UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

If you are the legally authorized representative for the subject, as you read the information in this Consent Form, you should put yourself in their place to decide whether or not to allow us to collect research information about them and to allow them to take part in this study. Therefore, for the rest of this form, the word "you" refers to the subject.

If you are an adult participant reading this form, the word "you" refers to you.

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Persistent Inflammation, Immunosuppression and Catabolism Syndrome (PICS): A new Horizon for Surgical Care

Subtitle: Kidney Response to Sepsis Affects Angiogenic Balance and Likelihood of CCI and PICS

3. Who do you call if you have questions about this research study?

Principal Investigator: Mark S. Segal, M.D. (352) 273-5357

Co-Investigators: Azra Bihorac, M.D. (352) 273-9009

4. Who is paying for this research study?

The sponsor of this study is the National Institute of Health and the Clinical and Translational Science Institute.

5. Why is this research study being done?

You are being asked to do this test because you are a part of a larger study that is studying the long-term effects of sepsis. Individuals who get really sick in the hospital with sepsis can lose a lot of muscle very quickly. However we usually determine how well your kidneys are doing by measuring a substance in your blood that comes from muscle. Thus if you lose muscle it may look like you have normal kidneys when you really don't. We would like to do a special test to accurately measure your kidney function that is independent of your muscle mass.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

This study will not affect your normal clinical care. The normal treatment for sepsis may involve the use of medications such as antibiotics, vasopressors, sedatives and steroids. You may also need to have supportive care including oxygen and intravenous fluids. Surgery may be needed to remove the source of infection.

7. What will be done only because you are in this research study?

At the first visit while you are in the hospital, two very thin tubes, called intravenous catheters or IVs, will be inserted into your veins using needles and taped in place if you do not have them already. We will use one of these IVs to inject very low doses of one the contrast agent, Iohexol. We will use the other IV to draw no more than 3 milliliters of blood (approximately ½ a teaspoon) approximately once an hour for 5 times. After all the blood draws the IVs will be removed. If you agree the injection, but don't want the blood draws, you have the option of having us collecting your urine over 4 hours. Before the injection of the Iohexol you will be asked to void and your urine will be collected over the next 4 hours. If you refuse the injection of Iohexol, we would still want to collect your urine for a specific amount of time as well perform specialized tests on your blood or urine to give us information about your kidney function. If you are readmitted to the intensive care unit, we may ask you to redo the injection.

At the second visit, approximately one year after discharge, we will ask you to come to the CRC at UF Health Shands Hospital. If you are of child bearing potential, then we will ask you to give us a urine specimen so that we can make sure you are not pregnant. Even if we did not inject Iohexol during your hospitalization we would still like to check your kidney function at your one year visit.

Again, two very thin tubes, called intravenous catheters or IVs, will be inserted into your veins using needles and taped in place if you do not have them already. We will use one of these IVs to inject very low doses of one the contrast agent, Iohexol. We will use the other IV to draw no more than 3 milliliters of blood (approximately ½ a teaspoon) approximately once an hour for 5 times. After all the blood draws the IVs will be removed. If you agree the injection, but don't want the blood draws, you have the option of having us collecting your urine over 4 hours. Before the injection of the Iohexol you will be asked to void and your urine will be collected over the next 4 hours. If you refuse the injection we would still want to collect your urine for a specific amount of time as well perform specialized tests on your blood or urine to give us information about your kidney function.

The information gathered through these test will be combined with the other information gathered through the large observational study you are already participating in.

The results of the following tests are being done for research purposes only and might not be evaluated or used to diagnose/treat the participant's medical problems. The results might not be entered into the participant's medical record. These tests may need to be repeated by the participant's primary care doctor if required for the participant's medical care in the future: Blood tests performed for research purposes only.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

Your participation in this study will last approximately one year. There will be a follow up appointment approximately one year after you enroll in the study.

9. How many people are expected to take part in this research study?

Approximately 400 subjects.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

You may experience pain and bruising during the insertion of two very thin tubes (intravenous catheters) into your veins. Having these tubes in your veins could cause redness or cause an infection. After removal of the tubes you may have a bruise and experience pain that could last for 3 days. Tape will be used to keep the catheter in the arm from moving around. The tape can cause a skin rash. If this happens, it should go away in a short time.

Measurement of glomerular filtration rate (test that measures what percent of your kidney is working) may involve the injection of a drug called Iohexol into your veins. This is non-radioactive dye that is approved by the Food and Drug Administration and is usually used for X-rays. Doses that are used for regular medical care are more than 100 times larger than the dose that will be used in this study. Such low doses have been used in many studies to measure kidney function. The chance of this dye having a negative effect on you in this study is extremely low. At the doses used in this study no negative effects have been reported. At much higher doses, however, the following side effects are known to occur: 1) Allergic reactions: ranging from mild flushing and hives that only lasts a short time to death. 2) Common side effects: warmth and flushing of the skin. 3) Less common side effects: chills; dizziness or lightheadedness; headache; nausea or vomiting; pain or burning at the place of injection; sweating; unusual or metallic taste; or unusual thirst. Iohexol may have risks to the embryo, fetus, or newborn if you are breastfeeding. Therefore, women of childbearing potential will have a pregnancy test as part of the study. If it is positive, no GFR studies will be performed during your pregnancy. If you are breastfeeding no GFR studies will be performed as well.

If you do not have a foley, collection of your urine may be inconvenient.

Other possible risks to you may include: None

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit to you for participating in this research study.

11b. How could others possibly benefit from this study?

This research may benefit society in the future. This study may one day result in new tests or treatments for the care of persons who sustain sepsis.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. You may terminate (end) future participation at any time. Any identifiable research or medical record information for your participation in this study prior to the date you formally terminate participation and any blood samples obtained to that point will continue to be stored anonymously as described above. You may also withdraw from this study completely and have all samples destroyed. To formally withdraw your consent for participation in this research study and to have all data destroyed, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed in this form. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Florida or on your current or future medical care at Shands/UF Hospital.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The study doctor considers it advisable for a clinical reason or if the doctor decides it is in your best interest.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Services

The Sponsor will pay for all medical services required as part of your participation in this study as described above in the question "*What Will Be Done Only Because You Are In This Research Study.*" If you receive a bill for these services, please contact Mark S. Segal, M.D. at (352) 273-5357.

Items/Services Not Paid for by the Sponsor

All other medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services.

15. Will you be paid for taking part in this study?

Yes. You will receive $25 in compensation for the inpatient portion of the study which is your first visit and $75 compensation for completing your one year follow up visit at the CRC as an outpatient. This outpatient appointment will occur at the same time as the one year follow up appointment for the main study. You will receive a debit card with the amount allotted to you after each study visit. We will also provide you with a parking voucher.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Medical record information including:
- Laboratory, microbiology, and other test results
- X-ray, CT, MRI, US and all other imaging results
- Records about any medication you receive during hospital admission
- Records of physical exams during hospital admission
- Records of all vital signs and cardiac monitoring during hospital admission
- Records of any procedures or interventions during hospital admissions
- Demographic information
- Condition at discharge and discharge facility
- Social Security Number for payment for study participation

The study site personnel for the principal investigator will maintain a research file with your data that has been collected along with your subject identification number given to you at enrollment as well as name and account information. This file will be kept in a secure location designated by the Principal Investigator. Only the Principal Investigator and designated research staff will have access to this file. All study related documents will be kept in a locked file cabinet and all electronic records will be maintained on encrypted hard drives of study computers. All computers and network servers used in this study will be encrypted and password protected.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To help determine how and why people respond to injury and to identify differences in how the body responds to injury.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).

- United States agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others disclosed until the end of the study. If you withdraw your permission for the use and sharing of your PHI, then your information will be removed from the database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization | Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting and Authorizing | Date

If you are not the subject, please print your name

_____

and indicate one of the following:

_____ The subject's parent
_____ A surrogate
_____ A proxy
_____ The subject's guardian
_____ A durable power of attorney
_____ Other, please explain:

_____ _____

Legally Authorized Representative Signature | Date

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____

Assent Signature of Participant Date

Withdrawal from Study

You are free to withdraw your consent and stop participating in this study at any time. If you do withdraw your consent, you will not lose any benefits to which you are entitled. Withdrawal from the study will not affect your medical care in any way. To notify the investigators of your withdrawal from the study please sign the below and mail to the address provided. Also, please contact Frederick Moore, MD at 352-273-5670 or pager (352) 413-5721 if you decide to withdraw from the study for any reason.

_____ _____

Signature of Person Withdrawing from Study Date

If you withdraw from the study, we ask that you agree to allow us to continue using all information about you that has already been collected as part of the study prior to your withdrawal. Then any identifiable research or medical record information obtained to that point would continue to be stored anonymously. If you agree to allow us to use this information please sign below.

_____ _____

Signature of Person Allowing Use of Subject's Information after Withdrawal from Study Date