CM4620-205 Informed Consent Form

A Single-Blind Dose-Ranging Pharmacodynamic Study of Auxora for the Treatment of Patients with Critical COVID-19 Pneumonia

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Clinical Trial Number: NCT04661540

Permission to Take Part in a Human Research Study

Title of Research Study: A Single-Blind Dose-Ranging Pharmacodynamic Study of Auxora for the Treatment of Patients with Critical COVID-19 Pneumonia (CM4620-205)

Investigator: Richard G. Wunderink MD

Supported By: This research is supported by CalciMedica, Inc. 505 Coast Boulevard South, Suite 307 La Jolla, CA 92037

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

To make reading this consent form easier, please note that the word “you” refers either to you if you are the patient (research subject) or to the patient (research subject) if you are his/her family member

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have been diagnosed with COVID-19 (corona virus) with pneumonia and are on a breathing machine. Clinical trials are a type of research study to help doctors find ways to improve health and medical care.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to see if an experimental drug called Auxora is safe to use for people who have COVID-19 with pneumonia and are on a ventilator (breathing

machine). Experimental means that Auxora (the study drug) has not been approved by the U.S. Food and Drug Administration (FDA).

Pneumonia is an infection in the lungs. Your lungs have filled with fluid which can cause fever, chills, fatigue, cough, congestion, and difficulty breathing. This infection often leads to inflammation . This can lead to complications in other parts of the body.

This study is designed to help doctors understand how to safely give the study drug to patients who have critical COVID-19 with pneumonia. The study is testing the study drug and comparing it to placebo (a substance that has no medical effect). You will also receive the hospital standard of care for COVID-19 with pneumonia.

If you consent to participate in this study, you will be assigned to receive Auxora or Placebo in a 3:1 ratio. This means that for every 3 patients receiving Auxora, 1 will receive placebo.

This is a single-blind study. You will not know if you are receiving Auxora or Placebo, this will be referred to as “study drug” throughout the rest of the document.

This study will have 3 groups or Cohorts.The first group of patients will consist of 4-8patients who will receive up to 3 doses of study drug as follows:
Day 1: 1.25 mL/kg
Day 2 1.0 mL/kg
Day 3: 1.0 mL/kg

The next group will consist of 8-12 patients who will receive up to 4 doses of study drug as follows:
Day 1: 1.25 mL/kg
Day 2: 1.25 mL/kg
Day 3: 1.0 mL/kg
Day 4: 1.0 mL/kg

The next group will consist of 8-12 patients who will receive up to 5 doses of study drug as follows:
Day 1: 1.25 mL/kg
Day 2: 1.25 mL/kg
Day 3: 1.0 mL/kg
Day 4: 1.0 mL/kg
Day 5 1.0 mL/kg.

The study drug has been used in past clinical trials to treat subjects suffering from other diseases. Starting in April 2020, it has been used in a clinical trial to treat patients with severe COVID-19 pneumonia. The safety data collected from these clinical trials supports continued clinical study research of Auxora.

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How long will the research last and what will I need to do?
If you decide to take part in the study, you will not be asked to spend time in the hospital that you would not be spending anyway due to your diagnosis of COVID-19 with pneumonia.

Blood samples will also be collected at certain time points for monitoring of the drug level and safety monitoring. Some of these tests may be part of your standard of care in patients who have COVID pneumonia.

We expect that you will be in this research study for up to 30 days This includes the time you are hospitalized for COVID-19 with pneumonia and phone call 30 days from your first dose if you are discharged from the hospital before 25 days.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
Because the study drug is still under development, not all the risks may be known. Some side effects are rare and life-threatening, your study doctor will be closely watching your medical status for any side effects and will provide treatment as necessary. There may be other risks not yet known when you take the study drug alone or when it is used with other medications. If important information is learned during the study which might affect you or make you change your mind about being in the study, the study doctor will tell you. The study doctor is trained to take the right measures to reduce risks and limit any discomfort you might feel. If you need more information, please ask your study doctor.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include helping your pneumonia, but this is not guaranteed.

Just by taking part in this research study, you may be helping future patients by providing important information about the study drug and by contributing to medical knowledge.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose not to participate, you will still be able to receive standard care for your disease such as supportive care, including fluid replacement, pain killers, oxygen, feeding via a tube or into a vein, as well as a variety of different treatment strategies. You can speak with your primary doctor or other healthcare professionals regarding options and alternatives for treatment.

Permission to Take Part in a Human Research Study

Your alternative to participating in this research study is to not participate.

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

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at study pager 312-695-9285 or the MICU Research office at 312-926-2752 Monday through Friday, 7:00am to 3:30pm.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect up to 36 people at Northwestern will be in this research study

What happens if I say "Yes, I want to be in this research"?
If you agree to take part, the study doctor will first check your symptoms and your general health. It is important to be honest with your study doctors about your health history or it may not be safe for you to take part.

A day-by-day description of the study tests follows:

<u>Screening (to determine if you are a candidate for this study)</u>
The following checks will be done:

- The study doctor will assess your overall health, review your medical history, signs and symptoms you had at check-in to the emergency room, including any medications you may be taking or have taken in the past
- Record your vital signs such as: blood pressure, breathing rate, pulse, temperature and check the level of oxygen in your blood, which may be measured more than once.
- Your height and weight will be recorded
- Blood may be taken for testing at the hospital laboratory if it was not already done as part of your routine care to check your general health and the amount of oxygen in your cells and tissues as well as a small amount for a pregnancy test (if you are female and are able to have children)
- An EKG will be done if not done previously as part of your care. An electrocardiogram (EKG) is a test that gives us a measure of the heart's electrical

activity. You will be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on the body. This test takes about 10 minutes.

After checking the results of the items listed above, your study doctor will confirm if you are a match (eligible) for the study. If so, the following additional checks will be done:

- Review any medications you are taking, review your medical status, ask how you are feeling
- Blood samples will be taken for study-specific testing including general health tests as well as 'biomarkers' which are present in your body and help scientists understand how your body is coping with the disease
- A bronchoscopy will be performed, this may already be part of your standard of care. This is done by passing a small tube through your breathing tube. Sterile water is injected into your lung and immediately removed from your lung and sent for testing. This tests helps to diagnose types of infection and other conditions.

When your study doctor confirms that you meet the study requirements for taking part, you will start the study. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get; it will be decided using a computer. Because of the way this study is designed, you will have a 75% chance of being given the study drug plus standard of care or a 25% chance of being given the placebo plus standard of care. The study doctor will know which treatment you are getting

Whether assigned study drug or placebo:
Your study doctor will arrange for it to be given as soon as possible, within 8 hours. The study drug is given through a small tube and a needle directly into your vein, slowly over 4 hours (known as 'intravenous or IV infusion')

<u>Approximately 24 hours from start of the first infusion</u>
The following checks will be done:

- Your study doctor will check your vital signs, including how much oxygen is in your blood, review any medications you are taking, review your medical status, and ask how you are feeling
- An EKG will be done
- Blood samples will be taken for general health and study-specific testing
- Blood samples may be taken to check the concentration of the study drug in your blood
- The second infusion of study drug (lasting 4 hours) will begin

<u>Approximately 48 hours from the start of the first infusion</u>
The following checks will be done:

- Your study doctor will check your vital signs, including how much oxygen is in your blood, review any medications you are taking, review your medical status, ask how you are feeling.
- An EKG will be done.
- Blood samples will be taken for general health and study-specific testing

- Blood samples may be taken to check the concentration of the study drug in your blood.
- The third infusion of study drug (lasting 4 hours) will begin
- If you are in Cohort 1 there may be another blood sample collected at the end of the study drug infusion.

Approximately 72 hours from the start of the first infusion
The following checks will be done:

- Your study doctor will check your vital signs, including how much oxygen is in your blood, review any medications you are taking, review your medical status, ask how you are feeling
- An EKG will be done
- Blood samples will be taken for general health and study-specific testing
- If you are in Cohort 1 a bronchoscopy will be done to collect fluid from your lungs.
- If you are in Cohort 2 or 3 blood samples may be taken to check the concentration of the study drug in your blood
- If you are in Cohort 2 or 3 the fourth infusion of study drug (lasting 4 hours) will begin
- If you are in Cohort 2 or 3 there may be another blood sample collected at the end of the study drug infusion.

Approximately 96 hours from the start of the first infusion
The following checks will be done:

- Your study doctor will check your vital signs, including how much oxygen is in your blood, review any medications you are taking, review your medical status, ask how you are feeling
- An EKG will be done
- Blood samples will be taken for general health and study-specific testing
- If you are in Cohort 3, blood samples may be taken to check the concentration of the study drug in your blood.
- If you are in Cohort 2 a bronchoscopy will be done to collect fluid from your lungs.
- If you are in Cohort 3 the fifth infusion of study drug (lasting 4 hours) will begin.
- If you are in Cohort 3 there may be another blood sample collected at the end of the study drug infusion.

Approximately 120 hours from the start of the first infusion
The following checks will be done:

- Your study doctor will check your vital signs, including how much oxygen is in your blood, review any medications you are taking, review your medical status, ask how you are feeling
- An EKG will be done
- Blood samples will be taken for general health and study-specific testing
- If you are in Cohort 3 a bronchoscopy will be done to collect fluid from your

lungs.

Approximately 144 hours from the start of the first infusion, if you are still in the intensive care unit,

The following checks will be done:

- Your study doctor will check your vital signs, including how much oxygen is in your blood, review any medications you are taking, review your medical status, ask how you are feeling
- An EKG will be done
- Blood samples will be taken for general health and study-specific testing
- Blood samples maybe taken to check the concentration of the study drug in your blood.

Days 7 – 30 (If still hospitalized)

The study doctor will review your medical status, and ask how you are feeling every 2 days until you are discharged (or up to Day 30)

Day 30

- If you are discharged from the hospital prior to Day 25 the study team will call you by phone. During this phone call, the study team will review your medical status, ask how you are feeling, and ask if you are on supplemental oxygen.

Blood samples will be collected during your stay in hospital as part of routine care, to allow your doctors to assess your medical status and make treatment decisions. In addition, blood samples will be taken for study-specific testing from Day 1 through 144 hours. The amount of blood will range from approximately 3 teaspoons per day to not more than 6 teaspoons per day.

Some of the blood samples collected will be sent to specialty laboratories (located in the USA) to perform specialized tests. The test results will not be shared with your study doctor as they are designed to help CalciMedica's experts understand how the study drug works. Any blood samples which are used for testing are destroyed after the results of the tests are recorded (within 3 months).

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

If you take part in this research, you will be responsible to:

- You are not permitted to take part in any other research study until 30 days after entering this study.
- You should avoid becoming pregnant or fathering a child, as described in the Reproductive Health section, for 39 months (3 ¼ years) following your study participation
- You should avoid taking immunosuppressive treatments (these are treatments that reduce or stop your body's own immune system activity). Your study doctor has been provided with a list of these prohibited medications.
- You should inform your study doctor or the study staff of any concerns you may have or any new health issues you may experience

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you. Your participation in this study is strictly voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this informed consent.

If you decide to leave the research, contact the study doctor or study staff as soon as possible. They will make sure that proper procedures are followed, and a final visit is made for your safety.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. However, if you decide to leave the study before it ends, the study doctor will ask to see you before you are released from the study.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care in order to continue to follow you for safety. If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?
Based on the information gathered in prior research studies, the following are a list of possible risks associated with Auxora:

- Pain at the site of infusion
- Redness at the site of infusion
- Headache
- Increased heart rate and/or blood pressure
- Rapid Breathing
- Cough
- May feel full soon after beginning a meal
- Nausea
- Diarrhea
- Vomiting
- Abdominal Pain
- Decreased appetite
- Elevated glucose, cholesterol, and/or triglycerides during the infusion of study drug
- Lowered phosphate, and/or potassium levels in the blood
- Skin rashes, skin burn, and sensitivity to the sun (tanning beds should be avoided)

It is also not possible to rule-out the chance of an allergic reaction to the study drug. Some symptoms of allergic reactions are mild (hives, itching) while others can be life-

threatening (difficulty breathing, swelling of the throat).

Risks associated with bronchoscopy:

- Bleeding.
- Infection.
- Hole in the airway (bronchial perforation)
- Sore throat or hoarseness
- Irritation of the airways (bronchospasm)
- Irritation of the vocal cords (laryngospasm)
- Air in the space between the lung covering (pleural space) that causes the lung to collapse (pneumothorax)

Risks associated with electrocardiogram (EKG):

- The test may cause some redness or itching where the pads are placed.

In addition, there are risks associated with some of the tests performed for the study, however, many of these tests are routine and would be performed anyway as standard care for patients who have COVID-19 with pneumonia

The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

It is very important that you tell the study doctor and the study staff about any side effects that you might experience. You may experience side effects or discomforts that are not listed on this form. In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Your study doctor will tell you of any information learned during the study, including changes to the risks, that might cause you to change your mind about taking part in the study.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The effects of Auxora on an unborn child have not been studied. The research may hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You should not be or become pregnant or father a baby and/or breastfeed and/or donate eggs/sperm while on this research study. You should not agree to take part in

this study if there is any possibility that you are pregnant, breastfeeding, or planning a pregnancy (including impregnating a female partner) during this study or for 39 months (3 ¼ years) after your last dose of study drug. The 39 months (3 ¼ years) requirement was mandated by the FDA because the effects of Auxora on pregnancy are not known.

If you are sexually active, both men and women should use at least two very effective birth control methods during the study, and for 39 months (3 ¼ years) after the last dose of study drug. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms. Your study doctor will confirm for you appropriate contraceptive methods. If you are not able to follow this requirement, you should not agree to take part in this study in order to prevent the possibility of harm to an unborn child. Male subjects should also avoid donating sperm for 39 months (3 ¼ years) after the last dose of study drug.

If you or your partner become pregnant while participating in this research study or for 39 months (3 ¼ years) after the last dose of the study drug, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

You or your partner should practice effective methods of birth control until you or your partner are considered to be at least 1 year postmenopausal.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you, nor will you be paid to take part in the study.

A pharmaceutical company called CalciMedica is the sponsor of the study. CalciMedica is based in La Jolla, California, and is involved in the discovery and development of medicines.

The study drug and all study-specific tests and medical checks required by the study are provided at no cost to you. All procedures, tests and medical checks which are routine for patients who have COVID-19 with pneumonia will be charged to your insurance carrier in the usual way.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?
You may not receive direct medical benefit from receiving the study drug. It is possible if you are assigned to receive the study drug, it may help your pneumonia, but this is not guaranteed.

Just by taking part in this research study, you may be helping future patients by providing important information about the study drug and by contributing to medical knowledge.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, other representatives of this institution, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.

Unless required by law, your name will not be disclosed outside the research institution. Your name will be available only to the following people or agencies: the study doctor and study staff and authorized representatives of the study doctor, Institutional Review Boards (IRBs) (groups that ensure the study is run properly), health authority inspectors such as the U.S. Food & Drug Administration, CalciMedica and its designees (study monitors and auditors (people that review the study data and documents)), and authorized Clinical Research Organization representatives (people that help CalciMedica run the study). The above-mentioned individuals will use the personal information collected as part of this study, including your medical records ("Study Information") to check that the study is conducted correctly and to ensure the accuracy of the study information. These people are all obligated to maintain confidentiality by the nature of their work, and/or are bound by confidentiality agreements. If required, the study doctor may contact your personal doctor to collect additional medical information and your past medical history.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

The study doctor may only share your study information with people whom you have permitted to see it. However, once your study information is shared as authorized, it may no longer be protected by Federal law and might be redisclosed without your permission.

While participating in this study, the study doctor will replace your name with a special code that identifies you. This code, along with your study information, will be used by the study Sponsor, CalciMedica and its representatives, for the study purposes mentioned above and to help establish whether the study drug is safe. CalciMedica may share your coded information, as necessary, with CalciMedica affiliates who work within the limits of this consent; people and companies who work with CalciMedica and who work within the limits of this consent; Ethics committees (also called Institutional Review Boards, 'IRBs') and Regulatory agencies such as the US Food & Drug Administration, the National Health Authorities, and the European Medicines Agency.

Study Information, your study code, and results of tests on blood samples collected as part of this study will be included in CalciMedica's secure electronic trial systems (including databases). These systems will be managed and monitored by the Sponsor or companies who work with them.

The Study Information will be kept confidential within the limits of the law and used only for the research purposes mentioned above. If the results of this study are published or presented in a meeting, you will not be named, and nobody will be able to tell that you were in the study from the publication or presentation.

Your participation in this study is voluntary and you may cancel this consent at any time and without any reason. If you do so, your participation in the study will end and the study staff will stop collecting information from you, however, for safety reasons you will be asked to complete a final study assessment visit.

However, CalciMedica will continue to retain and use any research results that have already been collected. If you wish to leave the study, please inform your study doctor.

If you have any questions about the collection and/or use of your information, or would like to exercise rights that you may have regarding this information, you should ask your study doctor.

Permission to Take Part in a Human Research Study

This authorization will not expire.

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.

Can I be removed from the research without my OK?
The person in charge of the research study, the sponsor, the FDA or the IRB can remove you from the research study without your approval. The study doctor may choose to take you out of the study because of unexpected or serious side effects, or for other scientific, technical, logistical, or safety considerations.

Possible reasons for removal include:

- Staying in the study would be harmful to you
- You need treatment that is not allowed in this study
- You failed to follow study instructions
- You become pregnant
- You have a do not intubate order
- The study is cancelled

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

What else do I need to know?
If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

It is important that you follow carefully all the instructions given by the study doctor and his/her study staff regarding this study. If you become ill or are physically injured as a direct result of participation in this study, please contact the study doctor right away at the telephone number listed on page one of this consent form. He/she will treat you or refer you for treatment.

The reasonable costs of such treatment may be covered by the Sponsor. CalciMedica may provide payment for medical expenses for injuries:

- If you received appropriate medical care
- If you followed all instructions
- If the injury or illness is considered to be a direct result of taking the study drug or

study required procedures (and not by procedures that were part of, or recommended as, usual medical care, including the performance of a contrast-enhanced CT scan) that are not the result of the natural course of any underlying disease and/or preexisting disease process present prior to the proper administration of the study drug (Auxora)

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the Sponsor has to check to see if you receive Medicare and if you do, it must report the payment it makes to Medicare.

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

For more information on the declaration, please see:
https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor, or involved institutions from their legal and professional responsibilities.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research

study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- CalciMedica, Inc., who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy

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laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Richard G. Wunderink MD
Institution: Northwestern University, Feinberg School of Medicine
Department: Division of Pulmonary and Critical Care Medicine
Address: 303 E. Superior St., Simpson Querrey Building 5th floor, Chicago IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____

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Printed Name of Person Obtaining Consent

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Signature Block for Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

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Consent of the Participant to Continue to be in the Study after Regaining Consciousness:

Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision at the time due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. When you sign below, you are saying you understand the information we gave you about the study and in this form. If you sign this form it means that you agree to continue being in this study. You will be given a copy of this consent after it is signed.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Consent for study participant who cannot physically sign the informed consent document to continue to be in the study:

The study participant has indicated that he/she is physically unable to sign the informed consent document. One or more members of the study team read the consent document to the study participant, discussed it with the study participant, and gave the study participant an opportunity to ask questions.

_____ _____
Signature of Impartial Witness Date

_____
Printed Name of Impartial Witness