RESEARCH CONSENT/AUTHORIZATION FORM

STUDY TITLE: 19 Versus 22-Gauge Fine Needle Biopsy (FNB) Needles for Endoscopic Ultrasound Guided Liver Biopsy (EUS-LB)

PRINCIPAL INVESTIGATOR: David L. Diehl, M.D., F.A.C.P., F.A.S.G.E.
SITE(S): Geisinger Medical Center, Danville, PA
PHONE NUMBER: 570-271-6856
24-HOUR PHONE NUMBER: 570-271-6211 (HOSPITAL SWITCHBOARD)

- **You are asked to take part in this study because we hope to evaluate the diagnostic ability of two EUS needles for obtaining liver biopsy specimens**
- **Please read this form. You may also request that the form is read to you. You are encouraged to ask any questions that you may have about this study, now, during or after the project is complete. Your participation is voluntary.**

This research has no external sources of funding.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the ability for 2 different EUS needle sizes (19 and 22 gauge) to obtain liver tissue

WHO WILL BE IN THE STUDY?

You are being asked to participate in this study because you are going to have an EUS-guided liver biopsy. 20 patients will be enrolled in this study

WHAT WILL I BE ASKED TO DO?

As is the standard prior to EUS guided liver biopsy, you will undergo a medical history, as well as routine labs to look at your blood counts and clotting function. Once this information has been obtained, you will be consented for the procedure by one of the participating endoscopists.

During the EUS-guided liver biopsy, it is our practice to do 4 separate needle into the liver (2 into the left lobe of the liver and 2 into the right). All 4 passes are done with a standard 19 gauge biopsy needle.

During this study, we will be seeing if using a smaller gauge needle (22 gauge) can provide adequate tissue samples that are comparable to the standard larger 19 gauge needle. Just like the normal operating procedure, 4 passes will be made into the liver. 2 of the needle passes will be done with the 19-gauge needle and 2 with the 22-gauge needle. The order of which needle will be used first will be determined randomly.

After the liver biopsy, you will be taken to the recovery room and monitored for one hour after the procedure, as is the standard policy at Geisinger Medical Center.

A telephone call will be made by one of the endoscopy nurses the day after the procedure to check on you. In addition, you will receive a phone call by one of the study investigators 1 week after your procedure to check if you had any issues after your test. No reimbursement or compensation will be received for your participation in this project.

HOW LONG WILL I BE IN THE STUDY?

You will be in the research study for approximately one week after you have undergone your EUS, at which time you will receive a phone call.

Follow up in the clinic to review the results of the liver biopsy wil be arranged, again which is the standard approach. The use and disclosure of your protected health information "by study doctor and staff" will conclude at the end of the study.

WHAT ARE THE RISKS OF THE STUDY?

The risks of study participation are the same as that of EUS all risks shall be explained as a part of your consent form for the EUS procedure itself. There are no added risks associated with study participation when compared to the standard of care.

Should complications from your EUS procedure occur, they shall be treated by the standard of care received by non-study participants.

We will not be enrolling people who are pregnant in the study. However, if you become pregnant, the study poses no additional risk to your embryo or fetus.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There are no direct benefits from participating in the study. The information that is learned will be useful for patients who need liver biopsy in the future.

WHAT OTHER OPTIONS ARE THERE?

Your participation in this study is completely voluntary and you have the right not to participate at any point. Should you choose not to participate, the EUS guided liver biopsy will be done in the standard fashion with 4 passes with the standard 19-gauge needle.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. To the extent practical, the study doctor/Principal Investigator and staff will provide this information in a way that does not identify you directly.

Methods to maintain your confidentiality will include using a random patient number to identify you during your participation in the study. We will also store the information gathered during the study on a password-protected drive and not open this information on a compute other than at Geisinger Health Systems. All physical forms for the study will remain in a locked storage device and all information will be destroyed after the study is complete and the manuscript has been written. If data or information from the research study is submitted for publication in a medical journal or is presented at a medical meeting, your identity as a research participant will not be revealed.

Geisinger Clinic has several departments that are responsible for making sure research is performed according to federal and state regulations. The staff members of these departments may review your medical record and research data for this study. This review will be administrative in nature and no PHI will be sent outside Geisinger Clinic.

Organizations may inspect and/or copy your research records (including information kept in your hospital medical record) for quality assurance and data analysis. Those organizations include groups such as, Geisinger IRB members and staff

You have the right to access your medical records at any point during participation in the study. The study results will be retained in your research record for data analysis or any regulatory review for at least six years or until after the study is completed, whichever is longer. At that time the research information not already in your medical record will be destroyed or information identifying you will be removed from the study results at Geisinger Clinic and/or could be used for future research. Any research information in your medical record will be kept indefinitely.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS?

This study poses no additional costs to you. The cost of the procedure itself will be billed to your insurance as is the standard of care in this situation. You will be responsible for any expenses that incur for the procedure itself.

WHAT HAPPENS IF I AM HURT WHILE I AM IN THE STUDY?

In the case of injury or illness resulting from this research study, medical treatment is available but will be provided at the usual charge. Immediately contact your study doctor David L. Diehl at (570) 271-6856.

You or your insurance company will also be charged for continuing medical care and/or hospitalization required for any such injury or illness.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

No funds have been set aside to compensate you in the event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this research study is voluntary. You may choose not to be in the study or withdraw from the study at any time. You may also withdraw your consent/authorization for us to use your data/samples. Data/samples that have already been collected cannot be withdrawn.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits. It will not affect your access to health care at Geisinger Clinic.

If you do decide to withdraw, we ask that you contact the principal investigator in writing to state that you are withdrawing from the study. Please contact: David L. Diehl Geisinger Medical Center, 100 N. Academy Ave., Danville, PA 17822-2111 . If you decide to stop participating in the research study, we encourage you to talk to the principal investigator and your regular doctor first.

We will also inform you of information that may affect your health or welfare during your participation in this research study.

A Data Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the research study.

The study doctor may decide to take you off this research study if the EUS needle is no longer available, your clinical condition worsens or new information becomes available which excludes you from the study.

If you agree to allow your biopsy sample to be kept for research, you are free to change your mind at any time. We ask that you contact the study doctor in writing to state that you are withdrawing permission for your biopsy sample to be used for research. Any unused biopsy sample will be destroyed unless it has been already de-identified.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the research study, contact the study doctor DAVID L. DEIHL at (570) 271-6856.

Please contact the Human Research Protection Program (HRPP) staff of the Geisinger Institutional Review Board (IRB) at (570) 271-8663 to:

- **Discuss problems, concerns, and questions**
- **Obtain information**
- **Offer input**

The IRB is a group of people unaffiliated with the research study, who review the research to protect your rights.

SIGNATURE

I agree to take part in this research study. By signing this consent form, I have not given up any of my legal rights. You will get a signed copy of this form.

_____ _____

Research Participant's Signature Date

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information.

_____ _____

Person Obtaining Consent Signature Date