Northwell Health

Consent for Participation in a Research Study

Study Title: ROIDS-Dose (Randomized Open Investigation Determining Steroid Dose)

Principal Investigator: Stella Hahn, MD

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	Prior studies have shown that dexamethasone, a steroid, at a dose of 6 mg was beneficial in patients with severe COVID infection who have low oxygen saturation or require oxygen. This study compares dexamethasone 6 mg to a higher, weight-based, dose to see if it would be more effective.
What will happen to me during the study?	If you agree to participate, you will be randomized to receive either dexamethasone 6 mg or a weight-based dose of dexamethasone (0.2 mg/kg) intravenously for 10 days. The remainder of the study will be per usual clinical care as determined by your primary providers.
How long will I participate?	The medication will be dosed for 10 days while you are admitted in the hospital (and may be continued after discharge to complete the course, if determined by your physicians as necessary). The research team will collect data regarding your hospitalization and discharge, but no additional testing will be required. You may have one follow up survey via email, text, or phone call after 28 days, to check on your condition.
Will taking part expose me to risks?	Dexamethasone is a steroid and steroids can cause high blood sugar levels and may put you at higher risk of infection. The benefits of dexamethasone 6 mg outweigh the risks in patients who have COVID and have low oxygen levels. The higher dose of steroids may increase the risk of high blood sugar and infection.

Are there any benefits to participation?	The higher dose of steroids may have the potential to increase survival in patients with severe COVID infection and low oxygen levels.
What are my alternatives to participation?	If you are identified as someone with low oxygen but decide not participate in the study, you will receive the standard of care which includes dexamethasone 6 mg.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

As the participant's legally authorized representative or next of kin, you are being asked to give consent for the participant to be in a research study. You are being asked to do this because the participant is not able to give consent. When making this decision you should take into account the wishes of the participant. If you agree to allow the participant to take part in this research, the participant will also be asked to give consent if the ability to make healthcare decisions is regained.

Why is this research study being done?
Dexamethasone has been approved by the Food and Drug Administration (FDA) for the treatment of severe COVID-19 infection, but higher doses have not been directly compared to the current recommended dose. The purpose of this research study is to compare the current standard dose of dexamethasone to a weight-based dosing to determine if it would be more effective against COVID-19 pneumonia. Higher doses of steroids are routinely given in other lung conditions with high inflammation.

You are being asked to participate in this study because you have been diagnosed with severe COVID-19 infection and are being admitted to the hospital for treatment.

How many people will take part in this study?
This research study hopes to enroll 142 patients in the Northwell Health System. We hope to enroll 42 patients at Long Island Jewish Medical Center, 42 patients at North Shore University Hospital, 12 patients at Lenox Hill Hospital, 12 patients at Plainview Hospital, 12 patients at Valley Stream Hospital, 12 patients at South Shore Hospital, and 10 at Mather Hospital

How long will you be in this study?
If you choose to take part in this study, you will receive either the standard dose (which you would receive regardless of participation in this study) or a weight-based dose of the medication for 10 days. Additional testing will not be required as part of the study other than what is required for your clinical care as determined by your treating physicians. You will not require any follow up

with the research team during your hospitalization, but we will be tracking your course. You will have one follow up survey via email, text, or phone call after 28 days, to check on your condition.

What will happen in this research study?
In this study you will be assigned to one of two different groups. This means that you will be assigned to a group by chance (like flipping a coin). You will have an equal chance of being in either group. Both study groups will receive treatment. The different treatment groups are as follows:

Group 1: Patients will receive the standard 6 mg of dexamethasone
Group 2: Patients will receive a higher, weight-based dexamethasone dose (no less than 6 mg and no more than 20 mg)

You will receive the medication for 10 days. The remainder of the study will be per usual clinical care as determined by your primary providers. The research team will collect data regarding your hospitalization and discharge, but no additional testing will be required. If you are discharged before day 28, you will receive one follow up survey via email, text, or phone call after to check on your condition.

You will stay in the hospital for as long as is needed to treat you, regardless of your enrollment in the study.

What are the risks of the research study? What could go wrong?
Dexamethasone is a steroid and it is possible that steroids may cause high blood sugar levels and may put you at higher risk of infection. These are the main concerns, but the benefit of steroids in severe COVID infection outweighs the risks and usual clinical care would be able to treat these conditions, if they were to arise.

You may also experience minor side effects such as vision changes, swelling, weight gain, sleep problems (insomnia), mood changes, acne, dry skin, bruising or discoloration, slow wound healing, increased sweating, headache, dizziness, spinning sensation, nausea, stomach pain, bloating, muscle weakness and changes in the shape or location of body fat (especially in your arms, legs, face, neck, breasts and waist). Most of these side effects are seen with longer duration of use and are reversible once medication is stopped. Lastly, there is an unlikely risk of serious allergic reaction (anaphylaxis) while taking dexamethasone.

You will be closely watched for side effects. You should report any unusual events to the study staff.

With any research study that collects personal information, there is a small risk of loss of confidentiality, but your information is stored in a password protected platform and will only be accessible to a few research members involved in the trial. No identifying information will be released or published.

What are the benefits of this research study?

The higher dose of steroids may have the potential to increase survival in patients with severe COVID-19 infection. Information learned in this study may help to treat future patients.

Your group might receive more effective treatment and/or have fewer side effects than the other treatment group(s).

If you do not want to take part in this research study, what are your other choices?
Even if you do not participate in this study, you should receive the standard dexamethasone dose of 6 mg for your condition. You also have other choices for treatment. Talk to your doctor about your other options which may include:

- Another research treatment
- Standard treatment
- No treatment
- Comfort care

Your doctor can also tell you the important risks and benefits associated with alternative treatment options.

Are there any costs for being in this research study?
You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?
You will not be paid for being in this study.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this study is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study, you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by your doctor, researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- it is not in your best interest to continue this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the medical records and questionnaires. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as OHRP, the Food and Drug Administration, etc.
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

We will do our best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to

know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part, or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Stella Hahn
410 Lakeville Road
Suite 107
New Hyde Park, NY 11042

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Will my information be used for research in the future?
Information for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified data to be used by future researchers without additional consent

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Stella Hahn at (516) 465-5400. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given/e-mailed to you.

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Legally Authorized Representative's printed name

_____ _____
Legally Authorized Representative's signature Date

Description of signer's authority to act on behalf of the participant:

_____

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____

Investigator's signature **Date**

_____

Investigator's printed name