CONSENT FORM

HBO Therapy in Sickle Cell Pain Crisis, Initial Enrollment Consent

Title of this Research Study

(HAVOC) Hyperbaric Oxygen Therapy in Sickle Cell Pain Crisis

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.

Invitation:

You are invited to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to take part:

- Informed consent form
- "What Do I Need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Summary:

We are conducting a research study using hyperbaric oxygen (HBO) to treat sickle cell pain crises. If you were to require inpatient treatment for a sickle cell pain crisis in the future, we would like to invite you to participate. You need not participate in this study. We would treat you fully for your condition whether or not you participate in the trial. We wish to see if adding HBO treatment to your other medical treatments would reduce your pain and/or shorten your hospital course. If you choose to participate, you would be placed in an oxygen pressure chamber twice daily for up to three treatments each lasting about 2 hours. There is a possible risk of pressure on the ears being the most common side effect.

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

You are being asked to be in this research study because you are 19 years of age or

older and have been treated for sickle cell pain crises in the past. If you were to require inpatient treatment for a sickle cell pain crisis, we would like to involve you in this study. We would review the risks and benefits with you a second time, and again ask for your consent to take part in the trial. If you are pregnant or plan to become pregnant during this study, you may not be in this study.

What is the reason for doing this research study?
The purpose of this research study is to explore if off-label use of hyperbaric oxygen therapy will decrease hospital length of stay and pain associated with acute sickle cell pain crisis.

What will be done during this research study?
If you are diabetic we will check your blood sugar before and after the treatments. If you are a female of child-bearing potential, you will be required to have a pregnancy test, and the test must be negative, before starting hyperbaric oxygen treatments.

If you agree to be in this study, you will receive 1-3 hyperbaric oxygen sessions, depending on your response to the therapy. Each treatment session will be approximately two hours in length and will consist of lying in a hyperbaric chamber under pressurized oxygen to a maximum pressure of 2.5 atmosphere. TV's are mounted toward the chambers and a supply of movies and TV channels are available for viewing during this time. If at any time, you wish to stop the session, you are free to, which entails depressurization at a safe rate, which takes approximately 2 minutes in an emergency or 10 minutes routinely. From this information, we will ask you to provide information about level of pain before and after treatments as well as track your length of stay in the hospital related to your condition. Pain assessments in which you rate your pain on a 0-10 pain scale will occur at initial Emergency Department presentation and then every morning of admission on morning rounds from that point on until discharge. Hyperbaric oxygen sessions will be continued until pain is completely resolved or after the third session (the maximum number of sessions determined for this study. These.research procedures will be done in addition to standard medical care for sickle cell crisis.

No special follow up will be required of you.

What are the possible risks of being in this research study?
Hyperbaric oxygen therapy is generally a safe procedure. Complications are rare, but this treatment does carry some possible risks which include temporary nearsightedness (myopia) caused by temporary eye lens change that usually resolve within 2-3 weeks following treatment, middle ear injuries (including leaking fluid and

eardrum rupture) due to increased air pressure, lung collapse caused by air pressure changes (barotrauma), seizures as a result of too much oxygen (oxygen toxicity) in your central nervous system, and in certain circumstances, fire (due to the oxygenrich environment of the treatment chamber). It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits to you?
You may not get any benefit from being in this research study. Possible benefits may include decreased pain and shortened length of stay in the hospital related to your sickle cell pain crisis

What are the possible benefits to other people?
Possible benefits to other people include the advancement of medical knowledge as well as a change in therapy in the treatment of sickle cell crisis patients

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate. Alternatives to being in this research study include receiving the current standard of care without hyperbaric oxygen therapy

What will being in this research study cost you?
The pregnancy testing for females of child bearing age/potential and 1-3 sessions of hyperbaric oxygen therapy with be provided at no cost to you. Costs related to your routine medical care will be billed to you or your insurance company. Your health insurance company may or may not pay for these charges. You will be responsible for any applicable insurance deductibles and co-payments. This is because they are the same standard of care you would receive if you were not taking part in the study. If you wish to speak with a financial counselor about your insurance coverage and benefits, let the investigator or other study personnel know. A contact for personal assistance will be made available for you. There will be no additional charges for care above the standard of care, i.e., hyperbaric oxygen therapy.

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?
This research is being paid for by the Department of Hyperbaric Medicine, a division of the University of Nebraska Medical Center.

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

Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Emergency medical treatment for this injury or problem will be available at the Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider.

UNMC/Nebraska Medicine has no plans to pay for any required treatment or provide other compensation. If you have insurance, your insurance company may or may not pay the costs of medical treatment. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay for the medical treatment.

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

How will information about you be protected?

You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

Who can see information about you?

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC/Nebraska Medicine. Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?" You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office for Human Research Protections (OHRP)
    - The Food and Drug Administration (FDA)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
    - Your health insurance company

You are authorizing us to use and disclose your PHI for as long as the research

study is being conducted. You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

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

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. 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:

Jeffrey S. Cooper, M.D.
981150 Nebraska Medical Center
Department of Emergency Medicine
Omaha, NE 68198

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 UNMC/Nebraska Medicine. Your doctor will still take care of you and you will not lose any benefits to which you are entitled. If you were to present with a sickle cell pain crisis, we would go through the consent process again, and you could elect not to participate in the study at that time as well.

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

You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or UNMC/Nebraska Medicine. 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 study drugs or stop other related procedures. They will advise you how to withdraw safely. If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?

You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "What Do I Need to Know Before Being in a Research Study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

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 _____

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 _____
Date _____

Authorized Study Personnel
Principal
* Cooper, Jeffrey
phone: 402-552-2490
alt #: 402-559-4000
degree: MD

Secondary
* Coffey, Shaila
phone: 402-559-6123
alt #: 402-559-6802
degree: MD

Participating Personnel
* Baker, Susan
alt #: 402-552-2490
degree: APRN

* Barksdale, Aaron
phone: 402-559-9994
alt #: 402-559-9994
degree: MD

* Bulian, Brady
alt #: 605-660-6109
degree: DO

* Christiansen, Hannah
phone: 402-559-6475
alt #: 402-559-4000
degree: MD

* Gundabolu, Krishna
phone: 402-559-8052
alt #: 402-559-8052
degree: MBBS

* Jensen, Chris (Chris)
phone: 402-559-6982
alt #: 402-559-4000
degree: MD

* Jones, Drea (Drea)
phone: 402-559-0282
alt #: 402-201-7268

* Nester, Alex
phone: 402-836-9412
alt #: 402-559-5154

degree: MD

* Perry, Thomas
phone: 402-559-6706
alt #: 402-559-4000
degree: DO

Lead Coordinator
Zimmerman, Brooklin
phone: 402-559-5237
alt #: 402-836-9405
degree: MSN, BA, RN

degree: MD

* Thacker, Jenny
phone: 402-559-5413
degree: MD

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.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

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.