INFORMED CONSENT DOCUMENT

Project Title: 3D BREAST IMAGING FOR COSMETIC AND RECONSTRUCTIVE BREAST SURGERY: DOES 3D IMAGING IMPROVE PATIENT REPORTED OUTCOMES IN PRIMARY BREAST AUGMENTATION?

Principal Investigator: Terence Myckatyn (314) 996-3255

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

- If you have any questions about anything in this form, you should ask the research team for more information.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have chosen to have breast augmentation surgery.

The purpose of this research study is to determine if a new method of 3D imaging provides patients with greater satisfaction after surgery or not. 3D imaging is an innovative technology that allows your surgeon to share with you images of how you could look after your procedure.

How it works

Trying to imagine the final look of your plastic surgery can be challenging. 3D imaging maps your anatomy and creates simulated images based on the procedure you are considering. Our surgeons will use those images to show you the areas involved and discuss your options. The 3D capacity allows you to see the proposed changes from different angles to clarify the possibilities. You can actually compare your current breasts with the potential changes and see which image you prefer the most before your breast augmentation.

Traditionally, surgeons have taken 2D photographic images of your breasts before surgery. These pictures are used during your pre-surgery consultation with your surgeon to help determine the optimal size of implant that would make you most satisfied with the result. Additionally, the surgeon may show you before and after pictures of patients that were similar in body size and age to you so that you could see what the potential outcome may be. Your surgeon will discuss the shape, size and position of the results you like best. While these results can not be duplicated exactly, the pictures are

a way of communicating what you like and don't like with your surgeon, especially when it comes to the size of implant.

The three-dimensional images may better help you decide which options are right for you because you would be able to have a simulation of what the end result would be on your own body. However, there has not been a formal study of the different imaging techniques to prove that the 3D images result in greater patient satisfaction or not.

WHAT WILL HAPPEN DURING THIS STUDY?

You will undergo all of the normal pre-surgery consultation and evaluations that take place prior to breast augmentation surgery whether you choose to participate in this study or not. Standard 2D and 3D photos are part of this evaluation for all patients.

If you decide to be included in the study, you will be given a questionnaire to complete. This questionnaire (Breast-Q) will ask you questions about your body image and feelings about your breast appearance. The questionnaire will take you approximately 5-10 minutes to complete. The responses from the surveys and the information obtained from your medical records will be kept confidential. You are certainly encouraged to not answer any question that makes you feel uncomfortable.

You will be randomized (like a flip of the coin) to have either further consultation using the simulation images created with the use of the 3D photographs with your surgeon or to not see these simulation images as part of your pre-surgery consultation. You have a 50/50 chance for either option.
If you are randomized to have further consultation using the 3D simulation images, your surgeon will use the images and mapping features to show you a simulated "after" image of what your body may appear like after surgery based on the implants you have chosen. If you are not randomized to have the 3D simulation, your surgeon will show you various before and after photographs of prior patients with your similar body size to help you decide which size implant will be the best fit for your desired result.
Your surgery and post-operative care will be unchanged by your participation in this study. It is routine for you to see your surgeon for follow-up visits after surgery to make sure there are no complications and that you are healing well. At approximately 6 months after surgery, you will have your "after" photos taken by both 2D and 3D imaging techniques. You will also be asked to re-take the Breast –Q questionnaire to assess your feelings about your body image and satisfaction with surgery. No further follow-up will be required and your participation in the study will be complete.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making photographs of you. It is standard practice for plastic surgeons to take before and after photos of their patients to keep in their clinic charts. Because you are having breast surgery, only pictures of your breasts will be taken. Your face will not be included;

therefore they will not be identifiable in that manner. The 3D images that are taken as part of this study will also be included in your clinic chart. Therefore, these photos will be accessible to you, your surgeon, anyone with access to your medical record which includes the surgeon's clinical staff (nurse, physician assistant, medical assistant, etc.), and the members of the research team.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 150 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 7 months: from the time of your pre-surgical consultation to your 6 month follow-up appointment after your surgery. All of the study procedures will occur during your normal office appointments. The extra time involved for study procedures will add approximately 15-20 minutes to the length of your appointments.

No long term follow-up is involved.

WHAT ARE THE RISKS OF THIS STUDY?

There is a rare possibility that your data could be shared in a way that could identify you. Every effort will be made to protect your personal health information. There is, however, always a risk of a breach of confidentiality.

If any particular question of the Breast-Q questionnaire makes you uncomfortable, you may discuss its importance and the need to answer it with a member of the research team. You may choose not to answer any question with which you feel uncomfortable.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit directly from being in this study. If you are randomized to receive the 3D images with simulation, you may have a better visualization of how the results of your augmentation may appear as you are discussing the procedure with your surgeon during the consultation.

However, we hope that, in the future, other women seeking to have breast augmentation surgery might benefit from this study because we will have more information on which imaging techniques provide the greatest level of patient satisfaction following surgery.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have to pay any extra costs for being in this research study. The 3D images will be

provided at no cost to you as part of this study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be given a $75 check upon the completion of the baseline Breast-Q questionnaire and 3D images. You will be given another $75 check at the completion of the Breast-Q questionnaire and repeat 3D images after surgery at your six month follow-up visit. The total compensation you could receive is $150.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Dr. Terry Myckatyn at (**314) 996-3255** and/or the Human Research Protection Office at 1-(800)-438-0445.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants.) The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, only the research team here at Washington University will know

your name. You will be assigned a study "ID" that will be used for study documents (questionnaires, 3D images). Only a member of the study team will know which ID is linked to you. You will not be identified personally in any report from this study. Your personal medical reports will be kept private. Hard copy study documents, photographs, and paper questionnaires will be stored in a secure area with limited access, under double lock protection within the designated area of the clinical research team here at WU. Hard copy records will not be allowed to be transported or transferred outside this storage area.

This consent form or similar documentation that you are participating in a research study will be included in your clinical medical record. Anyone with access to your medical record, including your health insurance company will be able to see that you are participating in a research study.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpo.wustl.edu/participants/withdrawing-from-a-study/) or you may request that the Investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared if necessary for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants under Withdrawing from a Research Study.

You can request to be withdrawn from this study at any time. Your questionnaire responses and 3D images will be destroyed.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact the study coordinator listed on the front page of this consent form**.** If you experience a research-related injury, please contact Dr. Myckatyn at (314) 996-3255.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found by clicking "Participants" on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 04/26/18.

_____ _____

(Signature of Participant) (Date)

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(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)