Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Andrew Scanga, MD **Revision Date: March 06, 2014**

Study Title: A randomized controlled prospective study to compare the incidence of biliary complications after liver transplantation.

Institution/Hospital: VUMC

This informed consent applies to adults.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you are scheduled to have a liver transplant or are on the waiting list for a liver transplant.

During your surgery the surgeon will be reconstructing your bile duct (a tube that carries bile from the liver to the gallbladder and small intestine). Based on their personal experience, some surgeons routinely put a stent in place during the bile duct reconstruction, while some do not. Your surgeon has agreed to abide by the randomization decision made at the time of your surgery (see Section 2 below).The stent being used is a smooth plastic feeding tube.

The practice of using stents in biliary anastomosis (the connection of two structures) is not uniform and there are no established guidelines to support their use. This study is designed to see if the use of a stent during biliary re-construction is necessary or not. We do not know if the use of this internal stent will prevent post-operative bile duct blockages without causing further complications.

We expect to enroll about 135 people into this study at Vanderbilt.

2. What will happen and how long will you be in the study?

If you agree to participate in this study, we will ask you to sign this document.

You will be randomized (like the flip of a coin) to one of two groups:

- Group 1: Will undergo biliary reconstruction with stent placement at the anastomosis site
- Group 2: Will undergo biliary reconstruction without stent placement at the anastomosis site

On the day of your operation the randomization will be done using a sealed envelope that will be opened during the operation. The randomization arm will be revealed to the surgeon immediately prior to the start of the biliary anastomoses. You will be told which are you were randomized to after your operation is completed and you are awake.

Both groups will be followed per standard of care after the operation. Both groups will have their medical records reviewed.

If you were randomized to receive the stent placement, you will have an abdominal x-ray about 3 months after your surgery to see if the stent has been expelled or if an endoscopic procedure needs to be done to remove the stent. This x-ray is standard of care. It is expected that the stent will migrate out of your system on its own in the early weeks following your transplant.

3. Costs to you if you take part in this study:

All procedures in this study are considered standard of care and will be billed to your insurance or to you.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

Since all procedures are considered standard of care for this institution there are no additional side effects anticipated as a result of your participation in this study. It is not currently known which procedure is better for preventing complications. Both are associated with potential side effects. You may develop strictures or blockages of the bile duct which could cause infection and pain. These events can occur with and without a stent. Side effects and risks associated with your routine care will be discussed with you by your provider.

Breach of Confidentiality: Breach of confidentiality may occur if your health information is obtained by people not involved in the study. Loss of confidentiality will be minimized by storing data in a locked office. Electronic information will be password-protected.

5. Risks that are not known:

There may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. The information obtained by this study will help transplant patients in the future.
b) The benefits you might get from being in this study. You may or may not benefit from your participation in this study.

8. Other treatments you could get if you decide not to be in this study:

You do not have to participate in this study

9. Payments for your time spent taking part in this study or expenses:

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

10. Reasons why the study doctor may take you out of this study:

The doctor may take you out of this study if he/she believes that it is in your best interest. If you are taken out of the study, you will be told the reason why.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Lanla Conteh, MD at [redacted] or my Faculty Advisor, Andrew Scanga, MD at [redacted]. If you cannot reach the research staff, please page the study doctor at [redacted].

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at [redacted] or toll free at [redacted]

13. Confidentiality:

You will be assigned a code number and will not be identified by name. Subject confidentiality is held strictly in trust by the participating investigators and their staff. This confidentiality extends to the clinical information relating to participating subjects. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Scanga and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data

gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Scanga and his study team may share the results of your study and/or non-study linked medical record to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, Food and Drug Administration (FDA). Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Scanga in writing and let him know that you withdraw your consent. His mailing address is: [redacted]. [redacted]. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____ Time _____

Date of IRB Approval: 12/14/2017
Date of Expiration: 12/13/2018