Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Title of research study: Adult Consent to Participate in the Research Study: Prevena Incision Management System versus Dermabond in the Prevention of Groin Wound Infections in Patients Who Undergo Vascular Surgery

Version Date: [insert a version date here corresponding to the date of submission to the IRB]

Investigator: Linda M. Harris, MD, FACS

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are scheduled to have surgery on one or more of your blood vessels that will require your surgeon to make an incision (cut) in your groin area to perform the operation.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ***[Insert contact information for the research team].*** You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu

if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?

This research study is being done to evaluate the ability of two commonly used wound care treatments (Prevena Incision Management System or Dermabond) in preventing infections of a surgical groin incision in patients who have vascular surgery (an operation on blood vessels). We will also evaluate the cost of each treatment. Information from this study will help surgeons to make better decisions regarding which treatment can best prevent infection. Answers from this study can potentially save future patients the time and hardship associated with the additional care necessary to treat wound infections and may possibly lower health care costs by reducing or eliminating the expenses that arise from treating infections.

How long will the research last?

We expect that you will be in this research study until your first postoperative visit with your surgeon or his/her designee which should be between 25-40 days following your operation.

How many people will be studied?

We expect about 140 people in this research study. Half will be treated with Prevena Incision Management System and the other half will be treated with Dermabond.

What happens if I say yes, I want to be in this research?

If you agree to be a part of this study, your surgeon will perform the operation on your blood vessels exactly as if you were not part of the study. At the end of your operation, the treatment used to prevent infection of your groin incision will be chosen by chance, like flipping a coin instead of by your surgeon. Each of these treatments is commonly used and the surgeons participating in this study have had much experience with both. Your chances of getting Prevena Incision Management System or Dermbond will be equal. Both you and your surgeon will know which treatment you received. Prevena is Incision Management System is made up of a dressing that is placed on the incision to cover and protect it from bacteria in the surrounding area. The dressing is connected with a small tube to a lightweight battery powered remote which creates a vacuum like seal that helps to remove any fluids from the incision which can cause infection. The Prevena Incision Management System must be used for at least 4 days. If the Prevena device is used on your incision, your nurse will take care of it while you are in the hospital. If you are discharged before Prevena is removed, you and a family member or helper will be instructed on how to care for the device as well as given written instructions. This is currently standard of care for patients who receive this dressing. Dermabond is a surgical glue placed on the incision to hold it together and prevent infection. It is used instead of skin stitches, and has a coating that fights bacteria and is water resistant. Your care in the hospital after your operation will be exactly the same as if you were not part of the study. No additional blood work or testing will be required because of being in the study and the length of your hospital stay will not be affected. If you should develop infection of your groin incision, your surgeon will have full control in deciding the necessary testing and treatment. As a part of standard care, you will see your surgeon between 25-40 days following your surgery to check your incision for healing and to evaluate your operation. No additional testing or treatment will be required because of your involvement in the study. This visit will complete your participation in this research project. Information from your hospital medical and financial record including past medical history, operation details, postoperative care, cost and

reimbursement will be gathered by a study coordinator as well as information from your follow-up visit. This will be entered into a password protected database which will be kept in a locked office. Your protected health information and hospital financial records will not be personally identified in the data base. All research team members will have access to this data on an as needed basis.

What are my responsibilities if I take part in this research?

If you take part in this research and are chosen to receive The Prevena Incision Management System, you, a family member or helper may be responsible for caring for the device if you are discharged from the hospital before the device is ready to be removed. If this happens, you and your family/helper will be taught how to care for the device, given written instructions and the name and number of a contact person should you have any questions regarding the device while you are at home.

What happens if I do not want to be in this research?

Your participation in this research study is completely voluntary. You may choose not to enroll in this study and it will not affect the care that you receive. At the completion of your operation, your surgeon will decide which wound treatment to use rather than the decision being made by chance.

What happens if I say yes, but I change my mind later?

You can change your mind right up to the time that your surgery is to be completed and it will not be held against you. Your care will be the same regardless of your participation in the study and there will be no consequence of withdrawing. If the Prevena Incision Management System has been used, you have the right at any time following surgery to ask that it be removed after thorough discussion with your surgeon. Premature removal of the system may be associated with increased risk of infection.

Is there any way being in this study could be bad for me?

Both Prevena Incision Management System and Dermabond are current wound treatments that are used commonly to prevent infection of surgical incisions, so the risks of participating in this study beyond those routinely associated with an operation on blood vessels requiring groin incision are minimal. There are no additional psychological, legal, social or economic risks associated with this study. Taking part in this research study will lead to no additional costs to you. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. Allergic reaction which is uncommon for either Prevena Incision Management system or Dermabond may be a potential risk. To minimize this risk you will not be able to participate if you have a known allergy to adhesives, formaldehyde, cyancoacetate or silver. Loss of privacy/confidentiality is an unlikely but possible risk. We will take every effort to assure confidentiality. You will be assigned a study number which we will use to identify all information that we collect about you. This information will be recorded on a case report form and kept in a locked cabinet. Your name and other identifying information will not be put on the case report form. However, your name and other identifying information such as your medical record number, hospital account number, hospital discharge date and research study number will be placed on a list to help us collect your information correctly (for example: to make sure that information from your hospital stay is coordinated with information from your follow-up visit with your surgeon). We will keep this list in a separate locked cabinet in the study coordinator's office. Information that we collect will also be

entered into database on a password protected computer in the coordinator's office which will remain locked when not in use.

Will being in this study help me in any way?

We cannot promise any benefits to you from your taking part in this research. However, information obtained from this study may help to determine the best way to prevent infection of groin incisions after surgery. This may benefit you if you require future surgery on the blood vessels in the groin, and would benefit future patients, surgeons and hospitals by limiting the time, expense and hardship associated with treating groin infections.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including your hospital medical and financial records and surgeon office record, to people who have a need to review this information. We cannot promise complete privacy. Monitors or auditors from the sponsor (Acelity), the Institutional Review Board (IRB), will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential. A description of this clinical trial will be available on http://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 this Web site at any time. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

Although unlikely, the principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal would include your failure to see your surgeon for follow-up within 25-40 days after your operation.

What else do I need to know?

This research is being funded by Acelity the company that makes the Prevena Incision Management System. Although it is very unlikely that you would be injured from taking part in this study, it is important that you tell your study doctor if you feel that you have been injured because of participating in this study. You can tell the doctor in person or call. You will get medical treatment if you are injured as a result of taking part in this study. Your study doctor will explain the treatment options to you and tell you where you can get treatment. Generally, this care will be billed to you, your insurance or other third party. Buffalo General Medical Center, Kaleida Health has no program to pay for medical care for research-related injury.

You will not be paid for participating in this study.

If you are interested in learning the results of the study you may contact the study coordinator. This study is expected to take place during 2016. Results are not likely to be available until June of 2017.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

Information from your full medical records such as but not limited to your past medical history, current medications, type of operation performed, postoperative course including assessment of your groin incision for healing, use of antibiotics, length of stay in the hospital and if infection should occur, treatment that was provided during and after your hospitalization (up to 40 days following your operation).

Information from your hospital financial record such as but not limited to the total cost of your hospital stay, breakdown of costs such as the cost of your operation, nursing care, tests or procedures which may be completed, costs of antibiotics, cost of Prevena Incision Management System or Dermabond. The amount of reimbursement the hospital received from your insurer will also be collected.

B. Who is authorized to provide or collect this information?

___√__ KALEIDA Health, Buffalo NY
__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

___√__ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
___√__ The sponsor of this research study **Acelity** or its agents

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National

Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

D. How long will this information be kept by the Principal Investigator?

√ This authorization will expire at the end of the research study. After that time, authorization may not be used to acquire additional information about you.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):
[Insert name and address of individual or position associated with the research study that will be responsible for handling such requests.]

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study. You will likely receive either the Dermabond or the Preveena, but no data will be gathered on the outcomes from your incisions.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	