ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **"Hemolysis and Platelet Activation during Continuous Flow Mechanical Circulatory Support (Aim 2)"**

Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Omar Saeed, MD. You can reach Dr. Saeed at:

Office Address:
3400 Bainbridge Avenue, 7 Floor
Bronx, NY 10467
718-920-2248

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by:
Division of Cardiology, Department of Medicine, Montefiore Medical Center

Why is this study being done?

The overall goal of this study is to understand why in some cases clotting occurs during blood flow support provided by a device called a Continuous Flow Pump and whether the study drug may reduce the likelihood of clotting. Clotting can lead to severe side effects such as stroke and it is important to understand why it occurs to improve how we treat and prevent it.

In this research study, we will try to determine if a medication, called Sildenafil, may be effective in reducing activity of specific blood particles that may lower the chances of clot formation. We will test samples of your blood and urine to find out if sildenafil leads to reduced activity of such blood particles.

If you chose to enroll into this study, then you will receive treatment with either sildenafil or placebo. The placebo is a pill that looks like sildenafil but has no effect on the body after it is taken (no active medication). For the purposes of this study neither you nor the

study doctor will know if you received sildenafil or a placebo until the study is completed.

Sildenafil is approved by the U.S. Food and Drug Administration (FDA) for patients with pulmonary hypertension (i.e. high blood pressure in the blood vessels of the lungs). This medication is routinely given to patients with high blood pressure in the blood vessels of their lungs and is generally well tolerated. However, the FDA has not approved **sildenafil** to prevent blood clots in heart assist devices. This is the question that is being tested by this study.

Why am I being asked to participate?

You are being asked to participate in this study because you are being supported by a device called a Continuous Flow Pump that assists your heart in creating adequate blood flow as part of your standard clinical care.

How many people will take part in the research study?

You will be one of about **62** people who will be participating in this study.

How long will I take part in this research?

You will participate in the study for **15 days**.

What will happen if I participate in the study?

You will continue to be treated with whatever routine aspirin and coumadin therapy you have been prescribed while you are enrolled in this research study.

You will be asked to sign this consent form before participating in the study. After enrollment into the study, we will collect 2 teaspoons of blood from you. Then we will inflate a blood pressure cuff on your arm for 5 minutes. After deflating it, we will measure the blood flow to understand the health of your blood vessels. Blood flow will be measured by using an ultrasound to see the change in the size of the artery in your arm and as well as the change in temperature of your finger.

Then you will be randomly assigned (like by flipping a coin) to either one of two study groups, **sildenafil group** or **placebo group**. Your chance of getting either sildenafil or placebo in this study is 50/50.

After study group assignment on day 1, your blood pressure will be checked to make sure it is safe to take the study drug. If safe, you will receive 20 mg of the study drug. Then your blood pressure will be monitored for 2 hours and if it is stable you will be asked to take 20 mg of the study drug every 8 hours starting the next day for a total of 6 days and return to the clinic on day 8. In clinic, we will give you a 20 mg dose of the study drug and after two hours we will collect 2 teaspoons of blood and check the blood flow in your arm after inflating a blood pressure cuff. Then you will return to clinic on the

next weekday and if your blood pressure is in the safe range, you will receive 40 mg of the study drug. Then your blood pressure will be monitored for 2 hours and if it is stable you will be asked to take 40 mg of the study drug every 8 hours starting the next day.

You will be asked to return to the clinic on day 15 and we will give you a 40 mg dose of the study drug and after two hours we will collect 2 teaspoons of blood and we check the blood flow in your arm after inflating a blood pressure cuff. This will end your participation in the study.

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.

Genetic Testing

This study will not involve genetic research or genetic testing.

Specimen Banking (Future Use and Storage)

We will destroy the specimens (blood) when the study is complete.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study. We will reimburse you for transportation cost.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. All study drugs will be given to you free of charge. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document. If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to [**Omar Saeed, MD and 718-920-2626**].

What else do I have to do?

You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.

Confidentiality

We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- The research team and staff who work with them clinicians and staff at Montefiore who review your records for your care groups that review research (the Einstein IRB, and the Office for Human Research Protections)

These people, who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

The main risk of taking sildenafil is a mild drop in blood pressure which will be closely monitored during the study period and promptly addressed as necessary. Since you are being supported by a heart assist device your chances of experiencing a drop in blood pressure are **minimal** – (may occur in less than 1 out of every 100 patients). Other risks or complications that are most common (occurring in more than or equal to 3 out of 100 people taking sildenafil) are nose bleeding, headache, heart burn, flushing, insomnia, skin redness, shortness of breath, and runny nose. Although uncommon at the low doses being used in this study, there is a possibility of having more erections, as well as a prolonged erection that could be considered a medical emergency. During and after blood pressure cuff inflation you may feel temporary soreness in the arm but this technique is known to be very safe and without any known long term side effects.

Blood Draw

Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless "black and blue" may develop. Very rarely, fainting may occur.

Are there possible benefits to me?

If you are randomized to the group that receives the placebo as a study drug, you will get no benefit from participating in the Study. Since the expected effect of sildenafil is to prevent clotting, if you are randomized to receive sildenafil, you may be at a **lower risk** of forming a blood clot or having a stroke during the study period. In either case, your participation in the study will generate important information that may help others who will get heart assist devices in the future.

What choices do I have other than participating in this study?

You can decline to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Your other choices are:

- To continue on support with a Continuous Flow pump or other heart assist device(s) without participating in this research study.
- Sildenafil is available outside this study, and even after the study is completed.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, the blood and urine samples you have already given may not be removed from the study and will still be used for analysis.

Can the study end my participation early?
Your participation will end if the investigator stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of person obtaining consent	Signature of person obtaining consent	Date