Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
***A randomized open-label trial of deprescribing proton pump inhibitors to reduce the risk of hepatic encephalopathy after transjugular intrahepatic portosystemic shunt creation***

CONCISE SUMMARY

The purpose of this study is to determine whether proton pump inhibitor (PPI) medications, commonly used medications to reduce stomach acid, increase risk of hepatic encephalopathy, confusion that can sometimes develop in patients with liver disease after the transjugular intrahepatic portosystemic shunt (TIPS) procedure.

If you decide to participate in this study you will be asked to either continue taking or discontinue taking your PPI medication. You will also be asked to take pencil and paper tests to measure hepatic encephalopathy, to fill out quality of life surveys, and to collect a stool sample at home and return it by mail. You will be asked to do these things once now and once approximately 4 weeks after your TIPS procedure. After you have performed these activities, you will have completed the study.

The potential benefit of participating in this study is that it may reduce your risk of hepatic encephalopathy. The potential risk of this study is that it may result in worsening symptoms of acid reflux (gastroesophageal reflux disease/GERD).

You are being asked to take part in this research study because you are being considered for transjugular intrahepatic portosystemic shunt (TIPS) procedure and you are taking a proton pump inhibitor (PPI). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

James Ronald, MD PhD will conduct the study and it is funded by the Duke University Radiology Department.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**
If you decide to participate, Dr. James Ronald will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand whether PPIs, commonly used medications to reduce stomach acid, increase risk of hepatic encephalopathy, confusion related to liver disease that can occur after TIPS.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 50 people will take part in this study at Duke.

## WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Physical exam and medical history
- If during your routine pre-TIPS medical evaluation it is determined you are pregnant, you will not be eligible for this study

If you are determined eligible for the study and decide to participate, you will have the following tests and procedures as part of the study:

- Pencil and paper tests of hepatic encephalopathy now and once again at your follow up appointment after TIPS
- Quality of life surveys now and once again at your follow up appointment after TIPS
- At home stool sample collection, returned by mail, now and once again at your follow up appointment after TIPS

You will be randomly assigned (like the flip of a coin) to receive either instructions to continue taking your PPI medication or to discontinue taking your PPI medication. You have a 1 in 2 chance of receiving instructions to discontinue taking your PPI medication.

Participating in this study is voluntary. If you refuse to participate you will not be penalized or lose benefits to which you would otherwise be entitled. If you initially chose to participate but then would like to stop participating you may contact the PI, James Ronald MD PhD, at 919-684-7299 and you will be removed from the study. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

## HOW LONG WILL I BE IN THIS STUDY?

This study will last approximately 6 to 8 weeks, starting at the time of this Interventional Radiology clinic visit, and ending at the time of your Interventional Radiology follow up clinic appointment approximately 4 weeks after your TIPS procedure.

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You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you after the study is completed if it is determined that discontinuation of your PPI is either helpful or harmful.

**WHAT ARE THE RISKS OF THE STUDY?**
The risk of this study is that stopping your PPI medication may result in worsening symptoms of acid reflux (gastroesophageal reflux disease/GERD). You will be provided with information on ways to counteract these acid reflux symptoms using other medications and through changes in your diet and other non-medical approaches.

There are no physical risks associated with the pencil and paper tests, quality of life surveys, and at home stool sample collection. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
If you agree to take part in this study, there may be direct medical benefit to you. Stopping your PPI medication may reduce your risk of hepatic encephalopathy after the TIPS procedure. We hope that in the future the information learned from this study will benefit other people with your condition.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of this study, you will be asked to have certain tests, x-rays, and/or procedures performed. Some of these tests, x-rays and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of

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tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**WHAT ARE THE COSTS TO YOU?**
There are no costs to you as a result of participating in this study.

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. James Ronald. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

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**WHAT ABOUT COMPENSATION?**
There will be no compensation as a result of participating in this study.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. James Ronald at 919-684-7299 during regular business hours and at 919-970-3619 after hours and on weekends and holidays.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. James Ronald in writing and let him know that you are withdrawing from the study. His mailing address is DUMC Box 3808, Duke North; 2301 Erwin Road, Room 1502; Durham, NC 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include development of serious adverse effects in you or other participants. If this occurs, you will be notified and your study doctor will discuss other options with you.

If you agree to allow your stool sample to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. James Ronald in writing and let him know you are withdrawing your permission for your identifiable stool sample to be used for future research. His mailing address is DUMC Box 3808, Duke North; 2301 Erwin Road, Room 1502; Durham, NC 27710. At that time we will ask you to indicate in

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writing if you want the unused identifiable stool sample destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Your stool samples and/or data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. James Ronald at 919-684-7299 during regular business hours and at 919-970-3619 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

**STATEMENT OF CONSENT**
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

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| _____ | _____ | _____ |
| Signature of Subject | Date | Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |