Rutgers-New Jersey Medical School
Department of Physical Medicine and Rehabilitation
Newark, NJ 07101

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Immunogram analysis to create norms for patients suffering from pain

Principal Investigator: John Bach MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form. The study doctor, John Bach, MD, or another member of the study team will also be asked to sign this informed consent.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Why is this study being done?

The purpose of this study is to find a way to measure the intensity of pain, using an Immunogram Analyzer (AI). This new tool is potentially very useful. There are no other devices that can help the doctor and patient actually measure the intensity of pain.

Why have you been asked to take part in this study?

Because you are an informed adult.

Who may take part in this study? And who may not?

Informed adults with and without pain are invited to take part in this study. Pregnant women are excluded because we want to keep the study as simple as possible, and pregnancy is an added variable we hope to address in another study.

How long will the study take and how many subjects will participate?

Three groups of 20 adults each, will be asked to participate. One group will be without pain. Another will be with milder pain, treatable with medication. The third group will be with great pain that is hard to control with medication.

What will you be asked to do if you take part in this research study?

You will be asked to donate one sample of blood, 3-4 ml, or about 1/10th of an ounce.

What are the risks and/or discomforts you might experience if you take part in this study?

When your blood is drawn, there may be a bruise, or bleeding, or infection, or nerve damage at the place where your blood is drawn. However, these risks are rare.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be: A better way to measure pain. This could lead to better and less costly medication for all patients suffering from pain.

What are your alternatives if you don't want to take part in this study?

There are no alternative pain measurement devices available. Your alternative is not to take part in this study.

Will there be any cost to you to take part in this study?

Pain patients will be asked for a $25.00 co-payment, and their insurance company will be asked for the balance of $75.00 for each test. You will not be required to pay any additional costs, even if your insurance company does not cover any part of the cost.

Will you be paid to take part in this study?

You will not be paid for your participation in this research study.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study coordinator:

Sam Sofer, PhD: 201 953 1719

If you have any questions about your rights as a research subject, you can call:

IRB Director (973)-972-3608 Newark

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. However, signing the form is not a condition for receiving any medical care outside the study.

What personal information will be used or disclosed?

No personally identifiable information such as name, address, date of birth, or social security number will be included in this study.

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____Date: _____