Project Title: Effect of Drain Care on Infection Rate and Quality of Life in Implant-Based Breast Reconstruction.
Principal Investigator/Researcher: Dr. Stephen Colbert
IRB Reference Number: 2092673

Written Consent to Participate in a Research Study

Key Information About the Study

You are being asked to participate in a research study. The purpose of the research study is to determine if there is a difference in infection risk in patients having breast reconstruction with a tissue expander when allowed to shower 48 hours after surgery rather than not showering until their surgical drains are removed. Possible benefits include the ability to shower and greater comfort after surgery. It is not known whether there is any difference in risk of infection related to drain care after this surgery, and this study is attempting to answer that question. It is possible that showering decreases risk of infection, increases it, or has no effect on it. Normal surgical steps will be taken to help minimize the risk of soft infection, such as sterile surgical technique throughout the surgery. If you develop a soft tissue infection, the infection will be immediately treated. At the conclusion of the study, you will be asked to participate in a brief quality of life survey related to your breast reconstruction and showering.

Please read this form carefully and take your time. You can discuss this study with your family, friends, or doctor if you want. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

You are being asked to participate in this study because you are undergoing first stage breast reconstruction with placement of a tissue expander or permanent breast implant. The purpose of the study is to determine if allowing you to shower 48 hours after surgery with drains still in place has an effect on infection rates. You will be asked to participate in a quality of life survey following the conclusion of the study.

What will happen during the study?

If you take part in this study, you will have the following tests and procedures:

You will be randomly placed in one of two treatments arms.

Group 1 will be allowed to shower 48 hours following surgery with surgical drains in place

Group 2 will not be allowed to shower until the drains have been removed.

There will be about *100 patients* participating in this study.

How long will I be in the study?

Your participation is expected to last 90 days. We will see you in our clinic on the day after surgery, then on a weekly basis for 90 days.

Are there benefits to taking part in the study?

You may or may not benefit as a result of your participation in the study. Information learned from the study may help other people in the future.

What are the possible risks of participating in this study?

There are risks expected when taking part in this study. There are some that we know about and some may not know about yet. Some risks include possible increase in infection.

To help lower these possible risks, we will have routine close follow ups. We would like you to watch closely for any signs of infection including fevers, chills, redness, swelling. We will also help minimize the risk of infection by providing you with standard sterile surgical technique, with proper prepping and draping, as well as sterile placement of drain tubes. If you develop an infection, it will be immediately treated according to normal standard care.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

What other choices do I have if I don't want to be in this study?

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study. The research team can share other options that may be available to you.

Will I receive compensation for taking part in this study?

You will not be compensated for taking part in this study.

Will there be any cost for taking part in this study?

You should not expect any additional costs by participating in this study.

You and/or your health plan/insurance will be billed for everything that is considered standard of care. This includes tests and procedures you would receive without being in this study. Some health plans/insurance companies will not pay for these costs for people who are in research studies. Check with your plan/company to find out what they will pay for.

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Other costs to you from being in this study may include testing or treatment for existing or new health conditions, insurance co-payments for doctor visits, transportation, parking, childcare, and/or time off work.

A social worker and financial counselor are available to discuss concerns with you. Please let the research staff know if you would like to visit with them and an appointment will be made.

You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential, including health information. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

We will scan a copy of this consent form into your medical record. We may also record your research information, including the results of tests and procedures, in your medical record if the information could be useful for future treatment.

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

We may share what we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.

Permission to Use your Protected Health Information:

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers,

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fax number, email addresses, medical record number, social security number, account numbers, health plan beneficiary number, certificate or license numbers, vehicle or device serial numbers, web address, IP address, biometric identifiers (finger/voice print), photos, and other characteristics that could identify you.

We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Study monitors and auditors who make sure that the study is being done properly. contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your permission for us to use and/or release your information will not expire unless you cancel your permission in writing.

You can cancel your permission at any time by writing to:
Investigator's Name: Dr. Stephen Colbert
Institution: University of Missouri
Department: Surgery. Division of Plastic Surgery
Address: 1 Hospital Drive

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You have the right to access your protected health information that is obtained or created during this research project until the end of study ends.
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If you have not already received a copy of the University of Missouri Health Care Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at 573-882-9054.

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The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher at 573-882-2276

If you have questions about your rights as a research participant, or have problems or complaints, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email muresearchrpa@missouri.edu.

Do I get a copy of this consent?

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

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Consent to Participate - Signatures

Subject's Signature	**Date**

Legally Authorized Representative (LAR)	**Date**

Relationship to Subject

Investigator Authorized to Obtain Consent	**Date**

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