Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Prospective Randomized Trial Evaluating the Effect of Closed Suction Drainage versus Closed Straight Drainage after Distal Pancreatectomy**

Application No.: **NA_00080937**

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1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- For clinical trials: A description of this clinical trial will be available at 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 the Web site at any time.
- If you have clinical tests done as part of this research study, a statement will be added to your medical record that you are in this research study. Results from any clinical tests you have will be included in your medical record. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.

2. Why is this research being done?

The primary purpose of this study is to determine if the type of surgical drain placed at the time of distal pancreatectomy affects the development of complications and pancreatic fistula formation.

In this study we will compare two different types of drains which are routinely used after distal pancreatectomy at Johns Hopkins Hospital. Both drains are closed systems and are the same size, but each work a little bit differently as one drain system uses suction while the other does not. Both types of drains are currently used for distal pancreatectomies at Johns Hopkins Hospital according to surgeon preference and there is no information to indicate that either is more or less effective. Our primary objective is to determine if one of these drains is more effective than the other in preventing post-operative fistula formation.

Adults who are undergoing a distal pancreatectomy may join if they agree.

How many people will be in this study?
About 300 participants will be in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- We will perform the operation in the same way that we always do.
- During the case your surgeon will determine whether there is any reason to prefer one kind of drain or the other, and will use the preferred drain if he believes it is better to do so. If there is no finding that indicates which drain is better, you will be randomly assigned to one type of drain.
- After the routine pancreas resection is completed, because you are in a research study, you will be randomly assigned (by chance, like flipping a coin) to receive either a closed suction drain or a non-suction drain. Randomization will occur by a telephone call from the operating room to a study coordinator who will use a computer program to randomly assign you to one of the two study groups.
- The drain (depending on the type you are assigned to receive) will be placed in the standard manner and location.
- Your post-operative care will be exactly the same with daily laboratory work, and other studies as clinically indicated. There will be no other changes in your care based upon being on this study or the type of drain that is used. Information from routine laboratory tests that are being done on the fluid in the drain (done to help determine when the drain can be removed) will be used as part of this research study.
- Drain removal time will be determined by your surgical team based on clinical judgment.
- We will follow and document your clinical course while in the hospital and at post-operative clinic visits for 90 days from the time of surgery. This will be done at the time of routine clinic visits or by telephone.
- No additional post-operative procedures will be needed for this study.

How long will you be in the study?
You will be in this study for 90 days.

4. What are the risks or discomforts of the study?

The only intervention in this study is the choice of surgical drain to be placed and the collection of follow-up information. The sizes of the two types of drains are the same and we do not believe you will have any difference in risks, discomforts, or inconveniences associated with the drain choice.

It is possible that one drain may lead to a higher rate of pancreatic fistula or complications than the other. However, both drains are currently used at Johns Hopkins Hospital and both are standard of care after this operation.

There is a risk of developing leakage from the pancreas after the operation no matter what type of drain is left in place. There is also a risk that intrabdominal fluid that accumulates after surgery may become infected. These complications can result in significant harm and even death. However, we believe that both methods of drainage are standard of care and therefore participation in this study represents no additional risk to you.

It is also possible that one type of drain may result in having to leave the drain in place for longer than the other which can be an inconvenience when you are discharged home and may even require additional medical care.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

If you decide not to join this study, the type of drain used will be left to the discretion of your surgeon and you will not be included in the data analysis. You will still receive the standard of care.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and other details.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Johns Hopkins may see or give out your information. These include people who review research studies, their staff, lawyers, or other Johns Hopkins staff.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Matthew Weiss at 410-614-3368. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Matthew Weiss at 410-614-3368 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Matthew Weiss at 410-614-3398 during regular office hours or the on call physician for the Cameron Surgical Service at 410-955-5000 and ask them to contact Dr. Matthew Weiss after hours and on weekends.

d. What happens to Data and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data or the specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and specimens collected from you.
- If data or specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- If data or specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea

e. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.
- Suburban Hospital
- Sibley Memorial Hospital

15. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

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Signature of Participant Date/Time

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Signature of Person Obtaining Consent Date/Time

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Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required) Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.