



CONSENT FORM

IRB PROTOCOL # 144-20-FB

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IND #147771

Title of this Research Study

A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

Description

You are being asked to be in this research because you have pneumonia called COVID-19 caused by a new coronavirus, SARS-CoV-2.

Purpose

There is now one FDA approved medication to treat COVID-19. This approved drug is called remdesivir (Veklury®) and everyone in this study will be given remdesivir. The purpose of this research study is to learn if remdesivir and Interferon beta-1a (a drug approved for other purposes) affect the outcome of this infection.

Methods

If you decide to be in this study, you will be randomly put in one of two groups: (1) remdesivir IV and interferon beta-1a injections or (2) remdesivir IV and placebo injections. Both groups will also receive the best standard care. You will get remdesivir given by vein every day, for up to 10 days and interferon beta-1a (or placebo) by shot under the skin every other day for 4 doses. If you are discharged from the hospital early, the IVs and shots will stop. You will have routine blood tests while you are in the hospital, and after you are released from the hospital, up to 29 days. If you are discharged from the hospital, you will be asked to come back to the



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site for an exam and collection of blood and swabs on Day 15 and 29. If you can't come back for study visits, we will call you. We will also call you on Day 22 to check on your health

Risks and Side Effects

Remdesivir can cause liver damage, abnormal blood clotting tests, constipation, nausea, vomiting, decreased appetite, and headache. Interferon beta-1a can cause pain and redness of skin at site of injection, headache, influenza-like symptoms (for example, tiredness, fever, chest pain, back pain, muscle aches, joint pain), abdominal pain, swollen lymph nodes. It can cause lower number of white blood cells or platelets in the blood which can lead to infection or bleeding. Rarely it can cause liver damage. Interferon can cause depression.

Benefits and Alternatives

If the study drugs work, you may get better sooner. If you decide not to be in the study, you will still get the best standard care we can give you and you may be eligible to get remdesivir off study.

Additional Information

The research team will review the entire consent form with you. The following is a complete description of the study

Why are you being asked to be in this research study?

You are being asked to be in this research because you have pneumonia called COVID-19 caused by a new coronavirus, SARS-CoV-2. Up to 923 adults with COVID-19 will participate in this research study.

What is the reason for doing this research study?

There is one approved medication to treat COVID-19 called remdesivir. Some people who become sick with COVID-19 have to be hospitalized. A small percent of hospitalized patients die. Data from an earlier study found that remdesivir may help hospitalized patients with COVID-19 recover faster than patients who do not get remdesivir. This study will compare the effect of giving remdesivir in combination with or without IFN beta 1-a in adult patients that are hospitalized with COVID-19. The drugs have been tested before in humans with other diseases. In this study, we would like to make sure that they are safe for use in humans with COVID-19 and see if they together can improve patients health when they are sick with COVID-19

What will be done during this research study?

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IRB
Approved 11/13/2020
Valid until 02/19/2021



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Screening: If you agree to be in this study, you will have some blood tests to see if it is safe for you to be in the study. You will also give some information about your health and any symptoms you may have, and get a physical exam. We may obtain some of this information from your inpatient hospital records. You will have a throat swab or a nose swab to look for the virus. If you are a woman of childbearing potential, you will be asked to complete a pregnancy test. The pregnancy test must be negative in order for you to participate. You cannot join this study if you have abnormal values for liver or kidney tests, are receiving a biologic therapy (including B-cell or T-cell targeted therapies) for the treatment of COVID-19 within the last 2 weeks. You may not be able to join this study if you have a history of chronic liver disease and a history of allergy to natural or recombinant interferon or human albumin.

If you qualify: If you qualify for this study and decide to join, you will be randomized (like the flip of a coin) to one of the two following groups:

- IV Remdesivir + Placebo injection
- IV Remdesivir + Interferon beta-1a injection

A placebo looks like the study drug but has no real medicine in it. Neither you nor the investigator will know what group you have been randomized to.

You will get 1 daily remdesivir infusion for up to 10 days and a subcutaneous injection of Interferon beta-1a every other day OR saline placebo every other day for 7 days (up to 4 subcutaneous injections) while you are a patient in the hospital. The infusion will be study drug and injection will be either study drug or placebo, depending on what group you are in.

You will complete a blood test and a throat swab or nose swab on Days 1, 3, 5, 8, and 11, as long as you remain a patient in the hospital. The blood tests and swabs are collected for research and safety tests. If you are already discharged from the hospital, you will be asked to come back for study visits on Days 15 and 29. You will get blood tests and a swab at these visits also. If you are unable to come back for study visits, the study team will call you. You will not receive infusions or subcutaneous injections after you discharged from the hospital. The study team will also call you on Day 22 to ask you about your health and recovery and if you were readmitted to a hospital.

The study team will also get information about you from your inpatient hospital records, such as whether you are receiving oxygen or need additional help breathing and what types of other medicines you are being given as part of your clinical care.



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While you are in this study:

- Refrain from drinking alcohol for 15 days after receiving remdesivir.
- Avoid getting pregnant during the study through Day 29.
- If you are breastfeeding you may not participate in the study (if you agree to discard the breastmilk from first dose of study drug until 3 weeks after last study drug is given, you can join the study).
- You should not volunteer for another study that gives volunteers any new study drug for COVID-19 for at least 30 days after you start receiving the study drug on Day 1. If you want to be in another study that follows people who have or have had COVID-19, you should talk to a member of the study team first, especially if the other study will collect blood from you.

OPTIONAL RESEARCH

Genetic Testing

If you agree to be in the study, you will also be asked if you consent to genetic testing. Participation in this part of the study is up to you and is completely voluntary. You can choose not to be part of that part of genetic testing at the end of this consent form.

We will do these tests to learn how your body responds to infection with the virus that causes COVID-19 and how you respond to IFN beta-1a.

This genetic research testing will give us information about how your body responds to infection with the virus that causes COVID-19 and how your body reacts to IFN beta-1a. With your consent, your genetic testing information and samples may be shared. A summary of the genetic results from all participants in this study can be placed in a public, unrestricted open access database that anyone can freely use. No individual genetic research testing information or results will be placed in an open access database. The risk of anyone identifying you with this information is very unlikely.

Since your genetic data and health information and samples may be stored and shared with other researchers, there may be a risk that information resulting from genetic research testing could be misused for discriminatory purposes. However, state and federal laws provide some protections against genetic discrimination. If you have any questions, please ask your Principal Investigator. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your information.



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We are doing genetic testing for research purposes only and will not diagnose or look for inherited disease or defects. The genetic research test results will not give information on paternity or your country/region of origin. We will not give you the results from the genetic research testing.

Consent to Genetic Testing

Participation in genetic testing is optional. You may participate in the study without participating in genetic testing.

Please read each of the choices below. Think about your choice. If you have any questions, please talk to the investigator or a member of the research team. Initial the line next to your choice.

Please initial your decision for us to use and/or share your information and samples for genetic research for this study:

_____ YES, you may use and/or share my information and samples for genetic research.

_____ NO, you may not use and/or share my information and samples for genetic research.

Secondary Research

We are asking permission to get extra blood samples from you during this study. We will save these extra samples, along with any leftover blood from routine tests. We will collect an additional 2-5 tablespoons of blood at each study visit. We will also save information about you. These samples and information may be used later for other research about COVID-19 or SARS-CoV-2 or the drug remdesivir. We may or may not ask your permission to do this extra research in the future. Secondary research does not include genetic testing.

You will be asked separately to consent for blood collection for genetic research testing. This will involve immunophenotyping, which means we will collect your blood and use RNA and blood cells from your blood sample to understand how your body responds to INF beta-1a and how you react to the virus that causes COVID-19 illness. This genetic research is optional and you may choose not to be in that part of the study now or anytime during the study.



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The stored samples will be labeled with barcodes to protect your identity. Your samples collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit. We have no plans to pay you if any new drugs, products, or inventions are made using your samples that you donated. There are no benefits to you for donating your samples. No results from this future research will be entered into your medical record and we will not tell you the results of this research. You can withdraw your samples at any time by telling the investigator.

When we no longer need the sample(s) for this research, we may take the identifiers off the sample(s) and use them for future studies. This is called "biobanking." Your sample(s) could be used for other research studies without asking you for your permission. This future research may be related to the study you are in now, or to your disease or condition, or to a different disease, condition, or to the study of normal body function.

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease.

If you agree to take part in this tissue bank and your samples are used in future NIH sponsored genetic research, some of your genetic and health information will be placed into a scientific database that is maintained by the NIH. A researcher who wants to study the genetic information must apply and be approved to use the database. Researchers with an approved study may be able to see and use your information (along with that of many other people), but your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. As your genetic information is unique to you, however, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

The Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

Health insurance companies and group health plans may not request your genetic



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information that we get from this research.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

The genetic tests might include whole genome sequencing. Whole genome sequencing tests give investigators your entire genetic makeup. Since each person has a unique genetic makeup, it is possible (although unlikely) to identify a person through the results of genetic tests being performed in this study.

Consent to Specimen Banking

Participation in specimen banking is optional. You may participate in the study without participating in specimen banking.

Please read each of the choices below. Think about your choice. If you have any questions, please talk to the investigator or a member of the research team. Initial the line next to your choice.

_____ You agree to allow your specimens collected during this study as identified in this consent to be stored for future research. The stored specimens will not be identified by your name or any personal identification.

_____ You do NOT want to allow your specimens to be stored for future research.

What are the possible risks of being in this research study?

Risks associated with remdesivir: remdesivir has been given to a small number of healthy and sick people.

The most common side effects included:

- abnormal liver function tests
- abnormal blood clotting tests
- constipation
- nausea
- vomiting
- decreased appetite



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- headache

Remdesivir contains a compound can cause abnormal kidney function tests. We will be following your kidney function during the study to check for kidney damage.

None of the side effects in these studies have been serious. Some people may have some side effects after the infusion. Other people may have no side effects. These side effects are temporary and should not last more than a few days.

Remdesivir could cause allergic reactions like hives or trouble breathing. Allergic reactions may be severe or life-threatening.

The study drug was given to some people who were sick with another virus disease. One of these people died from a heart attack after receiving the study drug. However, this person was very sick otherwise, so we cannot say if the heart attack was caused by the study drug. None of the healthy people who have received the study drug in the other studies have had heart problems.

The most common side effects of interferon beta-1a include:

- pain and redness of skin at site of injection
- headache
- influenza-like symptoms (for example, tiredness, fever, chest pain, back pain, muscle aches, joint pain)
- abdominal pain
- increased lymph nodes
- lower number of white blood cells or platelets in the blood
- an increase in liver tests
- depression.

Remdesivir and Interferon beta-1a, alone or together, may cause other side effects we don't know about yet.

During this study, patients whose breathing gets worse and need to be placed on a ventilator (a breathing machine), or receive high levels of oxygen, will not be given any more study injections (IFN beta-1a or placebo). This will be done because early in this study the Data and Safety Monitoring Board (DSMB) saw that patients with worse respiratory disease may have more side effects if given IFN beta-1a. The DSMB is made up of doctors and other experts who are not directly involved in the study and who have a good understanding of severe coronavirus infections and research studies.



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Risks associated with study procedures:

Blood Tests: The blood tests can cause pain and a small risk of infection.

Loss of Confidentiality: We will be careful to keep your study information confidential, but there is a small risk that someone not involved in the study could get this information.

Pregnancy Risks:

It is possible that the medicines used in this study could injure a fetus if you, or your partner, become pregnant while taking them. You have already been told what is known about this possibility, and you are encouraged to ask further questions. You may want to discuss this with others before you agree to take part in this study. If you wish, we will arrange for a doctor, nurse, or counselor who is not part of this study to discuss the potential risks and benefits with you and anyone else you want to have present.

Because of the potential risks, you, or your partner, must not become pregnant while you are participating in this study. Women of child bearing age must have a negative pregnancy test before entering the study and before starting treatment. If you are sexually active and can get pregnant, or can get your partner pregnant, you must use ONE method of birth control every time you have sex, or you must not have sex. The use of hormonal contraceptives is not recommended while taking the study drugs and for 30 days after finishing the study. You cannot be enrolled in this study if you are nursing a child, unless you agree to discard breast milk from the time you start receiving the study drug until 3 weeks after you receive the last dose of study drug.

Women of childbearing potential should practice abstinence or use at least one primary form of contraception not including hormonal contraception from the time of screening through Day 29.

By signing this and being in the study, you are agreeing to not get pregnant while you are on the study and for 1 month after. Should you become pregnant while on this study, you should immediately notify the study personnel. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can refuse.

What are the possible benefits to you?

You may not get any benefit from being in this research study. If the study drugs you receive in this study work, you may benefit by getting better sooner and/or getting less severe disease. Preliminary results from the current study suggest that your time



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in the hospital may be shorter by taking remdesivir. Everyone in the study receives remdesivir.

What are the possible benefits to other people?

This study may help researchers learn more about the study drugs, if they are safe and work in hospitalized patients with COVID-19, and help assist with the development of treatments for COVID-19.

What are the alternatives to being in this research study?

You will receive standard care for patients with COVID-19 whether or not you are in the research study. If you choose not to take part in this research study, you may be eligible to get Remdesivir off study.

What will being in this research study cost you?

The study drugs, remdesivir and interferon beta-1a, and some lab test and swabs will be supplied by the sponsor. All other treatments, tests, hospitalization and other medical procedures are considered standard care and will be billed to your insurance company.

You or your insurance company will be responsible for your routine care while participating in this study. You will have to pay any insurance deductibles and co-payments. If you want to speak with someone about your insurance, just tell us.

Will you be paid for being in this research study?

You will not be paid to be in this research study.

Who is paying for this research?

The sponsor of the research is The National Institutes of Health (NIH). The study drug Remdesivir is provided by Gilead Sciences, Inc. and Interferon beta-1a is provided by EMD Serono Research & Development Institute, Inc.. The companies that make the study drugs are providing them to NIH without charge.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. All non-NIH investigators are not required to report their financial holdings to the NIH. The policy of the NIH is to evaluate investigators at least yearly for any conflicts of interest. Research participants may review the system used by the NIH for assessing conflicts of interest by checking the web site link:
<http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf>.



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This institution may receive money to participate in this trial.

What should you do if you are injured or have a medical problem during this research study?

Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at this Institution. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment of any injury related to being in this study, for routine medical care, or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

No long term medical care or financial compensation for research-related injuries will be provided by the NIH or the federal government.

Signing this does not mean you have given up any of your legal rights.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures, such as the remdesivir and IFN beta-1a used in this study. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government.

Information about this program can be found at <https://www.hrsa.gov/cicp/about/index.html> or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within 1 year of the administration or use of the covered countermeasure.

How will information about you be protected?

In the course of this research we may collect information about you. This can be



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things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible. In the future, we may take the identifiers off the information. It is possible that this information without identifiers could then be used for other research by us, or by another researcher, without asking you for your permission.

We will keep your study information private. All files with information that could identify you will be kept in locked cabinets or secure password protected computers. People responsible for making sure that the research is done properly may look at your study records. This might include people involved in this study from this hospital and the US including the NIH and their designees (Division of Microbiology and Infectious Disease (DMID), National Institute of Allergy and Infectious Disease) and the US Food and Drug Administration, and the drug company that makes the study drug (Gilead Sciences, Inc.) but also may include the company that monitors the study (EMMES). All of these people will also keep your identity private. Results from this study, but not your identity, may be shared with local medical providers or government health organizations to help them better understand COVID-19. When results of an NIH research study are reported in medical journals or at scientific meetings, the patients who take part in the study are not named or identified.

To help us protect your privacy, we have a Certificate of Confidentiality (Certificate) from the NIH. Study staff cannot provide to any person not connected with the research your name, or any materials that contain identifiable, sensitive information about you, unless permitted by a legal exception, such as state laws that require reporting of some contagious diseases. The most important protection provided by the Certificate is that the study staff cannot be forced to provide any of your identifiable, sensitive information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, such as if there is a court subpoena, without your permission. The study team will use the Certificate to resist any demands for information that would identify you.

Your information protected by the Certificate may still be disclosed or used when the information:

1. is disclosed to people connected with the research, for example, information may be used for program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal US Food and Drug Administration (FDA);
3. is necessary for your medical treatment and you have consented to this



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- disclosure;
4. is for other research;
 5. is disclosed with your consent (e.g., an insurer or medical care provider gets your written consent for us to disclose the research information).

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures.

Who can see information about you?

We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB



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- The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your PHI.

- The Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Division of Microbiology and Infectious Disease (DMID)
- National Institute of Allergy and Infectious Diseases (NIAID)
- Your health insurance company

We may share your PHI with other groups listed below. These groups are NOT required by HIPAA to protect your PHI. If we share your PHI with these other groups they may share it with others who also do not have to protect it under HIPAA.

- The Data and Safety Monitoring Committee (DSMC)

You are letting us use and share your research data for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?

Information obtained in the course of the research that will not be shared with you is whether or not you have received the study drug or the placebo. By signing this consent form, you are temporarily giving up your right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

A description of this clinical trial will be available on 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.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Andre Kalil, MD



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4400 Emile St.
Omaha, NE 68105

What will happen if you decide not to be in this research study?

You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?

You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff.

If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

For your safety, please talk to the research team before you stop taking any research medicine or treatments. They will tell you how to do it safely. They may ask you if you will have some extra tests. You do NOT have to agree to do these tests.

You may also be taken off the study if:

- You experience serious side effects from the drug
- The investigator believes it is in your best medical interest
- The sponsor stops the study

Any research data we have already collected can still be used in the research.

You can decide later that you do not want us to use your stored samples for other research. To stop the use, contact a member of the research staff listed at the end of this consent form.

Will you be given any important information during the study?

We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?

We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*



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If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?

You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
 - Telephone: (402) 559-6463.
 - Email: IRBORA@unmc.edu
 - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
 - Telephone: (402) 559-6941
 - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____ Date _____

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



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My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent and Date

Authorized Study Personnel

Principal

* Kalil, Andre

phone: 402-559-8650

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What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ^

^ to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

^ to freely decide whether or not to take part in the research.

^ to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

^ to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

^ to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

^ to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

^ to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.