ADULT CONSENT - BIOMEDICAL
Patients

Title of this Research Study
SULFATION OF BILE ACIDS AS A BIOMARKER FOR HEPATOBILIARY DISEASES

Invitation
You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are an adult 19-65 years of age, who are visiting the hepatology clinic at UNMC as a patient with a hepatobiliary disease.

What is the reason for doing this research study?
The study may help finding a group of markers called bile acids to determine the severity of hepatic diseases. This study is solely being performed to investigate the role of these markers.

What will be done during this research study?
At your consent you will provide a urine sample (2 tablespoons) every time a blood sample is taken from you during your hospitalization and/or follow-up visits as scheduled by your doctor in the course of your treatment and evaluation.

In addition, the following information will be recorded from your medical record by your physician: i) your MELD score, ii) your serum liver-enzyme levels, iii) the compensation status of your liver condition, iv) the occurrence of any hepatobiliary complications related to your diseases, v) your liver condition before and after liver transplant surgery (if any). Your medical record will be accessed to obtain these data for up to two years.

What are the possible risks of being in this research study?
Urine collection does not have any risk associated with it.

What are the possible benefits to you?
You will not get any benefit from being in this research study .

What are the possible benefits to other people?

The study may help finding a group of markers called bile acids to determine the severity of hepatic diseases. An understanding of the role of bile acid sulfation in liver diseases may help better predict the prognosis of the diseases and identify new targets for diseases therapy.

What are the alternatives to being in this research study?
Instead of being in this study you can choose not to participate.

What will being in this research study cost you?
Thereis no cost to you to be in this research study.

Will you be paid for being in this research study?
You will not be financially compensated by participating in this research project.

Who is paying for this research?
This research is being paid for by grant funds from the Center of Clinical Research-The University of Nebraska Medical Center.

What should you do if you are injured or have a medical problem during this research study?
If you are injured or have a medical problem as a result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called protected health information (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures, as well as your medical history.

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 and than Nebraska Medical Center.

Your PHI will be used only for the purpose (s) described in the section What is the reason for doing this research study?

Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and

with any person or agency required by law.

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.

The information form in this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

What are your rights as a research participant?
You have rights as a research subject. These rights havebeen 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 complaints about the research, talk to the investigator or contact the Institutional Review Board (IRB) by:
·Telephone(402) 559-6463
·E-mail:IRBORA@unmc.edu
·Mail:UNMC Institutional Review Board, 987830 Nebraska Medical Center,Omaha, NE 68198-7830

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 study will not affect your medical care or your relationship with the investigator, the University of Nebraska Medical Center or the Nebraska Medical Center.Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this study (withdraw) at any time before, during, or after the study begins. Your doctor will still take care of you. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator, the University of Nebraska Medical Center, or the Nebraska Medical Center. You will not lose any benefits to which you are entitled.

You may be taken off the study if you dont follow instructions of the investigator or the research team.

If the research team gets any new information during this research study that may

affect whether you would want to continue being in this study you will be informed promptly.

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study. If you have any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Subject:_____Date:_____Time:_____

My signature certifies that all elements of informed consent described on this consent form have been explained fully to the subject. In my judgement, the participant 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

* Alnouti, Yazen
phone: 402-559-4631
alt #: 402-559-4631
degree: Ph.D

Secondary

* Olivera Martinez, Marco
phone: 402-559-6209
alt #: 402-559-6209
degree: MD

* Rochling, Fedja
phone: 402-559-6209
alt #: 402-559-6209
degree: MB, BCh

Participating Personnel

* Alamoudi, Jawaher
alt #: 402-559-2407
degree: M.S.

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.

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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.