Combined Consent and Authorization to Participate in a Research Study

RANDOMIZED CLINICAL TRIAL COMPARING 1-PORT AND 2-PORT TISSUE EXPANDERS FOR BREAST RECONSTRUCTION

Principal Investigator: Lesley Wong (MD)
Emergency Contact: Lesley Wong, MD at 859-257-8143

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

We are doing a study comparing two types of tissue expanders used during your breast reconstructive procedure. Tissue expanders are used to stretch the breast skin remaining after the mastectomy by injecting fluid into a port within the expander. When there is sufficient skin, the tissue expander is removed and replaced with a permanent implant in a second stage of reconstruction. One of the known surgical complications after breast reconstruction is development of a seroma which is a collection of fluid under the mastectomy skin. Drains are placed at the time of surgery to prevent this complication. One of the expanders we are studying has a drain built into the expander. These expanders are approved by the Food and Drug Administration (FDA), but there are no direct comparisons between this expander and the type without a built-in drain. You are being invited to take part in this research study because you are a person that will be undergoing mastectomy and reconstruction that will require the use of tissue expanders to reconstruct your breast. You are being invited to participate in this research because you are a female patient, who is not pregnant, undergoing mastectomy and immediate reconstruction for breast cancer, or a positive gene mutation (BRCA). If you volunteer to take part in this study, you will be one of about 60 people to do so at the University of Kentucky.

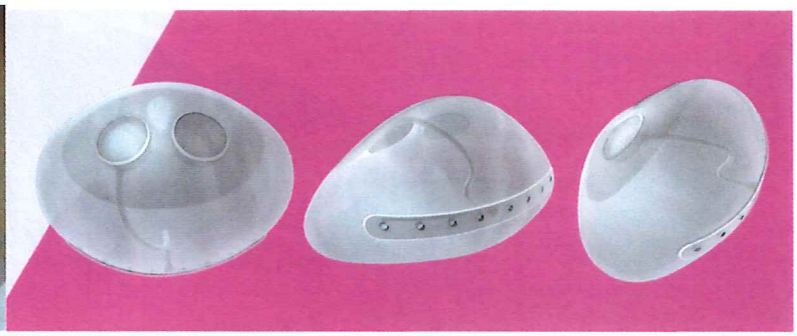
WHO IS DOING THE STUDY?

The individuals in charge of this study are Lesley Wong (MD), who is the principal investigator (PI), of the Division of Plastic Surgery as well as Ashley Kerekes (MD), Ryan Wilson (MD), and Ashley Boustany (MD) of the Division of Plastic Surgery at the University of Kentucky. Members of this research team will be assisting at different points of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

The use of tissue expanders is the most common form of breast reconstruction after mastectomy. The purpose of this study is to compare the use of two types of tissue expanders, one with a built-in drain and one without the drain. Both expanders will still use the standard drains used routinely in mastectomy and reconstruction. We will do this in order to see if complications (seroma, wound breakdown, skin necrosis, and infection) are different between the two expanders.

1- port expander



2- port expander

This study uses devices that are approved by the Food and Drug Administration (FDA). The type of expander that each patient receives will be randomly chosen. The type of expander will not impact our current management or treatment of your reconstruction. We are hopeful that this comparison will eventually provide data that would potentially increase the chances of reduced complication rate and improved outcomes for breast reconstruction subjects in the future.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

Those people who are not eligible for this study are pregnant women and those individuals under the age of 18.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

For all participants, the research procedures will take in the operating room suite for placement of the expander, and in inpatient room and the clinic for routine surgical and postoperative care. No additional time to the time you are in the operating room in the hospital or in the clinic is needed between the two types of expanders. We will be recording complications until the expander is ready to be replaced with the permanent implant which is typically two to three months after the mastectomy and first stage of reconstruction.

WHAT WILL YOU BE ASKED TO DO?

Before you begin the study, you will be asked questions by an investigator about your basic medical history including smoking history, diabetes, high blood pressure, heart problems, anemia, cancer, medicines taken, hospitalizations and previous treatments with radiation therapy and/or chemotherapy for your breast cancer (if applicable). This information will be used to check if the measurement results will be affected by these factors and will not be used for other purposes. Your health information will be stored in a locked room. Only the researchers will have access to that information. Recording this information does not require hospitalization, and does not prevent you from getting your usual health care treatments, blood tests, or any other services. No needles or drugs are involved.

During the surgery we will be recording the amount of fluid initially placed into the expander. This is determined by the amount of skin and clinical assessment of this skin following the mastectomy. It is not determined by the type of expander that is placed.

Following the surgery, we will be recording complications (seroma, infection, skin necrosis, and explantation). Your treatment will not be affected by the type of expander that is used.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are very minimal risks to your health directly related to you participation in this study. There are no known differences in the complications between the two types of expanders and both are currently being used for reconstruction across the country. The possibility of unforeseen hazards cannot be ruled out. All data from this study will be recorded and kept on file. We will take great care to keep data confidential. They are stored in a room with access limited to the investigators and collaborators included in this protocol; this room is locked at all times. We assure that this data will not be disclosed to any other persons.

We will try to avoid any discomfort or risk to you. The University of Kentucky Albert B. Chandler Hospital is properly equipped to deal with discomfort symptoms and its professional personnel are trained to administer emergency care. If you feel uncomfortable in any way, the study will be stopped.

You are responsible for telling us if you have diseases that may be affected or aggravated by undergoing breast reconstruction.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no expectation that you will get any direct benefit from taking part in this study. Your willingness to take part, however, may, in the future, help doctors better understand and/or improve their efforts to improve outcomes related to breast reconstruction and decrease the complications associated with breast reconstruction.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, you still have the option to request either one of the two different tissue expanders available for breast reconstruction as part of your standard care.

WHAT WILL IT COST YOU TO PARTICIPATE?

There will be no additional cost to participate in this study

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are

costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key.

We will also make every effort to password protect the electronic data of your health information. Your electronic data will not be accessible to the persons outside the research team. Your electronic health data will only be used for research purposes and will be separated from your name and other identifying private information.

Officials of the Food and Drug Administration (FDA) and the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you. The data recorded will no longer be entered into the study. You will continue to receive standard postoperative care.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

The risks of having tissue expander reconstruction will not increase by participating in this study if you are involved in another research study.

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Lesley Wong (MD) at 859-257-8143 immediately. Lesley Wong, MD will determine what type of treatment, if any, is best for you at that time. If you are unable to contact them, then you may seek treatment at your closest medical facility.

It is important for you to understand that the University of Kentucky Albert B. Chandler Hospital does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky Albert B. Chandler Hospital will not pay for any wages you may lose if you are harmed by this study.

Medical costs that result from research related harm cannot be included as regular medical costs. Therefore, the medical costs related to your care and treatment because of research-related harm will be your responsibility; or your insurer may agree to pay those costs (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances). You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the principal investigators, Lesley Wong at 859-257-8143. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

POTENTIAL FUTURE USE

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Lesley Wong (MD) regarding your willingness to participate in future research studies about how to prevent, detect, or treat complications of breast reconstruction?

☐ **Yes** ☐ **No** _____**Initials**

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case the data will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

No funding is being supplied to conduct this study.

The investigators have no financial interest or conflicts of interest relating to this study.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information
- Medical History
- Blood flow measurements

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- Food and Drug Administration

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Lesley Wong (MD) , Division of Plastic Surgery, K454 Ky Clinic, 740 S. Limestone Street, Lexington, KY 40536-0284 and inform her of your decision
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject/participant or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____

Signature of research subject Date

_____

Printed name of research subject

_____ _____

Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____

Signature of Principal Investigator or Sub/Co-Investigator