first and final visit, without regard as to whether the subject completes the entire study. Subjects will be paid at the end of their participation in the research study.

Statement of Consent:
I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Cellular Sciences, Inc./Emphycorp.
- Representatives of Missouri State University.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

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.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date